Samaritan Health Plans

Prior Authorization Criteria

Employer Large Group Plans

PLEASE READ: This document contains information about the criteria for coverage of provider administered drugs (PAD) and oral chemotherapy drugs for this plan.

Updated on 06/18/2025. For more recent information or other questions, please contact Pharmacy Services at **541-768-5207** or toll free **888-435-2396** (TTY 800-735-2900) or visit **samhealthplans.org**. Pharmacy Services is available Monday through Friday, from 8 a.m. to 5 p.m.

Acitretin

Prior Authorization Guideline

Guideline ID	GL-116496
Guideline Name	Acitretin
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Acitretin	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe psoriasis

AND

2 - Trial and failure, contraindication or intolerance to at least 2 conventional therapies (e.g., topical corticosteroids, Vitamin D analogs, Tazorac, topical tacrolimus, Elidel, phototherapy)

AND

3 - All of the following:

- Patient does not have severely impaired liver function
- Patient does not have severely impaired kidney function
- Patient does not have chronic abnormally elevated blood lipid values
- Medication is not being used concomitantly with methotrexate
- Medication is not being used concomitantly with tetracycline

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - For females of childbearing age and able to bear children ONLY, all of the following:

- Patient has had 2 negative urine or serum pregnancy tests prior to therapy
- Patient is using 2 effective forms of birth control starting 1 month prior to acitretin treatment
- Patient is receiving monthly pregnancy testing during therapy

Product Name: Acitretin	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - For females of childbearing potential ONLY: Submission of medical records (e.g., chart notes) confirming ongoing pregnancy monitoring

2 . Revision History

Date	Notes

9/24/2022	2023 New Implementation

Actemra (tocilizumab)

Prior Authorization Guideline

Guideline ID	GL-116585
Guideline Name	Actemra (tocilizumab)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/12/2024

1 . Indications

Drug Name: Actemra IV & SC (tocilizumab), Tofidence IV (tocilizumab-bavi), Tyenne IV & SC (tocilizumab-aazg)
Rheumatoid arthritis (RA) Indicated for the treatment of adult patients with moderately- to severely-active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs). **Systemic Juvenile Idiopathic Arthritis (SJIA)** Indicated for the treatment of active systemic juvenile idiopathic arthritis in patients 2 years of age and older. **Polyarticular Juvenile Idiopathic Arthritis (PJIA)** Indicated for the treatment of active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. **Giant Cell Arteritis (GCA)** Indicated for the treatment of giant cell arteritis (GCA) in adult patients.
Drug Name: Actemra SC (tocilizumab)
Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) Indicated for slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).
Drug Name: Tyenne SC (tocilizumab-aazg)

Off Label Uses: Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
Tocilizumab SC has been used for slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).

Drug Name: Actemra (tocilizumab IV)

Cytokine Release Syndrome Indicated for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome in adults and pediatric patients 2 years of age and older.

Coronavirus Disease 2019 (COVID-19) Indicated for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adult patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Drug Name: Tofidence IV (tocilizumab-bavi), Tyenne IV (tocilizumab-aazg)

Off Label Uses: Cytokine Release Syndrome Tocilizumab IV has been used for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome in adults and pediatric patients 2 years of age and older [1].

Coronavirus Disease 2019 (COVID-19) Tocilizumab IV has been used for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adult patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) [1].

2 . Criteria

Product Name: Actemra IV or SC, Tofidence IV, Tyenne IV or SC	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- One formulary adalimumab product manufactured by AbbVie, Amgen, BI, or Sandoz**
- Rinvoq (upadacitinib)
- Simponi (golimumab)
- Xeljanz/XR (tofacitinib/ER)

OR

4.2 For continuation of prior Actemra therapy, defined as no more than a 45-day gap in therapy

AND

5 - Both of the following: (Applies to Tofidence IV, Tyenne IV or SC only)

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 6-month trial of Actemra (tocilizumab)

AND

5.2 Submission of medical records documenting why the covered product has not been effective

Product Name: Actemra IV or SC, Tofidence IV, Tyenne IV or SC	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Actemra IV or SC, Tofidence IV, Tyenne IV or SC	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active systemic juvenile idiopathic arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:

- Minimum duration of a 3-month trial and failure of methotrexate
- Minimum duration of a 1-month trial of nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen)
- Minimum duration of a 2-week trial of systemic glucocorticoid (e.g., prednisone)

AND

4 - Both of the following: (Applies to Tofidence IV, Tyenne IV or SC only)

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 6-month trial of Actemra (tocilizumab)

AND

4.2 Submission of medical records documenting why the covered product has not been effective

Product Name: Actemra IV or SC, Tofidence IV, Tyenne IV or SC	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in clinical features or symptoms (e.g., pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline

Product Name: Actemra IV or SC, Tofidence IV, Tyenne IV or SC	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active polyarticular juvenile idiopathic arthritis

AND

2 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [5]:

- leflunomide

- methotrexate

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Enbrel (etanercept)
- One formulary adalimumab product manufactured by AbbVie, Amgen, BI, or Sandoz**
- Xeljanz (tofacitinib)

OR

4.2 For continuation of Actemra therapy, defined as no more than a 45-day gap in therapy

AND

5 - Both of the following: (Applies to Tofidence IV, Tyenne IV or SC only)

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 6-month trial of Actemra (tocilizumab)

AND

5.2 Submission of medical records documenting why the covered product has not been effective

Product Name: Actemra IV or SC, Tofidence IV, Tyenne IV or SC	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 5]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Actemra IV or SC, Tofidence IV [off-label], Tyenne IV or SC	
Diagnosis	Giant Cell Arteritis (GCA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of giant cell arteritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Trial and failure, contraindication, or intolerance to a glucocorticoid

AND

4 - Both of the following: (Applies to Tofidence IV, Tyenne IV or SC only)
4.1 Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 6-month trial of Actemra (tocilizumab)

AND

4.2 Submission of medical records documenting why the covered product has not been effective

Product Name: Actemra IV or SC, Tofidence IV [off-label], Tyenne IV or SC	
Diagnosis	Giant Cell Arteritis (GCA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy.

Product Name: Actemra SC, Tyenne SC [off-label]	
Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by the following [6-8]:

1.1 Exclusion of other known causes of interstitial lung disease (ILD)

AND

1.2 One of the following:

1.2.1 In patients not subjected to surgical lung biopsy, the presence of idiopathic interstitial pneumonia (e.g., fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on high-resolution computed tomography (HRCT) revealing SSc-ILD or probable SSc-ILD

OR

1.2.2 In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD

AND

2 - Prescribed by or in consultation with a pulmonologist or rheumatologist

AND

3 - Both of the following: (Applies to Tyenne SC only)

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 6-month trial of Actemra (tocilizumab)

AND

3.2 Submission of medical records documenting why the covered product has not been effective

Product Name: Actemra SC, Tyenne SC [off-label]	
Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy.

Product Name: Actemra IV, Tofidence IV [off-label], Tyenne IV [off-label]	
Diagnosis	Coronavirus disease 2019 (COVID-19)
Approval Length	14 Days [B]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of COVID-19

AND

2 - Patient is hospitalized

AND

3 - Currently receiving systemic corticosteroids

AND

4 - Patient requires one of the following:
- Supplemental oxygen
- Non-invasive mechanical ventilation
- Invasive mechanical ventilation

- Extracorporeal membrane oxygenation (ECMO)

AND

5 - Both of the following: (Applies to Tofidence IV and Tyenne IV only)
5.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial of Actemra (tocilizumab)

AND

5.2 Submission of medical records documenting why the covered product has not been effective

Product Name: Actemra IV, Tofidence IV [off-label], Tyenne IV [off-label]	
Diagnosis	Cytokine Release Syndrome (CRS) Risk due to CAR T-Cell Therapy
Approval Length	2 Month [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient will receive or is receiving chimeric antigen receptor (CAR) T-cell immunotherapy (i.e., Kymriah [tisagenlecleucel], Yescarta [axicabtagene ciloleucel])

AND

2 - Prescribed by or in consultation with an oncologist or hematologist

AND

3 - Both of the following: (Applies to Tofidence IV and Tyenne IV only)
3.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial of Actemra (tocilizumab)

AND

3.2 Submission of medical records documenting why the covered product has not been effective

3 . Endnotes

A. Patients should have Actemra on board for initial CAR T-cell therapy and be evaluated for signs and symptoms of CRS for at least 4 weeks after, up to a total of 4 doses of Actemra with at least 8 hours between doses. [1]

B. The recommended dosage of Actemra for treatment of adult patients with COVID-19 is 8 mg/kg administered as a single 60-minute intravenous infusion. If clinical signs or symptoms worsen or do not improve after the first dose, one additional infusion of Actemra may be administered at least 8 hours after the initial infusion. [1]

4 . References

1. Actemra Prescribing Information. Genentech, Inc. South San Francisco, CA. February 2022.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.
3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
4. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. Arthritis Rheumatol. 2022;74(4):553-569.
5. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Rheumatol. 2019;71(6):846-863.
6. Khanna D, Lin CJF, Furst DE, et al. Tocilizumab in systemic sclerosis: a randomized, double-blind, placebo-controlled, phase 3 trial. Lancet Respir Med. 2020;8:963–74.
7. Fischer A, Swigris JJ, Groshong SD, et al. Clinically significant interstitial lung disease in limited scleroderma: histopathology, clinical features, and survival. Chest 2008; 134:601.
8. UptoDate [internet database]. Waltham, MA. UpToDate, Inc. Clinical manifestations, evaluation, and diagnosis of interstitial lung disease in systemic sclerosis (scleroderma). Available by subscription at: https://www.uptodate.com. Accessed April 11, 2021.
9. Tofidence Prescribing Information. Biogen MA Inc. Cambridge, MA. September 2023.
10. Tyenne Prescribing Information. Fresenius Kabi USA, LLC. Lake Zurich, IL. March 2024.

5 . Revision History

Date	Notes
7/12/2024	Addition of Tyenne SC; combined Tofidence and Tyenne criteria with A ctemra criteria

Actimmune (interferon Gamma-1b)

Prior Authorization Guideline

Guideline ID	GL-116553
Guideline Name	Actimmune (interferon Gamma-1b)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Actimmune	
Diagnosis	Chronic granulomatous
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic granulomatous disease

AND

2 - Will be used to reduce the frequency and severity of serious infections

AND

3 - Patient is currently on an antibacterial/antifungal prophylaxis regimen

AND

4 - Submission of medical records (e.g., chart notes) documenting the following:

- Baseline body surface area (BSA)
- Prescribed dose is within FDA limits*

Notes	*For BSA 0.5m2 or less: 1.5 mcg/kg/dose 3 times weekly, for BSA greater than 0.5m2: 50mcg/m2 3 times weekly

Product Name: Actimmune	
Diagnosis	Malignant osteopetrosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe malignant osteopetrosis

AND

2 - Submission of medical records (e.g., chart notes) documenting the following:

- Baseline body surface area (BSA)
- Prescribed dose is within FDA limits*

Notes	*For BSA 0.5m2 or less: 1.5 mcg/kg/dose 3 times weekly, for BSA greater than 0.5m2: 50mcg/m2 3 times weekly

Product Name: Actimmune	
Diagnosis	All indications listed above

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/14/2022	2023 New Implementation

Actimmune (interferon gamma-1b)

Prior Authorization Guideline

Guideline ID	GL-123571
Guideline Name	Actimmune (interferon gamma-1b)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	3/21/2016
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Actimmune (interferon gamma-1b)
Chronic Granulomatous Disease (CGD) Indicated for reducing the frequency and severity of serious infections associated with Chronic Granulomatous Disease (CGD). **Severe Malignant Osteopetrosis (SMO)** Indicated for delaying time to disease progression in patients with severe, malignant osteopetrosis (SMO).

2 . Criteria

Product Name: Actimmune	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Chronic granulomatous disease (CGD)
- Severe, malignant osteopetrosis (SMO)

Product Name: Actimmune	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Background

Benefit/Coverage/Program Information
Effective date Prior to 3/8/2023 Updates the effective date was 1/1/2021

4 . References

1. Actimmune Prescribing Information. Horizon Therapeutics USA, Inc. Deerfield, IL. March 2021.

5 . Revision History

Date	Notes
4/11/2023	Annual review

Acute Infectious Disease

Prior Authorization Guideline

Guideline ID	GL-125930
Guideline Name	Acute Infectious Disease
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Avycaz, Cresemba, Fetroja, Nuzyra, Recarbrio, Vabomere, Xenleta, Xerava	
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of and FDA-approved indication or an off-label use supported by guidelines

AND

2 - Prescribed by or in consultation with an infectious disease specialist

2 . Revision History

Date	Notes
5/26/2023	New program

Adakveo (crizanlizumab-tmca)

Prior Authorization Guideline

Guideline ID	GL-118143
Guideline Name	Adakveo (crizanlizumab-tmca)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	3/1/2023
P&T Approval Date:	1/15/2020
P&T Revision Date:	02/13/2020 ; 01/20/2021 ; 01/19/2022 ; 1/18/2023

1 . Indications

Drug Name: Adakveo (crizanlizumab-tmca)
Sickle Cell Disease Indicated to reduce the frequency of vasoocclusive crises in adults and pediatric patients aged 16 years and older with sickle cell disease.

2 . Criteria

Product Name: Adakveo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of Sickle Cell Disease

AND

2 - Patient is 16 years of age and older

AND

3 - Documentation of 2 vaso-occlusive events that required medical facility visits and treatments in the past 12 months (e.g., sickle cell crisis, acute pain episodes, acute chest syndrome, hepatic sequestration, splenic sequestration, priapism) [1, 2]

AND

4 - Trial and failure or inadequate response, contraindication, or intolerance to one of the following: [3, 4, 5, 6]

- Hydroxyurea
- L-glutamine (i.e., Endari)

AND

5 - Prescribed by or in consultation with one of the following:

- Hematologist/Oncologist
- Specialist with expertise in the diagnosis and management of sickle cell disease

Product Name: Adakveo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction in annual rate of vaso-occlusive events, increased time between each vaso-occlusive event)

3 . References

1. Adakveo (crizanlizumab) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2022.
2. Ataga K, Kutlar A, Kanter J et al. Crizanlizumab for the Prevention of Pain Crises in Sickle Cell Disease. New England Journal of Medicine. 2017;376(5):429-439. doi:10.1056/nejmoa1611770.
3. Evidence-Based Management of Sickle Cell Disease: Expert Panel Report, 2014. Nhlbi.nih.gov. https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816_0.pdf. Published 2014. Accessed December 6, 2021.
4. Brawley O, Cornelius L, Edwards L et al. National Institutes of Health Consensus Development Conference Statement: Hydroxyurea Treatment for Sickle Cell Disease. Ann Intern Med. 2008;148(12):932. doi:10.7326/0003-4819-148-12-200806170-00220.
5. Niihara Y, Miller S, Kanter J et al. A Phase 3 Trial of l-Glutamine in Sickle Cell Disease. New England Journal of Medicine. 2018;379(3):226-235. doi:10.1056/nejmoa1715971.
6. Brandow A, Carroll C, Creary S et al. American Society of Hematology 2020 guidelines for sickle cell disease: management of acute and chronic pain. Blood Adv. 2020;4(12):2656-2701. doi:10.1182/bloodadvances.2020001851.

4 . Revision History

Date	Notes
1/4/2023	2023 UM Annual Review. Updated references

Adasuve (loxapine)

Prior Authorization Guideline

Guideline ID	GL-120911
Guideline Name	Adasuve (loxapine)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	4/8/2014
P&T Revision Date:	03/18/2020 ; 03/17/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Adasuve (loxapine)
Agitation Indicated for the acute treatment of agitation associated with schizophrenia or bipolar I disorder in adults. Limitations of Use: As part of the Adasuve REMS Program to mitigate the risk of bronchospasm, Adasuve must be administered only in an enrolled healthcare facility.

2 . Criteria

Product Name: Adasuve	
Approval Length	1 Time [A]
Guideline Type	Prior Authorization
Approval Criteria	

1 - One of the following diagnoses:

- Bipolar I disorder
- Schizophrenia

AND

2 - For the treatment of acute agitation

AND

3 - Patient does not have a history of lung disease associated with bronchospasm [e.g., asthma, chronic obstructive pulmonary disease (COPD)]

3 . Endnotes

A. Because clinical trials in patients with asthma or COPD demonstrated that the degree of bronchospasm, as indicated by changes in forced expiratory volume in 1 second (FEV1), was greater following a second dose of Adasuve, limit Adasuve use to a single dose within a 24 hour period.

4 . References

1. Adasuve Prescribing Information. Galen US, Inc.; Souderton, PA. January 2022.

5 . Revision History

Date	Notes
2/3/2023	2023 Annual Review - no criteria changes

Administrative Non-Formulary & Excluded Drug Exceptions Process

Prior Authorization Guideline

Guideline ID	GL-116520
Guideline Name	Administrative Non-Formulary & Excluded Drug Exceptions Process
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: A non-formulary or excluded* contraceptive drug	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 Both of the following:

- Patient is using the requested product for contraception or other FDA-approved condition**
- The requested product is medically necessary***

OR

1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

Notes	*Please consult client-specific resources to confirm whether benefit exclusions should be reviewed for medical necessity. **Examples of non-contraception uses: (1) Abnormal or excessive bleeding disorders (eg, amenorrhea, oligomenorrhea, menorrhagia, dysfunctional uterine bleeding); (2) Acne; (3) Decrease in bone mineral density; (4) Dysmennorrhea; (5) Endometriosis; (6) Hirsutism; (7) Irregular menses / cycles; (8) Ovarian cysts; (9) Perimenopausal symptoms; (10) History of Pelvic Inflammatory Disease (PID); (11) Polycystic Ovarian Syndrome (PCO or PCOS); (12) Premenstrual Syndrome (PMS); (13) Premenstrual Dysphoric Disorder (PMDD); (14) Prevention of endometrial and/or ovarian cancer; (15) Prevention of menstrual migraines; (16) Turner's syndrome; (17) Uterine fibroids or adenomyosis. ***Any justification of medical necessity/appropriateness provided by the prescriber is adequate to approve access.

Product Name: A non-formulary or excluded* drug	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - Both of the following:

1.1 One of the following:

1.1.1 Patient has failed or has contraindications or intolerance to at least three equivalent formulary drugs. If only one or only two equivalents are available, the patient must have failed or had contraindications or intolerance to all available equivalent formulary drugs. The clinician's judgment should be used to determine equivalent formulary drugs for the indication provided.

OR

1.1.2 Both of the following:

1.1.2.1 Only over-the-counter (OTC) equivalents are available

AND

1.1.2.2 Patient has tried and failed or has contraindications or intolerance to 3 OTC equivalents. If only one or only two equivalents are available, the patient must have failed or had contraindications or intolerance to all available OTC equivalents [document drug(s), dose, duration of trial] The clinician's judgment should be used to determine equivalent formulary drugs for the indication provided.

OR

1.1.3 No formulary or OTC drug is appropriate to treat the patient's condition

AND

1.2 One of the following:

1.2.1 Both of the following:

1.2.1.1 Requested drug is FDA-approved for the condition being treated

AND

1.2.1.2 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)

OR

1.2.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

Notes	*Please consult client-specific resources to confirm whether benefit exclusions should be reviewed for medical necessity. *For Premium Drug Exclusion on Premium formulary, if the target drug is listed on the PREMVDL grid, the patient must try and fail, or have specific medical reason(s) for why the number of alternatives specified by the grid is not appropriate.

2 . Revision History

Date	Notes

11/1/2022	Per TSK004583729 copy over OptumRx Standard guidelines for Samaritan 2023 Implementation

Aduhelm (aducanumab-avwa) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-124387
Guideline Name	Aduhelm (aducanumab-avwa) - PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	2/18/2021
P&T Revision Date:	06/16/2021 ; 06/24/2021 ; 05/19/2022 ; 06/15/2022 ; 02/16/2023 ; 5/18/2023

1 . Indications

Drug Name: Aduhelm (aducanumab-avwa)
Alzheimer's Disease Indicated for the treatment of Alzheimer's disease. Treatment with ADUHELM should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with ADUHELM. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

2 . Criteria

Product Name: Aduhelm	
Diagnosis	Alzheimer's Disease
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization, Non-Formulary

Approval Criteria

1 - Both of the following:

1.1 Based on the National Institute on Aging and the Alzheimer's Association (NIA-AA) criteria, one of the following: [1,2,9]

- Diagnosis of mild cognitive impairment due to Alzheimer's disease
- Diagnosis of probable Alzheimer's disease dementia

AND

1.2 Submission of medical records (e.g., chart notes) confirming both of the following:

- Clinical Dementia Rating-Global (CDR-G) score of 0.5 or Clinical Dementia Rating Sum of Boxes (CDR-SB) score of 0.5-4 [3,4]
- Mini-Mental State Examination score of 24-30 [3,4]

AND

2 - Submission of medical records (e.g., chart notes) confirming the presence of beta-amyloid protein deposition, as evidenced by one of the following:

2.1 Positive amyloid positron emission tomography (PET) scan

OR

2.2 Both of the following:

- Attestation that the patient does not have access to amyloid PET scanning
- Cerebrospinal fluid (CSF) biomarker or blood testing documents abnormalities suggestive of beta-amyloid accumulation (e.g., Aβ42 level, Aβ42:Aβ40 ratio)

AND

3 - Provider attests that the patient's ApoE e4 carrier status is known prior to initiating treatment and a shared decision-making conversation regarding the results has been completed

AND

4 - Other differential diagnoses (e.g., dementia with Lewy bodies (DLB), frontotemporal dementia (FTD), vascular dementia, pseudodementia due to mood disorder, vitamin B12 deficiency, encephalopathy, etc.) have been ruled out

AND

5 - Both of the following:

- Patient is not currently taking an anticoagulant or antiplatelet agent (unless aspirin 325 mg/day or less) [3,4]
- Patient has no history of transient ischemic attack (TIA) or stroke within previous year prior to initiating treatment [3,4]

AND

6 - Counseling has been provided on the risk of amyloid-related imaging abnormalities (ARIA-E and ARIA-H) and patient and/or caregiver are aware to monitor for headache, dizziness, visual disturbances, nausea, and vomiting [5]

AND

7 - Submission of medical records (e.g., chart notes) confirming a baseline brain magnetic resonance imaging (MRI) has been completed within 12 months prior to initiating treatment

AND

8 - Not used in combination with other Aβ monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Leqembi)

AND

9 - Prescribed by a neurologist, geriatrician, or geriatric psychiatrist

Product Name: Aduhelm	
Diagnosis	Alzheimer's Disease

Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization, Non-Formulary

Approval Criteria

1 - Patient is benefitting from therapy as defined by both of the following:

1.1 Based on the National Institute on Aging and the Alzheimer's Association (NIA-AA) criteria, one of the following: [1,2,9]

- Patient continues to have a diagnosis of mild cognitive impairment due to Alzheimer's disease
- Patient continues to have a diagnosis of probable Alzheimer's disease dementia

AND

1.2 Submission of medical records (e.g., chart notes) confirming both of the following:

- Clinical Dementia Rating-Global (CDR-G) score of 0.5 or Clinical Dementia Rating Sum of Boxes (CDR-SB) score of 0.5-4 [3,4]
- Mini-Mental State Examination score of 24-30 [3,4]

AND

2 - Submission of medical records (e.g., chart notes) confirming follow-up brain magnetic resonance imaging (MRI) has been completed after the initiation of therapy prior to the 5th infusion treatment to show one of the following:

2.1 Both of the following:

- Less than 10 new incident microhemorrhages
- 2 or less focal areas of superficial siderosis

OR

2.2 If 10 or more new incident microhemorrhages or greater than 2 focal areas of superficial siderosis are present then both of the following:

- Patient has been clinically evaluated for ARIA related signs or symptoms (e.g., dizziness, visual disturbances)

- Follow-up MRI demonstrates radiographic stabilization (i.e., no increase in size or number of ARIA-H)

AND

3 - Not used in combination with other Aβ monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Leqembi)

AND

4 - Prescribed by a neurologist, geriatrician, or geriatric psychiatrist

3 . Definitions

Definition	Description
ARIA-E	Amyloid related imaging abnormality due to edema/effusion [5]
ARIA-H	Amyloid related imaging abnormality due to micro hemorrhages and hemosiderin deposits [5]

4 . References

1. McKhann GM, Knopman DS, Chertkow H, et al. The diagnosis of dementia due to Alzheimer's disease: recommendations from the National Institute on Aging-Alzheimer's Association workgroups on diagnostic guidelines for Alzheimer's disease. Alzheimers Dement. 2011;7(3):263-269.
2. Albert MS, DeKosky ST, Dickson D, et al. The diagnosis of mild cognitive impairment due to Alzheimer's disease: recommendations from the National Institute on Aging-Alzheimer's Association workgroups on diagnostic guidelines for Alzheimer's disease. Alzheimers Dement. 2011;7(3):270-279.
3. ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT02477800.
4. ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT02484547.
5. Aducanumab [unapproved dossier], Cambridge, MA: Biogen; 2020.
6. O'Bryant SE, Waring SC, Cullum CM, et al. Staging Dementia Using Clinical Dementia Rating Scale Sum of Boxes Scores: A Texas Alzheimer's Research Consortium Study. Arch Neurol. 2008;65(8):1091–1095.
7. Folstein MF, Folstein SE, McHugh PR. "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. J Psychiatr Res. 1975;12(3):189-198.
8. Sevigny, J., Chiao, P., Bussière, T. et al. The antibody aducanumab reduces Aβ plaques in Alzheimer's disease. Nature 537, 50–56 (2016).
9. Per clinical consult with neurologist, January 21, 2021.
10. Aduhelm prescribing information. Biogen, Inc. Cambridge, MA. February 2023.

11. Blennow K, Mattsson N, Scholl M, et al. Amyloid biomarkers in Alzheimer's disease. Trends Pharmacol Sci 2015;36:297–309.
12. ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT01677572.
13. ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT04241068.
14. Wolk DA, Dickerson BC. Clinical features and diagnosis of Alzheimer disease. UpToDate Web site. http://www.uptodate.com. Accessed February 1, 2023.

5 . Revision History

Date	Notes
5/3/2023	Annual review - updated references.

Aldurazyme (laronidase)

Prior Authorization Guideline

Guideline ID	GL-126324
Guideline Name	Aldurazyme (laronidase)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	2/2/2004
P&T Revision Date:	06/17/2020 ; 06/16/2021 ; 06/15/2022 ; 6/21/2023

1 . Indications

Drug Name: Aldurazyme (laronidase)
Mucopolysaccharidosis I (MPS I) Indicated for adult and pediatric patients with Hurler and Hurler-Scheie forms of Mucopolysaccharidosis I (MPS I) and for patients with the Scheie form who have moderate to severe symptoms. The risks and benefits of treating mildly affected patients with the Scheie form have not been established. Aldurazyme has not been evaluated for effects of the central nervous system manifestations of the disorder.

2 . Criteria

Product Name: Aldurazyme	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of Hurler or Hurler-Scheie forms of Mucopolysaccharidosis I (MPS I)

OR

1.2 Diagnosis of Scheie form of Mucopolysaccharidosis I (MPS I) in patients with moderate to severe symptoms

Product Name: Aldurazyme	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . References

1. Aldurazyme Prescribing Information, BioMarin Pharmaceutical Inc. Novato, CA. December 2019.

4 . Revision History

Date	Notes
6/6/2023	Anual Review - Reauth criteria created with 24 month approval duratio n. Initial auth reduced to 12 month approval

Alecensa (alectinib)

Prior Authorization Guideline

Guideline ID	GL-116538
Guideline Name	Alecensa (alectinib)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Alecensa	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic anaplastic lymphoma kinase positive non-small cell lung cancer

AND

2 - Prescribed by or in consultation a hematologist or oncologist

Product Name: Alecensa

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation showing continued adherence and toleration with lack of disease progression

2 . Revision History

Date	Notes
9/14/2022	New Implementation

Alfa Interferons

Prior Authorization Guideline

Guideline ID	GL-126457
Guideline Name	Alfa Interferons
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	3/17/2000
P&T Revision Date:	06/17/2020 ; 06/16/2021 ; 06/15/2022 ; 6/21/2023

1 . Indications

Drug Name: Intron A (interferon alfa-2b)
Hairy Cell Leukemia Indicated for the treatment of patients 18 years of age or older with hairy cell leukemia. **Malignant Melanoma** Indicated as adjuvant to surgical treatment in patients 18 years of age or older with malignant melanoma who are free of disease but at high risk for systemic recurrence, within 56 days of surgery. **Follicular Lymphoma** Indicated for the initial treatment of clinically aggressive follicular Non-Hodgkin's Lymphoma in conjunction with anthracycline-containing combination chemotherapy in patients 18 years of age or older. Efficacy of Intron A therapy in patients with low-grade, low-tumor burden follicular Non-Hodgkin's Lymphoma has not been demonstrated. **Condylomata Acuminata** Indicated for intralesional treatment of selected patients 18 years of age or older with condylomata acuminata involving external surfaces of the genital and perianal areas. The use of this product in adolescents has not been studied. **AIDS-Related Kaposi's Sarcoma** Indicated for the treatment of selected patients 18 years of age or older with AIDS-Related Kaposi's Sarcoma. The likelihood of response to Intron A therapy is greater in patients who are without systemic symptoms, who have limited lymphadenopathy

and who have a relatively intact immune system as indicated by total CD4 count.

Chronic Hepatitis C Indicated for the treatment of chronic hepatitis C in patients 18 years of age or older with compensated liver disease who have a history of blood or blood-product exposure and/or are HCV antibody positive. Studies in these patients demonstrated that Intron A therapy can produce clinically meaningful effects on this disease, manifested by normalization of serum alanine aminotransferase (ALT) and reduction in liver necrosis and degeneration. A liver biopsy should be performed to establish the diagnosis of chronic hepatitis. Patients should be tested for the presence of antibody to HCV. Patients with other causes of chronic hepatitis, including autoimmune hepatitis, should be excluded. Prior to initiation of Intron A therapy, the physician should establish that the patient has compensated liver disease. The following patient entrance criteria for compensated liver disease were used in the clinical studies and should be considered before Intron A treatment of patients with chronic hepatitis C: - No history of hepatic encephalopathy, variceal bleeding, ascites, or other clinical signs of decompensation - Bilirubin less than or equal to 2 mg/dL - Albumin stable and within normal limits - Prothrombin time less than 3 seconds prolonged - WBC greater than or equal to 3,000/mm3 - Platelets greater than or equal to 70,000/mm3. Serum creatinine should be normal or near normal. Prior to initiation of Intron A therapy, CBC and platelet counts should be evaluated in order to establish baselines for monitoring potential toxicity. These tests should be repeated at Weeks 1 and 2 following initiation of Intron A therapy, and monthly thereafter. Serum ALT should be evaluated at approximately 3-month intervals to assess response to treatment. Patients with preexisting thyroid abnormalities may be treated if thyroid-stimulating hormone (TSH) levels can be maintained in the normal range by medication. TSH levels must be within normal limits upon initiation of Intron A treatment and TSH testing should be repeated at 3 and 6 months. Intron A in combination with Rebetol is indicated for the treatment of chronic hepatitis C in patients 3 years of age and older with compensated liver disease previously untreated with alpha interferon therapy and in patients 18 years of age and older who have relapsed following alpha interferon therapy. See Rebetol prescribing information for additional information.

Chronic Hepatitis B Indicated for the treatment of chronic hepatitis B in patients 1 year of age or older with compensated liver disease. Patients who have been serum HBsAg positive for at least 6 months and have evidence of HBV replication (serum HBeAg positive) with elevated serum ALT are candidates for treatment. Studies in these patients demonstrated that Intron A therapy can produce virologic remission of this disease (loss of serum HBeAg), and normalization of serum aminotransferases. Intron A therapy resulted in the loss of serum HBsAg in some responding patients. Prior to initiation of Intron A therapy, it is recommended that a liver biopsy be performed to establish the presence of chronic hepatitis and the extent of liver damage. The physician should establish that the patient has compensated liver disease. The following patient entrance criteria for compensated liver disease were used in the clinical studies and should be considered before Intron A treatment of patients with chronic hepatitis B: - No history of hepatic encephalopathy, variceal bleeding, ascites, or other signs of clinical decompensation - Bilirubin normal - Albumin stable and within normal limits - Prothrombin Time - adults < 3 seconds prolonged, pediatrics less than or equal to 2 seconds prolonged - WBC greater than or equal to 4,000/mm^3 - Platelets - adults greater than or equal to 100,000/mm^3, pediatrics greater than or equal to 150,000/mm^3. Patients with causes of chronic hepatitis other than chronic hepatitis B or chronic hepatitis C should not be treated with Intron A. CBC and platelet counts should be evaluated prior to initiation of Intron A therapy in order to establish baselines for monitoring potential toxicity. These tests should be repeated at treatment Weeks 1, 2, 4, 8, 12, and 16. Liver function tests, including serum ALT, albumin, and bilirubin, should be evaluated at treatment Weeks 1, 2, 4, 8, 12, and 16. HBeAg, HBsAg, and ALT should be evaluated at the end of therapy, as well as 3- and 6-months post-therapy, since patients may become virologic responders during the 6-month period following the end of treatment. In clinical studies in adults, 39% (15/38) of responding patients lost HBeAg 1 to 6

months following the end of Intron A therapy. Of responding patients who lost HBsAg, 58% (7/12) did so 1 to 6 months post-treatment. A transient increase in ALT greater than or equal to 2 x baseline value (flare) can occur during Intron A therapy for chronic hepatitis B. In clinical trials in adults and pediatrics, this flare generally occurred 8 to 12 weeks after initiation of therapy and was more frequent in Intron A responders (adults 63%, 24/38; pediatrics 59%, 10/17) than in non-responders (adults 27%, 13/48; pediatrics 35%, 19/55). However, in adults and pediatrics, elevations in bilirubin 3 mg/dL (2 times ULN) occurred infrequently (adults 2%, 2/86; pediatrics 3%, 2/72) during therapy. When ALT flare occurs, in general, Intron A therapy should be continued unless signs and symptoms of liver failure are observed. During ALT flare, clinical symptomatology and liver function tests including ALT, prothrombin time, alkaline phosphatase, albumin, and bilirubin, should be monitored at approximately 2-week intervals.

Drug Name: Pegasys (peginterferon alfa-2a)

Chronic Hepatitis C As part of a combination regimen with other hepatitis C virus (HCV) antiviral drugs, is indicated for the treatment of adults with chronic hepatitis C (CHC) with compensated liver disease. For information about the safe and effective use of other HCV antiviral drugs to be used in combination with Pegasys, refer to their prescribing information. Pegasys in combination with ribavirin is indicated for treatment of pediatric patients 5 years of age and older with CHC and compensated liver disease. Pegasys monotherapy is only indicated for the treatment of patients with CHC with compensated liver disease if there are contraindications or significant intolerance to other HCV antiviral drugs. Limitations of use: - Pegasys alone or in combination with ribavirin without additional HCV antiviral drugs is not recommended for treatment of patients with CHC who previously failed therapy with an interferon-alfa. - Pegasys is not recommended for treatment of patients with CHC who have had solid organ transplantation.

Chronic Hepatitis B Indicated for the treatment of adult patients with HBeAg-positive and HBeAg-negative chronic hepatitis B infection who have compensated liver disease and evidence of viral replication and liver inflammation. Indicated for the treatment of HBeAg-positive CHB in non-cirrhotic pediatric patients 3 years of age and older with evidence of viral replication and elevations in serum alanine aminotransferase (ALT).

2 . Criteria

Product Name: Intron A	
Diagnosis	Chronic Hepatitis C
Approval Length	48 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C

AND

2 - Patients without decompensated liver disease**

AND

3 - For patients who have not previously been treated with interferon

AND

4 - One of the following:

- Contraindication or intolerance to ribavirin
- Used in combination with ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

Notes	**Defined as Child-Pugh Class B or C

Product Name: Intron A or Pegasys	
Diagnosis	Chronic Hepatitis B
Approval Length	48 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis B infection

AND

2 - Patients without decompensated liver disease**

Notes	**Defined as Child-Pugh Class B or C

Product Name: Pegasys	
Diagnosis	Chronic Hepatitis C
Approval Length	28 Week(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - Patient without decompensated liver disease**

AND

3 - One of the following:

3.1 Used in combination with one of the following:

- Sovaldi (sofosbuvir)
- Ribavirin

OR

3.2 Contraindication or intolerance to all other HCV agents (e.g., Sovaldi [sofosbuvir], ribavirin)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

Notes	**Defined as Child-Pugh Class B or C

Product Name: Pegasys	
Diagnosis	Chronic Hepatitis C
Approval Length	20 Week(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has an undetectable HCV RNA at week 24

AND

2 - Additional treatment weeks of peginterferon are required to complete treatment regimen

AND

3 - Patient has not exceeded 48 weeks of therapy with peginterferon

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

Product Name: Intron A	
Diagnosis	Condylomata acuminata

Approval Length	6 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of condylomata acuminata (genital or perianal)

Product Name: Intron A	
Diagnosis	Diagnoses other than hepatitis and condylomata acuminata
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of hairy cell leukemia

OR

1.2 Diagnosis of AIDS-related Kaposi's sarcoma

OR

1.3 All of the following:

1.3.1 Diagnosis of metastatic renal cell carcinoma

AND

1.3.2 Used in combination with Avastin (bevacizumab)

AND

1.3.3 Prescribed by or in consultation with an oncologist

OR

1.4 Diagnosis of malignant melanoma

OR

1.5 Diagnosis of Stage III or IV follicular Non-Hodgkin's Lymphoma

OR

1.6 As maintenance therapy for the treatment of multiple myeloma (non-FDA approved indication)

3 . References

1. Pegasys Prescribing Information. Genentech, Inc. South San Francisco, CA. March 2021.
2. Intron A Prescribing Information. Merck & Co. Whitehouse Station, NJ. November 2021.
3. Avastin Prescribing Information. Genentech, Inc. South San Francisco, CA. January 2021.
4. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com/. Accessed May 5, 2022.
5. Sovaldi Prescribing Information. Gilead Sciences, Inc. Foster City, CA. September 2019.

4 . Revision History

Date	Notes
6/8/2023	Annual Review - no criteria changes. PegIntron removed from criteria a s product is obsolete.

Alpha-1 Proteinase Inhibitors

Prior Authorization Guideline

Guideline ID	GL-120995
Guideline Name	Alpha-1 Proteinase Inhibitors
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	2/25/2016
P&T Revision Date:	03/18/2020 ; 01/20/2021 ; 03/17/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Aralast NP (alpha-1-proteinase inhibitor [human])
Alpha-1 proteinase inhibitor deficiency (also known as alpha-1-antitrypsin (AAT) deficiency) Indicated for chronic augmentation therapy in adults with clinically evident emphysema due to severe congenital deficiency of Alpha1-PI (alpha1-antitrypsin deficiency). Aralast NP increases antigenic and functional (anti-neutrophil elastase capacity, ANEC) serum levels and antigenic lung epithelial lining fluid levels of Alpha1-PI. The effect of augmentation therapy with Alpha1-PI, including Aralast NP, on pulmonary exacerbations and on the progression of emphysema in alpha-1-antitrypsin deficiency has not been conclusively demonstrated in randomized, controlled clinical trials. Clinical data demonstrating the long-term effects of chronic augmentation and maintenance therapy with Aralast NP or Aralast are not available. Aralast NP is not indicated as therapy for lung disease patients in whom severe congenital Alpha-1-PI deficiency has not been established.
Drug Name: Glassia (alpha-1-proteinase inhibitor [human])
Alpha-1 proteinase inhibitor deficiency (also known as alpha-1-antitrypsin (AAT) deficiency) Indicated for chronic augmentation and maintenance therapy in individuals with clinically evident emphysema due to severe hereditary deficiency of Alpha1-PI, also known as alpha1-antitrypsin (AAT) deficiency. Glassia increases antigenic and functional (anti-neutrophil elastase capacity, ANEC) serum levels and antigenic lung epithelial lining fluid levels of Alpha1-PI. Limitations of Use: The effect of augmentation therapy with Glassia or any Alpha1-PI product

on pulmonary exacerbations and on the progression of emphysema in Alpha1-PI deficiency has not been conclusively demonstrated in randomized, controlled clinical trials. Clinical data demonstrating the long-term effects of chronic augmentation and maintenance therapy of individuals with Glassia are not available. Glassia is not indicated as therapy for lung disease in patients in whom severe Alpha1-PI deficiency has not been established.

Drug Name: Prolastin-C (alpha-1-proteinase inhibitor [human]), Prolastin-C liquid (alpha-1-proteinase inhibitor [human])

Alpha-1 proteinase inhibitor deficiency (also known as alpha-1-antitrypsin (AAT) deficiency) Indicated for chronic augmentation and maintenance therapy in adults with clinical evidence of emphysema due to severe hereditary deficiency of Alpha1-PI (alpha1-antitrypsin deficiency). Prolastin-C increases antigenic and functional (anti-neutrophil elastase capacity, ANEC) serum levels and antigenic lung epithelial lining fluid levels of Alpha1-PI. Limitations of Use: The effect of augmentation therapy with any Alpha-1-PI product on pulmonary exacerbations and on the progression of emphysema in Alpha1-PI deficiency has not been conclusively demonstrated in randomized, controlled clinical trials. Clinical data demonstrating the long-term effects of chronic augmentation or maintenance therapy with Prolastin-C are not available. Prolastin-C is not indicated as therapy for lung disease in patients in whom severe Alpha-1-PI deficiency has not been established.

Drug Name: Zemaira (alpha-1-proteinase inhibitor [human])

Alpha-1 proteinase inhibitor deficiency (also known as alpha-1-antitrypsin (AAT) deficiency) Indicated for chronic augmentation and maintenance therapy in adults with Alpha1-PI deficiency and clinical evidence of emphysema. Zemaira increases antigenic and functional (ANEC) serum levels and lung epithelial lining fluid levels of Alpha1-PI. Clinical data demonstrating the long-term effects of chronic augmentation therapy of individuals with Zemaira are not available. The effect of augmentation therapy with Zemaira or any Alpha1-PI product on pulmonary exacerbations and on the progression of emphysema in Alpha1-PI deficiency has not been demonstrated in randomized, controlled clinical trials. Zemaira is not indicated as therapy for lung disease patients in whom severe Alpha1-PI deficiency has not been established.

2 . Criteria

Product Name: Aralast NP, Glassia, Prolastin-C, Prolastin-C liquid, or Zemaira	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of congenital alpha-1 antitrypsin (AAT) deficiency

AND

2 - Diagnosis of emphysema [A]

AND

3 - One of the following:

3.1 Pi*ZZ, Pi*Z(null) or Pi*(null)(null) protein phenotypes (homozygous) [6]

OR

3.2 Other rare AAT disease genotypes associated with pre-treatment serum alpha1-antitrypsin (AAT) level less than 11 micromole per liter [e.g., Pi(Malton, Malton), Pi(SZ)] [B]

AND

4 - One of the following:

4.1 Circulating pre-treatment serum alpha1-antitrypsin (AAT) level less than 11 micromole per liter (which corresponds to less than 80 mg/dL if measured by radial immunodiffusion or less than 57 mg/dL if measured by nephelometry) [B, 10]

OR

4.2 Patient has a concomitant diagnosis of necrotizing panniculitis

AND

5 - Continued optimal conventional treatment for emphysema (e.g., bronchodilators)

AND

6 - One of the following: [8, 9, 10]

6.1 The FEV1 level is less than or equal to 65% of predicted

OR

6.2 Patient has experienced a rapid decline in lung function (i.e., reduction of FEV1 more than 120 mL/year) that warrants treatment [9]

OR

6.3 Patient has a concomitant diagnosis of necrotizing panniculitis

AND

7 - Patient is NOT a current smoker [C]

Product Name: Aralast NP, Glassia, Prolastin-C, Prolastin-C liquid, or Zemaira	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Continued optimal conventional treatment for emphysema (e.g., bronchodilators)

3 . Endnotes

A. Currently, augmentation therapy is not recommended for patients without emphysema. [3, 8] Some individuals with AAT deficiency will not go on to develop panacinar emphysema, only those with evidence of such disease should be considered for augmentation therapy.
B. Population studies suggest a minimum plasma threshold of 11 µmol/L (corresponding to 80 mg/dL in some assays and ~57 mg/dL by nephelometry), below which there is insufficient AAT to protect the lung, leading to a risk of developing emphysema. [3, 6-9]
C. The GOLD report recommends reserving alpha-1 antitrypsin augmentation therapy for those with evidence of continued and rapid progression following smoking cessation. [8]

4 . References

1. Aralast NP Prescribing Information. Baxalta US Inc. Westlake Village, CA. December 2022.
2. Zemaira Prescribing Information. CSL Behring LLC. Kankakee, IL. September 2022.
3. American Thoracic Society/European Respiratory Society Statement: Standards for diagnosis and management of individuals with alpha-1 antitrypsin deficiency. Am J Resp Care Med 2003; 168:818-900.
4. Prolastin-C Prescribing Information. Grifols Therapeutics, Inc. Research Triangle Park, NC. January 2022.
5. Glassia Prescribing Information. Baxalta US Inc. Lexington, MA. September 2022.
6. Marciniuk DD, Hernandez P, Balter M, et al. Alpha-1 antitrypsin deficiency targeted testing and augmentation therapy: A Canadian Thoracic Society clinical practice guideline. Canadian Respiratory Journal 2012;19(2):109-116.
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10. Sandhaus RA, Turino G, Brantly ML, et al. The diagnosis and management of alpha-1 antitrypsin deficiency in the adult. Chronic Obstr Pulm Dis. 2016; 3(3): 668-682.

5 . Revision History

Date	Notes
2/22/2023	2023 UM Annual Review. No changes to criteria. Updated references

Alunbrig (brigatinib)

Prior Authorization Guideline

Guideline ID	GL-118641
Guideline Name	Alunbrig (brigatinib)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Alunbrig	
Approval Length	3 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Medication is being used for FDA approved indication

OR

1.2 Diagnosis is supported as a use in the National Cancer network (NCCN) Drugs and Biologics Compendium with a category of Evidence and Consensus of 1, 2A, or 2B

AND

2 - Prescribed by or in consultation with an oncologist or hematologist

Product Name: Alunbrig	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Background

Benefit/Coverage/Program Information

NCCN Categories of Evidence and Consensus:

Category	Level of Consensus
1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

Ambrisentan

Prior Authorization Guideline

Guideline ID	GL-116573
Guideline Name	Ambrisentan
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Ambrisentan	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension (PAH) World Health Organization (WHO Group 1)

AND

2 - One of the following:

2.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization

OR

2.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

3 - Patient is NOT pregnant

AND

4 - Patient does NOT have idiopathic pulmonary fibrosis, including idiopathic pulmonary fibrosis with pulmonary hypertension (WHO Group 3)

AND

5 - One of the following:

5.1 Documentation of failure or incomplete response to tadalafil

OR

5.2 Used in combination with tadalafil

AND

6 - Prescribed by or in consultation with one of the following:

- Cardiologist
- Pulmonologist

Product Name: Ambrisentan	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/19/2022	2023 New Implementation

Amondys 45 (casimersen) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-124011
Guideline Name	Amondys 45 (casimersen) - PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	5/20/2021
P&T Revision Date:	12/15/2021 ; 05/19/2022 ; 06/15/2022 ; 5/18/2023

1 . Indications

Drug Name: Amondys 45 (casimersen)
Duchenne muscular dystrophy (DMD) Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping. This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with Amondys 45. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

2 . Criteria

Product Name: Amondys 45	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Duchenne muscular dystrophy (DMD)

AND

2 - Documentation of a confirmed mutation of the dystrophin gene amenable to exon 45 skipping

AND

3 - Patient is 7 years of age or older

AND

4 - Prescribed by or in consultation with a neurologist who has experience treating children

AND

5 - Dose will not exceed 30 milligrams per kilogram of body weight infused once weekly

AND

6 - Patient is ambulatory, as evaluated via the 6-minute walk test (6MWT) or North Star ambulatory assessment (NSAA)

Product Name: Amondys 45	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is tolerating therapy

AND

2 - Prescribed by or in consultation with a neurologist who has experience treating children

AND

3 - Dose will not exceed 30 milligrams per kilogram of body weight infused once weekly

AND

4 - Patient is maintaining ambulatory status, as evaluated via the 6-minute walk test (6MWT) or North Star ambulatory assessment (NSAA)

Product Name: Amondys 45	
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting both of the following:

1.1 Diagnosis of Duchenne muscular dystrophy (DMD)

AND

1.2 Documentation of a confirmed mutation of the dystrophin gene amenable to exon 45 skipping

AND

2 - Patient is 7 years of age or older

AND

3 - Prescribed by or in consultation with a neurologist who has experience treating children

AND

4 - Dose will not exceed 30 milligrams per kilogram of body weight infused once weekly

AND

5 - Submission of medical records (e.g., chart notes, laboratory values) documenting the patient is ambulatory, as evaluated via the 6-minute walk test (6MWT) or North Star ambulatory assessment (NSAA)

3 . References

1. Amondys 45 Prescribing Information. Sarepta Therapeutics, Inc. Cambridge, MA. March 2023..

4 . Revision History

Date	Notes
5/4/2023	Annual review: Background and formatting updates.

Antiemetics for Chemotherapy

Prior Authorization Guideline

Guideline ID	GL-126397
Guideline Name	Antiemetics for Chemotherapy
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Emend (fosaprepitant) IV, Emend (aprepitant) capsules and for oral suspension, Cinvanti (aprepitant) IV, Varubi (rolapitant) tablets, Posfrea (palonosetron) IV	
Diagnosis	Prevention of acute and delayed nausea and vomiting associated with highly emetogenic chemotherapy
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chemotherapy-induced nausea and vomiting

AND

2 - Patient is receiving initial and repeat courses of highly emetogenic chemotherapy

AND

3 - Patient is receiving dexamethasone

AND

4 - Patient is receiving dolasetron, granisetron, ondansetron, or palonosetron

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Emend (fosaprepitant) IV, Emend (aprepitant) capsules and for oral suspension, Cinvanti (aprepitant) IV, Varubi (rolapitant) tablets, Akynzeo (fosnetupitant/palonosetron) IV, Akynzeo (netupitant/palonosetron) capsules, Posfrea (palonosetron) IV	
Diagnosis	Prevention of acute and delayed nausea and vomiting associated with moderately emetogenic chemotherapy
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chemotherapy-induced nausea and vomiting

AND

2 - Patient is receiving initial and repeat courses of moderately emetogenic chemotherapy

AND

3 - Patient is receiving dexamethasone

AND

4 - One of the following:

4.1 Patient is experiencing breakthrough nausea and vomiting

OR

4.2 Patient has one of the following risk factors:

- Younger age (less than 55 years)
- Female sex
- Previous history of chemotherapy-induced nausea and vomiting
- Little or no previous alcohol use
- Prone to motion sickness
- History of morning sickness during pregnancy
- Anxiety/high pretreatment expectation of nausea

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Akynzeo (fosnetupitant/palonosetron) IV, Akynzeo (netupitant/palonosetron) capsules, Posfrea (palonosetron) IV	
Diagnosis	Prevention of acute and delayed nausea and vomiting associated with highly emetogenic chemotherapy
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chemotherapy-induced nausea and vomiting

AND

2 - Patient is receiving initial and repeat courses of highly emetogenic chemotherapy

AND

3 - Patient is receiving dexamethasone

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Aloxi (palonosetron) IV; Sustol (granisetron extended release) IV, Posfrea (palonosetron) IV	
Diagnosis	Prevention of acute and delayed nausea and vomiting associated with moderately emetogenic chemotherapy
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chemotherapy-induced nausea and vomiting

AND

2 - Patient is receiving initial and repeat courses of moderately emetogenic chemotherapy

AND

3 - Patient is receiving dexamethasone

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Emend (fosaprepitant) IV, Emend (aprepitant) capsules and for oral suspension, Cinvanti (aprepitant) IV, Varubi (rolapitant) tablets, Akynzeo (fosnetupitant/palonosetron) IV,

Akynzeo (netupitant/palonosetron) capsules, Aloxi (palonosetron) IV; Sustol (granisetron extended release) IV, Posfrea (palonosetron) IV	
Diagnosis	All indications listed above
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	

2 . Revision History

Date	Notes
6/15/2023	New program
1/1/2025	Added Posfrea

Anti-Parkinson’s Agents

Prior Authorization Guideline

Guideline ID	GL-125146
Guideline Name	Anti-Parkinson’s Agents
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	5/22/1998
P&T Revision Date:	03/18/2020 ; 06/17/2020 ; 03/17/2021 ; 04/21/2021 ; 01/19/2022 ; 03/16/2022 ; 03/15/2023 ; 5/18/2023

1 . Indications

Drug Name: Rytary (carbidopa and levodopa) extended-release capsules
Parkinson’s disease Indicated for the treatment of Parkinson's disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication
Drug Name: Duopa (carbidopa and levodopa) enteral suspension
Advanced Parkinson's disease Indicated for the treatment of motor fluctuations in patients with advanced Parkinson’s disease.
Drug Name: Xadago (safinamide) tablets
Parkinson’s disease Indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes.
Drug Name: Gocovri (amantadine) extended-release capsules
Dyskinesia in Parkinson's disease Indicated for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications.

"Off" Episodes in Parkinson's Disease Indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes.
Drug Name: Osmolex ER (amantadine) extended-release tablets
Parkinson's Disease Indicated for the treatment of Parkinson's disease. **Drug-Induced Extrapyramidal Reactions** Indicated for the treatment of drug-induced extrapyramidal reactions in adult patients.
Drug Name: Dhivy (carbidopa-levodopa)
Parkinson's Disease Indicated for the treatment of Parkinson's disease, post-encephalitic parkinsonism, and symptomatic parkinsonism that may follow carbon monoxide intoxication or manganese intoxication.

2 . Criteria

Product Name: Rytary	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply) of ONE of the following:

- Generic carbidopa-levodopa immediate release
- Generic carbidopa-levodopa extended release

Product Name: Xadago	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply) of BOTH of the following:

- rasagiline mesylate
- selegiline

Product Name: Duopa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Patient is levodopa-responsive [A, B]

AND

3 - Patient experiences disabling “Off” periods for a minimum of 3 hours/day [B]

AND

4 - Disabling “Off" periods occur despite therapy with both of the following: [A, C]

- Oral levodopa-carbidopa

- One drug from a different class of anti-Parkinson's disease therapy (e.g., COMT inhibitor [entacapone, tolcapone], MAO-B inhibitor [selegiline, rasagiline], dopamine agonist [pramipexole, ropinirole])

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Duopa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Gocovri	
Diagnosis	Dyskinesia in Parkinson’s Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Patient is experiencing dyskinesia

AND

3 - Patient is receiving concurrent levodopa-based therapy [5, D]

AND

4 - Trial and failure or intolerance to amantadine immediate release

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Gocovri	
Diagnosis	"Off" Episodes in Parkinson's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Patient is experiencing "off" episodes [E, 6]

AND

3 - Used in combination with levodopa/carbidopa therapy [1]

AND

4 - Both of the following:

4.1 Trial and failure, or intolerance to amantadine immediate release

AND

4.2 Trial and failure, contraindication or intolerance to one of the following:

- MAO-B inhibitor (e.g., rasagiline, selegiline)
- Dopamine Agonist (e.g., pramipexole, ropinirole)
- COMT inhibitor (e.g., entacapone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Gocovri	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., decreased "off" periods, decreased "on" time with troublesome dyskinesia) [D]

Product Name: Osmolex ER	
Diagnosis	Parkinson's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Trial and failure, contraindication or intolerance to BOTH of the following:

2.1 amantadine immediate release

AND

2.2 ONE of the following: [9]

- carbidopa-levodopa
- MAO-B Inhibitor (e.g., rasagiline, selegiline)
- Dopamine Agonist (e.g., pramipexole, ropinirole)

AND

3 - Prescribed by or in consultation with a neurologist

Product Name: Osmolex ER	
Diagnosis	Drug-Induced Extrapyramidal Reactions
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is experiencing drug-induced extrapyramidal reactions

AND

2 - One of the following: [10]

2.1 Patient has persistent extrapyramidal symptoms despite a trial of dose reduction, tapering, or discontinuation of the offending medication

OR

2.2 Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

AND

3 - Trial and failure or intolerance to amantadine immediate release

AND

4 - Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist

Product Name: Osmolex ER	
Diagnosis	Parkinson's Disease, Drug-Induced Extrapyramidal Reactions
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Dhivy	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30-day supply) of both of the following:

- Generic carbidopa-levodopa immediate release (IR)
- Generic carbidopa-levodopa oral disintegraing tablet (ODT)

3 . Endnotes

A. The efficacy of Duopa was established in a randomized, double-blind, double-dummy, active controlled, parallel group, 12-week study in patients with advanced Parkinson's disease who were levodopa-responsive and had persistent motor fluctuations while on treatment with oral immediate-release carbidopa-levodopa and other Parkinson's disease medications. [2, 3]
B. Patients were eligible for participation in the studies if they were experiencing 3 hours or more of “Off” time on their current Parkinson's disease drug treatment and they demonstrated a clear responsiveness to treatment with levodopa. [2, 3]
C. Most patients (89%) were taking at least one concomitant medication for Parkinson’s disease (e.g., dopaminergic agonist, COMT-inhibitor, MAO B inhibitor) in addition to oral immediate-release carbidopa-levodopa. [2, 3]
D. The efficacy of Gocovri was established in two Phase III randomized, double-blind, placebo-controlled trials, a 12 week and 24 week study in patients with Parkinson's disease were treated with levodopa. Both studies demonstrate statistically significant and clinically relevant reduction in dyskinesia compared to placebo. Also, both studies showed that Gocovri-treated patients experienced an increase in functional time daily (defined as ON time without troublesome dyskinesia) compared to placebo-treated patients. [6, 7]
E. “Off” time is defined as the amount of time the Parkinson’s Disease medication was not controlling motor symptoms. [6]

4 . References

1. Duopa Prescribing Information. AbbVie Inc. North Chicago, IL. December 2019.
2. Olanow CW, Kieburtz K, Odin P, et al. Continuous intrajejunal infusion of levodopa-carbidopa intestinal gel for patients with advanced Parkinson’s disease: a randomised, controlled, double-blind, double-dummy study. Lancet Neurol. 2014 Feb;13(2):141-9.
3. Rytary Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. December 2019.
4. Xadago Prescribing Information. US WorldMeds, LLC. Louisville, KY. August 2021.
5. Gocovri Prescribing Information. Adamas Pharma, LLC. Emeryville, CA. January 2021.
6. Pahwa R, Tanner CM, Hauser RA, et al. ADS-5102 (Amantadine) Extended- Release Capsules for Levodopa-Induced Dyskinesia in Parkinson Disease (EASE LID Study): A Randomized Clinical Trial. JAMA Neurol. 2017 Aug:1;74(8): 941-949.
7. Pahwa R, Tanner CM, Hauser Ra, et al. Amantadine Extended Release for Levodopa-Induced Dyskinesia in Parkinson’s Disease (EASED Study). Mov Disorder. 2015 May; 30(6):788-95.
8. Osmolex ER Prescribing Information. Vertical Pharmaceuticals, LLC. Bridgewater, NJ. March 2021.
9. National Institute of Health and Clinical Excellence (NICE). Parkinson's disease in adults. NICE guideline [NG71]. July 2017. Available at: https://www.nice.org.uk/guidance/ng71/chapter/Recommendations. Accessed January 28, 2021.
10. Muench J, Hamer AM. Adverse effects of antipsychotic medications. Am Fam Physician. 2010 Mar 1;81(5):617-622.
11. Oertel W, Eggert K, Pahwa R, et al. Randomized, placebo-controlled trial of ADS-5102 (amantadine) extended-release capsules for levodopa-induced dyskinesia in Parkinson's disease (EASE LID 3). Mov Disord. 2017;32(12):1701-1709.

12. Dhivy Prescribing Information. Riverside Pharmaceuticals Corporation. Washington, DC. November 2021.

5 . Revision History

Date	Notes
5/16/2023	update guideline

Antipsychotics Step Therapy

Prior Authorization Guideline

Guideline ID	GL-116531
Guideline Name	Antipsychotics Step Therapy
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Vraylar	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - Trial and failure, intolerance to TWO generic second generation antipsychotics (e.g., Quetiapine, risperidone, ziprasidone, olanzapine)	

2 . Revision History

Date	Notes
10/27/2022	2023 New Implementation

Apretude

Prior Authorization Guideline

Guideline ID	GL-126002
Guideline Name	Apretude
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Apretude	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Requested drug is being used for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection

AND

2 - Submission of medical records (e.g., chart notes, lab values) documenting both of the following U.S. Food and Drug (FDA)-approved tests prior to use of Apretude:

- Negative HIV-1 antigen/antibody test
- Negative HIV-1 RNA assay

AND

3 - Trial and failure, contraindication, or intolerance to generic emtricitabine-tenofovir disoproxil fumarate 200/300mg

AND

4 - Patient weighs at least 35 kg

Product Name: Apretude	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Provider attests that patient is adherent to the testing appointments and scheduled injections of Apretude

AND

2 - Submission of medical records (e.g., chart notes, lab values) documenting both of the following U.S. Food and Drug (FDA)-approved tests prior to each maintenance injection of Apretude for HIV PrEP:

- Negative HIV-1 antigen/antibody test
- Negative HIV-1 RNA assay

AND

3 - Patient weighs at least 35 kg

2 . Revision History

Date	Notes
6/5/2023	New program

Arcalyst (rilonacept)

Prior Authorization Guideline

Guideline ID	GL-110150
Guideline Name	Arcalyst (rilonacept)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	8/19/2008
P&T Revision Date:	08/13/2020 ; 02/18/2021 ; 05/20/2021 ; 08/19/2021 ; 04/20/2022 ; 8/18/2022

1 . Indications

Drug Name: Arcalyst (rilonacept) injection
Cryopyrin-Associated Periodic Syndromes (CAPS) Indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and pediatric patients 12 years and older. **Deficiency of Interleukin-1 Receptor Antagonist (DIRA)** Indicated for the maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing at least 10 kg. **Recurrent Pericarditis** Indicated for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and pediatric patients 12 years and older.

2 . Criteria

Product Name: Arcalyst

Diagnosis	Cryopyrin-Associated Periodic Syndromes (CAPS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS) [A]

AND

2 - Prescribed by or in consultation with one of the following:

- Immunologist
- Allergist
- Dermatologist
- Rheumatologist
- Neurologist
- Specialist with expertise in the management of CAPS

AND

3 - The medication will not be used in combination with another biologic agent

Product Name: Arcalyst	
Diagnosis	Cryopyrin-Associated Periodic Syndromes (CAPS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced disease stability or improvement in clinical symptoms while on therapy as evidenced by one of the following:

- Improvement in rash, fever, joint pain, headache, or conjunctivitis
- Decreased number of disease flare days

- Normalization of inflammatory markers (C-reactive protein [CRP], erythrocyte sedimentation rate [ESR], serum amyloid A [SAA])
- Corticosteroid dose reduction
- Improvement in MD global score or active joint count

Product Name: Arcalyst	
Diagnosis	Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA)

AND

2 - Patient weighs at least 10 kg

AND

3 - Patient is currently in remission (e.g., no fever, skin rash, and bone pain; no radiological evidence of active bone lesions; C-reactive protein [CRP] less than 5 mg/L)

Product Name: Arcalyst	
Diagnosis	Recurrent Pericarditis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent pericarditis as evidenced by at least 2 episodes that occur a minimum of 4 to 6 weeks apart [1, 4-5]

AND

2 - Prescribed by or in consultation with a cardiologist

AND

3 - Trial and failure, contraindication, or intolerance to at least one of the following [4-5]:

- nonsteroidal anti-inflammatory drugs (e.g., ibuprofen, naproxen)
- colchicine
- corticosteroids (e.g., prednisone)

Product Name: Arcalyst	
Diagnosis	Recurrent Pericarditis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . Definitions

Definition	Description
CIAS1 gene:	Also known as cold-induced auto-inflammatory syndrome 1, is a gene responsible for the regulation of IL-1 production. Mutation(s) in this gene leads to CAPS. [2]
Chronic Infantile Neurologic Cutaneous and Articular Syndrome:	Also known as neonatal-Onset Multisystem Inflammation, is the most severe form of the CAPS. It is characterized by nearly continuous symptoms of inflammation presenting first during the neonatal period or early infancy with migratory and nonpruritic urticaria-like rash and fever. Other features of this disease include chronic aseptic meningitis, sensorineural hearing loss and ocular changes (conjunctivitis, optic nerve atrophy), and disabling arthropathy caused

	by overgrowth of the patella and epiphyses of the long bones. Approximately 20% of patients with this disease die before reaching adulthood. [2, 3]
Cryopyrin-Associated Periodic Syndromes (CAPS):	A group of rare, autosomal dominantly inherited auto-inflammatory conditions comprising of Familial-Cold Auto-inflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), Neonatal-Onset Multisystem Inflammatory Disease (NOMID) or also known as Chronic Infantile Neurologic Cutaneous Articular Syndrome (CINCA), which are caused by the CIAS1 gene mutation and characterized by recurrent symptoms (urticaria-like skin lesions, fever chills, arthralgia, profuse sweating, sensorineural hearing/vision loss, and increased inflammation markers the blood). Approximately 300 people in the United States are affected by CAPS. [2, 3]
Familial Cold Autoinflammatory Syndrome:	The mildest form of CAPS, is characterized by cold-induced, daylong episodes of fever associated with rash, arthralgia, headaches and less frequently conjunctivitis, but without other signs of CNS inflammation. Symptoms usually begin during the first 6 months of life and are predominantly triggered by cold exposure. Duration of episodes usually is less than 24 hours. [2, 3]
Muckle-Wells Syndrome:	A subtype of CAPS, which is characterized by episodic attacks of inflammation associated with a generalized urticaria-like rash, fever, malise, arthralgia, and progressive hearing loss. Duration of symptoms usually lasts from 24-48 hours. [2, 3]

4 . Endnotes

A. CAPS refer to rare genetic syndromes generally caused by mutations in the NLRP-3 [Nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3] gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]). CAPS disorders are inherited in an autosomal dominant pattern with male and female offspring equally affected. Features common to all disorders include fever, urticaria-like rash, arthralgia, myalgia, fatigue, and conjunctivitis. In most cases, inflammation in CAPS is associated with mutations in the NLRP-3 gene which encodes the protein cryopyrin, an important component of the inflammasome. Mutations in NLRP-3 result in an overactive inflammasome resulting in excessive release of activated IL-1β that drives inflammation. [1]

5 . References

1. Arcalyst Prescribing Information. Regeneron Pharmaceuticals. Zug, Switzerland. May 2021.
2. Aksentijevich I, Putnam CD, Remmers EF, et al. The clinical continuum of cryopyrinopathies: novel CIAS1 mutations in North American Patients and a new cryopyrin model. Arthritis Rheum. 2007; 56(4):1273-1285.

3. McDermott M, Aksentijevich I. The auto-inflammatory syndromes. Curr Opin Allergy Clin Immunol. 2002; 2:511-516.
4. Chiabrando JG, Bonaventura A, Vecchie A, et al. Management of acute and recurrent pericarditis. J Am Coll Cardiol. 2020;75(1):76–92.
5. Klein AL, Imazio M, Cremer P, et al. Phase 3 trial of interleukin-1 trap rilonacept in recurrent pericarditis. N Engl J Med 2021;384:31-41.

6 . Revision History

Date	Notes
8/3/2022	Annual review - no criteria changes

Aripiprazole

Prior Authorization Guideline

Guideline ID	GL-117099
Guideline Name	Aripiprazole
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: generic aripiprazole tablets, oral solution	
Diagnosis	Major Depressive Disorder (MDD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of major depressive disorder (MDD)

AND

1.1.2 Failure or intolerance to two first line antidepressant agents (e.g., sertraline, citalopram, venlafaxine, bupropion)

AND

1.1.3 Prescribed for concurrent use with an antidepressant

OR

1.2 Both of the following:

- Patient is new to plan (request within 3 months of starting on plan)
- Patient has been receiving aripiprazole therapy for 4 weeks or longer

Product Name: generic aripiprazole tablets, oral solution	
Diagnosis	Schizophrenia, Bipolar I, Irritability in Autism, Tourette's Disorder, ADHD, Conduct Disorder
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Patient has one of the following diagnoses:

- Schizophrenia
- Bipolar I disorder with acute manic or mixed episodes
- Irritability due to autism spectrum disorder
- Tourette's disorder
- Attention-Deficit/Hyperactivity disorder (ADHD)
- Conduct disorder with aggression

AND

1.1.2 Failure or intolerance to at least one of the following generic atypical antipsychotics:

- quetiapine
- ziprasidone
- risperidone
- olanzapine
- clozapine

OR

1.2 Both of the following:

- Patient is new to plan
- Patient has been receiving aripiprazole therapy with success

AND

2 - Patient meets one of the following age criterion:

- For diagnoses of Irritability in autism, conduct disorder, or Tourette's disorder: Patient is 6 years of age or older
- For diagnosis of ADHD: Patient is 8 years of age or older
- For diagnosis of Bipolar I disorder: Patient is 10 years of age or older
- For diagnosis of Schizophrenia: Patient is 13 years of age or older

Product Name: generic aripiprazole tablets, oral solution	
Diagnosis	All Indications Listed Above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
11/18/2022	New Implementation

Austedo (deutetrabenazine)

Prior Authorization Guideline

Guideline ID	GL-126334
Guideline Name	Austedo (deutetrabenazine)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Austedo	
Diagnosis	Huntington’s Disease Chorea
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Huntington’s Disease Chorea

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Member is 18 years or older

AND

4 - Submission of medical records documenting both of the following:

- The degree of chorea present and the impact on functional ability and/or quality of life as a baseline
- Assessment of mental status, specifically for depression and suicidality?

Product Name: Austedo	
Diagnosis	Huntington's Disease Chorea
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient have documentation of clinical response such as improvement in chorea, ability to perform ADLs, reduction in falls, or increase in quality of life.

AND

2 - Documentation of continued monitoring of mental status specifically for depression and suicidality.

Product Name: Austedo	
Diagnosis	Tardive Dyskinesia
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Tardive Dyskinesia with all of the following:

- At least one month of past or current exposure to a dopamine receptor blocker
- Dyskinetic or dystonic involuntary movements
- Exclusion of other causes of abnormal movements

AND

2 - Prescribed by or in consultation with a neurologist or psychiatrist

AND

3 - Clear documentation that the tardive dyskinesia causes significant functional impairment

AND

4 - Documentation of the degree of tardive dyskinesia with the AIMS scale as a baseline

AND

5 - One of the following:

5.1 Tried and failed an 8-week trial of at least two other agents within the same therapeutic category at a clinically effective and maximally tolerated dose for the member's primary neuropsychiatric diagnosis

OR

5.2 The provider submit documentation that the medications precipitating the tardive dyskinesia are medically necessary

AND

6 - Trial and failure, contraindication, or intolerance to the following:

- Clonazepam
- Amantadine

Product Name: Austedo	
Diagnosis	Tardive Dyskinesia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g. chart notes) documenting follow-up AIMS assessment showing improvement from baseline

AND

2 - Submission of medical records (e.g. chart notes) documenting improvement in function such as ability to perform ADLs, reduction in falls, and increase in quality of life

2 . Revision History

Date	Notes
6/9/2023	New Program

Avonex (interferon beta-1a)

Prior Authorization Guideline

Guideline ID	GL-121462
Guideline Name	Avonex (interferon beta-1a)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name: Brand Avonex	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsing forms of multiple sclerosis

AND

2 - Prescribed by or in consultation with neurologist

AND

3 - Trial and failure, contraindication, or intolerance to all of the following (New Starts Only):

- dimethyl fumarate
- fingolimod
- glatopa/glatiramer acetate

Product Name: Brand Avonex	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy

2 . Revision History

Date	Notes
2/22/2023	New Program

Benlysta (belimumab)

Prior Authorization Guideline

Guideline ID	GL-124032
Guideline Name	Benlysta (belimumab)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	7/12/2011
P&T Revision Date:	10/16/2019 ; 08/13/2020 ; 02/18/2021 ; 08/19/2021 ; 12/15/2021 ; 08/18/2022 ; 09/21/2022 ; 4/19/2023

1 . Indications

Drug Name: Benlysta (belimumab IV), Benlysta (belimumab SC)
Systemic Lupus Erythematosus (SLE) Indicated for the treatment of patients aged 5 years and older with active, autoantibody-positive, systemic lupus erythematosus (SLE) who are receiving standard therapy. Limitations of Use: The efficacy of Benlysta has not been evaluated in patients with severe active central nervous system lupus. Use of Benlysta is not recommended in these situations. **Lupus Nephritis** Indicated for the treatment of patients aged 5 years and older with active lupus nephritis who are receiving standard therapy. Limitations of Use: The efficacy of Benlysta has not been evaluated in patients with severe active central nervous system lupus. Use of Benlysta is not recommended in these situations.

2 . Criteria

Product Name: Benlysta IV or Benlysta SC

Diagnosis	Systemic lupus erythematosus
Approval Length	6 months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active systemic lupus erythematosus (SLE)

AND

2 - Autoantibody positive (i.e., anti-nuclear antibody [ANA] titer greater than or equal to 1:80 or anti-dsDNA level greater than or equal to 30 IU/mL) [2, 3]

AND

3 - One of the following:

- For Benlysta IV, patient is 5 years of age or older
- For Benlysta SC, patient is 18 years of age or older

AND

4 - Trial and failure, contraindication, or intolerance to two standard of care treatments for active SLE (e.g., antimalarials [e.g., Plaquenil (hydroxychloroquine)], corticosteroids [e.g., prednisone], or immunosuppressants [e.g., methotrexate, Imuran (azathioprine)]) [5]

AND

5 - Currently receiving at least one standard of care treatment for active SLE (e.g., antimalarials [e.g., Plaquenil (hydroxychloroquine)], corticosteroids [e.g., prednisone], or immunosuppressants [e.g., methotrexate, Imuran (azathioprine)]) [2, 3]

AND

6 - Prescribed by or in consultation with a rheumatologist

Product Name: Benlysta IV or Benlysta SC	
Diagnosis	Lupus nephritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active lupus nephritis

AND

2 - One of the following:

- For Benlysta IV, patient is 5 years of age or older
- For Benlysta SC, patient is 18 years of age or older

AND

3 - Currently receiving standard of care treatment for active lupus nephritis (e.g., corticosteroids [e.g., prednisone] with mycophenolate or cyclophosphamide) [1, 4]

AND

4 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Rheumatologist

Product Name: Benlysta IV or Benlysta SC	
Diagnosis	All indications listed above
Approval Length	6 months [2, A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., decrease or stabilization of symptoms, improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications)

Product Name: Benlysta IV	
Diagnosis	Systemic lupus erythematosus
Approval Length	6 months [A]
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of active systemic lupus erythematosus (SLE)

AND

2 - Autoantibody positive (i.e., anti-nuclear antibody [ANA] titer greater than or equal to 1:80 or anti-dsDNA level greater than or equal to 30 IU/mL) [2, 3]

AND

3 - Patient is 5 years of age or older

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to two standard of care treatments for active SLE (e.g., antimalarials [e.g., Plaquenil (hydroxychloroquine)], corticosteroids [e.g., prednisone], or immunosuppressants [e.g., methotrexate, Imuran (azathioprine)]) [5]

AND

5 - Currently receiving at least one standard of care treatment for active SLE (e.g., antimalarials [e.g., Plaquenil (hydroxychloroquine)], corticosteroids [e.g., prednisone], or immunosuppressants [e.g., methotrexate, Imuran (azathioprine)]) [2, 3]

AND

6 - Prescribed by or in consultation with a rheumatologist

Product Name: Benlysta IV	
Diagnosis	Lupus nephritis
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of active lupus nephritis

AND

2 - Patient is 5 years of age or older

AND

3 - Currently receiving standard of care treatment for active lupus nephritis (e.g., corticosteroids [e.g., prednisone] with mycophenolate or cyclophosphamide) [1, 4]

AND

4 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Rheumatologist

3 . Endnotes

A. SLE is a disease that fluctuates. The undulating course of typical lupus patients requires frequent reassessment. A 6-month authorization period is reasonable. [2]

4 . References

1. Benlysta Prescribing Information. GlaxoSmithKline LLC. Philadelphia, PA. July 2022.
2. Per clinical consult with rheumatologist, October 4, 2017.
3. American College of Rheumatology Ad Hoc Committee on Systemic Lupus Erythematosus Guidelines. Guidelines for referral and management of systemic lupus erythematosus. Arthritis Rheum. 1999 Sep;42(9):1785-96.
4. American College of Rheumatology Guidelines for Screening, Case Definition, Treatment and Management of Lupus Nephritis. Arthritis Care Res (Hoboken). 2012 Jun; 64(6): 797-808.
5. Fanouriakis A, Kostopoulou M, Alunno A, et al. Ann Rheum Dis 2019;78:736–745.

5 . Revision History

Date	Notes
3/31/2023	Update to age criteria

Bicalutamide

Prior Authorization Guideline

Guideline ID	GL-116497
Guideline Name	Bicalutamide
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Bicalutamide	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic prostate cancer

AND

2 - Used in combination with luteinizing hormone-releasing hormone (LHRH) analog (e.g., goserelin, leuprolide)

AND **3** - Prescribed by or in consultation with an oncologist

Product Name: Bicalutamide	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	

2 . Revision History

Date	Notes
9/24/2022	2023 New Implementation

Bosentan

Prior Authorization Guideline

Guideline ID	GL-116574
Guideline Name	Bosentan
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Bosentan	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension (PAH) World Health Organization (WHO Group 1)

AND

2 - Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization

AND

3 - Documentation of New York Heart Association (NYHA) Functional Classification II, III, or IV symptoms

AND

4 - Documentation of normal liver function tests prior to initiation of treatment

AND

5 - Patient is NOT pregnant

AND

6 - Will not be used concomitantly with glyburide or cyclosporine

AND

7 - Prescribed by or in consultation with one of the following:

- Cardiologist
- Pulmonologist

Product Name: Bosentan	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/19/2022	2023 New Implementation

Botox (onabotulinumtoxinA)

Prior Authorization Guideline

Guideline Name	Botox (onabotulinumtoxinA)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	3/1/2025

1 . Indications

Drug Name: Botox (onabotulinumtoxin A)
Adult Bladder Dysfunction 1) Overactive Bladder: Indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication. 2) Detrusor Overactivity associated with a Neurologic Condition: Indicated for the treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) in adults who have an inadequate response to or are intolerant of an anticholinergic medication. 2) Detrusor Overactivity associated with a Neurologic Condition: Indicated for the treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) in adults who have an inadequate response to or are intolerant of an anticholinergic medication. **Pediatric Detrusor Overactivity associated with a Neurologic Condition** Indicated for the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients 5 years of age and older who have an inadequate response to or are intolerant of anticholinergic medication. **Chronic Migraine** Indicated for the prophylaxis of headaches in adult patients with chronic migraine (greater than or equal to 15 days per month with headache lasting 4 hours a day or longer). Important Limitations: Safety and effectiveness have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month) in seven placebo-controlled studies. **Spasticity** Indicated for the treatment of spasticity in patients 2 years of age and older. Limitations of use: Botox has not been shown to improve upper extremity functional abilities, or range of motion at a joint affected by a fixed contracture.

Cervical Dystonia (Spasmodic Torticollis) Indicated for the treatment of cervical dystonia in adults to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.

Primary Axillary Hyperhidrosis Indicated for the treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents. Limitations: The safety and effectiveness of Botox for hyperhidrosis in other body areas have not been established. Weakness of hand muscles and blepharoptosis may occur in patients who receive Botox for palmar hyperhidrosis and facial hyperhidrosis, respectively. Patients should be evaluated for potential causes of secondary hyperhidrosis (e.g., hyperthyroidism) to avoid symptomatic treatment of hyperhidrosis without the diagnosis and/or treatment of the underlying disease. Safety and effectiveness of Botox have not been established for the treatment of axillary hyperhidrosis in pediatric patients under age 18.

Blepharospasm and strabismus Indicated for the treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders (involving muscles of the face) in patients 12 years of age and above.

Off Label Uses: Chronic Low Back Pain [2, 3] Used in the treatment of chronic low back pain.

Other Uses [2, 3] Used in the treatment of achalasia, chronic anal fissures, dynamic muscle contracture in pediatric cerebral palsy patients, sialorrhea, hand tremor, and oromandibular dystonia.

Drug Name: Botox Cosmetic (onabotulinumtoxin A)

Cosmetic Uses [Non-approvable Use] Indicated in adult patients for the temporary improvement in the appearance of: 1) Moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity 2) Moderate to severe lateral canthal lines associated with orbicularis oculi activity 3) Moderate to severe forehead lines associated with frontalis muscle activity **Please Note: The request for Botox (onabotulinumtoxin A) injections to treat the appearance of facial lines is not authorized given that this use is for cosmetic purposes only.

2 . Criteria

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Adult Bladder Dysfunction OR Neurogenic Detrusor Overactivity (NDO)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following: [1, 3, E, F]

- Urinary incontinence that is associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis)

- Overactive bladder with symptoms (e.g., urge urinary incontinence, urgency, and frequency)
- Neurogenic detrusor overactivity (NDO)

AND

2 - Trial and failure, contraindication, or intolerance to at least one oral anticholinergic (antispasmodic or antimuscarinic) agent [e.g., Bentyl (dicyclomine), Donnatal (atropine/ scopolamine/ hyoscyamine/ phenobarbital), Levsin/Levsinex (hyoscyamine), Ditropan (oxybutynin), Enablex (darifenacin), or VESIcare (solifenacin)]

AND

3 - Patient is routinely performing clean intermittent self-catheterization (CIC) or is willing/able to perform CIC if he/she has post-void residual (PVR) urine volume greater than 200 mL

AND

4 - Prescribed by or in consultation with a urologist

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Blepharospasm, Strabismus, VII Cranial Nerve Disorders
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 One of the following:

1.1.1 All of the following:

1.1.1.1 Diagnosis of blepharospasm associated with dystonia (e.g., benign essential blepharospasm)

AND

1.1.1.2 Patient is 18 years of age or older

AND

1.1.1.3 Trial and failure, contraindication or intolerance to Xeomin

OR

1.1.2 Patient is 12 thru 17 years of age

OR

1.2 Diagnosis of strabismus

OR

1.3 Diagnosis of VII cranial nerve disorders (hemifacial spasms)

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Blepharospasm
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - At least 3 months have or will have elapsed since the last treatment

AND

3 - One of the following:

3.1 Both of the following:

- Patient is 18 years of age or older
- Trial and failure, contraindication or intolerance to Xeomin

OR

3.2 Patient is 12 thru 17 years of age

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Cervical Dystonia
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cervical dystonia (also known as spasmodic torticollis)

AND

2 - Trial and failure, contraindication or intolerance to one of the following:

- Xeomin
- Dysport
- Myobloc

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Cervical Dystonia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - At least 3 months have or will have elapsed since the last treatment

AND

3 - Trial and failure, contraindication or intolerance to one of the following:

- Xeomin
- Dysport
- Myobloc

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Spasticity
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of upper limb spasticity

AND

1.1.2 Trial and failure, contraindication or intolerance to one of the following:

- Xeomin
- Dysport

OR

1.2 Both of the following:

1.2.1 Diagnosis of lower limb spasticity

AND

1.2.2 Trial and failure, contraindication or intolerance to Dysport

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Upper Limb Spasticity
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - At least 3 months have or will have elapsed since the last treatment

AND

3 - Trial and failure, contraindication or intolerance to one of the following:

- Xeomin
- Dysport

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Lower Limb Spasticity
Approval Length	3 Month [B]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - At least 3 months have or will have elapsed since the last treatment

AND

3 - Trial and failure, contraindication or intolerance to Dysport

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Adult Bladder Dysfunction, Strabismus, VII Cranial Nerve Disorders
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - At least 3 months have or will have elapsed since the last treatment

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Primary Axillary Hyperhidrosis
Approval Length	1 Time(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary axillary hyperhidrosis [G]

AND

2 - One of the following:

2.1 Score of 3 or 4 on the Hyperhidrosis Disease Severity Scale (HDSS) [A, 1, 4]

OR

2.2 Skin maceration with secondary infection [5]

AND

3 - Trial and failure, contraindication, or intolerance to topical prescription strength drying agents [e.g., Drysol, Hypercare, Xerac AC (aluminum chloride hexahydrate)]

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Primary Axillary Hyperhidrosis
Approval Length	1 Time(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - At least a 2-point improvement in HDSS [1, 4]

AND

2 - At least 3 months have or will have elapsed since the last series of injections [1, 4]

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Migraine
Approval Length	3 Month [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic migraines [I]

AND

2 - Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [M]

AND

3 - Patient is 18 years of age or older [N]

AND

4 - Patient has greater than or equal to 8 migraine days per month [1, 13-16, L]

AND

5 - Prescribed by or in consultation with one of the following specialists:

- Neurologist

- Pain specialist
- Headache specialist

AND

6 - History of failure (after at least a two month trial), contraindication or intolerance to TWO of the following preventive treatments for migraine from different mechanisms of action: [H, J, O, P, Q, R]

- Elavil [amitriptyline] or Effexor [venlafaxine]
- Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]
- Atenolol, propranolol, nadolol, timolol, metoprolol
- Candesartan
- Lisinopril

AND

7 - Trial and failure, contraindication or intolerance to one of the following:

- Aimovig
- Ajovy

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Migraine
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., a reduction in headache frequency and/or intensity, a reduction in the number of workdays missed due to migraines) [19]

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of therapy

AND

3 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist

AND

4 - Patient continues to be monitored for medication overuse headache (MOH) [M]

AND

5 - At least 3 months have or will have elapsed since the last series of injections

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Anal Fissure (Off-Label)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic anal fissure [8, 9]

AND

2 - At least 2 months of one of the following symptoms:

- Nocturnal pain and bleeding
- Postdefecation pain

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies:

- Topical nitrates (e.g. Glyceryl trinitrate (Nitroglycerin))
- Topical calcium channel blockers (CCBs) (e.g., diltiazem, nifedipine)

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Anal Fissure (Off-Label)
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Incomplete healing of fissure
- Recurrence of fissure

AND

2 - Patient demonstrates positive clinical response to therapy

AND

3 - At least 3 months have or will have elapsed since the last series of injections

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Back Pain [D] (Off-Label)
Approval Length	1 treatment session (series of injections) [K]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of low back pain

AND

2 - Low back pain has lasted for greater than or equal to six (6) months

AND

3 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Neurosurgeon
- Orthopedist
- Pain specialist

AND

4 - Trial and failure (at least 3 months), contraindication, or intolerance to both of the following conventional therapies: [10-12]

- At least one oral NSAID medication
- At least one opioid medication

AND

5 - Trial and failure or inadequate response to one of the following: [10]

- Physical therapy
- Nonpharmacologic therapy (e.g., spinal manipulation, massage therapy, transcutaneous electrical nerve stimulation (TENS), acupuncture/acupressure, and surgery)

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Back Pain [D] (Off-Label)
Approval Length	1 treatment session (series of injections) [K]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - At least 3 months have or will have elapsed since the last series of injections

AND

3 - Treatment has not exceeded two treatment sessions total per year

Notes	Authorization will not exceed more than two treatment sessions total per year (including initial authorization).

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Achalasia (Off-Label)
Approval Length	6 Month [C]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of achalasia

AND

2 - One of the following:

2.1 High risk of complication from or failure to one of the following: [6, 7]

- Pneumatic dilation
- Myotomy

OR

2.2 Prior dilation caused esophageal perforation

OR

2.3 Patient has an increased risk of dilation-induced perforation due to one of the following:

- Epiphrenic diverticulum
- Hiatal hernia

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Achalasia (Off-Label)
Approval Length	6 Month [C]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (i.e., improvement or reduction in symptoms of dysphagia, regurgitation, chest pain)

AND

2 - At least 6 months have or will have elapsed since the last series of injections [C]

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	All other diagnoses
Approval Length	6 months unless the FDA-approved treatment duration is less than 6 months. If FDA-approved treatment duration is less than 6 months, utilize the FDA-approved duration for authorization period.
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Requested drug is FDA-approved for the condition being treated

AND

1.1.2 Additional requirements listed in the “Indications and Usage” and “Dosage and Administration” sections of the prescribing information (or package insert) have been met (e.g.: first line therapies have been tried and failed, any testing requirements have been met, etc)

OR

1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met **AND** **2** - Trial and failure, contraindication, or intolerance to two appropriate formulary alternatives (if available)

Product Name: All Products	
Diagnosis	Cosmetic Use
Guideline Type	Prior Authorization
Approval Criteria **1** - Requests for coverage of any Botox product for treating the appearance of facial lines are not authorized and will not be approved. These uses are considered cosmetic only.	

3 . Endnotes

A. Hyperhidrosis Disease Severity Scale • The HDSS is a 4-point scale designed to assess the severity of hyperhidrosis in everyday clinical practice or in clinical research and the effectiveness of treatment. • The HDSS can be administered by an interviewer or self-completed by the patient. • The HDSS assess disease severity based on the extent of sweating-related impairment of daily activities. (1) Question - My (underarm) sweating is never noticeable and never interferes with my daily activities, Score - 1; (2) Question - My (underarm) sweating is tolerable but sometimes interferes with my daily activities, Score - 2; (3) Question - My (underarm) sweating is barely tolerable and frequently interferes with my daily activities, Score - 3; (4) Question - My (underarm) sweating is intolerable and always interferes with my daily activities, Score - 4

B. This recommendation is based on results from the PREEMPT 2 trial. The primary endpoint of PREEMPT 2 was the mean change from baseline in frequency of headache days for the 28-day period ending with week 24. [13, 14]

C. Approximately 50% of achalasia patients relapse and require repeat treatments at 6 to 24-month intervals. [6]

D. An evidence-based review by the American Academy of Neurology (AAN) concluded that botulinum neurotoxin (BoNT) is possibly effective for the treatment of chronic predominantly unilateral low back pain (LBP) [one Class II study]. The AAN recommends that BoNT may be considered as a treatment option for patients with chronic predominantly unilateral LBP (Level C). [12]

E. An evidence-based review by the AAN established BoNT as safe and effective for the treatment of neurogenic detrusor overactivity (NDO) in adults (one Class I study and one Class II study). Data on the use of BoNT is probably safe and effective for the treatment of detrusor sphincter dyssynergia (DSD) in patients with spinal cord injury (2 Class II studies). On basis of one Class I study, BoNT does not provide significant benefit for the treatment of DSD in patients with multiple sclerosis (MS). The AAN recommends that BoNT should

be offered as a treatment option for neurogenic detrusor overactivity (Level A), and that BoNT should be considered for DSD in patients with spinal cord injury (Level B). [12]

F. BoNT is not effective in patients with DSD due to multiple sclerosis in a multicenter, double-blind, placebo-controlled trial; however, in patients with DSD due to spinal cord injury, open-label clinical studies showed improvements in urodynamic parameters [recommendation for DSD: Adult, Class IIb, Category B]. For NDO, the use of BoNT (refractory to antispasmodics) in a randomized, double-blind, placebo-controlled clinical trial of 59 patients (n = 53 with spinal cord injury and n = 6 with multiple sclerosis) showed significant improvement in daily incontinence episodes in weeks 1 through 24 (except for weeks 12 and 18) compared to placebo [recommendation for NDO: Adult, Class IIb, Category B]. [12]
G. The safety and effectiveness of Botox for hyperhidrosis in areas other than the axillae have not been established. [1]
H. Clinical benefit from prophylactic therapy may take as long as 2 to 3 months to manifest. [17, 18] Recommended first-line agents for the prevention of migraine headache are atenolol, nadolol, propranolol, timolol, amitriptyline, venlafaxine, topiramate, divalproex sodium, and sodium valproate. [17]
I. Safety and effectiveness have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month) in seven placebo-controlled studies. [1] An evidence-based review by the American Academy of Neurology determined that, based on available evidence, Botox was probably ineffective in episodic migraine and tension-type headaches, and should not be considered in patients with these conditions. [12]
J. The effects of Botox in reducing the frequency of headache days in the PREEMPT trial and in the pooled analysis of the PREEMPT trials were very modest. Given the experience and evidence we have for other prophylactic treatments in the management of migraine, which are supported by national guidelines, it is reasonable to require failure with other prophylactic treatments before approving use of Botox. [17]
K. A single small randomized trial (n = 31) compared paravertebral injections of botulinum toxin with saline injections and found significant benefit of botulinum toxin up to eight weeks after injection. There is currently no consensus on number of injections or treatment length for low back pain. [12]
L. The International Classification of Headache Disorders, 3rd addition (beta version) distinguishes chronic and episodic migraine [20]. Chronic migraine is described as headache occurring on 15 or more days per month for more than 3 months, which has the features of migraine headache on at least 8 days per month. Episodic migraine is not clearly defined, but is applied when a patient is diagnosed with migraine but does not meet criteria for chronic migraine.
M. Medication overuse headache (MOH) is defined as headache occurring greater than or equal to 15 days per month. It develops as a consequence of regular overuse of acute or symptomatic headache medication for more than 3 months [20]. Current evidence suggests the best treatment strategy is withdrawal of the offending medication.
N. The safety and effectiveness of Botox for chronic headache in patients below the age of 18 years have not been established. In a 12-week, multicenter, double-blind, placebo-controlled clinical trial, 123 adolescent patients (ages 12 to below 18 years) with chronic migraine were randomized to receive Botox 74 Units, Botox 155 Units, or placebo, for one injection cycle. This trial did NOT establish the efficacy of Botox, compared with placebo, for the prophylaxis of headaches in adolescents with chronic migraine. [1]
O. The American Academy of Neurology supports the use of the following medications for the prevention of episodic migraine in adult patients (with level A or B evidence): antidepressants [i.e., Elavil (amitriptyline), Effexor (venlafaxine)], antiepileptics [i.e., Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], and beta-blockers [i.e., atenolol, propranolol, nadolol, timolol, metoprolol] [21]. They also support the use of Botox (onabotulinumtoxin A) as an efficacious treatment option for chronic migraine.

Botox (onabotulinumtoxin A) is not however recommended for episodic migraine treatment.

P. The US Headache Consortium Consensus (Table e-1) recommends that therapy be initiated with medications that have the highest level of evidence-based therapy while also taking into account patient specific comorbidities [17]. Each medication should be given an adequate trial, it may take two to three months to achieve clinical benefit, and six months to achieve maximal benefit.
Q. The Samaritan Large Group clinical team consulted with a neurologist [22]. He confirmed that preventative treatment for chronic migraine and episodic migraine are similar. The choice of preventative medication will not vary much between the episodic vs chronic subtypes. The choice of agent will largely depend more on patient specific factors.
R. The National Institute for Health and Care Excellence guidelines for the management of migraine recommend Botox (onabotulinumtoxin A) as an option in chronic migraine after failure of at least three other prophylactic medications and that the patient is being managed for medication overuse [23].

4 . References

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13. Aurora SK, Dodick DW, Turkel CC, et al. OnabotulinumtoxinA for treatment of chronic migraine: results from the double-blind, randomized, placebo-controlled phase of the PREEMPT 1 trial. Cephalagia. 2010;30:793-803.
14. Diener HC, Dodick DW, Aurora SK, et al. OnabotulinumtoxinA for treatment of chronic migraine: results from the double-blind, randomized, placebo-controlled phase of the PREEMPT 2 trial. Cephalagia. 2010;30:804-814.
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16. Per clinical consultation with neurologist, January 7, 2011.
17. Silberstein SD, Holland S, Freitag F, et al; Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Neurology 2012 Apr 24;78(17):1337-45.
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Brineura (cerliponase alfa)

Prior Authorization Guideline

Guideline ID	GL-127088
Guideline Name	Brineura (cerliponase alfa)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 05/19/2022 ; 05/18/2023 ; 5/18/2023

1 . Indications

Drug Name: Brineura (cerliponase alfa)
Late Infantile Neuronal Ceroid Lipofuscinosis Type 2 Indicated to slow the loss of ambulation in symptomatic pediatric patients 3 years of age and older with late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency.

2 . Criteria

Product Name: Brineura	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of symptomatic late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) (also known as tripeptidyl peptidase 1 (TPP1) deficiency)

AND

2 - Diagnosis is confirmed by tripeptidyl peptidase 1 (TPP1) enzyme detected by a dried blood spot test and CLN2 genotype analysis

AND

3 - Patient is 3 years of age or older

AND

4 - Patient does not have acute intraventricular access-related complications (e.g., leakage, device failure, or device-related infections)

AND

5 - Patient does not have ventriculoperitoneal shunts

AND

6 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis of CLN2

AND

7 - Administered by, or under the direction of, a physician knowledgeable in intraventricular administration [A]

Product Name: Brineura	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not have acute intraventricular access-related complications (e.g., leakage, device failure, or device-related infections)

AND

2 - Patient does not have ventriculoperitoneal shunts

AND

3 - Patient has experienced a benefit from therapy (e.g., improvement in walking or crawling, or no evidence of disease progression)

3 . Endnotes

A. Brineura (cerliponase alfa) is for intraventricular use only and should be administered by, or under the direction of a physician knowledgeable in intraventricular administration. [2]

4 . References

1. Batten Disease Support and Research Association: Batten Disease Neuronal Ceroid Lipofuscinosis. Available at: http://bdsra.org/wp-content/uploads/2012/01/Batten-Disease-An-Easy-To-Understand-Guide.pdf. Accessed March 29, 2022.
2. Brineura Prescribing Information. BioMarin Pharmaceutical Inc. Novato, CA. July 2020.
3. Fietz M, AlSayed M, Burke D, et al. Diagnosis of neuronal ceroid lipofuscinosis type 2 (CLN2 disease): Expert recommendations for early detection and laboratory diagnosis. Molecular Genetics and Metabolism. 2016 Sep;119(1-2):160-7.
4. National Institutes of Health (NIH). Bethesda, MD. CLN2 Disease. Available at: https://ghr.nlm.nih.gov/condition/cln2-disease. Accessed March 29, 2022.

5 . Revision History

Date	Notes
6/26/2023	Update effective date

Brukinsa (zanubrutinib)

Prior Authorization Guideline

Guideline ID	GL-118671
Guideline Name	Brukinsa (zanubrutinib)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Brukinsa	
Diagnosis	Mantle cell lymphoma (MCL)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mantle cell lymphoma (MCL)

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has received one prior treatment for mantle cell lymphoma (MCL)

AND

4 - Prescribed by an oncologist

AND

5 - Patient does not have CNS lymphoma

Product Name: Brukinsa	
Diagnosis	Marginal zone lymphoma (MZL)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of marginal zone lymphoma (MZL)

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has received one prior treatment (anti-CD20 based) for refractory marginal zone lymphoma (MZL)

AND

4 - Prescribed by an oncologist

AND

5 - Patient does not have CNS lymphoma

Product Name: Brukinsa	
Diagnosis	Waldenstrom's macroglobulinemia (WM)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Waldenstrom's macroglobulinemia (WM)

AND

2 - Patient is 18 years of age or older

AND

3 - Prescribed by an oncologist

AND

4 - Patient does not have CNS lymphoma

Product Name: Brukinsa	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
12/21/2022	New Implementation

Cablivi (caplacizumab-yhdp)

Prior Authorization Guideline

Guideline ID	GL-101562
Guideline Name	Cablivi (caplacizumab-yhdp)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	4/1/2022
P&T Approval Date:	4/17/2019
P&T Revision Date:	02/13/2020 ; 02/18/2021 ; 2/17/2022

1 . Indications

Drug Name: Cablivi (caplacizumab-yhdp)
Acquired Thrombotic Thrombocytopenic Purpura (aTTP) Indicated for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy.

2 . Criteria

Product Name: Cablivi	
Diagnosis	Acquired Thrombotic Thrombocytopenic Purpura (aTTP)
Approval Length	3 Months [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP)

AND

2 - First dose was/will be administered by a healthcare provider as a bolus intravenous injection

AND

3 - Used in combination with immunosuppressive therapy (e.g., rituximab, glucocorticoids) [3]

AND

4 - One of the following:

4.1 Used in combination with plasma exchange

OR

4.2 Both of the following:

- Patient has completed plasma exchange
- Less than 59 days have or will have elapsed beyond the last plasma exchange [B]

AND

5 - Prescribed by or in consultation with a hematologist or oncologist[2]

3 . Endnotes

A. Three month approval duration, based on package insert stating longest therapy in trial was 77 days.
B. Per package insert, after the plasma exchange period can use injection once daily for 30 days beyond the last plasma exchange and after the initial treatment course, if signs of persistent underlying disease are present treatment can be extended for a maximum of 28 days, totaling 58 days of therapy after last plasma exchange.

4 . References

1. Cablivi Prescribing Information. Cambridge, MA. Genzyme Corporation. October 2021
2. Understanding TTP. https://www.understandingttp.com/patient/ttp-treatment/#overview-of-treatment. Accessed January 28, 2021.
3. FDA News Release: FDA approves first therapy for the treatment of adult patients with a rare blood clotting disorder. U.S. Food and Drug Administration; February 6, 2019. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm630851.htm. Accessed January 28, 2021.

5 . Revision History

Date	Notes
1/6/2022	2022 Annual Review - No changes to criteria, updated background info rmation

Cabometyx (cabozantinib)

Prior Authorization Guideline

Guideline ID	GL-116561
Guideline Name	Cabometyx (cabozantinib)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Cabometyx	
Diagnosis	Advanced renal cell carcinoma (RCC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of Advanced renal cell carcinoma (RCC)

OR

1.2 Diagnosis is supported as a use in the National Cancer network (NCCN) Drugs and Biologics Compendium with a category of Evidence and Consensus of 1, 2A, or 2B

AND

2 - Patient is 12 years or older

AND

3 - Prescribed by or in consultation with an oncologist or hematologist

Product Name: Cabometyx	
Diagnosis	Differentiated thyroid cancer (DTC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of Differentiated thyroid cancer (DTC)

OR

1.2 Diagnosis is supported as a use in the National Cancer network (NCCN) Drugs and Biologics Compendium with a category of Evidence and Consensus of 1, 2A, or 2B

AND

2 - Patient is 12 years or older

AND

3 - Prescribed by or in consultation with an oncologist or hematologist

Product Name: Cabometyx	
Diagnosis	Hepatocellular carcinoma (HCC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of Hepatocellular carcinoma (HCC)

OR

1.2 Diagnosis is supported as a use in the National Cancer network (NCCN) Drugs and Biologics Compendium with a category of Evidence and Consensus of 1, 2A, or 2B

AND

2 - Patient is 12 years or older

AND

3 - Prescribed by or in consultation with an oncologist or hematologist

AND

4 - Trial and failure, intolerance or contraindication to Stivarga or Cyramza

Product Name: Cabometyx	
Diagnosis	All indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Background

Benefit/Coverage/Program Information

Compendia Requirements

NCCN Categories of Evidence and Consensus:

Category	Level of Consensus
1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

3 . Revision History

Date	Notes
10/27/2022	New Implementation

Cabotegravir Containing Agents - PA, NF

Prior Authorization Guideline

Guideline ID	GL-121685
Guideline Name	Cabotegravir Containing Agents - PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	3/17/2021
P&T Revision Date:	04/21/2021 ; 11/18/2021 ; 03/16/2022 ; 05/19/2022 ; 09/21/2022 ; 12/14/2022 ; 3/15/2023

1 . Indications

Drug Name: Cabenuva (cabotegravir and rilpivirine) Injection
Treatment of HIV-1 Infection Indicated as a complete regimen for the treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 35kg to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.
Drug Name: Vocabria (cabotegravir) Tablet
Treatment of HIV-1 Infection Indicated in combination with EDURANT (rilpivirine) for short-term treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 35kg who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine. Vocabria may be used as: 1) Oral lead-in to assess the tolerability of cabotegravir prior to administration of Cabenuva extended-release injectable suspension for HIV-1 treatment. 2) Oral therapy for patients who will miss planned injection dosing with Cabenuva for HIV-1 treatment. **HIV-1 Pre-Exposure Prophylaxis** Indicated in at-risk adults and adolescents weighing at least 35 kg for short-term pre exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-

1 infection. Vocabria may be used as: 1) Oral lead-in to assess the tolerability of cabotegravir prior to administration of Apretude extended-release injectable suspension for HIV-1 PrEP. 2) Oral therapy for patients who will miss planned injection dosing with Apretude for HIV-1 PrEP.

Drug Name: Apretude (cabotegravir) Injection
HIV-1 Pre-exposure prophylaxis (PrEP) Indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to initiating Apretude (with or without an oral lead-in with oral cabotegravir) for HIV-1 PrEP.

2 . Criteria

Product Name: Vocabria*, Cabenuva*	
Diagnosis	Treatment of HIV-1 Infection
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of HIV-1 infection

AND

1.2 Patient is 12 years of age or older

AND

1.3 Patient's weight is greater than or equal to 35 kg

AND

1.4 Patient is currently virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable, uninterrupted antiretroviral regimen for at least 6 months

AND

1.5 Patient has no history of treatment failure or known/suspected resistance to either cabotegravir or rilpivirine

AND

1.6 Provider attests that patient would benefit from long-acting injectable therapy over standard oral regimens

AND

1.7 Prescribed by or in consultation with a clinician with HIV expertise

OR

2 - For continuation of prior therapy

Notes	*If patient meets criteria above, please approve both Vocabria and Cab enuva at GPI list “CABOTEGRPA”.

Product Name: Vocabria*, Cabenuva*	
Diagnosis	Treatment of HIV-1 Infection
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - All of the following:

1.1 Diagnosis of HIV-1 infection

AND

1.2 Patient is 12 years of age or older

AND

1.3 Patient's weight is greater than or equal to 35 kg

AND

1.4 Patient is currently virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable, uninterrupted antiretroviral regimen for at least 6 months

AND

1.5 Patient has no history of treatment failure or known/suspected resistance to either cabotegravir or rilpivirine

AND

1.6 Provider attests that patient would benefit from long-acting injectable therapy over standard oral regimens

AND

1.7 Prescribed by or in consultation with a clinician with HIV expertise

OR

2 - Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 70-day gap in therapy [A]

Notes	*If patient meets criteria above, please approve both Vocabria and Cab enuva at GPI list “CABOTEGRPA”.

Product Name: Vocabria**, Apretude**	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Requested drug is being used for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection

AND

2 - Patient's weight is greater than or equal to 35 kg

AND

3 - Documentation of both of the following U.S. Food and Drug (FDA)-approved test prior to use of Vocabria or Apretude:

- Negative HIV-1 antigen/antibody test
- Negative HIV-1 RNA assay

AND

4 - One of the following:

4.1 Trial of, contraindication or intolerance to generic emtricitabine-tenofovir disoproxil fumarate 200/300mg

OR

4.2 Provider attests to both of the following:

- Patient would benefit from long-acting injectable therapy over standard oral regimens
- Patient would be adherent to testing and dosing schedule

Notes	**If patient meets criteria above, please approve both Vocabria and Apretude at GPI list “APRETUDEPA”

Product Name: Vocabria**, Apretude**	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Provider attests that patient is adherent to the testing appointments and scheduled injections of Apretude

AND

2 - Documentation of both of the following U.S. Food and Drug (FDA)-approved test prior to each maintenance injection of Apretude for HIV PrEP:

- Negative HIV-1 antigen/antibody test
- Negative HIV-1 RNA assay

Notes	**If patient meets criteria above, please approve both Vocabria and Apretude at GPI list “APRETUDEPA”

Product Name: Vocabria**, Apretude**	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Requested drug is being used for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection

AND

2 - Patient's weight is greater than or equal to 35 kg

AND

3 - Submission of medical records (e.g., chart notes) confirming documentation of both the following U.S. Food and Drug (FDA)-approved test prior to use of Vocabria or Apretude:

- Negative HIV-1 antigen/antibody test
- Negative HIV-1 RNA assay

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

4.1 Trial of, contraindication or intolerance to generic emtricitabine-tenofovir disoproxil fumarate 200/300mg

OR

4.2 Both of the following:

- Patient would benefit from long-acting injectable therapy over standard oral regimens
- Patient would be adherent to testing and dosing schedule

Notes	**If patient meets criteria above, please approve both Vocabria and Apretude at GPI list “APRETUDEPA”

Product Name: Vocabria**, Apretude**	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Provider attests that patient is adherent to the testing appointments and scheduled injections of Apretude

AND

2 - Submission of medical records (e.g., chart notes) confirming documentation of both of the following U.S. Food and Drug (FDA)-approved test prior to each maintenance injection of Apretude for HIV PrEP:

- Negative HIV-1 antigen/antibody test

• Negative HIV-1 RNA assay	
Notes	**If patient meets criteria above, please approve both Vocabria and Apretude at GPI list “APRETUDEPA”

3 . Endnotes

A. Continuation of therapy for Cabenuva and Vocabria in NF criteria will allow for a 70-day gap to account for the 2-month dosing schedule +/- 7 days. [1]

4 . References

1. Cabenuva Prescribing Information. ViiV Healthcare Company. Research Triangle Park, NC. April 2022.
2. Vocabria Prescribing Information. ViiV Healthcare Company. Research Triangle Park, NC. March 2022.
3. Apretude Prescribing information. ViiV Healthcare Company. Research Triangle Park, NC. December 2021.

5 . Revision History

Date	Notes
3/15/2023	Annual review - no changes.

CGRP Inhibitors

Prior Authorization Guideline

Guideline ID	GL-126337
Guideline Name	CGRP Inhibitors
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Aimovig, Ajovy	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 Months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of episodic migraines

AND

1.1.2 Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Diagnosis of chronic migraines

AND

1.2.2 Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Two of the following [D, E, F, G, 10]:

3.1 One of the following:

- History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine)
- Patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine)

OR

3.2 One of the following:

- History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- Patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate)

OR

3.3 One of the following:

- History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol
- Patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, metoprolol

OR

3.4 One of the following:

- History of failure (after at least a two month trial) or intolerance to Atacand (candesartan)
- Patient has a contraindication to Atacand (candesartan)

AND

4 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Product Name: Aimovig, Ajovy	
Diagnosis	Preventive Treatment of Migraine
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

4 - For Chronic Migraine only: Patient continues to be monitored for medication overuse headache (MOH) [H]

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Product Name: Nurtec ODT	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	6 Months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of episodic migraines

AND

1.2 Patient has 4 to 18 migraine days per month, but no more than 18 headache days per month [26]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Two of the following [D, E, F, G, 10]:

3.1 One of the following:

- History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine)
- Patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine)

OR

3.2 One of the following:

- History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- Patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate)

OR

3.3 One of the following:

- History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol
- Patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, metoprolol

OR

3.4 One of the following:

- History of failure (after at least a two month trial) or intolerance to Atacand (candesartan)
- Patient has a contraindication to Atacand (candesartan)

AND

4 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	Note: For use for preventive treatment of migraine, please enter a qualit y limit override of #16 tablets per 30 days (MDD, 0.54) for 6 months.

Product Name: Nurtec ODT	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	Nurtec ODT: For use for preventive treatment of migraine, please enter a quality limit override of #16 tablets per 30 days (MDD, 0.54) for 12 mo nths.

Product Name: Emgality 100 mg/mL	
Diagnosis	Episodic Cluster Headaches
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of episodic cluster headache

AND

2 - Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months [21]

AND

3 - Patient is 18 years of age or older [I]

AND

4 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

5 - Medication will not be used in combination with another injectable CGRP inhibitor

Product Name: Emgality 100 mg/mL	
Diagnosis	Episodic Cluster Headaches
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

3 - Medication will not be used in combination with another injectable CGRP inhibitor

Product Name: Nurtec ODT	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine with or without aura

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Patient has fewer than 15 headache days per month [23]

AND

4 - Patient is 18 years of age or older [I]

AND

5 - One of the following: [24]

- Trial and failure or intolerance to three triptans (e.g., eletriptan, rizatriptan, sumatriptan) and NSAID (ibuprofen, naproxen, diclofenac) combined treatment
- Trial and failure or intolerance to NSAID treatment alone if triptans contraindicated
- Contraindication to all triptans and NSAIDs

AND

6 - If patient has 4 or more headache days per month, patient must meet one of the following [D, 24]:

6.1 Currently being treated with Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications

OR

6.2 Currently being treated with Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications

OR

6.3 Currently being treated with a beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications

OR

6.4 Currently being treated with Atacand (candesartan) unless there is a contraindication or intolerance to this medication

AND

7 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

8 - Medication will not be used in combination with another oral CGRP inhibitor

Product Name: Nurtec ODT	
Diagnosis	Acute Treatment of Migraine
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)

AND

2 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

3 - Medication will not be used in combination with another oral CGRP inhibitor

Product Name: Ubrelvy	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine with or without aura

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Will not be used for preventive treatment of migraine

AND

4 - Patient has fewer than 15 headache days per month [23]

AND

5 - Patient is 18 years of age or older [I]

AND

6 - One of the following: [24]

- Trial and failure or intolerance to three triptans (e.g., eletriptan, rizatriptan, sumatriptan) and NSAID (ibuprofen, naproxen, diclofenac) combined treatment
- Trial and failure or intolerance to NSAID treatment alone if triptans contraindicated
- Contraindication to all triptans and NSAIDs

AND

7 - If patient has 4 or more headache days per month, patient must meet one of the following [D, 24]:

7.1 Currently being treated with Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications

OR

7.2 Currently being treated with Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications

OR

7.3 Currently being treated with a beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications

OR

7.4 Currently being treated with Atacand (candesartan) unless there is a contraindication or intolerance to this medication

AND

8 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

9 - Medication will not be used in combination with another oral CGRP inhibitor

Product Name: Ubrelvy	
Diagnosis	Acute Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)

AND

2 - Will not be used for preventive treatment of migraine

AND

3 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

4 - Medication will not be used in combination with another oral CGRP inhibitor

Product Name: Nurtec ODT	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	6 Months [E]
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming both of the following:

1.1 Diagnosis of episodic migraines

AND

1.2 Patient has 4 to 18 migraine days per month, but no more than 18 headache days per month [26]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming two of the following [D, E, F, G, 10]:

3.1 One of the following:

- History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine)

- Patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine)

OR

3.2 One of the following:

- History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- Patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate)

OR

3.3 One of the following:

- History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol
- Patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, metoprolol

OR

3.4 One of the following:

- History of failure (after at least a two month trial) or intolerance to Atacand (candesartan)
- Patient has a contraindication to Atacand (candesartan)

AND

4 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	Note: For use for preventive treatment of migraine, please enter a qualit y limit override of #16 tablets per 30 days (MDD, 0.54) for 6 months.

Product Name: Nurtec ODT	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of migraine with or without aura

AND

2 - Submission of medical records (e.g., chart notes) confirming drug will be used for the acute treatment of migraine

AND

3 - Submission of medical records (e.g., chart notes) confirming patient has fewer than 15 headache days per month [23]

AND

4 - Patient is 18 years of age or older [I]

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following: [24]

- Trial and failure or intolerance to three triptans (e.g., eletriptan, rizatriptan, sumatriptan) and NSAID (ibuprofen, naproxen, diclofenac) combined treatment
- Trial and failure or intolerance to NSAID treatment alone if triptans contraindicated
- Contraindication to all triptans and NSAIDS

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming that if patient has 4 or more headache days per month, patient must meet one of the following [D, 24]:

6.1 Currently being treated with Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications

OR

6.2 Currently being treated with Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications

OR

6.3 Currently being treated with a beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications

OR

6.4 Currently being treated with Atacand (candesartan) unless there is a contraindication or intolerance to this medication

AND

7 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

8 - Medication will not be used in combination with another oral CGRP inhibitor

Product Name: Ubrelvy	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)

Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of migraine with or without aura

AND

2 - Submission of medical records (e.g., chart notes) confirming drug will be used for the acute treatment of migraine

AND

3 - Submission of medical records (e.g., chart notes) confirming drug will not be used for preventive treatment of migraine

AND

4 - Submission of medical records (e.g., chart notes) confirming patient has fewer than 15 headache days per month [23]

AND

5 - Patient is 18 years of age or older [I]

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following: [24]

- Trial and failure or intolerance to three triptans (e.g., eletriptan, rizatriptan, sumatriptan) and NSAID (ibuprofen, naproxen, diclofenac) combined treatment
- Trial and failure or intolerance to NSAID treatment alone if triptans contraindicated
- Contraindication to all triptans and NSAIDS

AND

7 - Paid claims or submission of medical records (e.g., chart notes) confirming that if patient has 4 or more headache days per month, patient must meet one of the following [D, 24]:

7.1 Currently being treated with Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications

OR

7.2 Currently being treated with Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications

OR

7.3 Currently being treated with a beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications

OR

7.4 Currently being treated with Atacand (candesartan) unless there is a contraindication or intolerance to this medication

AND

8 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

9 - Medication will not be used in combination with another oral CGRP inhibitor

2 . Endnotes

A. The International Classification of Headache Disorders, 3rd addition (beta version) distinguishes chronic and episodic migraine [11]. Chronic migraine is described as headache occurring on 15 or more days per month for more than 3 months, which has the features of migraine headache on at least 8 days per month. Episodic migraine is not

clearly defined, but is applied when a patient is diagnosed with migraine but does not meet criteria for chronic migraine.

B. While every patient with chronic migraine should receive preventive therapy, not every patient with episodic migraine needs prevention [12]. Appropriate candidates for preventative treatment include those with at least 4 days per month of headache-related disability.
C. The phase 3 inclusion criteria for the erenumab (LIBERTY, STRIVE, ARISE) and galcanezumab (EVOLVE-1, EVOLVE-2) pivotal trials in episodic migraine required that patients had 4 to 14 migraine days per month [3-9]. The LEADER trial evaluated patients who had failed two to four prior preventive migraine treatments (PMTs). At the start of the trial, 38.6%, 37.8%, and 22.8% of patients had failed two, three, and four prior PMTs, respectively [2].
D. The American Academy of Neurology supports the use of the following medications for the prevention of episodic migraine in adult patients (with level A or B evidence): antidepressants [i.e., Elavil (amitriptyline), Effexor (venlafaxine)], antiepileptics [i.e., Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], beta-blockers [i.e., atenolol, propranolol, nadolol, timolol, metoprolol], and candesartan [16, 24].
E. The US Headache Consortium Consensus (Table e-1) recommends that therapy be initiated with medications that have the highest level of evidence-based therapy while also taking into account patient specific comorbidities [15]. Each medication should be given an adequate trial, it may take two to three months to achieve clinical benefit, and six months to achieve maximal benefit.
F. The OptumRx clinical team consulted with a neurologist on the prospective review of the CGPR Inhibitors [14]. He confirmed that preventative treatment for chronic migraine and episodic migraine are similar. The choice of preventative medication will not vary much between the episodic vs chronic subtypes. The choice of agent will largely depend more on patient specific factors. Also, he felt that this agent will most likely fall into a similar place in therapy as Botox (onabotulinumtoxin A).
G. The National Institute for Health and Care Excellence guidelines for the management of migraine recommend Botox (onabotulinumtoxin A) as an option in chronic migraine after failure of at least three other prophylactic medications and that the patient is being managed for medication overuse [13].
H. Medication overuse headache (MOH) is defined as headache occurring greater than or equal to 15 days per month. It develops as a consequence of regular overuse of acute or symptomatic headache medication for more than 3 months [11]. Current evidence suggests the best treatment strategy is withdrawal of the offending medication.
I. The safety and effectiveness in pediatric patients has not been established [1, 17-19, 20, 22].
J. Headache specialists are physicians certified by the United Council for Neurologic Subspecialties (UCNS). [25]

3 . References

1. Aimovig Prescribing Information. Amgen Inc. Thousand Oaks, CA. November 2021.
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4 . Revision History

Date	Notes
6/9/2023	Update guideline

CGRP Inhibitors - PA, NF

Prior Authorization Guideline

Guideline ID	GL-125980
Guideline Name	CGRP Inhibitors - PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	5/17/2018
P&T Revision Date:	07/17/2019 ; 11/14/2019 ; 01/15/2020 ; 03/18/2020 ; 05/14/2020 ; 08/13/2020 ; 12/16/2020 ; 01/20/2021 ; 07/21/2021 ; 09/15/2021 ; 11/18/2021 ; 01/19/2022 ; 03/16/2022 ; 04/20/2022 ; 07/20/2022 ; 08/18/2022 ; 02/16/2023 ; 6/21/2023

1 . Indications

Drug Name: Aimovig (erenumab-aooe), Ajovy (fremanezumab-vfrm), Vyepti (eptinezumab-jjmr)
Preventive Treatment of Migraine Indicated for the preventive treatment of migraine in adults.
Drug Name: Emgality (galcanezumab-gnlm)
Preventive Treatment of Migraine Indicated for the preventive treatment of migraine in adults. **Episodic Cluster Headache** Indicated for the treatment of episodic cluster headache in adults.
Drug Name: Nurtec ODT (rimegepant sulfate)
Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults. **Preventive Treatment of Episodic Migraine** Indicated for the preventive treatment of episodic migraine in adults.

Drug Name: Qulipta (atogepant)
Preventive Treatment of Migraine Indicated for the preventive treatment of migraine in adults.

Drug Name: Ubrelvy (ubrogepant)
Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Not indicated for the preventive treatment of migraine.

2 . Criteria

Product Name: Aimovig, Ajovy, or Vyepti	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 Months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of episodic migraines

AND

1.1.2 Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Diagnosis of chronic migraines

AND

1.2.2 Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Two of the following [D, E, F, G, 10]:

3.1 One of the following:

- History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine)
- Patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine)

OR

3.2 One of the following:

- History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- Patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate)

OR

3.3 One of the following:

- History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol
- Patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, metoprolol

OR

3.4 One of the following:

- History of failure (after at least a two month trial) or intolerance to Atacand (candesartan)
- Patient has a contraindication to Atacand (candesartan)

AND

4 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Product Name: Aimovig, Ajovy, or Vyepti	
Diagnosis	Preventive Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

4 - For Chronic Migraine only: Patient continues to be monitored for medication overuse headache (MOH) [H]

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Product Name: Emgality 120 mg/mL	
Diagnosis	Preventive Treatment of Migraine
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of episodic migraines

AND

1.1.2 Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Diagnosis of chronic migraines

AND

1.2.2 Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Two of the following [D, E, F, G, 10]:

3.1 One of the following:

- History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine)
- Patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine)

OR

3.2 One of the following:

- History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- Patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate)

OR

3.3 One of the following:

- History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol
- Patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, metoprolol

OR

3.4 One of the following:

- History of failure (after at least a two month trial) or intolerance to Atacand (candesartan)
- Patient has a contraindication to Atacand (candesartan)

AND

4 - Trial and failure, contraindication, or intolerance to both of the following:

- Aimovig
- Ajovy

AND

5 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

6 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	Approval Length: 6 months [E]. *QL Override for Emgality (For new starts only): For migraine, please enter 2 PAs with the same start date as follows: First PA: Approve two pens or syringes per 30 days for 1 month with a fill count of 2 (Loading dose has a MDD of 0.067); Second PA: Approve one pen or syringe per 30 days (no overrides needed) for 6 months.

	(Emgality 120 mg/mL is hard-coded with a quantity of one prefilled pen /syringe per 30 days)

Product Name: Emgality 120 mg/mL	
Diagnosis	Preventive Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

4 - For Chronic Migraine only: Patient continues to be monitored for medication overuse headache (MOH) [H]

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

AND

6 - Trial and failure, contraindication, or intolerance to both of the following:

- Aimovig
- Ajovy

Product Name: Nurtec ODT	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	6 Months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of episodic migraines

AND

1.2 Patient has 4 to 18 migraine days per month, but no more than 18 headache days per month [26]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - History of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following [D, E, F, G, 10]:

- Elavil (amitriptyline) or Effexor (venlafaxine)
- Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol)

- Atacand (candesartan)

AND

4 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	Note: For use for preventive treatment of migraine, please enter a qualit y limit override of #16 tablets per 30 days (MDD, 0.54) for 6 months.

Product Name: Nurtec ODT	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	Nurtec ODT: For use for preventive treatment of migraine, please enter a quality limit override of #16 tablets per 30 days (MDD, 0.54) for 12 mo nths.

Product Name: Qulipta	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 Months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of episodic migraines

AND

1.1.2 Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month [28]

OR

1.2 All of the following:

1.2.1 Diagnosis of chronic migraines

AND

1.2.2 Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - History of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following [D, E, F, G, 10]:

- Elavil (amitriptyline) or Effexor (venlafaxine)
- Dapakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol)
- Atacand (candesartan)

AND

4 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Diagnosis	Preventive Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

4 - For Chronic Migraine only: Patient continues to be monitored for medication overuse headache (MOH) [H]

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Product Name: Emgality 100 mg/mL	
Diagnosis	Episodic Cluster Headaches
Approval Length	3 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of episodic cluster headache

AND

2 - Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months [21]

AND

3 - Patient is 18 years of age or older [I]

AND

4 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

5 - Medication will not be used in combination with another injectable CGRP inhibitor

Product Name: Emgality 100 mg/mL	
Diagnosis	Episodic Cluster Headaches
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

3 - Medication will not be used in combination with another injectable CGRP inhibitor

Product Name: Nurtec ODT	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine with or without aura

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Patient has fewer than 15 headache days per month [23]

AND

4 - Patient is 18 years of age or older [I]

AND

5 - One of the following: [24]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

6 - If patient has 4 or more headache days per month, patient must be currently treated with one of the following: [D, 24]:

- Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications
- Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications
- Atacand (candesartan) unless there is a contraindication or intolerance to this medication

AND

7 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

8 - Medication will not be used in combination with another oral CGRP inhibitor

Product Name: Nurtec ODT	
Diagnosis	Acute Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)

AND

2 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

3 - Medication will not be used in combination with another oral CGRP inhibitor

Product Name: Ubrelvy	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine with or without aura

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Patient has fewer than 15 headache days per month [23]

AND

4 - Patient is 18 years of age or older [I]

AND

5 - One of the following: [24]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

6 - If patient has 4 or more headache days per month, patient must be currently treated with one of the following: [D, 24]:

- Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications
- Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications
- Atacand (candesartan) unless there is a contraindication or intolerance to this medication

AND

7 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

8 - Medication will not be used in combination with another oral CGRP inhibitor

Product Name: Ubrelvy	
Diagnosis	Acute Treatment of Migraine

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)

AND

2 - Will not be used for preventive treatment of migraine

AND

3 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

4 - Medication will not be used in combination with another oral CGRP inhibitor

Product Name: Emgality 120 mg/mL	
Diagnosis	Preventive Treatment of Migraine
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Submission of medical records (e.g., chart notes) confirming a diagnosis of episodic migraines

AND

1.1.2 Submission of medical records (e.g., chart notes) confirming the patient has 4 to 14 migraine days per month, but no more than 14 headache days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Submission of medical records (e.g., chart notes) confirming a diagnosis of chronic migraines

AND

1.2.2 Submission of medical records (e.g., chart notes) confirming the patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming two of the following [D, E, F, G, 10]:

3.1 One of the following:

- History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine)
- Patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine)

OR

3.2 One of the following:

- History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- Patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate)

OR

3.3 One of the following:

- History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol
- Patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, metoprolol

OR

3.4 One of the following:

- History of failure (after at least a two month trial) or intolerance to Atacand (candesartan)
- Patient has a contraindication to Atacand (candesartan)

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to both of the following:

- Aimovig
- Ajovy

AND

5 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

6 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	Approval Length: 6 months [E]. *QL Override for Emgality (For new starts only): For migraine, please enter 2 PAs with the same start date as follows: First PA: Approve two pens or syringes per 30 days for 1 month with a fill count of 2 (Loading dose has a MDD of 0.066); Second PA: Approve one pen or syringe per 30 days (no overrides needed) for 6 months. (Emgality 120 mg/mL is hard-coded with a quantity of one prefilled pen/syringe per 30 days)

Product Name: Qulipta	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	6 Months [E]
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming both of the following:

1.1 Diagnosis of episodic migraines

AND

1.2 Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month [28]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming history of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following [D, E, F, G, 10]:

- Elavil (amitriptyline) or Effexor (venlafaxine)
- Dapakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol)
- Atacand (candesartan)

AND

4 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Product Name: Nurtec ODT	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	6 Months [E]
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming both of the following:

1.1 Diagnosis of episodic migraines

AND

1.2 Patient has 4 to 18 migraine days per month, but no more than 18 headache days per month [26]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming history of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following [D, E, F, G, 10]:

- Elavil (amitriptyline) or Effexor (venlafaxine)
- Dapakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol)
- Atacand (candesartan)

AND

4 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	Note: For use for preventive treatment of migraine, please enter a qualit y limit override of #16 tablets per 30 days (MDD, 0.54) for 6 months.

Product Name: Nurtec ODT	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of migraine with or without aura

AND

2 - Submission of medical records (e.g., chart notes) confirming drug will be used for the acute treatment of migraine

AND

3 - Submission of medical records (e.g., chart notes) confirming patient has fewer than 15 headache days per month [23]

AND

4 - Patient is 18 years of age or older [I]

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following: [24]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming that if patient has 4 or more headache days per month, patient must be currently treated with one of the following: [D, 24]:

- Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications
- Dapakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications
- Atacand (candesartan) unless there is a contraindication or intolerance to this medication

AND

7 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist

- Headache specialist [J]

AND

8 - Medication will not be used in combination with another oral CGRP inhibitor

Product Name: Ubrelvy	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of migraine with or without aura

AND

2 - Submission of medical records (e.g., chart notes) confirming drug will be used for the acute treatment of migraine

AND

3 - Submission of medical records (e.g., chart notes) confirming patient has fewer than 15 headache days per month [23]

AND

4 - Patient is 18 years of age or older [I]

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following: [24]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)

- Contraindication to all triptans

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming that if patient has 4 or more headache days per month, patient must be currently treated with one of the following: [D, 24]:

- Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications
- Dapakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications
- Atacand (candesartan) unless there is a contraindication or intolerance to this medication

AND

7 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [J]

AND

8 - Medication will not be used in combination with another oral CGRP inhibitor

3 . Endnotes

A. The International Classification of Headache Disorders, 3rd addition (beta version) distinguishes chronic and episodic migraine [11]. Chronic migraine is described as headache occurring on 15 or more days per month for more than 3 months, which has the features of migraine headache on at least 8 days per month. Episodic migraine is not clearly defined, but is applied when a patient is diagnosed with migraine but does not meet criteria for chronic migraine.
B. While every patient with chronic migraine should receive preventive therapy, not every patient with episodic migraine needs prevention [12]. Appropriate candidates for preventative treatment include those with at least 4 days per month of headache-related disability.
C. The phase 3 inclusion criteria for the erenumab (LIBERTY, STRIVE, ARISE) and galcanezumab (EVOLVE-1, EVOLVE-2) pivotal trials in episodic migraine required that patients had 4 to 14 migraine days per month [3-9]. The LEADER trial evaluated patients

who had failed two to four prior preventive migraine treatments (PMTs). At the start of the trial, 38.6%, 37.8%, and 22.8% of patients had failed two, three, and four prior PMTs, respectively [2].

D. The American Academy of Neurology supports the use of the following medications for the prevention of episodic migraine in adult patients (with level A or B evidence): antidepressants [i.e., Elavil (amitriptyline), Effexor (venlafaxine)], antiepileptics [i.e., Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], beta-blockers [i.e., atenolol, propranolol, nadolol, timolol, metoprolol], and candesartan [16, 24].
E. The US Headache Consortium Consensus (Table e-1) recommends that therapy be initiated with medications that have the highest level of evidence-based therapy while also taking into account patient specific comorbidities [15]. Each medication should be given an adequate trial, it may take two to three months to achieve clinical benefit, and six months to achieve maximal benefit.
F. The Samaritan Large Group clinical team consulted with a neurologist on the prospective review of the CGPR Inhibitors [14]. He confirmed that preventative treatment for chronic migraine and episodic migraine are similar. The choice of preventative medication will not vary much between the episodic vs chronic subtypes. The choice of agent will largely depend more on patient specific factors. Also, he felt that this agent will most likely fall into a similar place in therapy as Botox (onabotulinumtoxin A).
G. The National Institute for Health and Care Excellence guidelines for the management of migraine recommend Botox (onabotulinumtoxin A) as an option in chronic migraine after failure of at least three other prophylactic medications and that the patient is being managed for medication overuse [13].
H. Medication overuse headache (MOH) is defined as headache occurring greater than or equal to 15 days per month. It develops as a consequence of regular overuse of acute or symptomatic headache medication for more than 3 months [11]. Current evidence suggests the best treatment strategy is withdrawal of the offending medication.
I. The safety and effectiveness in pediatric patients has not been established [1, 17-19, 20, 22].
J. Headache specialists are physicians certified by the United Council for Neurologic Subspecialties (UCNS). [25]

4 . References

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5 . Revision History

Date	Notes
5/26/2023	Updated criteria for Qulipta with expanded indication of preventative tr eatment of migraine. Updated background and references.

Cimzia (certolizumab pegol)

Prior Authorization Guideline

Guideline ID	GL-116586
Guideline Name	Cimzia (certolizumab pegol)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Indications

Drug Name: Cimzia (certolizumab pegol)
Rheumatoid Arthritis (RA) Indicated for the treatment of adults with moderately to severely active rheumatoid arthritis. **Psoriatic Arthritis (PsA)** Indicated for the treatment of adult patients with active psoriatic arthritis (PsA). **Plaque Psoriasis (PsO)** Indicated for the treatment of adults with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy. **Ankylosing Spondylitis (AS)** Indicated for the treatment of adults with active ankylosing spondylitis. **Non-radiographic Axial Spondyloarthritis (nr-axSpA)** Indicated for the treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation. **Crohn’s Disease (CD)** Indicated for reducing signs and symptoms of Crohn's disease (CD) and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.

2 . Criteria

Product Name: Cimzia	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active RA

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4, 5]:

- methotrexate
- leflunomide
- sulfasalazine

Product Name: Cimzia	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4, 5]:

- Reduction in the total active (swollen and tender) joint count from baseline

- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Cimzia	
Diagnosis	Psoriatic Arthritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [6]:

- actively inflamed joints
- dactylitis
- enthesitis
- axial disease
- active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Product Name: Cimzia	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 6]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name: Cimzia	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [8]:

- Greater than or equal to 3% body surface area involvment
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [9]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name: Cimzia	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1, 8]:

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name: Cimzia	
Diagnosis	Ankylosing Spondylitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses [7]

Product Name: Cimzia	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following [1, 7]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name: Cimzia	
Diagnosis	Non-radiographic Axial Spondyloarthritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active non-radiographic axial spondyloarthritis

AND

2 - Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) [1, 7]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [7]

Product Name: Cimzia	
Diagnosis	Non-radiographic Axial Spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following [1, 7]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Function
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name: Cimzia	
Diagnosis	Crohn’s disease
Approval Length	16 Weeks [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn’s disease

AND

2 - One of the following [2, 3]:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CDAI) greater than 220

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [2, 3]:

- 6-mercaptopurine
- Azathioprine
- Corticosteroids (e.g., prednisone)
- Methotrexate

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name: Cimzia	
Diagnosis	Crohn's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline

- Reversal of high fecal output state

3 . Endnotes

A. The recommended initial adult dose of Cimzia is 400 mg (given as two subcutaneous injections of 200 mg) initially, and at Weeks 2 and 4. In patients who obtain a clinical response, the recommended maintenance regimen is 400 mg every four weeks.

4 . References

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5 . Revision History

Date	Notes
10/28/2022	Bulk copy OptumRx SP to Samaritan SP for 1/1/2023 Implementation

Cinqair (reslizumab)

Prior Authorization Guideline

Guideline ID	GL-124534
Guideline Name	Cinqair (reslizumab)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	5/19/2016
P&T Revision Date:	02/13/2020 ; 03/17/2021 ; 03/16/2022 ; 05/19/2022 ; 5/18/2023

1 . Indications

Drug Name: Cinqair (reslizumab)
Severe Eosinophilic Asthma Indicated for the add-on maintenance treatment of patients with severe asthma aged 18 years and older with an eosinophilic phenotype. Limitation of Use: Cinqair is not indicated for treatment of other eosinophilic conditions; Cinqair is not indicated for the relief of acute bronchospasm or status asthmaticus.

2 . Criteria

Product Name: Cinqair	
Approval Length	6 Months [H]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe asthma [1]

AND

2 - Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter [1, B, D]

AND

3 - One of the following:

3.1 Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months [A]

OR

3.2 Prior asthma-related hospitalization within the past 12 months [D]

AND

4 - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

4.1 Both of the following: [C, E, F]

- High-dose inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate equivalent/day]
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium)

OR

4.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol], Breo Ellipta [fluticasone/vilanterol])

AND

5 - Age greater than or equal to 18 years

AND

6 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/immunologist

Product Name: Cinqair	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications)

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

3 . Background

Clinical Practice Guidelines

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 1. Low, medium and high daily doses of inhaled corticosteroids in adolescents and adults 12 years and older [6]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	> 500-1000	> 1000
Beclometasone dipropionate (DPI or pMDI, extrafine particle*, HFA)	100-200	> 200-400	> 400
Budesonide (DPI, or pMDI, standard particle, HFA)	200-400	> 400-800	> 800
Ciclesonide (pMDI, extrafine particle*, HFA)	80-160	> 160-320	> 320
Fluticasone furoate (DPI)	100		200
Fluticasone propionate (DPI)	100-250	> 250-500	> 500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	> 250-500	> 500
Mometasone furoate (DPI)	Depends on DPI device – see product information		
Mometasone furoate (pMDI, standard particle, HFA)	200-400		> 400

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

This is not a table of equivalence, but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

4 . Endnotes

A. In two duplicate 52-week Phase III studies, eligible patients were required to have experienced at least one asthma exacerbation that required a systemic corticosteroid for at least 3 days within the past 12 months. [2, 3]
B. The Institute for Clinical and Economic Review (ICER) defines eosinophilic inflammation as a blood eosinophil level greater than or equal to 150 cells per microliter at initiation of therapy. This is the lowest measured threshold for eosinophilic asthma in pivotal trials. [8]
C. The ERS/ATS guidelines define severe asthma as that which requires treatment with high-dose ICSs plus a second controller (or systemic corticosteroids [CSs]) to prevent progression to uncontrolled disease status or continuing uncontrolled disease status despite this therapy. [4]
D. Recommended per national P&T committee meeting, December 2015, regarding similar agent first-in-class IL-5 antagonist Nucala (mepolizumab) in the use of severe eosinophilic asthma.
E. In the pivotal study for Nucala (mepolizumab), another IL-5 antagonist indicated for severe eosinophilic asthma, patients met the inclusion criteria with a well-documented requirement for regular treatment with high dose ICS (i.e., greater than or equal to 880 mcg/day fluticasone propionate or equivalent daily), with or without maintenance oral corticosteroids, in the 12 months prior to Visit 1. [5]
F. The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention update lists anti-interleukin- 5 treatment or anti-interleukin 5 receptor treatment as an add on option for patients with severe eosinophilic asthma that is uncontrolled on two or more controllers plus as-needed reliever medication (Step 4-5 treatment). [6]
G. Asthma treatment can often be reduced, once good asthma control has been achieved and maintained for three months and lung function has hit a plateau. However the approach to stepping down will depend on patient specific factors (e.g., current medications, risk factors). At this time evidence for optimal timing, sequence and magnitude of treatment reductions is limited. It is feasible and safe for most patients to reduce the ICS dose by 25-50% at three month intervals, but complete cessation of ICS is associated with a significant risk of exacerbations [6].
H. The GINA Global Strategy for Asthma Management and Prevention update recommends that patients with asthma should be reviewed regularly to monitor their symptom control, risk factors and occurrence of exacerbations, as well as to document the response to any treatment changes. Ideally, response to Type 2-targeted therapy should be re-evaluated every 3-6 months, including re-evaluation of the need for ongoing biologic therapy for patients with good response to Type 2 targeted therapy. [6]

5 . References

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4. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. Eur Respir J. 2014; 43:343-373.
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6. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention (2022 update). 2022 www.ginasthma.org. Accessed April 2023
7. Per clinical consult with allergist specialist. May 4, 2016.
8. Institute for Clinical and Economic Review (ICER). Biologic therapies for treatment of asthma associated with type 2 inflammation: effectiveness, value, and value-based price benchmarks. https://icer.org/wp-content/uploads/2020/10/ICER_Asthma-Final-Report_Unredacted_08122020.pdf. Published December 20, 2018. Accessed April 15, 2022.

6 . Revision History

Date	Notes
4/24/2023	2023 UM Annual Review. No criteria changes. Background updates

Clinical Duplicates Prior Authorization (PA) Program

Prior Authorization Guideline

Guideline ID	GL-125162
Guideline Name	Clinical Duplicates Prior Authorization (PA) Program
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	10/20/2021
P&T Revision Date:	11/18/2021 ; 01/19/2022 ; 03/16/2022 ; 04/20/2022 ; 05/19/2022 ; 06/15/2022 ; 08/18/2022 ; 09/21/2022 ; 10/19/2022 ; 11/17/2022 ; 04/19/2023 ; 04/19/2023 ; 6/21/2023

1 . Criteria

Product Name: Acuvail, Adlarity, Ala-Scalp lotion, Alkindi Sprinkle, Brand Allzital, Alocril, Alrex, Analpram-HC lotion, Antara, Aspruzyo Sprinkle, Brand Baclofen, Baclofen suspension, Brand Fenofibrate micronized capsules, Apexicon E cream, Betoptic-S, Bryhali lotion, Brand Butalbital/apap 50-300 mg capsules, Capex shampoo, Clarinex-D, Conjupri, Consensi, Cordran cream/tape, Cortisone tablets, Brand Cyclobenzaprine/Gabapentin pak 10/300, Brand Decadron, Denavir cream, Dexabliss, Brand Durezol, Durlaza, Dutoprol, Dxevo, Ecoza, Brand Epaned, Ertaczo, Exelderm, Brand Sulconazole nitrate cream/solution, Flector patch, Fleqsuvy susp, Brand Diclofenac epolamine patch, Fosamax+D, Gialax, Gilphex TR, Giltuss, Giltuss TR, Gimoti, Glycate, Brand Glycopyrrolate, Halog ointment/solution, Hemady, Hidex, Impeklo, Inderal XL, Innopran XL, Karbinal ER, Katerzia, Kristalose, Lexette foam, Brand Halobetasol foam, Brand Levamlodipine, Licart patch, Loreev XR, Brand Lotemax gel, Lotemax ointment, Luzu cream, Brand Luliconazole cream, Lyvispah, generic methocarbamol 1000 mg, Brand Mentax cream, Generic metformin 625 mg, Brand Millipred, Motofen, Naprelan, Brand Naproxen ER, Neotuss Plus, Nexiclon XR, Brand Clonidine ER (Nexiclon XR ABA), Brand Norgesic Forte, Brand Orphengesic Forte, Oravig, Ortikos, Otovel, Brand Ciprofloxacin/Fluocinolone PF soln, Oxistat, Ozobax, Pandel cream, Pliaglis cream, Brand Lidocaine/Tetracaine cream, Generic prednisolone,

Brand Psorcon cream, Qbrelis, Qmiiz ODT, Rayos, Relafen DS, Reltone, Brand Ursodiol, Sancuso, Seglentis, Semprex-D, Sitavig, Sivextro tab, Sorilux, Brand Calcipotriene Aer, Sulfamylon cream, Synera, Taperdex, Brand Trianex oint, Ultravate lotion, Brand Valsartan oral solution, Vanatol LQ, Vanatol S, VTOL, Verdeso, Veregen, Vusion, Brand Miconazole Nitrate/Zinc Oxide/White Petrolatum oint, Xolegel, Yosprala, Brand Aspirin/Omeprazole tab, Zcort, Zilretta inj, Zuplenz	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 One of the following:

1.1.1 Both of the following:

1.1.1.1 Requested drug is FDA-approved for the condition being treated

AND

1.1.1.2 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)

OR

1.1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

AND

1.2 One of the following:

1.2.1 Patient has failed or has contraindications or intolerance to at least three generic formulary drugs. If only one or only two generic drugs are available, the patient must have failed or had contraindications or intolerance to all available generic formulary drugs. The clinician's judgment should be used to determine appropriate generic formulary drugs for the indication provided.*

OR

1.2.2 Both of the following:

1.2.2.1 Only over-the-counter (OTC) equivalents are available

AND

1.2.2.2 Patient has tried and failed or has contraindications or intolerance to three OTC equivalents. If only one or only two equivalents are available, the patient must have failed or had contraindications or intolerance to all available OTC equivalents [document drug(s), dose, duration of trial] The clinician's judgment should be used to determine equivalent formulary drugs for the indication provided.*

OR

1.2.3 No formulary or OTC drug is appropriate to treat the patient's condition

Notes	*Please consult client-specific resources to determine appropriate gene ric formulary drugs.

Product Name: Abilify Mycite, Spritam	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 One of the following:

1.1.1 Both of the following:

1.1.1.1 Requested drug is FDA-approved for the condition being treated

AND

1.1.1.2 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)

OR

1.1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

AND

1.2 One of the following:

1.2.1 Patient has failed or has contraindications or intolerance to at least three generic formulary drugs. If only one or only two generic drugs are available, the patient must have failed or had contraindications or intolerance to all available generic formulary drugs. The clinician's judgment should be used to determine appropriate generic formulary drugs for the indication provided.*

OR

1.2.2 Both of the following:

1.2.2.1 Only over-the-counter (OTC) equivalents are available

AND

1.2.2.2 Patient has tried and failed or has contraindications or intolerance to three OTC equivalents. If only one or only two equivalents are available, the patient must have failed or had contraindications or intolerance to all available OTC equivalents [document drug(s), dose, duration of trial] The clinician's judgment should be used to determine equivalent formulary drugs for the indication provided.*

OR

1.2.3 No formulary or OTC drug is appropriate to treat the patient's condition

OR

1.2.4 For continuation of prior therapy

Notes	*Please consult client-specific resources to determine appropriate generic formulary drugs.

2 . Revision History

Date	Notes
5/1/2023	Added Baclofen suspension to guideline

Colony-Stimulating Factors (CSFs) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-126095
Guideline Name	Colony-Stimulating Factors (CSFs) - PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	9/1/2024
P&T Approval Date:	8/1/2006
P&T Revision Date:	01/15/2020 ; 04/15/2020 ; 08/13/2020 ; 02/18/2021 ; 04/21/2021 ; 12/15/2021 ; 04/20/2022 ; 11/17/2022 ; 02/16/2023 ; 03/15/2023 ; 04/19/2023 ; 06/21/2023 ; 11/16/2023 ; 03/20/2024 ; 04/17/2024

1 . Indications

Drug Name: Fulphila (pegfilgrastim-jmdb, G-CSF), Fylnetra (pegfilgrastim-pbbk), Nyvepria (pegfilgrastim-apgf, G-CSF), Stimufend (pegfilgrastim-fpgk), Ziextenzo (pegfilgrastim-bmez, G-CSF)
Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Limitations of Use: Pegfilgrastim is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. **Off Label Uses: Hematopoietic Subsyndrome of Acute Radiation Syndrome** To increase survival in patients acutely exposed to myelosuppressive doses of radiation. [1, 33, 35, M] **Treatment of High-Risk Febrile Neutropenia (FN)** For the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34, 35]
Drug Name: Granix (tbo-filgrastim, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to reduce the duration of severe neutropenia in adult and pediatric patients 1 month and older with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia.

Off Label Uses: Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Hematopoietic Subsyndrome of Acute Radiation Syndrome To increase survival in patients acutely exposed to myelosuppressive doses of radiation. [16]

Drug Name: Leukine (sargramostim, GM-CSF)

Acute Myeloid Leukemia (AML) Following Induction Chemotherapy Indicated to shorten time to neutrophil recovery and to reduce the incidence of severe, life-threatening, or fatal infections following induction chemotherapy in adult patients 55 years and older with acute myeloid leukemia (AML).

Autologous Peripheral Blood Progenitor Cell Mobilization and Collection Indicated in adult patients with cancer undergoing autologous hematopoietic stem cell transplantation for the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis.

Autologous Peripheral Blood Progenitor Cell and Bone Marrow Transplantation Indicated for the acceleration of myeloid reconstitution following autologous peripheral blood progenitor cell (PBPC) or bone marrow transplantation in adult and pediatric patients 2 years of age and older with non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL) and Hodgkin's lymphoma (HL).

Allogeneic Bone Marrow Transplantation (BMT) Indicated for the acceleration of myeloid reconstitution in adult and pediatric patients 2 years of age and older undergoing allogeneic bone marrow transplantation from HLA-matched related donors.

Allogeneic or Autologous Bone Marrow Transplantation: Treatment of Delayed Neutrophil Recovery or Graft Failure Indicated for the treatment of adult and pediatric patients 2 years and older who have undergone allogeneic or autologous bone marrow transplantation in whom neutrophil recovery is delayed or failed.

Hematopoietic Syndrome of Acute Radiation Syndrome (H-ARS) Indicated to increase survival in adult and pediatric patients from birth to 17 years of age acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]).

Off Label Uses: Febrile Neutropenia (FN), Prophylaxis Has been used in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever [11]

Human Immunodeficiency Virus (HIV)-Related Neutropenia Has been prescribed for HIV-related neutropenia [37]

Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN

in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Neulasta, Neulasta Onpro (pegfilgrastim, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Neulasta is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Hematopoietic Subsyndrome of Acute Radiation Syndrome Indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Off Label Uses: Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Neupogen (filgrastim, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by FN, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.

Patients with Acute Myeloid Leukemia (AML) Receiving Induction or Consolidation Chemotherapy Indicated for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of adults with AML.

Patients with Cancer Undergoing Bone Marrow Transplantation (BMT) Indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation.

Patients Undergoing Autologous Peripheral Blood Progenitor Cell (PBPC) Collection and Therapy Indicated for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.

Patients with Severe Chronic Neutropenia (SCN) Indicated for chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

Hematopoietic Syndrome of Acute Radiation Syndrome Indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Off Label Uses: Human Immunodeficiency Virus (HIV)-Related Neutropenia Has been prescribed for HIV-related neutropenia. [11-15, 37]

Hepatitis-C Interferon Induced Neutropenia Neupogen has been prescribed for interferon-induced neutropenia in Hepatitis C virus infected patients [4-10, 23, 24]

Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN

in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Nivestym (filgrastim-aafi, G-CSF), Zarxio (filgrastim-sndz, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by FN, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.

Patients with Acute Myeloid Leukemia (AML) Receiving Induction or Consolidation Chemotherapy Indicated for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with AML.

Patients with Cancer Undergoing Bone Marrow Transplantation Indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation.

Patients Undergoing Peripheral Blood Progenitor Cell (PBPC) Collection and Therapy Indicated for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.

Patients with Severe Chronic Neutropenia (SCN) Indicated for chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

Off Label Uses: Hematopoietic Subsyndrome of Acute Radiation Syndrome Has been used to increase survival in patients acutely exposed to myelosuppressive doses of radiation. [1, 33, 35, M]

Hepatitis-C Interferon Induced Neutropenia Has been prescribed for interferon-induced neutropenia in Hepatitis C virus infected patients [4-10, 23, 24, M]

Human Immunodeficiency Virus (HIV)-Related Neutropenia Has been prescribed for HIV-related neutropenia. [11, 37]

Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Releuko (filgrastim-ayow)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by FN, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.

Patients with Acute Myeloid Leukemia (AML) Receiving Induction or Consolidation Chemotherapy Indicated for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with AML.

Patients with Cancer Undergoing Bone Marrow Transplantation Indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in

patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation.

Patients with Severe Chronic Neutropenia (SCN) Indicated for chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

Off Label Uses: Patients Undergoing Peripheral Blood Progenitor Cell (PBPC) Collection and Therapy Indicated for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.

Hematopoietic Subsyndrome of Acute Radiation Syndrome Has been used to increase survival in patients acutely exposed to myelosuppressive doses of radiation. [1, 33, 35, M]

Hepatitis-C Interferon Induced Neutropenia Has been prescribed for interferon-induced neutropenia in Hepatitis C virus infected patients [4-10, 23, 24, M]

Human Immunodeficiency Virus (HIV)-Related Neutropenia Has been prescribed for HIV-related neutropenia. [11, 37]

Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Rolvedon (eflapegrastim-xnst)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Rolvedon is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Drug Name: Udenyca (pegfilgrastim-cbqv, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Limitations of Use: Udenyca is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Hematopoietic Subsyndrome of Acute Radiation Syndrome To increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Off Label Uses: Treatment of High-Risk Febrile Neutropenia (FN) For the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34, 35]

2 . Criteria

Product Name: Leukine, Neupogen, Nivestym, Releuko, or Zarxio	
Diagnosis	Bone Marrow/Stem Cell Transplant
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient has non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT)

OR

1.2 Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

OR

1.3 Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Patient is 2 years of age or older (applies to Leukine only)

AND

4 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name: Neupogen	
Diagnosis	Bone Marrow/Stem Cell Transplant
Approval Length	3 months or duration of therapy
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 Patient has non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT)

OR

1.2 Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

OR

1.3 Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following:

- Nivestym
- Zarxio

Product Name: Leukine	
Diagnosis	Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy
Approval Length	3 months or duration of therapy [C]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML) [A]

AND

2 - Patient has completed induction or consolidation chemotherapy [27]

AND

3 - Patient is 55 years of age or older [3, B]

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Neupogen, Nivestym, Releuko, or Zarxio	
Diagnosis	Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy
Approval Length	3 months or duration of therapy [C]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML) [A]

AND

2 - Patient has completed induction or consolidation chemotherapy [27]

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

AND

4 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name: Neupogen	
Diagnosis	Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy
Approval Length	3 months or duration of therapy [C]
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML) [A]

AND

2 - Patient has completed induction or consolidation chemotherapy [27]

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following:

- Nivestym
- Zarxio

Product Name: Fulphila, Fylnetra, Granix, Leukine (Off-Label), Neulasta/Neulasta Onpro*, Releuko, Neupogen, Nivestym, Nyvepria, Stimufend, Udenyca/Udenyca Onbody*, Zarxio, or Ziextenzo	
Diagnosis	Febrile Neutropenia Prophylaxis
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient will be receiving prophylaxis for febrile neutropenia (FN) due to one of the following:

1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer (see Table 1 in Background section) [16-19, 34, D, E]

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown [E]

OR

1.3 One of the following:

1.3.1 Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN (see Table 2 in Background section) [16, 17, 34, I]

OR

1.3.2 Both of the following:

1.3.2.1 Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN (see Table 3 in Background section) [16, J]

AND

1.3.2.2 Patient has one or more risk factors associated with chemotherapy induced infection, FN, or neutropenia [16, 17, 34, K]

OR

1.4 Both of the following:

1.4.1 Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [L]

AND

1.4.2 Patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis) [16, 17, 34]

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - One of the following:

3.1 Trial and failure or intolerance to both of the following (applies to Neupogen, Releuko, and Granix only):

- Nivestym
- Zarxio

OR

3.2 Trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, Stimufend, and Ziextenzo only):

- Neulasta/Neulasta Onpro
- Udenyca/Udenyca Onbody

Notes	*If patient meets criteria above, please approve both Neulasta/Neulasta Onpro, Udenyca/Udenyca Onbody at GPI list “FILGRASTPA”.

Product Name: Fulphila, Fylnetra, Granix, Neupogen, Nyvepria, Ziextenzo	
Diagnosis	Febrile Neutropenia Prophylaxis
Approval Length	3 months or duration of therapy
Guideline Type	Non Formulary

Approval Criteria

1 - Patient will be receiving prophylaxis for febrile neutropenia (FN) due to one of the following:

1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer (see Table 1 in Background section) [16-19, 34, D, E]

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown [E]

OR

1.3 One of the following:

1.3.1 Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN (see Table 2 in Background section) [16, 17, 34, I]

OR

1.3.2 Both of the following:

1.3.2.1 Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN (see Table 3 in Background section) [16, J]

AND

1.3.2.2 Patient has one or more risk factors associated with chemotherapy induced infection, FN, or neutropenia [16, 17, 34, K]

OR

1.4 Both of the following:

1.4.1 Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [L]

AND

1.4.2 Patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis) [16, 17, 34]

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Neupogen and Granix only):

- Nivestym
- Zarxio

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, and Ziextenzo only):

- Neulasta/Neulasta Onpro
- Udenyca/Udenyca Onbody

Product Name: Rolvedon	
Diagnosis	Febrile Neutropenia Prophylaxis
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient will be receiving prophylaxis for febrile neutropenia (FN) due to one of the following:

1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense

chemotherapy protocol for primary breast cancer (see Table 1 in Background section) [16-19, 34, D, E]

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown [E]

OR

1.3 One of the following:

1.3.1 Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN (see Table 2 in Background section) [16, 17, 34, I]

OR

1.3.2 Both of the following:

1.3.2.1 Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN (see Table 3 in Background section) [16, J]

AND

1.3.2.2 Patient has one or more risk factors associated with chemotherapy induced infection, FN, or neutropenia [16, 17, 34, K]

OR

1.4 Both of the following:

1.4.1 Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [L]

AND

1.4.2 Patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis) [16, 17, 34]

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Trial and failure or intolerance to ONE of the following:

- Neulasta/Neulasta Onpro
- Udenyca/Udenyca Onbody

Product Name: Rolvedon	
Diagnosis	Febrile Neutropenia Prophylaxis
Approval Length	3 months or duration of therapy
Guideline Type	Non Formulary

Approval Criteria

1 - Patient will be receiving prophylaxis for febrile neutropenia (FN) due to one of the following:

1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer (see Table 1 in Background section) [16-19, 34, D, E]

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown [E]

OR

1.3 One of the following:

1.3.1 Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN (see Table 2 in Background section) [16, 17, 34, I]

OR

1.3.2 Both of the following:

1.3.2.1 Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN (see Table 3 in Background section) [16, J]

AND

1.3.2.2 Patient has one or more risk factors associated with chemotherapy induced infection, FN, or neutropenia [16, 17, 34, K]

OR

1.4 Both of the following:

1.4.1 Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [L]

AND

1.4.2 Patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis) [16, 17, 34]

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to ONE of the following:

- Neulasta/Neulasta Onpro
- Udenyca/Udenyca Onbody

Product Name: Fulphila, Fylnetra, Granix, Leukine, Neulasta/Neulasta Onpro*, Neupogen, Nivestym, Nyvepria, Releuko, Stimufend, Udenyca/Udenyca Onbody*, Zarxio, or Ziextenzo	
Diagnosis	Treatment of High-Risk Febrile Neutropenia (Off-label) [34]
Approval Length	3 Months or duration of therapy
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [34, I]

AND

2 - Diagnosis of febrile neutropenia (FN)

AND

3 - Patient is at high risk for infection-associated complications [16, 17, 34]

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

AND

5 - One of the following:

5.1 Trial and failure or intolerance to both of the following (applies to Neupogen, Releuko, and Granix only):

- Nivestym
- Zarxio

OR

5.2 Trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, Stimufend, and Ziextenzo only):

- Neulasta/Neulasta Onpro
- Udenyca/Udenyca Onbody

Notes	*If patient meets criteria above, please approve both Neulasta/Neulasta Onpro, Udenyca/Udenyca Onbody at GPI list “FILGRASTPA”.

Product Name: Fulphila, Fylnetra, Granix, Neupogen, Nyvepria, Ziextenzo	
Diagnosis	Treatment of High-Risk Febrile Neutropenia (Off-label) [34]
Approval Length	3 Months or duration of therapy
Guideline Type	Non Formulary

Approval Criteria

1 - Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [34, I]

AND

2 - Diagnosis of febrile neutropenia (FN)

AND

3 - Patient is at high risk for infection-associated complications [16, 17, 34]

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Neupogen and Granix only):

- Nivestym
- Zarxio

OR

5.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, and Ziextenzo only):

- Neulasta/Neulasta Onpro
- Udenyca/Udenyca Onbody

Product Name: Neupogen, Nivestym, Releuko, or Zarxio	
Diagnosis	Severe Chronic Neutropenia (SCN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For patients with severe chronic neutropenia (SCN) (i.e., congenital, cyclic, and idiopathic neutropenias with chronic absolute neutrophil count [ANC] less than or equal to 500 cells/mm^3) [16]

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name: Neupogen	
Diagnosis	Severe Chronic Neutropenia (SCN)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - For patients with severe chronic neutropenia (SCN) (i.e., congenital, cyclic, and idiopathic neutropenias with chronic absolute neutrophil count [ANC] less than or equal to 500 cells/mm^3) [16]

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following:

- Nivestym
- Zarxio

Product Name: Fulphila (Off-Label), Fylnetra (Off-label), Granix (Off-Label), Leukine, Neulasta, Neupogen, Nivestym (Off-Label), Nyvepria (Off-Label), Releuko (Off-Label), Stimufend (Off-label), Udenyca, Zarxio (Off-Label), or Ziextenzo (Off-Label)	
Diagnosis	Acute Radiation Syndrome (ARS)
Approval Length	1 Months [N]
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient was/will be acutely exposed to myelosuppressive doses of radiation

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - One of the following:

3.1 Trial and failure or intolerance to both of the following (applies to Neupogen, Granix and Releuko only):

- Nivestym
- Zarxio

OR

3.2 Trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, and Stimufend, Ziextenzo only):

- Neulasta

- Udenyca

Product Name: Fulphila (Off-Label), Fylnetra (Off-Label), Granix (Off-Label), Neupogen, Nyvepria (Off-Label), Ziextenzo	
Diagnosis	Acute Radiation Syndrome (ARS)
Approval Length	1 Months [N]
Guideline Type	Non Formulary

Approval Criteria

1 - Patient was/will be acutely exposed to myelosuppressive doses of radiation

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Neupogen only):

- Nivestym
- Zarxio

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, and Ziextenzo only):

- Neulasta
- Udenyca

Product Name: Leukine, Neupogen, Nivestym, Releuko, or Zarxio	
Diagnosis	Human Immunodeficiency Virus (HIV)-Related Neutropenia (Off-Label)
Approval Length	6 months [11, 15, H]
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is infected with HIV virus [11- 13]

AND

2 - ANC less than or equal to 1,000 (cells/mm3) [12, 13]

AND

3 - Prescribed by or in consultation with one of the following:

- Hematologist/oncologist
- Infectious disease specialist

AND

4 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name: Neupogen	
Diagnosis	Human Immunodeficiency Virus (HIV)-Related Neutropenia (Off-Label)
Approval Length	6 months [11, 15, H]
Guideline Type	Non Formulary

Approval Criteria

1 - Patient is infected with HIV virus [11- 13]

AND

2 - ANC less than or equal to 1,000 (cells/mm3) [12, 13]

AND

3 - Prescribed by or in consultation with one of the following:

- Hematologist/oncologist
- Infectious disease specialist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following:

- Nivestym
- Zarxio

Product Name: Neupogen, Nivestym, Releuko, Zarxio	
Diagnosis	Hepatitis-C Treatment Related Neutropenia (Off-Label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Patient is infected with Hepatitis C virus

AND

1.1.2 Patient is undergoing treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

AND

1.1.3 Patient has neutropenia (absolute neutrophil count [ANC] less than or equal to 500 cells/mm3) after dose reduction of Peg-Intron or Pegasys [F]

OR

1.2 Both of the following:

1.2.1 Patient is experiencing interferon-induced neutropenia (ANC less than or equal to 500 cells/mm3) due to treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

AND

1.2.2 One of the following: [G]

1.2.2.1 Patient with Human Immunodeficiency Virus (HIV) co-infection

OR

1.2.2.2 Status post liver transplant

OR

1.2.2.3 Patient with established cirrhosis

AND

2 - Prescribed by or in consultation with one of the following:

- Hematologist/oncologist
- Infectious disease specialist
- Hepatologist
- Gastroenterologist

AND

3 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name: Neupogen	
Diagnosis	Hepatitis-C Treatment Related Neutropenia (Off-Label)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Patient is infected with Hepatitis C virus

AND

1.1.2 Patient is undergoing treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

AND

1.1.3 Patient has neutropenia (absolute neutrophil count [ANC] less than or equal to 500 cells/mm3) after dose reduction of Peg-Intron or Pegasys [F]

OR

1.2 Both of the following:

1.2.1 Patient is experiencing interferon-induced neutropenia (ANC less than or equal to 500 cells/mm3) due to treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

AND

1.2.2 One of the following: [G]

1.2.2.1 Patient with Human Immunodeficiency Virus (HIV) co-infection

OR

1.2.2.2 Status post liver transplant

OR

1.2.2.3 Patient with established cirrhosis

AND

2 - Prescribed by or in consultation with one of the following:

- Hematologist/oncologist
- Infectious disease specialist
- Hepatologist
- Gastroenterologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following:

- Nivestym
- Zarxio

3 . Background

Benefit/Coverage/Program Information

Table 1. Intergroup C9741 Protocol [19]

Regimen	Drugs	G-CSF
Sequential	Doxorubicin q2 weeks x4 cycles, then paclitaxel q2 weeks x4 cycles, then cyclophosphamide q2 weeks x 4cycles	Days 3 to 10 of each cycle
Concurrent	Doxorubicin + cyclophosphamide q2 weeks x4 cycles, then paclitaxel q2 weeks x4 cycles	Days 3 to 10 of each cycle

Table 2. Examples of chemotherapy regimens with a high risk of FN (> 20%) [16]

Cancer	Regimen
Bladder Cancer	• Dose-dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
Bone Cancer	• VAI (vincristine, doxorubicin or dactinomycin, ifosfamide) • VDC-IE (vincristine, doxorubicin or dactinomycin, and cyclophosphamide alternating with ifosfamide and etoposide) • Cisplatin/doxorubicin • VDC (cyclophosphamide, vincristine, doxorubicin or dactinomycin) • VIDE (vincristine, ifosfamide, doxorubicin or dactinomycin, etoposide)
Breast Cancer[18]	• Dose-dense AC followed by dose-dense paclitaxel (doxorubicin, cyclophosphamide, paclitaxel) • TAX (docetaxel, doxorubicin, cyclophosphamide) • TC (docetaxel, cyclophosphamide) • TCH (docetaxel, carboplatin, trastuzumab)
Colorectal Cancer	• FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, irinotecan)
Head and Neck Squamous Cell Carcinoma	• TPF (docetaxel, cisplatin, 5-fluorouracil)
Hodgkin Lymphoma	• Brentuximab vedotin + AVD (doxorubicin, vinblastine, dacarbazine) • Escalated BEACOPP (bleomycin, etoposide, doxorubivin, cyclophosphamide, vincristine, procarbazine, prednisone)
Kidney Cancer	• Doxorubicin/gemcitabine
Non-Hodgkin's Lymphomas	• Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) • ICE (ifosfamide, carboplatin, etoposide) • Dose-dense CHOP-14 (cyclophosphamide, doxorubicin, vincristine, prednisone) • MINE (mesna, ifosfamide, mitoxantrone, etoposide) • DHAP (dexamethasone, cisplatin, cytarabine) • ESHAP (etoposide, methylprednisolone, cisplatin, cytarabine) • HyperCVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone)
Melanoma	• Dacarbazine-based combination with IL-2, interferon alfa (dacarbazine, cisplatin, vinblastine, IL-2, interferon alfa)
Multiple Myeloma	• DT-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide) +/- bortezomib (VTD-PACE)
Ovarian Cancer	• Topotecan • Docetaxel

Pancreatic Cancer	• FOLFIRINOX (fluorouracil, leucovorin, irinotecan, oxaliplatin)
Soft Tissue Sarcoma	• MAID (mesna, doxorubicin, ifosfamide, dacarbazine) • Doxorubicin • Ifosfamide/doxorubicin
Small Cell Lung Cancer	• Topotecan
Testicular Cancer	• VIP (etoposide, ifosfamide, cisplatin) • VeIP (vinblastine, ifosfamide, cisplatin) • TIP (paclitaxel, ifosfamide, cisplatin)

Table 3. Examples of chemotherapy regimens with an intermediate risk of FN (10-20%) [16]

Cancer	**Regimen**
Occult Primary-Adenocarcinoma	• Gemcitabine/docetaxel
Breast Cancer	• Docetaxel • AC (doxorubicin, cyclophosphamide) + sequential docetaxel (adjuvant) (taxane portion only) • Paclitaxel every 21 days•
Cervical Cancer	• Cisplatin/topotecan • Paclitaxel/cisplatin • Topotecan • Irinotecan
Colorectal Cancer	• FOLFOX (fluorouracil, leucovorin, oxaliplatin)
Non-Hodgkin's Lymphomas (NHL)[26]	• GDP (gemcitabine, dexamethasone, cisplatin/carboplatin) • CHOP (cyclophosphamide, doxorubivin, vincristine, prednisone) including regimens with pegylated liposomal doxorubicin • CHP (cyclophosphamide, doxorubicin, prednisone) + brentuximab vedotin • Bendamustine
Non-Small Cell Lung Cancer	• Cisplatin/paclitaxel • Cisplatin/vinorelbine • Cisplatin/docetaxel • Cisplatin/etoposide • Carboplatin/paclitaxel • Docetaxel
Ovarian Cancer	• Carboplatin/docetaxel
Prostate Cancer	• Cabazitaxel

Testicular Cancer	• Etoposide/cisplatin • BEP (bleomycin, etoposide, cisplatin)
Esophageal and Gastric Cancer	• Irinotecan/cisplatin • Epirubicin/cisplatin/5-flurouracil • Epirubicin/cisplatin/capecitabine
Small Cell Lung Cancer	• Etoposide/carboplatin
Uterine Cancer	• Docetaxel

Table 4. Examples of FDA-approved chemotherapeutic agents with dose-limiting myelosuppression

Generic Name	**Brand Name**
Busulfan	Busulfex®, Myleran®
Carboplatin	Paraplatin®
Carmustine (BCNU)	BiCNU®, Gliadel®
Chlorambucil	Leukeran®
Cladribine	Luestatin®
Cyclophosphamide	Cytoxan®
Cytarabine	N/A
Dacarbazine (DTIC)	DTIC-Dome®
Dactinomycin	Actinomycin D®, Cosmegen®
Daunorubicin	Cerubidine®
Daunorubicin Liposomal	DaunoXome®
Doxorubicin	Adriamycin PFS®, Adriamycin RDF®, Adriamycin®
Doxorubicin Liposomal	Doxil®
Etoposide	Etopophos®, Toposar®, VePesid®
Fluorouracil (5-FU)	Adrucil®, Efudex®, Fluoroplex®
Floxuridine	FUDR®
Fludarabine	Fludara®
Hydroxyurea	Droxia®, Hydrea®
Ifosfamide/Mesna	Ifex®, Mesnex®
Lomustine (CCNU)	CeeNU®
Mechlorethamine (Nitrogen Mustard)	Mustargen®
Melphalan	Alkeran®
Mercaptopurine (6-MP)	Purinethol®
Methotrexate	Rheumatrex®, Trexall®
Mitomycin	N/A
Mitoxantrone	Novantrone®
Paclitaxel	Onxol™, Taxol®
Procarbazine	Matulane®
Teniposide	Vumon®
Thioguanine (6-TG)	Tabloid®
Thiotepa	Thiotepa®
Vinblastine	N/A

Vincristine	Vincasar® PFS
Vinorelbine	Navelbine®

4 . Endnotes

A. Currently there is no information available about the effect of longer acting pegylated G-CSF in patients with myeloid leukemias, therefore pegylated G-CSF should not be used in such patients outside of clinical trials. [17]
B. The safety and efficacy of Leukine in AML induction or consolidation in adults younger than 55 years old have not been established in clinical trials. [3]
C. Per hematology/oncology consultant and member of P&T, most cycles of induction or consolidation chemotherapy last ~ 1 month, but patients who complete therapy typically receive 1 induction and 2-3 consolidations, so re-approval would need to occur every month.
D. The safety and efficacy of pegylated G-CSF has not been fully established in the setting of dose-dense chemotherapy. [17]
E. Per hematology/oncology consultant and member of P&T, in general, dose-dense regimens require growth factor support for chemotherapy administration. [16] Also, Neulasta is commonly used to support dose dense regimens in current community practice. It would be reasonable to allow Neulasta use [in the INT C9741 Protocol] and to broaden its use for other forms of dose dense chemotherapy.
F. The product information for both PEG-Intron and Pegasys recommends dose reduction in patients with neutropenia with an ANC level < 750 cells/mm^3. [21, 22]
G. Per GI consultant and member of P&T, his medical group of practicing hepatologists recommends Neupogen for a special subpopulation of patients with HIV infection, status post liver transplant, or established cirrhosis who experience interferon-induced neutropenia (ANC less than or equal to 500 cells/mm^3) due to treatment with Peg-Intron or Pegasys.
H. Guidelines issued by the U.S. Public Health Service (USPHS) and the Infectious Diseases Society of America (IDSA) recommend for HIV-related neutropenia, the length of therapy with G-CSF and GM-CSF is 2-4 weeks. The clinical benefit of G-CSF therapy was evaluated in a randomized, double-blind, placebo controlled trial of 30 patients evaluating G-CSF 03 mg/mL subcutaneously 3 times a week or placebo for 12 weeks. The 6 month approval duration mirrors the 6 month approval duration for the erythropoietic agents, as G-CSF has been effective when used alone or in conjunction with epoetin alfa in adults with acquired immunodeficiency syndrome (AIDS) to ameliorate the hematologic toxicity (severe anemia and/or granulocytopenia) associated with zidovudine therapy. [11, 15, 37]
I. Note: This list is NOT inclusive of all chemotherapy regimens with a high risk of FN: See Table 2 in Background section
J. Note: This list is NOT inclusive of all chemotherapy regimens with an intermediate risk of FN: See Table 3 in Background section
K. Risk factors are based on provider information, not the list in the table below. Examples of risk factors may include (but are NOT limited to): Risk factors associated with chemotherapy-induced infection, FN, or neutropenia • Age > 65 years [16, 17] • History of extensive prior chemotherapy or radiation therapy including large radiation ports [16, 17] • Previous episodes of FN [16, 17] • Administration of combined chemoradiotherapy [17] • Pre-existing neutropenia or bone marrow involvement with tumor [16, 17] • Pre-existing conditions [16] • Neutropenia • Active infection/open wounds • Recent surgery • Poor performance status [16, 17] • Poor renal function [16] • Liver dysfunction [16] • Poor nutritional status [17] • More advanced cancer [17] • Hypotension and multiorgan

dysfunction (Sepsis syndrome) [16, 17] • Pneumonia [16] • Invasive fungal infection [16, 17] • Other clinically documented infections [16] • Hospitalization at the time of fever [16] • Anticipated prolonged (> 10 days) and profound neutropenia (< 100/mm^3) [17] • Uncontrolled primary disease [17] • Other serious comorbidities [17]

L. Note: This list is NOT all inclusive: See Table 4 in Background section
M. The FDA defines biosimilar as a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. [33] The American Society of Clinical Oncology states that pegfilgrastim, filgrastim, tbo-filgrastim, and filgrastim-sndz (and other biosimilars as they become available) can be used for the prevention of treatment-related febrile neutropenia. The choice of agent depends on convenience, cost, and clinical situation. [34] NCCN lists FDA-approved biosimilars as appropriate substitutes for filgrastim and pegfilgrastim. Limited data suggest that patients can alternate between the biosimilar and the originator biologic without any clinically meaningful differences regarding efficacy or safety. [16]
N. The efficacy of G-CSFs or GM-CSF for the acute radiation syndrome setting was studied in non-human primate models of radiation injury measuring 60-day survival. An expert panel convened by the World Health Organization recommends that patients receive G-CSF or GM-CSF treatment until their absolute neutrophil count reaches and maintains a level greater than 1.0 x 10^9 cells per liter in the absence of active infection. Patients with severe hematopoietic injury may recover, either spontaneously or after G-CSF treatment alone. In most cases, a duration of two to three weeks would be expected. [1-3, 36]

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6 . Revision History

Date	Notes
8/14/2024	Minor update to guideline

Commercial MEDLIMIT CDUR Criteria

Prior Authorization Guideline

Guideline ID	GL-116521
Guideline Name	Commercial MEDLIMIT CDUR Criteria
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Requested opioid pain medication	
Diagnosis	Level of Care Change
Approval Length	1 Time(s)
Guideline Type	Administrative
Approval Criteria **1** - Provider confirms replacement prescription(s) of opioid medication(s) is needed because the patient is physically changing locations and cannot take their prescription with them [such as admission to a long term care (LTC) facility]	

Product Name: Requested opioid pain medication	
Diagnosis	Pain Due to Cancer or Sickle Cell Anemia
Approval Length	12 Months to override MME edit

Guideline Type	Administrative
Approval Criteria **1** - Confirmation opioids are being used for the management of cancer pain or sickle cell anemia	

Product Name: Requested opioid pain medication	
Diagnosis	Hospice, Long Term Care, or End-of-Life Care Enrollment
Approval Length	12 Months to override MME edit
Guideline Type	Administrative
Approval Criteria **1** - Patient is currently enrolled in hospice, end-of-life care, or resides in a long term care facility	

Product Name: Requested opioid pain medication	
Diagnosis	Other Pain
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria **1** - A written or verbal supporting statement is received from the requesting prescriber attesting that in his/her clinical judgment, the requested dose exceeding the current cumulative morphine milligram equivalent (MME) threshold* is medically required	
Notes	*MME is calculated using all of the member's current opioid prescriptio ns *Note: Ask provider, "Will there be a dose escalation in the patient's opi oid utilization in the next 90 days?" If yes, approve MME level 90 daily M ME above the rejected level.

2 . Endnotes

A. All opioid medication edits are subject to review and modification (either to increase or decrease existing MME Limits) based on an Exception request received from the member or the member's provider. The decision to remove, modify, or retain an existing restriction

on opioid pain medications will be based on evidence of new clinical information which is documented in the form of a written supporting statement received from the prescriber and which contains all of the required elements as outlined in the criteria above.

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4 . Revision History

Date	Notes
11/1/2022	Per TSK004583729 copy over OptumRx Standard guidelines for Samaritan 2023 Implementation

Compounded Drugs

Prior Authorization Guideline

Guideline ID	GL-116528
Guideline Name	Compounded Drugs
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Compounded drugs**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Administrative

Approval Criteria

1 - Each active ingredient in the compounded drug is FDA-approved or national compendia* supported for the condition being treated

AND

2 - The therapeutic amounts are supported by national compendia* or two peer-reviewed literature for the condition being treated in the requested route of delivery

AND

3 - If any prescription ingredients require prior authorization and/or step therapy, all drug-specific criteria must be also met

AND

4 - The compounded drug must not include any ingredient that has been withdrawn or removed from the market due to safety reasons (refer to Table 1)

AND

5 - The patient has tried and failed therapy or had an intolerance to two FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless one of the following criteria are met:

5.1 Patient has a contraindication to commercially available products

OR

5.2 One or no other therapeutic alternatives are commercially available

OR

5.3 Prepared in a strength not commercially available or currently in short supply

OR

5.4 Prepared in a different dosage form for a patient who is unable to take the commercially available formulation (mixing or reconstituting commercially available products based on the manufacturer's instructions or the product's approved labeling does NOT meet this criteria).

OR

5.5 Patient has an allergy or sensitivity to inactive ingredients (e.g. dyes, preservatives, sugars, etc.) that are found in commercially available products.

AND

6 - The compounded drug must not be used for a cosmetic purpose.

AND

7 - If the compound is subject to the drug-specific/targeted compound program, the member meets all the applicable drug-specific criteria below for all the targeted ingredient(s) used in the requested compound product.

Notes	Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section. *Approved national compendia are referenced in the "Coverage of Off-Label or Non-FDA Approved Indications" Guideline **Administrative guideline may not apply to all compound reviews, depending on the ingredients being used and client elections.

2 . Background

Benefit/Coverage/Program Information

Table 1: Drugs that were withdrawn from the market due to safety or effectiveness

3,3',4',5-tetrachlorosalicylanilide	Methopholine Methoxylflurane
Adenosine phosphate	Methoxyflurane
Adrenal cortex	Mibefradil dihydrochloride
Alatrofloxacin mesylate	Nitrofurazone
Aminopyrine	Nomifensine maleate
Astemizole	Novobiocin
Azaribine	Ondansetron hydrochloride
Benoxaprofen	Oxyphenisatin
Bithionol	Oxyphenisatin acetate

Bromfenac sodium	Pemoline
Bromocriptine mesylate	Pergolide mesylate
Butamben	Phenacetin
Camphorated oil	Phenformin hydrochloride
Carbetapentane citrate	Phenylpropanolamine
Casein, iodinated	Pipamazine
Cerivastatin sodium	Polyethylene glycol 3350, sodium chloride, sodium bicarbonate, potassium chloride, and bisacodyl
Chloramphenicol	
Chlorhexidine gluconate	Potassium arsenite
Chlormadinone acetate	Potassium chloride
Chloroform	Povidone
Cisapride	Propoxyphene
Cobalt	Rapacuronium bromide
Dexfenfluramine hydrochloride	Reserpine
Diamthazole dihydrochloride	Rofecoxib
Dibromsalan	Sibutramine hydrochloride
Diethylstilbestrol	Sparteine sulfate
Dihydrostreptomycin sulfate	Sulfadimethoxine
Dipyrone	Sulfathiazole
Encainide hydrochloride	Suprofen
Esmolol hydrochloride	Sweet spirits of nitre
Etretinate	Tegaserod maleate
Fenfluramine hydrochloride	Temafloxacin hydrochloride
Flosequinan	Terfenadine

Gatifloxacin	Tetracycline
Gelatin	Ticrynafen
Glycerol, iodinated	Tribromsalan
Gonadotropin, chorionic	Trichloroethane
Grepafloxacin	Troglitazone
Mepazine	Trovafloxacin mesylate
Metabromsalan	Urethane
Methamphetamine hydrochloride	Valdexocib
Methapyrilene	Vinyl chloride
	Zirconium
	Zomepirac sodium

Diclofenac Compounds

There is little to no evidence-based literature support for the use of diclofenac for indications and in dosage forms not currently approved by the FDA. Use of compounds containing diclofenac should be limited to the following FDA-approved indications.

1. Diclofenac is indicated for a number of conditions including:
• Management of mild to moderate acute pain or osteoarthritis pain,
• Relief of signs and symptoms of ankylosing spondylitis and rheumatoid arthritis
• Relieve acute pain associated with minor sprains, strains, and contusions
• Treatment of primary dysmenorrhea
• Treatment of acute migraine attacks with or without aura in adults
• Treatment of actinic keratosis
• Treatment of postoperative inflammation in patients who have undergone cataract surgery and temporary relief of pain and photophobia associated with corneal refractive surgery.

2. Safety and efficacy in pediatric populations has not been established.

3. Diclofenac is commercially available in the several dosage forms: oral capsules, oral tablets, oral solution, topical patch, topical gel, topical solution, topical ointment and ophthalmic solution.

Flurbiprofen Compounds

There is little to no evidence-based literature support for the use of flurbiprofen for indications and in dosage forms not currently approved by the FDA. Use of compounds containing flurbiprofen should be limited to the following FDA-approved indications.

- Flurbiprofen tablets are indicated for relief of the signs and symptoms of rheumatoid arthritis and osteoarthritis.
- Flurbiprofen ophthalmic solution is indication for preventing intraoperative miosis.
- Flurbiprofen as a topically compounded formulation has not been shown to be more effective than currently commercially available topical NSAID products.
- Flurbiprofen is commercially available as a 50 and 100 mg oral tablet and also as 0.03% sterile ophthalmic solution.

Fluticasone Compounds

There is little to no evidence-based literature support for the use of fluticasone for indications and in dosage forms not currently approved by the FDA. Use of compounds containing fluticasone should be limited to the following FDA-approved indications.

- Fluticasone cream indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 3 months of age or older.

Fluticasone is commercially available in the several dosage forms: topical cream, topical lotion, topical ointment, nasal spray and various aerosols and powders for inhalation

Gabapentin Compounds

There is little to no evidence-based literature support for the use of gabapentin for indications or in dosage forms not currently approved by the FDA. Use of compounds containing gabapentin should be limited to the following FDA-approved indications.

- Gabapentin is indicated for treatment postherpetic neuralgia in adults (Gralise prescribing information, 2012; Horizant prescribing information, 2013; Neurontin prescribing information, 2015).
- Gabapentin is indicated as adjunctive therapy in the treatment of partial onset seizures, with and without secondary generalization, in adults and pediatric patients 3 years and older with epilepsy (Neurontin prescribing information, 2015).
- Gabapentin is indicated for the treatment of moderate to severe primary restless leg syndrome (Horizant prescribing information, 2013).

Ketamine Compounds

There is little to no evidence-based literature support for the use of ketamine for indications or in dosage forms not currently approved by the FDA. Use of compounds containing ketamine should be limited to the following FDA-approved indications.

- Ketamine is indicated as the sole anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation (Ketalar prescribing information, 2016)
- Ketamine is indicated for the induction of anesthesia prior to the administration of other general anesthetic agents (Ketalar prescribing information, 2016)
- Ketamine is indicated to supplement low-potency agents, such as nitrous oxide (Ketalar prescribing information, 2016)
- Esketamine (the S-enantiomer of racemic ketamine) is indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults (Spravato prescribing information, 2019). Coverage of compounds with racemic ketamine will continue to be limited to the FDA approved indications listed above.

Ketoprofen Compounds

There is little to no evidence-based literature support for the use of ketoprofen for indications and in dosage forms not currently approved by the FDA. Use of compounds containing ketoprofen should be limited to the following FDA-approved indications.

- Ketoprofen immediate-release capsules and ketoprofen extended-release capsules are indicated for the management of the signs and symptoms of rheumatoid arthritis and osteoarthritis.
- Ketoprofen immediate-release capsules are indicated for the management of pain and for treatment of primary dysmenorrhea.
- Ketoprofen extended-release capsules are not recommended for treatment of acute pain because of its extended-release characteristics.
- Ketoprofen as a topically compounded formulation has not been shown to be more effective than currently commercially available topical NSAID products.
- Ketoprofen is commercially available as a 50 and 75 mg oral capsule and 200 mg extended release oral capsule.

Levocetirizine Compounds

There is little to no evidence-based literature support for the use of levocetirizine for indications and in dosage forms not currently approved by the FDA. Use of compounds containing levocetirizine should be limited to the following FDA-approved indications.

- Levocetirizine dihydrochloride, a histamine (H1) receptor antagonist, is indicated for:
    - Treatment of perennial allergic rhinitis in adults and children 6 months of age or older.
    - Treatment of seasonal allergic rhinitis in adults and children 2 years of age and older
    - Uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 months of age and older

- Levocetirizine is commercially available as a 5 mg oral tablet and 2.5 mg/mL oral solution.

Mometasone Compounds

There is little to no evidence-based literature support for the use of mometasone for indications and in dosage forms not currently approved by the FDA. Use of compounds containing mometasone should be limited to the following FDA-approved indications.

- Mometasone cream & ointment are indicated for the treatment of relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patient's ≥ 2 years of age.
- Mometasone lotion is indicated for the treatment of relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patient's ≥12 years of age.
- Mometasone is commercially available inseveral dosage forms: topical cream, topical lotion, topical ointment, nasal spray,powder for inhalation and sinus implant.

Acyclovir ointment 5% Compounds

There is little to no evidence-based literature support for the use of Acyclovir ointment 5% for indications and in dosage forms not currently approved by the FDA. Use of compounds containing Acyclovir ointment 5% should be limited to the following FDA-approved indications.

- Acyclovir ointment 5% is indicated for the management of initial genital herpes and in limited non-life-threatening mucocutaneous Herpes simplex virus infection in immunocompromised patients.
- Acyclovir is commercially available in several dosage forms: topical ointment, topical cream, buccal tablet, tablet, capsule, oral suspension, and intravenous solution.

Doxepin cream 5% Compounds

There is little to no evidence-based literature support for the use of Doxepin cream 5% for indications and in dosage forms not currently approved by the FDA. Use of compounds containing Doxepin cream 5% should be limited to the following FDA-approved indications.

- Doxepin cream 5% is indicated for short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.
- Doxepin cream 5% is commercially available in several dosage forms: topical cream, capsule, tablet, and oral concentrate

3 . Endnotes

A. Compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. [1]
B. Compound drugs are customized in the following ways to meet patients need: (1) Removal of a nonessential ingredient for patients' allergies; and (2) Change in medication formulation (e.g., pill to solution in a patient with swallowing difficulties). [1]

C. Benefit design recommendations provided in the OptumRx Commercial Implementation Guide: (1) $200 Rx High Dollar Limit at Retail; (2) The processing of compound drugs will be subject to the same benefit plan edits: day supply, copay and drug coverage; (3) Multiple ingredient processing is recommended; (4) Bulk chemicals and compound kit recommended as standard exclusions.
D. Compounding does not generally include mixing or reconstituting commercially available products in accordance with the manufacturer's instructions or the product's approved labeling.

4 . References

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2. Application of Federal Low to Practice of Pharmacy Compounding. Available at: https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm155666.htm. Accessed July 6, 2022.
3. Drugs withdrawn or removed from the market for reasons of safety and effectiveness. Available at: https://www.ecfr.gov/cgi-bin/text-idx?SID=427cfbadfcc9a0a3cee36b57e99712ad&mc=true&node=se21.4.216_124&rgn=div8.Accessed July 6, 2022.
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8. Horizant prescribing information. Santa Clara, CA. July 2013
9. Neurontin prescribing information. Pfizer. New York, NY. September 2015.
10. Ketalar prescribing information. Par Pharmaceutical Companies. Spring Valley, NY. January 2016.
11. Ketoprofen Prescribing Information. Mylan Pharmaceuticals. Morgantown, WV. July 2015.
12. Ketoprofen Extended-Release Prescribing Information. Mylan Pharmaceuticals. Morgantown, WV. July 2015.
13. Xyzal Prescribing Information. UCB Pharma. Smyrna, GA. June 2016.
14. Elocon Cream, 0.1%. Merck & Co., Inc. Whitehouse Station, NJ. April 2013.
15. Elocon Lotion, 0.1%. Merck & Co., Inc. Whitehouse Station, NJ. September 2015.
16. Elocon Ointment, 0.1%. Merck & Co., Inc. Whitehouse Station, NJ. September 2015.
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18. Sinuva Prescribing Information. Intersect ENT, Inc. Menlo Park, CA. December 2017.
19. Zovirax Prescribing Information. Valeant Pharmaceuticals. Bridgewater, NJ. April 2018.
20. Zonalon Prescribing Information. Mylan Pharmaceuticals Inc. Morgantown, WV. June 2017.

5 . Revision History

Date	Notes

11/1/2022	2023 New Implementation

Continuous Glucose Monitor (CGM)

Prior Authorization Guideline

Guideline ID	GL-121369
Guideline Name	Continuous Glucose Monitor (CGM)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name: Continuous Glucose Monitors, Sensors, and Transmitters*	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Type 1 or Type 2 diabetes mellitus

AND

2 - All of the following:

2.1 Treated with multiple (three or more) daily administrations of insulin or continuous subcutaneous insulin infusion pump

AND

2.2 Patient consistently monitors blood glucose 3 or more times per day

AND

2.3 Patient is adherent to current diabetes treatment plan and participates in ongoing diabetes education and support

AND

2.4 Patient has one of the following:

2.4.1 Dawn phenomenon, known or suspected, Hypoglycemic unawareness (i.e., patient does not have symptoms with hypoglycemia)

OR

2.4.2 Nocturnal hypoglycemia, known or suspected

OR

2.4.3 Postprandial hyperglycemia, known or suspected

OR

2.4.4 Significant change to diabetes treatment regimen (e.g., initiation of insulin, change from multiple-dose insulin to insulin pump therapy)

OR

2.4.5 Unexplained hyperglycemia

Notes	*Please approve at NDC list: Group A NDC List (Dexcom G6) = SAMGROUPA Group B NDC List (Freestyle Libre) = SAMGROUPB

	Group C NDC List (Freestyle Libre 2) = SAMGROUPC

Product Name: Continuous Glucose Monitors, Sensors, and Transmitters*	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response	
Notes	*Please approve at NDC list: Group A NDC List (Dexcom G6) = SAMGROUPA Group B NDC List (Freestyle Libre) = SAMGROUPB Group C NDC List (Freestyle Libre 2) = SAMGROUPC

2 . Revision History

Date	Notes
2/22/2023	Update approval duration and notes

Corticosteroid Intravitreal Implants

Prior Authorization Guideline

Guideline ID	GL-125937
Guideline Name	Corticosteroid Intravitreal Implants
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Iluvien, Ozurdex, Retisert, Yutiq	
Diagnosis	Chronic diabetic macular edema or Macular edema due to central retinal vein occlusion
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Trial and failure of any one anti-VEGF therapy

AND

2 - Prescribed by or in consultation with an ophthalmologist

AND

3 - Patient is 12 years of age or older

Product Name: Iluvien, Ozurdex, Retisert, Yutiq	
Diagnosis	Branch retinal vein occlusion
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Failure of photocoagulation or not suitable for photocoagulation because of extent of macular hemorrhage

AND

2 - Trial and failure of any one anti-VEGF therapy

AND

3 - Prescribed by or in consultation with an ophthalmologist

AND

4 - Patient is 12 years of age or older

Product Name: Iluvien, Ozurdex, Retisert, Yutiq	
Diagnosis	Chronic non-infectious uveitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescribed by or in consultation with an ophthalmologist

AND

2 - Patient is 12 years of age or older

AND

3 - Trial and failure of ONE of the following:

- Both local and systemic corticosteroids, OR
- Immunosuppressive agents

Product Name: Iluvien, Ozurdex, Retisert, Yutiq	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Prescribed by or in consultation with an ophthalmologist

AND

3 - Patient is 12 years of age or older

2 . Revision History

Date	Notes
5/26/2023	New program

Coverage of Off-Label Non-FDA Approved Indications

Prior Authorization Guideline

Guideline ID	GL-116522
Guideline Name	Coverage of Off-Label Non-FDA Approved Indications
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: A drug (non-anti-cancer chemotherapeutic regimen) used for an off-label indication or non-FDA approved indication	
Diagnosis	Off-label non-cancer indication
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 Diagnosis is supported as a use in American Hospital Formulary Service Drug Information (AHFS DI) [1]

OR

1.2 Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of IIb or better (see DRUGDEX Strength of Recommendation table in Background section) [1]

OR

1.3 The use is supported by clinical research in two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal

Notes	Off-label use may be reviewed for medical necessity and denied as suc h if the off-label criteria are not met. Please refer to drug specific PA gui deline for off-label criteria if available.

Product Name: A drug or biological in an anti-cancer chemotherapeutic regimen	
Diagnosis	Off-label cancer indication
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 Diagnosis is supported as a use in AHFS DI [2]

OR

1.2 Diagnosis is supported as a use in the National Comprehesive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B (see NCCN Categories of Evidence and Consensus table in Background section) [2, A]

OR

1.3 Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of Class I, Class IIa, or Class IIb (see DRUGDEX Strength of Recommendation table in Background section) [2]

OR

1.4 Diagnosis is supported as an indication in Clinical Pharmacology [2]

OR

1.5 Off-label use is supported in one of the published, peer-reviewed medical literature listed below: [2, B]

- American Journal of Medicine
- Annals of Internal Medicine
- Annals of Oncology
- Annals of Surgical Oncology
- Biology of Blood and Marrow Transplantation
- Blood
- Bone Marrow Transplantation
- British Journal of Cancer
- British Journal of Hematology
- British Medical Journal
- Cancer
- Clinical Cancer Research
- Drugs
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology)
- Gynecologic Oncology
- International Journal of Radiation, Oncology, Biology, and Physics
- The Journal of the American Medical Association
- Journal of Clinical Oncology
- Journal of the National Cancer Institute
- Journal of the National Comprehensive Cancer Network (NCCN)
- Journal of Urology
- Lancet
- Lancet Oncology
- Leukemia
- The New England Journal of Medicine
- Radiation Oncology

OR

1.6 Diagnosis is supported as a use in Wolters Kluwer Lexi-Drugs rated as "Evidence Level A" with a "Strong" recommendation. (see Lexi-Drugs Strength of Recommendation table in Background section) [2, 4, 5]

Notes	Off-label use may be reviewed for medical necessity and denied as suc h if the off-label criteria are not met. Please refer to drug specific PA gui deline for off-label criteria if available.

2 . Background

Clinical Practice Guidelines

DRUGDEX Strength of Recommendation [6]

Class	Recommendation	Description
Class I	Recommended	The given test or treatment has been proven useful, and should be performed or administered.
Class IIa	Recommended, In Most Cases	The given test or treatment is generally considered to be useful, and is indicated in most cases.
Class IIb	Recommended, in Some Cases	The given test or treatment may be useful, and is indicated in some, but not most, cases.
Class III	Not Recommended	The given test or treatment is not useful, and should be avoided
Class Indeterminate	Evidence Inconclusive	

NCCN Categories of Evidence and Consensus [A]

Category	Level of Consensus
1	Based upon high-level evidence, there is uniform NCCN cons that the intervention is appropriate.
2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2B	Based upon lower-level evidence, there is NCCN consensus the intervention is appropriate.

	3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

Lexi-Drugs: Strength of Recommendation for Inclusion in Lexi-Drugs for Oncology Off-Label Use and Level of Evidence Scale for Oncology Off-Label Use [5]

Strength of Recommendation for Inclusion

Strong (for proposed off-label use)	The evidence persuasively supports the off-label use (ie, Level of Evidence A).
Equivocal (for proposed off-label use)	The evidence to support the off-label use is of uncertain clinical significance (ie, Level of Evidence B, C). Additional studies may be necessary to further define the role of this medication for the off-label use.
Against proposed off-label use	The evidence either advocates against the off-label use or suggests a lack of support for the off-label use (independent of Level of Evidence). Additional

	studies are necessary to define the role of this medication for the off-label use.

Level of Evidence Scale for Oncology Off-Label Use

A	**Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form (eg, results of the introduction of penicillin treatment) to support off-label use. Further research is unlikely to change confidence in the estimate of benefit.**
B	**Evidence from randomized, controlled trials with important limitations (eg, inconsistent results, methodologic flaws, indirect, imprecise); or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate.**
C	**Evidence from observational studies (eg, retrospective case series/reports providing significant impact on patient care); unsystematic clinical experience; or potentially flawed randomized, controlled trials (eg, when limited options exist for condition). Any estimate of effect is uncertain.**
G	**Use has been substantiated by inclusion in at least one evidence-based or consensus-based clinical practice guideline.**

3 . Endnotes

A. NCCN Categories of Evidence and Consensus. Category 1: The recommendation is based on high-level evidence (i.e., high-powered randomized clinical trials or meta-analyses), and the NCCN Guideline Panel has reached uniform consensus that the recommendation is indicated. In this context, uniform means near unanimous positive support with some possible neutral positions. Category 2A: The recommendation is based on lower level evidence, but despite the absence of higher level studies, there is uniform consensus that the recommendation is appropriate. Lower level evidence is interpreted broadly, and runs the gamut from phase II to large cohort studies to case series to individual practitioner

experience. Importantly, in many instances, the retrospective studies are derived from clinical experience of treating large numbers of patients at a member institution, so NCCN Guideline Panel Members have first-hand knowledge of the data. Inevitably, some recommendations must address clinical situations for which limited or no data exist. In these instances the congruence of experience-based judgments provides an informed if not confirmed direction for optimizing patient care. These recommendations carry the implicit recognition that they may be superseded as higher level evidence becomes available or as outcomes-based information becomes more prevalent. Category 2B: The recommendation is based on lower level evidence, and there is nonuniform consensus that the recommendation should be made. In these instances, because the evidence is not conclusive, institutions take different approaches to the management of a particular clinical scenario. This nonuniform consensus does not represent a major disagreement, rather it recognizes that given imperfect information, institutions may adopt different approaches. A Category 2B designation should signal to the user that more than one approach can be inferred from the existing data. Category 3: Including the recommendation has engendered a major disagreement among the NCCN Guideline Panel Members. The level of evidence is not pertinent in this category, because experts can disagree about the significance of high level trials. Several circumstances can cause major disagreements. For example, if substantial data exist about two interventions but they have never been directly compared in a randomized trial, adherents to one set of data may not accept the interpretation of the other side's results. Another situation resulting in a Category 3 designation is when experts disagree about how trial data can be generalized. An example of this is the recommendation for internal mammary node radiation in postmastectomy radiation therapy. One side believed that because the randomized studies included this modality, it must be included in the recommendation. The other side believed, based on the documented additional morbidity and the role of internal mammary radiation therapy in other studies, that this was not necessary. A Category 3 designation alerts users to a major interpretation issue in the data and directs them to the manuscript for an explanation of the controversy. [3]

B. Abstracts (including meeting abstracts) are excluded from consideration. When evaluating peer-reviewed medical literature, the following (among other things) should be considered: 1) Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence 2) Whether the administered chemotherapy regimen is adequately represented in the published evidence. 3) Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. 4) Whether the study is appropriate to address the clinical question. The following should be considered: a) Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover.); b) That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and c) That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs. [2]

4 . References

1. Center for Medicaid & Medicare Services. Medicare Prescription Drug Benefit Manual. Chapter 6 – Part D Drugs and Formulary Requirements. Section 10.6. Available at: https://www.cms.gov/Medicare/Prescription-Drug-

Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. Accessed October 11, 2021.
2. Center for Medicaid & Medicare Services. Medicare Benefit Policy Manual. Chapter 15 - Covered Medical and Other Health Services. Section 50.4.5. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf. Accessed October 11, 2021.
3. National Comprehensive Cancer Network Categories of Evidence and Consensus. Available at: https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx. Accessed September 9, 2020.
4. Center for Medicaid & Medicare Services. Medicare Benefit Policy Manual. Wolters Kluwer Clinical Drug Information Lexi-Drugs Compendium Revision Request - CAG-00443O. Available at: https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=31#decision. Accessed October 11, 2021.
5. Wolters Kluwer Clinical Drug Information's Request for CMS evaluation of Lexi-Drugs as a compendium for use in the determination of medically-accepted indications of drugs/biologicals used off-label in anti-cancer chemotherapeutic regimens. Available at: https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/downloads/covdoc31.pdf. Accessed October 11, 2021.
6. Micromedex Healthcare Series. Recommendation, Evidence, and Efficacy Ratings. https://www.micromedexsolutions.com/micromedex2/librarian/ssl/true/CS/6E0ED9/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/8B9F5B/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.IntermediateToDocumentLink?docId=3198&contentSetId=50. Accessed October 11, 2021.

5 . Revision History

Date	Notes
11/1/2022	Per TSK004583729 copy over OptumRx Standard guidelines for Samaritan 2023 Implementation

Crysvita (burosumab-twza)

Prior Authorization Guideline

Guideline ID	GL-110082
Guideline Name	Crysvita (burosumab-twza)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	6/20/2018
P&T Revision Date:	12/18/2019 ; 08/13/2020 ; 08/19/2021 ; 8/18/2022

1 . Indications

Drug Name: Crysvita (burosumab-twza)
X-Linked Hypophosphatemia (XLH) Indicated for the treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older. **Tumor-Induced Osteomalacia** Indicated for the treatment of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adult and pediatric patients 2 years of age and older.

2 . Criteria

Product Name: Crysvita	
Diagnosis	X-Linked Hypophosphatemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of X-linked hypophosphatemia

AND

2 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Specialist experienced in the treatment of inborn errors of metabolism

AND

3 - One of the following:

3.1 Patient is 6 months to 17 years of age

OR

3.2 Both of the following:

3.2.1 Patient is 18 years of age or older

AND

3.2.2 Patient is a candidate for pharmacologic therapy by meeting one of the following: [2]

- Spontaneous insufficiency fractures
- Pending orthopedic procedures (e.g., joint replacement)
- Biochemical evidence of osteomalacia (i.e., elevated serum alkaline phosphatase)
- Disabling skeletal pain

AND

4 - Trial and failure, contraindication, or intolerance to conventional treatment with both of the following: [2, 3]

- Phosphate supplementation

- Vitamin D analog-based therapy (e.g, calcitriol, paricalcitol, doxercalciferol)

Product Name: Crysvita	
Diagnosis	X-Linked Hypophosphatemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy (e.g., improvement in rickets, improvement in serum phosphorus or Radiographic Global Impression of Change [RGI-C] scores)

Product Name: Crysvita	
Diagnosis	Tumor-Induced Osteomalacia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of FGF23-related hypophosphatemia in Tumor-Induced Osteomalacia (TIO)

AND

2 - Tumor could not be curatively resected or localized

AND

3 - Patient is 2 years of age or older

AND

4 - Trial and failure, contraindication, or intolerance to conventional treatment with both of the following: [4, 5]

- Phosphate supplementation
- Vitamin D analog-based therapy (e.g., calcitriol, paricalcitol, doxercalciferol)

AND

5 - Prescribed by or in consultation with one of the following:

- Oncologist
- Endocrinologist

Product Name: Crysvita	
Diagnosis	Tumor-Induced Osteomalacia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy (e.g., increase in serum phosphorus level, improvement in osteoid thickness, osteoid surface, osteoid volume, mineralization lag time, or improvement as indicated by bone biopsy)

3 . References

1. Crysvita Prescribing Information. Ultragenyx Pharmaceutical Inc. Novato, CA. June 2020.
2. Carpenter TO, Imel EA, Holm IA, et al. A Clinician's guide to x-linked hypophosphatemia. J Bone Miner Res. 2011;26(7):1381-1388. doi:10.1002/jbmr.340.
3. Linglart A, Biosse-Duplan M, Briot K, et al. Therapeutic management of hypophosphatemic rickets from infancy to adulthood. Endocr Connect. 2014;3(1):R13-R30. doi:10.1530/EC-13-0103.
4. Chong W, Molinolo A, Chen C, Collins M. Tumor-induced osteomalacia. Endocr Relat Cancer. 2011;18(3):R53-R77.
5. Athonvarangkul D, Insogna K. New Therapies for Hypophosphatemia-Related to FGF23 Excess. Calcif Tissue Int. 2020.
6. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000 Feb 29 – Identifier NCT02304367, Study of KRN23 in Adult Subjects With Tumor-Induced Osteomalacia (TIO) or Epidermal Nevus Syndrome (ENS); December 1, 2014 [cited 2020 Jun 26]. Available from https://clinicaltrials.gov/ct2/show/NCT02304367.

7. Imanishi Y, Ito N, Rhee Y et al. Interim Analysis of a Phase 2 Open-Label Trial Assessing Burosumab Efficacy and Safety in Patients with Tumor-Induced Osteomalacia. J Bone Miner Res. 2020; 36(2):262-270.
8. Jan de Beur SM, Miller PD, Weber TJ, et al. Burosumab for the Treatment of Tumor-Induced Osteomalacia. J Bone Miner Res. 2021;36(4):627-635.

4 . Revision History

Date	Notes
8/3/2022	Annual Review - No clinical criteria changes

Daliresp (roflumilast)

Prior Authorization Guideline

Guideline ID	GL-116508
Guideline Name	Daliresp (roflumilast)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Daliresp	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe chronic obstructive pulmonary disease (COPD)

AND

2 - Patient has chronic bronchitis

AND

3 - Trial and failure, contraindication, or intolerance to 2 previous COPD therapies (e.g., Advair HFA, Advair Diskus, Breo Ellipta, Combivent Respimat, Anoro Ellipta, Dulera, Symbicort)

Product Name: Daliresp	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/10/2022	2023 New Implementation

Daxxify (botulinum toxin type a injection)

Prior Authorization Guideline

Guideline ID	
Guideline Name	Daxxify (botulinum toxin type a injection)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	11/1/2023
P&T Approval Date:	10/18/2023
P&T Revision Date:	

1 . Indications

Drug Name: Daxxify (botulinum toxin type a injection)
Cervical Dystonia indicated for the treatment of cervical dystonia in adult patients. **Cosmetic Uses [Non-approvable Use]** Indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients. **Please Note: The request for Daxxify (botulinum toxin type a injection) injections to treat the appearance of glabellar lines is not authorized given that this use is for cosmetic purposes only.

2 . Criteria

Product Name: Daxxify	
Diagnosis	Cervical Dystonia

Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cervical dystonia

AND

2 - Trial and failure, contraindication, or intolerance to one of the following:

- Xeomin
- Dysport
- Myobloc

Product Name: Daxxify	
Diagnosis	Cervical Dystonia
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - At least 3 months have or will have elapsed since the last treatment

Product Name: Daxxify	
Diagnosis	Cosmetic Use
Guideline Type	Prior Authorization

Approval Criteria

1 - Requests for coverage of any Daxxify product for treating the appearance of facial lines are not authorized and will not be approved. These uses are considered cosmetic only.

3 . References

1. Daxxify Prescribing Information. Revance Therapeutics, Inc. Newark, CA. August 2023

4 . Revision History

Date	Notes

10/11/2023	New Program for Daxxify

Dimethyl Fumarate

Prior Authorization Guideline

Guideline ID	GL-116534
Guideline Name	Dimethyl Fumarate
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Generic dimethyl fumarate	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsing forms of multiple sclerosis

AND

2 - Prescribed by or in consultation with a neurologist

Product Name: Generic dimethyl fumarate

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
9/12/2022	2023 New Implementation

Dojolvi (triheptanoin)

Prior Authorization Guideline

Guideline ID	GL-111073
Guideline Name	Dojolvi (triheptanoin)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	11/1/2022
P&T Approval Date:	9/16/2020
P&T Revision Date:	09/15/2021 ; 9/21/2022

1 . Indications

Drug Name: Dojolvi (triheptanoin)
Long-Chain Fatty Acid Oxidation Disorders (LC-FAOD) Indicated as a source of calories and fatty acids for the treatment of pediatric and adult patients with molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD).

2 . Criteria

Product Name: Dojolvi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD) has been confirmed by at least two of the following:

- Disease specific elevation of acyl-carnitines on a newborn blood spot or in plasma
- Low enzyme activity in cultured fibroblasts
- One or more known pathogenic mutations in CPT2, ACADVL, HADHA, or HADHB

AND

2 - Not used with any other medium-chain triglyceride (MCT) product

AND

3 - Prescribed by or in consultation with a clinical specialist knowledgeable in appropriate disease-related dietary management (e.g., geneticist, cardiologist, gastroenterologist, etc.)

Product Name: Dojolvi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescriber attests to continued need of therapy [A]

AND

2 - Not used with any other medium-chain triglyceride (MCT) product

AND

3 - Prescribed by or in consultation with a clinical specialist knowledgeable in appropriate disease-related dietary management (e.g., geneticist, cardiologist, gastroenterologist, etc.)

3 . Endnotes

A. This reauthorization criteria was recommended by the clinical consultant since LA-FAODs are progressive even with therapy. Patients will need lifelong therapy even though positive clinical response may not be seen.

4 . References

1. Dojolvi (triheptanoin) prescribing information. Ultragenyx Pharmaceutical Inc. Novato, CA. November 2021.
2. Per clinical consult with internal medicine/pediatric specialist, September 24, 2020.

5 . Revision History

Date	Notes
9/14/2022	Annual Review

DPP4 Inhibitors

Prior Authorization Guideline

Guideline ID	GL-117434
Guideline Name	DPP4 Inhibitors
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Generic alogliptin, Brand Nesina, Tradjenta, Onglyza, Januvia	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Diagnosis of Type 2 Diabetes

AND

2 - One of the following

- Trial and failure of metformin
- Concurrently using metformin

AND

3 - One of the following:

- Trial and failure or concurrently using sulfonylurea
- Trial and failure or concurrently using insulin

2 . Revision History

Date	Notes
11/30/2022	Update guideline

DPP4 Inhibitors - SCP

Prior Authorization Guideline

Guideline ID	GL-117433
Guideline Name	DPP4 Inhibitors - SCP
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Tradjenta, Onglyza, Januvia	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Diagnosis of Type 2 Diabetes

AND

2 - One of the following

- Trial and failure of metformin
- Concurrently using metformin

AND

3 - One of the following:

- Trial and failure or concurrently using sulfonylurea
- Trial and failure or concurrently using insulin

2 . Revision History

Date	Notes
11/30/2022	Update Criteria

Dronabinol

Prior Authorization Guideline

Guideline ID	GL-116498
Guideline Name	Dronabinol
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Dronabinol	
Diagnosis	Nausea and Vomiting Associated with Cancer Chemotherapy (CINV)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Trial and failure, contraindication, or intolerance to one 5HT-3 receptor antagonist (e.g., Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron])

AND

2 - Trial and failure, contraindication, or intolerance to one of the following: Compazine (prochlorperazine), Decadron (dexamethasone), Haldol (haloperidol), Zyprexa (olanzapine)

Product Name: Dronabinol	
Diagnosis	AIDS Anorexia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anorexia with weight loss in patients with AIDS

AND

2 - Patient is on antiretroviral therapy

Product Name: Dronabinol	
Diagnosis	Nausea and Vomiting Associated with Cancer Chemotherapy (CINV), AIDS Anorexia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
9/24/2022	2023 New Implementation

Dupixent (Dupilumab)

Prior Authorization Guideline

Guideline ID	GL-126338
Guideline Name	Dupixent (Dupilumab)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Dupixent	
Diagnosis	Asthma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe asthma

AND

2 - Patient is 6 years of age or older

AND

3 - One of the following:

3.1 Patient has inadequate control of asthma symptoms with both of the following:

- Inhaled corticosteroid (e.g, fluticasone)
- Long-acting beta2 agonist (LABA) (e.g., salmeterol)

OR

3.2 Patient has inadequate control of asthma symptoms with both of the following:

- Inhaled corticosteroid (e.g., fluticasone)
- Long-acting muscarinic antagonist (e.g., tiotropium)

Product Name: Dupixent	
Diagnosis	Atopic Dermatitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe atopic dermatitis

AND

2 - Patient is experiencing functional impairment (i.e., inability to use hands or feet for activities of daily living or significant facial involvement preventing normal social interaction)

AND

3 - One or more of the following:

- At least 10% of body surface area involvement OR hand, foot or mucous membrane involvement
- Hand, foot or mucous membrane involvement

AND

4 - All of the following:

- Failed, contraindicated or intolerance to a 12-week trial of a topical calcineurin inhibitor (e.g. tacrolimus)
- Failed, contraindicated or intolerance to a 12-week trial of at least 2 prescription strength topical corticosteroids (e.g., betamethasone, fluticasone, mometasone)
- Failed, contraindicated or intolerance to a 12-week trial of oral immunomodulator therapy (e.g. cyclosporine, methotrexate, azathioprine, mycophenolate mofetil, oral corticosteroids)

AND

5 - Patient is 6 months of age or older

AND

6 - Prescribed by or in consultation with a dermatologist

Product Name: Dupixent	
Diagnosis	Eosinophilic Esophagitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Eosinophilic Esophagitis (EoE)

AND

2 - Patient weigh ≥ 40 kg (88lbs)

AND

3 - Patient has two or more episodes of dysphagia per week

AND

4 - Patient has had an inadequate response (8-week trial), intolerance or contraindication to high-dose Proton Pump Inhibitor therapy (e.g., Omeprazole at least 20mg twice daily, lansoprazole 30mg twice daily, pantoprazole 40mg twice daily)

AND

5 - Patient has had an inadequate response (8- to 12- week trial), intolerance, or contraindication to swallowed inhaled respiratory corticosteroid therapy (e.g., budesonide or fluticasone)

AND

6 - Patient is 12 years of age or older

AND

7 - Prescribed by or in consultation with

- Gastroenterologist
- Immunologist

AND

8 - Patient has no known hypersensitivity to dupilumab or any of its excipients

Product Name: Dupixent	
Diagnosis	Chronic rhinosinusitis with nasal polyps (CRSwNP)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Chronic rhinosinusitis with nasal polyps (CRSwNP), which includes objective evidence of the presence of bilateral nasal polyps

AND

2 - Medication will not be used in combination with other biologics (e.g., Nucala, Xolair) for eosinophilic indications

AND

3 - Failure to adequately reduce symptoms after at least 2 months of saline nasal irrigations and intranasal corticosteroids (INCS) use at doses appropriate for nasal polyp treatment

AND

4 - Trial and failure to systemic corticosteroid treatment for nasal polyps at least once within the last 2 years or prior nasal polyp removal surgery

AND

5 - Patient will continue to use an INCS (unless not tolerated or contraindicated) while on biologic therapy

AND

6 - Prescribed by or in consultation with

- Ear nose throat doctor
- Immunologist

AND

7 - Patient is 18 years of age or older

AND

8 - Patient has no known hypersensitivity to dupilumab or any of its excipients

Product Name: Dupixent	
Diagnosis	Prurigo Nodularis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Prurigo Nodularis for at least 3 months

AND

2 - Severe or very severe itch (WI-NRS score ≥7) reported within the past week

AND

3 - Patient has at least 20 PN lesions in total on both legs and/or both arms and/or trunk

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - Patient is 18 years of age or older

AND

6 - Patient has no known hypersensitivity to dupilumab or any of its excipients

Product Name: Dupixent	
Diagnosis	All Indications Listed Above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	

2 . Revision History

Date	Notes
6/9/2023	Update guideline

Dysport (abobotulinumtoxinA)

Prior Authorization Guideline

Guideline ID	GL-111548
Guideline Name	Dysport (abobotulinumtoxinA)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	11/1/2022
P&T Approval Date:	8/18/2009
P&T Revision Date:	12/18/2019 ; 07/15/2020 ; 09/16/2020 ; 04/21/2021 ; 09/15/2021 ; 9/21/2022

1 . Indications

Drug Name: Dysport (abobotulinumtoxinA)
Cervical Dystonia Indicated for the treatment of cervical dystonia in adults. **Glabellar Lines** Indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adult patients less than 65 years of age. Note: This indication is generally a plan exclusion. Drugs prescribed to primarily improve or otherwise modify the member's external appearance are excluded from coverage. **Spasticity** Indicated for the treatment of spasticity in patients 2 years of age and older.

2 . Criteria

Product Name: Dysport	
Diagnosis	Cervical Dystonia (also known as spasmodic torticollis)

Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cervical dystonia (also known as spasmodic torticollis) [2, 3]

Product Name: Dysport	
Diagnosis	Cervical Dystonia (also known as spasmodic torticollis)
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - At least 3 months have elapsed since the last treatment [A]

Product Name: Dysport	
Diagnosis	Spasticity
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of spasticity [3]

AND

2 - Patient is 2 years of age or older

Product Name: Dysport	
Diagnosis	Spasticity
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - At least 3 months have elapsed since the last treatment [A]

3 . Endnotes

A. In the pivotal clinical trial, doses of 500 Units and 1000 Units were divided among selected muscles. Repeat treatment should be administered when the effect of a previous injection has diminished, but no sooner than 12 weeks after the previous injection. A majority of patients in clinical studies were retreated between 12-16 weeks; however some patients had a longer duration of response, i.e., 20 weeks. [1]

4 . References

1. Dysport Prescribing Information. Ipsen Biopharmaceuticals, Inc. Cambridge, MA. July 2020.
2. Truong D, Duane DD, Jankovic J, et al. Efficacy and safety of botulinum type A toxin (Dysport) in cervical dystonia: results of the first US randomized, double-blind, placebo-controlled study. Mov Disord. 2005;20(7):783-791.
3. Simpson D, Hallett M, Ashman E et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. Neurology. 2016;86(19):1818-1826.

5 . Revision History

Date	Notes
9/6/2022	Annual review - added age criterion for spasticity indication to align wit h prescribing information.

Elaprase (idursulfase)

Prior Authorization Guideline

Guideline ID	GL-109068
Guideline Name	Elaprase (idursulfase)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	9/1/2022
P&T Approval Date:	7/30/2004
P&T Revision Date:	07/08/2020 ; 07/21/2021 ; 7/20/2022

1 . Indications

Drug Name: Elaprase (idursulfase) [1]
Hunter Syndrome Is indicated for patients with Hunter syndrome (Mucopolysaccharidosis II, MPS II). Elaprase has been shown to improve walking capacity in patients 5 years and older. In patients 16 months to 5 years of age, no data are available to demonstrate improvement in disease-related symptoms or long term clinical outcome; however, treatment with Elaprase has reduced spleen volume similarly to that of adults and children 5 years of age and older. The safety and efficacy of Elaprase have not been established in pediatric patients less than 16 months of age.

2 . Criteria

Product Name: Elaprase (idursulfase)	
Approval Length	60 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Hunter syndrome (Mucopolysaccharidosis II, MPS II)

3 . References

1. Elaprase Prescribing Information. Takeda Pharmaceuticals U.S.A., Inc. Lexington, MA. October 2021.

4 . Revision History

Date	Notes
7/6/2022	Annual Review, no criteria changes.

Elrexfio (elranatamab-bcmm)

Prior Authorization Guideline

Guideline ID	GL-124083
Guideline Name	Elrexfio (elranatamab-bcmm)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	11/1/2023
P&T Approval Date:	10/18/2023
P&T Revision Date:	

1 . Indications

Drug Name: Elrexfio (elranatamab-bcmm)
Multiple Myeloma Indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial(s).

2 . Criteria

Product Name: Elrexfio

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - Disease is one of the following:

- Relapsed
- Refractory

AND

3 - Patient has received at least four prior lines of therapy which include all of the following:

- An immunomodulatory agent (e.g., lenalidomide, thalidomide)
- A proteasome inhibitor (e.g., bortezomib, carfilzomib)
- A CD38-directed monoclonal antibody (e.g., daratumumab)

Product Name: Elrexfio	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Elrexfio Prescribing Information. Pfizer, Inc. New York, NY. August 2023.

4 . Revision History

Date	Notes
9/28/2023	New program

Empaveli (pegcetacoplan)

Prior Authorization Guideline

Guideline ID	GL-115065
Guideline Name	Empaveli (pegcetacoplan)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	10/15/2022
P&T Approval Date:	7/21/2021
P&T Revision Date:	10/20/2021

1 . Indications

Drug Name: Empaveli (pegcetacoplan)
Paroxysmal Nocturnal Hemoglobinuria Indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).

2 . Criteria

Product Name: Empaveli	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

Product Name: Empaveli	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy (e.g., improvement in hemoglobin level, hemoglobin stabilization, decrease in the number of red blood cell transfusions)	

3 . References

1. Empaveli Prescribing Information. Apellis Pharmaceuticals, Inc. Waltham, MA. May 2021.
2. Per clinical consultation with specialist, June 18, 2021.
3. Kulasekararaj AG., et al. “Ravulizumab (ALXN1210) vs Eculizumab in C5-Inhibitor–Experienced Adult Patients with PNH: the 302 Study.” Blood, vol. 133, no. 6, 2019, pp. 540–549.
4. Hillmen P, et al. “Pegcetacoplan versus Eculizumab in Paroxysmal Nocturnal Hemoglobinuria.” New England Journal of Medicine, vol. 384, no. 11, 2021, pp. 1028–1037.

4 . Revision History

Date	Notes
10/6/2022	GPI Reclassification

Enbrel (etanercept)

Prior Authorization Guideline

Guideline ID	GL-117591
Guideline Name	Enbrel (etanercept)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Enbrel	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

Product Name: Enbrel	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Enbrel	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:

- leflunomide
- methotrexate

Product Name: Enbrel	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Enbrel	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [5]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Product Name: Enbrel	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 5]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name: Enbrel	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe chronic plaque psoriasis

AND

2 - One of the following [6]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [7]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name: Enbrel	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1, 6]:

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name: Enbrel	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [8]

Product Name: Enbrel	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following [1, 8]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

2 . References

1. Enbrel Prescribing Information. Amgen. Thousand Oaks, CA. April 2021.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.
3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
4. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Rheumatol. 2019;71(6):846-863.
5. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
6. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
7. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
8. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613.

3 . Revision History

Date	Notes
12/5/2022	New Implementation

Enjaymo (sutimlimab-jome)

Prior Authorization Guideline

Guideline ID	GL-122716
Guideline Name	Enjaymo (sutimlimab-jome)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	4/20/2022
P&T Revision Date:	4/19/2023

1 . Indications

Drug Name: Enjaymo (sutimlimab-jome)
Cold agglutinin disease Indicated for the treatment of hemolysis in adults with cold agglutinin disease.

2 . Criteria

Product Name: Enjaymo	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of cold agglutinin disease (CAD) based on ALL of the following: [A, 2, 3]

- Presence of chronic hemolysis (e.g., bilirubin level above the normal reference range, elevated lactated dehydrogenase [LDH], decreased haptoglobin, increased reticulocyte count)
- Positive polyspecific direct antiglobulin test (DAT)
- Monospecific DAT strongly positive for C3d
- Cold agglutinin titer greater than or equal to 64 measured at 4 degree celsius
- Direct antiglobulin test (DAT) result for Immunoglobulin G (IgG) of 1 plus or less

AND

2 - Patient does not have cold agglutinin syndrome secondary to other factors (e.g., overt hematologic malignancy, primary immunodeficiency, infection, rheumatologic disease, systemic lupus erythematosus or other autoimmune disorders) [A, 1, 3]

AND

3 - Baseline hemoglobin level less than or equal to 10.0 gram per deciliter (g/dL) [3]

AND

4 - One of the following: [B,1, 3]

- Prescribed dose will not exceed 6,500 mg on day 0, 7, and every 14 days thereafter for patients weighing between 39 kg to less than 75 kg
- Prescribed dose will not exceed 7,500 mg on day 0, 7, and every 14 days thereafter for patients for patients weighing 75 kg or greater

AND

5 - Prescribed by or in consultation with a hematologist

Product Name: Enjaymo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy as evidenced by ALL of the following: [1, 3]

- The patient has not required any blood transfusions after the first 5 weeks of therapy with Enjaymo
- Hemoglobin level greater than or equal to 12 gram per deciliter (g/dL) or increased greater than or equal to 2 g/dL from baseline

AND

2 - One of the following: [B,1, 3]

- Prescribed dose will not exceed 6,500 mg on day 0, 7, and every 14 days thereafter for patients weighing between 39 kg to less than 75 kg
- Prescribed dose will not exceed 7,500 mg on day 0, 7, and every 14 days thereafter for patients for patients weighing 75 kg or greater

AND

3 - Prescribed by or in consultation with a hematologist

3 . Background

Clinical Practice Guidelines

Weight-Based Dosing

The dosing is 6,500mg or 7,500mg Enjaymo (based on body weight) intravenously over approximately 60 minutes on Day 0, Day 7, and every 14 days thereafter	
Body Weight Range	Dose
39kg to less than 75kg	6,500 mg
75kg or greater	7,500 mg

4 . Endnotes

A. Patients with a confirmed diagnosis of CAD based on chronic hemolysis, polyspecific direct antiglobulin test (DAT), monospecific DAT specific for C3d, cold agglutinin titer ≥64 at 4°C, and IgG DAT ≤1+ and a recent blood transfusion in the 6 months prior to enrollment were administered 6.5 g or 7.5 g Enjaymo (based on body weight). Patients with cold agglutinin syndrome secondary to infection, rheumatologic disease, systemic lupus erythematosus, or overt hematologic malignancy were excluded. [1]
B. The recommended dosage of Enjaymo for patients with CAD is based on body weight. For patients weighing 39 kg to less than 75 kg, the recommended dose is 6,500 mg and for patients weighing 75 kg or more, the recommended dose is 7,500 mg [1]

5 . References

1. Enjaymo Prescribing Information. Bioverativ USA Inc. Waltham, MA. January 2023.
2. Diagnosing Cold Agglutinin Disease (CAD) available at https://www.understandingcad.com/diagnosing-cold-agglutinin-disease/. Accessed March 8, 2022.
3. A Study to Assess the Efficacy and Safety of BIVV009 (Sutimlimab) in Participants with Primary Cold Agglutinin Disease Who Have a Recent History of Blood Transfusion (Cardinal Study). Available at https://clinicaltrials.gov/ct2/show/NCT03347396. Accessed March 8, 2022.
4. Roth, A., Barcellini, W., et al. Sutimlimab in Cold Agglutinin Disease. N Engl J Med 2021; 384:1323-1334. Available at https://www.nejm.org/doi/10.1056/NEJMoa2027760?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed. Accessed March 8, 2022.

6 . Revision History

Date	Notes
3/9/2023	2023 Annual Review.

Enspryng (satralizumab-mwge)

Prior Authorization Guideline

Guideline ID	GL-113446
Guideline Name	Enspryng (satralizumab-mwge)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	12/1/2022
P&T Approval Date:	10/21/2020
P&T Revision Date:	01/20/2021 ; 10/20/2021 ; 10/19/2022

1 . Indications

Drug Name: Enspryng (satralizumab-mwge)
Neuromyelitis Optica Spectrum Disorder (NMOSD) Indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

2 . Criteria

Product Name: Enspryng	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neuromyelitis optica spectrum disorder (NMOSD)

AND

2 - Patient is anti-aquaporin-4 (AQP4) antibody positive

AND

3 - Prescribed by or in consultation with one of the following:

- Neurologist
- Ophthalmologist

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to rituximab

OR

4.2 For continuation of prior Enspryng therapy

Product Name: Enspryng	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . References

1. Enspryng Prescribing Information. Genentech, Inc. South San Francisco, CA. March 2022.

4 . Revision History

Date	Notes
10/5/2022	Annual review: Background updates.

Entyvio (vedolizumab)

Prior Authorization Guideline

Guideline ID	GL-127406
Guideline Name	Entyvio (vedolizumab)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/15/2024
P&T Approval Date:	
P&T Revision Date:	09/18/2019 ; 11/14/2019 ; 08/13/2020 ; 09/16/2020 ; 09/15/2021 ; 04/20/2022 ; 08/18/2022 ; 09/21/2022 ; 10/19/2022 ; 12/14/2022 ; 7/19/2023

1 . Criteria

Product Name: Entyvio IV	
Diagnosis	Crohn's Disease (CD)
Approval Length	14 Weeks [1, A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - One of the following [2, 3]:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CDAI) greater than 220

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [2, 3]:

- 6-mercaptopurine
- azathioprine
- corticosteroids (e.g., prednisone)
- methotrexate

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following:

- Cimzia (certolizumab pegol)
- One formulary adalimumab product
- Rinvoq (Upadacitinib)
- One formulary ustekinumab product
- Skyrizi (risankizumab-rzaa)

OR

4.2 For continuation of prior Entyvio therapy, defined as no more than a 45-day gap in therapy

AND

5 - Prescribed by or in consultation with a gastroenterologist

Product Name: Entyvio SC

Diagnosis	Crohn's Disease (CD)
Approval Length	14 Weeks
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - One of the following:

2.1 Will be used as a maintenance dose following two doses of Entyvio IV* for induction

OR

2.2 Patient is currently established on Entyvio IV*

AND

3 - Prescribed by or in consultation with a gastroenterologist

Product Name: Entyvio IV & SC	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization (Entyvio SC) and Nonformulary (Entyvio IV)

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline

- Reversal of high fecal output state

Product Name: Entyvio IV	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	14 Weeks [1, A]
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [4, 5]:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, ESR, CRP)
- Dependent on, or refractory to, corticosteroids

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [4, 5]:

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*:

- One formulary adalimumab product
- Simponi (golimumab)
- One formulary ustekinumab product
- Rinvoq (upadacitinib)
- Xeljanz/XR (tofacitinib/ER)

OR

4.2 For continuation of prior Entyvio therapy, defined as no more than a 45-day gap in therapy

AND

5 - Prescribed by or in consultation with a gastroenterologist

Notes	* Includes attestation that the patient has failed to respond to the TNF i nhibitor mechanism of action in the past and should not be made to try a second TNF inhibitor. In this case, only a single step through a preferr ed agent is required.

Product Name: Entyvio SC	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	14 Weeks [1, A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following:

2.1 Will be used as a maintenance dose following two doses of Entyvio IV* for induction

OR

2.2 Patient is currently established on Entyvio IV*

AND

3 - Prescribed by or in consultation with a gastroenterologist

Notes	* This product will require prior authorization

Product Name: Entyvio IV & SC	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4, 5]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

2 . Endnotes

A. Entyvio should be discontinued in patients who do not show evidence of therapeutic benefit by week 14. [1]

3 . References

1. Entyvio Prescribing Information. Takeda Pharmaceuticals of America, Inc. Deerfield, IL. April 2024..
2. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018;113:481-517.
3. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508.
4. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.
5. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterol. 2020;158:1450-1461.

4 . Revision History

Date	Notes
	New Program

Epogen (epoetin alpha)

Prior Authorization Guideline

Guideline ID	GL-116556
Guideline Name	Epogen (epoetin alpha)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Epogen	
Diagnosis	Anemia due to Chronic Kidney Disease (CKD)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request:

- Hematocrit (Hct) < 30%
- Hemoglobin (Hgb) < 10 g/dL

AND

3 - One of the following:

3.1 Patient is on dialysis

OR

3.2 All of the following:

- Patient is NOT on dialysis
- The rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion
- Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal

Product Name: Epogen	
Diagnosis	Anemia in HIV Patients
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request:

- Hematocrit (Hct) < 36%
- Hemoglobin (Hgb) < 12 g/dL

AND

2 - Serum erythropoietin level less than or equal to 500 mU/mL

AND

3 - One of the following:

- Patient is receiving zidovudine therapy
- Diagnosis of HIV infection

Product Name: Epogen	
Diagnosis	Anemia due to Chemotherapy
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Verification of anemia as defined by one of the following laboratory values collected within the prior two weeks of the request:

- Hematocrit (Hct) < 30%
- Hemoglobin (Hgb) < 10 g/dL

AND

2 - Verification that other causes of anemia have been ruled out

AND

3 - Verification that the cancer is a non-myeloid malignancy

AND

4 - One of the following:

- Patient is concurrently on chemo
- Patient will receive concomitant chemo for a minimum of 2 months

• Anemia is caused by cancer chemo*

Notes	*Note: Epogen for Anemia due to Chemotherapy will not be approved if patient is NOT receiving cancer chemotherapy.

Product Name: Epogen	
Diagnosis	Anemia in Myelodysplastic Syndrome (MDS)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Myelodysplastic Syndrome (MDS)

AND

2 - One of the following:

- Serum erythropoietin less than or equal to 500 mU/mL
- Diagnosis of transfusion dependent MDS

Product Name: Epogen	
Diagnosis	All indications listed above
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy demonstrated by one of the following:

- Improvement in hematocrit and hemoglobin levels
- Significant decrease in transfusion requirements

Product Name: Epogen	
Diagnosis	Preoperative for Reduction of Allogeneic Blood Transfusion
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient scheduled for an elective, non-cardiac, non-vascular surgery

AND

2 - Perioperative hemoglobin is greater than 10 to less than or equal to 13 g/dL

AND

3 - Patient is at high risk of blood loss

AND

4 - Patient is unwilling or unable to donate autologous blood pre-operatively

2 . Revision History

Date	Notes
10/4/2022	2023 New Implementation

Erythropoietic Agents - PA, NF

Prior Authorization Guideline

Guideline ID	GL-125950
Guideline Name	Erythropoietic Agents - PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	3/17/2000
P&T Revision Date:	11/14/2019 ; 04/15/2020 ; 11/12/2020 ; 01/20/2021 ; 11/18/2021 ; 12/15/2021 ; 02/17/2022 ; 11/17/2022 ; 6/21/2023

1 . Indications

Drug Name: Aranesp (darbepoetin alfa)
Anemia Due to Chronic Kidney Disease Indicated for the treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and patients not on dialysis. **Anemia Due to Chemotherapy in Patients with Cancer** Indicated for treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of 2 additional months of planned chemotherapy. Limitations of Use: Aranesp has not been shown to improve quality of life, fatigue, or patient well-being. Aranesp is not indicated for use: (1) In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy; (2) In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure; (3) In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion; and (4) As a substitute for red blood cell (RBC) transfusions in patients who require immediate correction of anemia. **Off Label Uses: Anemia in patients with Myelodysplastic Syndrome (MDS)** Has been used for the treatment of anemia in patients with MDS. [20]

Drug Name: Epogen (epoetin alfa), Procrit (epoetin alfa), and Retacrit (epoetin alfa-epbx)
Anemia Due to Chronic Kidney Disease Indicated for the treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and not on dialysis to decrease the need for red blood cell (RBC) transfusion. **Anemia Due to Zidovudine in Patients with HIV-infection** Indicated for the treatment of anemia due to zidovudine administered at less than or equal to 4200 mg/week in patients with HIV-infection with endogenous serum erythropoietin levels of less than or equal to 500 mUnits/mL. **Anemia Due to Chemotherapy in Patients with Cancer** Indicated for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy and upon initiation, there is a minimum of 2 additional months of planned chemotherapy. Limitations of Use: Epoetin alfa has not been shown to improve quality of life, fatigue, or patient well-being. Epoetin alfa is not indicated for use: (1) In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy; (2) In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure; (3) In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion; (4) As a substitute for red blood cell (RBC) transfusions in patients who require immediate correction of anemia. **Reduction of Allogeneic Red Blood Cell Transfusions in Patients Undergoing Elective, Noncardiac, Nonvascular Surgery** Indicated to reduce the need for allogeneic RBC transfusions among patients with perioperative hemoglobin greater than 10 to less than or equal to 13 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery. Epoetin alfa is not indicated for patients who are willing to donate autologous blood preoperatively. Limitations of Use: Epoetin alfa has not been shown to improve quality of life, fatigue, or patient well-being. Epoetin alfa is not indicated for use: (1) In patients scheduled for surgery who are willing to donate autologous blood; (2) In patients undergoing cardiac or vascular surgery. **Off Label Uses: Anemia associated with HIV infection** Have been used for the treatment of anemia associated with HIV infection in patients not receiving zidovudine. [5] **Anemia in Hepatitis C virus (HCV) infected patients due to combination therapy of ribavirin and interferon or peg-interferon** Have been used for the treatment of anemia in patients with hepatitis C virus (HCV) infection who are being treated with the combination of ribavirin and interferon or peginterferon alfa. [20] **Anemia in patients with Myelodysplastic Syndrome (MDS)** Have been used for the treatment of anemia in patients with MDS. [5, 20]
Drug Name: Mircera (methoxy polyethylene glycol-epoetin beta)
Anemia Due to Chronic Kidney Disease Indicated for the treatment of anemia associated with chronic kidney disease (CKD) in: (1) adult patients on dialysis and adult patients not on dialysis; (2) pediatric patients 5 to 17 years of age on hemodialysis who are converting from another ESA after their hemoglobin level was stabilized with an ESA. Limitations of use: Mircera is not indicated and is not recommended: (1) In the treatment of anemia due to cancer chemotherapy; or (2) As a substitute for RBC transfusions in patients who require immediate correction of

anemia. Mircera has not been shown to improve symptoms, physical functioning, or health-related quality of life.

2 . Criteria

Product Name: Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia Due to Chronic Kidney Disease (CKD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Verification of iron evaluation for adequate iron stores^ [A, J]

AND

3 - Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request: [1-3, 9, 13-17, 29, 33, B]

- Hematocrit (Hct) less than 30%
- Hemoglobin (Hgb) less than 10 g/dL

AND

4 - One of the following: [1-3, 33, L]

4.1 Patient is on dialysis

OR

4.2 All of the following:

4.2.1 Patient is NOT on dialysis

AND

4.2.2 The rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion

AND

4.2.3 Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal

AND

5 - History of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp
- Retacrit or Procrit

Notes	^Authorization will be given if physician is aware of iron deficiency and i s taking steps to replenish iron stores.

Product Name: Mircera	
Diagnosis	Anemia Due to Chronic Kidney Disease (CKD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Verification of iron evaluation for adequate iron stores^ [A, J]

AND

3 - One of the following:

3.1 All of the following:

3.1.1 Patient is greater than or equal to 18 years of age

AND

3.1.2 Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request: [9, 13-17, 29, 31, B]

- Hematocrit (Hct) less than 30%
- Hemoglobin (Hgb) less than 10 g/dL

AND

3.1.3 One of the following: [31]

3.1.3.1 Patient is on dialysis

OR

3.1.3.2 All of the following:

3.1.3.2.1 Patient is NOT on dialysis

AND

3.1.3.2.2 The rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion

AND

3.1.3.2.3 Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal

OR

3.2 All of the following:

3.2.1 Patient is between 5 and 17 years of age

AND

3.2.2 Patient is on hemodialysis

AND

3.2.3 Patient's hemoglobin level has been stabilized by treatment with another erythropoietin stimulating agent (ESA) (e.g., Aranesp, Retacrit)

AND

3.2.4 Patient is converting to Mircera from another ESA (e.g., Aranesp, Retacrit)

AND

4 - History of use or unavailability of both of the following: [O]

- Aranesp
- Retacrit or Procrit

Notes	^Authorization will be given if physician is aware of iron deficiency and i s taking steps to replenish iron stores.

Product Name: Aranesp, Epogen, Mircera, Procrit, or Retacrit	
Diagnosis	Anemia Due to Chronic Kidney Disease (CKD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - One of the following:

2.1 Both of the following:

- Patient is on dialysis
- Most recent or average Hct over 3 months is 33% or less (Hgb 11 g/dL or less)

OR

2.2 Both of the following:

- Patient is not on dialysis
- Most recent or average (avg) Hct over 3 mo is 30% or less (Hgb 10 g/dL or less)

OR

2.3 Both of the following:

- Request is for a pediatric patient
- Most recent or average Hct over 3 mo is 36% or less (Hgb 12 g/dL or less)

AND

3 - One of the following: [1-3, 31, 33]

3.1 Decrease in the need for blood transfusion

OR

3.2 Hemoglobin (Hgb) increased greater than or equal to 1g/dL from pre-treatment level

AND

4 - Verification of iron evaluation for adequate iron stores^ [A, J]

Notes	^Authorization will be given if physician is aware of iron deficiency and i s taking steps to replenish iron stores.

Product Name: Epogen, Procrit	
Diagnosis	Anemia Due to Chronic Kidney Disease (CKD)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Verification of iron evaluation for adequate iron stores^ [A, J]

AND

3 - Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request: [1-3, 9, 13-17, 29, 33, B]

- Hematocrit (Hct) less than 30%
- Hemoglobin (Hgb) less than 10 g/dL

AND

4 - One of the following: [1-3, 33, L]

4.1 Patient is on dialysis

OR

4.2 All of the following:

4.2.1 Patient is NOT on dialysis

AND

4.2.2 The rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion

AND

4.2.3 Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming history of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp
- Retacrit or Procrit

Notes	^Authorization will be given if physician is aware of iron deficiency and i s taking steps to replenish iron stores.

Product Name: Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in Patients with HIV-infection
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Verification of iron evaluation for adequate iron stores^ [2-3, 33]

AND

2 - Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request:

- Hemoglobin (Hgb) less than 12 g/dL [11, 25-28, K]
- Hematocrit (Hct) less than 36%

AND

3 - Serum erythropoietin level less than or equal to 500 mU/mL [2-3, 24, 26, 33]

AND

4 - One of the following:

- Patient is receiving zidovudine therapy [2-3, 33]
- Diagnosis of HIV infection [off-label] [5, 11, 24-28]

AND

5 - History of use or unavailability of Retacrit or Procrit (applies to Epogen only) [0]

Notes	^Authorization will be given if physician is aware of iron deficiency and i s taking steps to replenish iron stores.

Product Name: Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in Patients with HIV-infection
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Verification of anemia as defined by one of the following: [2, 3, 33]

- Most recent or average hematocrit (Hct) over a 3-month period was below 36%
- Most recent or average hemoglobin (Hgb) over a 3-month period was below 12 g/dL

AND

2 - One of the following: [2, 3, 33]

2.1 Decrease in the need for blood transfusion

OR

2.2 Hemoglobin (Hgb) increased greater than or equal to 1g/dL from pre-treatment level

Product Name: Epogen, Procrit	
Diagnosis	Anemia in Patients with HIV-infection
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Verification of iron evaluation for adequate iron stores^ [2-3, 33]

AND

2 - Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request:

- Hemoglobin (Hgb) less than 12 g/dL [11, 25-28, K]
- Hematocrit (Hct) less than 36%

AND

3 - Serum erythropoietin level less than or equal to 500 mU/mL [2-3, 24, 26, 33]

AND

4 - One of the following:

- Patient is receiving zidovudine therapy [2-3, 33]
- Diagnosis of HIV infection [off-label] [5, 11, 24-28]

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming history of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

Notes	^Authorization will be given if physician is aware of iron deficiency and i s taking steps to replenish iron stores.

Product Name: Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia Due to Chemotherapy in Patients with Cancer
Approval Length	3 Months [C]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Verification that other causes of anemia have been ruled out [1-3, 33, M]

AND

2 - Verification of anemia as defined by one of the following laboratory values collected within the prior two weeks of the request: [1-3, 33]

- Hematocrit (Hct) less than 30%
- Hemoglobin (Hgb) less than 10 g/dL [N]

AND

3 - Verification of iron evaluation for adequate iron stores ^ [1-3, 8, 33, G]

AND

4 - Verification that the cancer is a non-myeloid malignancy [1-3, 33, F]

AND

5 - Patient is receiving chemotherapy [1-3, 33, D]

AND

6 - History of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp
- Retacrit or Procrit

Notes	^Authorization will be given if physician is aware of iron deficiency and i s taking steps to replenish iron stores.

Product Name: Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia Due to Chemotherapy in Patients with Cancer
Approval Length	3 Months [C]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Verification of anemia as defined by one of the following laboratory values collected within the prior two weeks of the request: [1-3, 33]

- Hemoglobin (Hgb) less than 10 g/dL
- Hematocrit (Hct) less than 30% [10, 18-19]

AND

2 - One of the following: [1-3, 33]

2.1 Decrease in the need for blood transfusion

OR

2.2 Hemoglobin (Hgb) increased greater than or equal to 1 g/dL from pre-treatment level

AND

3 - Patient is receiving chemotherapy [D]

Product Name: Epogen, Procrit	
Diagnosis	Anemia Due to Chemotherapy in Patients with Cancer
Approval Length	3 Months [C]

Guideline Type	Non Formulary

Approval Criteria

1 - Verification that other causes of anemia have been ruled out [1-3, 33, M]

AND

2 - Verification of anemia as defined by one of the following laboratory values collected within the prior two weeks of the request: [1-3, 33]

- Hematocrit (Hct) less than 30%
- Hemoglobin (Hgb) less than 10 g/dL [N]

AND

3 - Verification of iron evaluation for adequate iron stores ^ [1-3, 8, 33, G]

AND

4 - Verification that the cancer is a non-myeloid malignancy [1-3, 33, F]

AND

5 - Patient is receiving chemotherapy [1-3, 33, D]

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming history of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp
- Retacrit or Procrit

Notes	^Authorization will be given if physician is aware of iron deficiency and i s taking steps to replenish iron stores.

Product Name: Epogen, Procrit, or Retacrit

Diagnosis	Preoperative use for reduction of allogeneic blood transfusion in patients undergoing surgery
Approval Length	1 month [2]
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery

AND

2 - Hemoglobin (Hgb) is greater than 10 to less than or equal to 13 g/dL

AND

3 - Patient is at high risk for perioperative transfusions

AND

4 - Patient is unwilling or unable to donate autologous blood pre-operatively

AND

5 - Verification of iron evaluation for adequate iron stores^ [2-3, 33]

AND

6 - History of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

Notes	^Authorization will be given if physician is aware of iron deficiency and i s taking steps to replenish iron stores.

Product Name: Epogen, Procrit	
Diagnosis	Preoperative use for reduction of allogeneic blood transfusion in patients undergoing surgery
Approval Length	1 month [2]

Guideline Type	Non Formulary

Approval Criteria

1 - Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery

AND

2 - Hemoglobin (Hgb) is greater than 10 to less than or equal to 13 g/dL

AND

3 - Patient is at high risk for perioperative transfusions

AND

4 - Patient is unwilling or unable to donate autologous blood pre-operatively

AND

5 - Verification of iron evaluation for adequate iron stores^ [2-3, 33]

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming history of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

Notes	^Authorization will be given if physician is aware of iron deficiency and i s taking steps to replenish iron stores.

Product Name: Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in Myelodysplastic Syndrome (MDS) patients [off-label] [4-6, 20]
Approval Length	3 months [I]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Myelodysplastic Syndrome (MDS) [4]

AND

2 - One of the following: [4]

- Serum erythropoietin level less than or equal to 500 mU/mL
- Diagnosis of transfusion-dependent MDS

AND

3 - Verification of iron evaluation for adequate iron stores ^ [4, A, H]

AND

4 - History of use or unavailability of both of the following (applies to Epogen only): [0]

- Aranesp
- Retacrit or Procrit

Notes	^Authorization will be given if physician is aware of iron deficiency and i s taking steps to replenish iron stores.

Product Name: Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in Myelodysplastic Syndrome (MDS) patients [off-label]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Verification of anemia as defined by one of the following: [4, E]

- Most recent or average hematocrit (Hct) over a 3-month period was less than or equal to 36%

- Most recent or average hemoglobin (Hgb)over a 3-month period was less than or equal to 12 g/dL

AND

2 - One of the following: [1-3, 33]

2.1 Decrease in the need for blood transfusion

OR

2.2 Hemoglobin (Hgb) increased greater than or equal to 1 g/dL from pre-treatment level

Product Name: Epogen, Procrit	
Diagnosis	Anemia in Myelodysplastic Syndrome (MDS) patients [off-label] [4-6, 20]
Approval Length	3 months [I]
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Myelodysplastic Syndrome (MDS) [4]

AND

2 - One of the following: [4]

- Serum erythropoietin level less than or equal to 500 mU/mL
- Diagnosis of transfusion-dependent MDS

AND

3 - Verification of iron evaluation for adequate iron stores ^ [4, A, H]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming history of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp
- Retacrit or Procrit

Notes	^Authorization will be given if physician is aware of iron deficiency and i s taking steps to replenish iron stores.

Product Name: Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in HCV-infected patients due to ribavirin in combination with interferon or peg-interferon [off-label] [6]
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatitis C viral (HCV) infection [12, 20]

AND

2 - Verification of iron evaluation for adequate iron stores^ [2-3, 33]

AND

3 - Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request: [P]

- Hematocrit (Hct) less than 36%
- Hemoglobin (Hgb) less than 12 g/dL

AND

4 - Verification of both of the following:

4.1 Patient is receiving ribavirin

AND

4.2 Patient is receiving one of the following:

- interferon alfa-2b
- interferon alfacon-1
- peginterferon alfa-2b
- peginterferon alfa-2a

AND

5 - History of use or unavailability of Retacrit or Procrit (applies to Epogen only) [0]

Notes	^Authorization will be given if physician is aware of iron deficiency and i s taking steps to replenish iron stores.

Product Name: Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in HCV-infected patients due to ribavirin in combination with interferon or peg-interferon [off-label]
Approval Length	3 Months or if patient has demonstrated response to therapy, authorization will be issued for the full course of ribavirin therapy.
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Verification of anemia as defined by one of the following: [35]

- Most recent or average hematocrit (Hct) over a 3-month period was 36% or less
- Most recent or average hemoglobin (Hgb) over a 3-month period was 12 g/dL or less

AND

2 - One of the following: [2, 3, 33]

2.1 Decrease in the need for blood transfusion

OR

2.2 Hemoglobin (Hgb) increased greater than or equal to 1 g/dL from pre-treatment level

Product Name: Epogen, Procrit	
Diagnosis	Anemia in HCV-infected patients due to ribavirin in combination with interferon or peg-interferon [off-label] [6]
Approval Length	3 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of hepatitis C viral (HCV) infection [12, 20]

AND

2 - Verification of iron evaluation for adequate iron stores^ [2-3, 33]

AND

3 - Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request: [P]

- Hematocrit (Hct) less than 36%
- Hemoglobin (Hgb) less than 12 g/dL

AND

4 - Verification of both of the following:

4.1 Patient is receiving ribavirin

AND

4.2 Patient is receiving one of the following:

- interferon alfa-2b
- interferon alfacon-1
- peginterferon alfa-2b
- peginterferon alfa-2a

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming history of use or unavailability of Retacrit or Procrit (applies to Epogen only) [0]

Notes	^Authorization will be given if physician is aware of iron deficiency and i s taking steps to replenish iron stores.

Product Name: Aranesp, Epogen, Mircera, Procrit, or Retacrit	
Diagnosis	Other Off-Label Uses
Guideline Type	Prior Authorization

Approval Criteria

1 - Off-label guideline approval criteria have been met*

AND

2 - Off-label requests other than those listed above for coverage in patients with Hgb greater than 10 g/dL or Hct greater than 30% will not be approved [1-3, 31, 33]

Notes	*Off-label requests will be evaluated on a case-by-case basis by a clinic al pharmacist

Product Name: Epogen, Procrit	
Diagnosis	Other Off-Label Uses
Guideline Type	Non Formulary

Approval Criteria

1 - Off-label guideline approval criteria have been met*

AND

2 - Off-label requests other than those listed above for coverage in patients with Hgb greater than 10 g/dL or Hct greater than 30% will not be approved [1-3, 31, 33]

Notes	*Off-label requests will be evaluated on a case-by-case basis by a clinic al pharmacist

3 . Endnotes

A. Aranesp, Epogen, Mircera, Procrit, and Retacrit Prescribing Information recommend prior and during therapy, the patient's iron stores should be evaluated. Administer supplemental iron therapy when serum ferritin is less than 100 mcg/L or when serum transferrin saturation is less than 20%. The majority of patients with CKD will require supplemental iron during the course of ESA therapy. [1-3, 31, 33]
B. Aranesp, Epogen, Mircera, Procrit, or Retacrit Prescribing Information states that dialysis, and non-dialysis patients with symptomatic anemia considered for therapy should have a Hgb < 10 g/dL. [1-3, 31, 33]
C. ESA treatment duration for each course of chemotherapy includes the 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regimen. [18]
D. ESAs are not indicated for patients receiving myelosuppressive therapy when the anticipated outcome is cure. [1-3, 33]
E. NCCN panel recommends MDS patients aim for a target hemoglobin level of less than or equal to 12 g/dL. [4]
F. The American Cancer Society definition of "non-myeloid malignancy" is any malignancy that is not a myeloid leukemia. Non-myeloid cancers include all types of carcinoma, all types of sarcoma, melanoma, lymphomas, lymphocytic leukemias (ALL and CLL), and multiple myeloma. [30]
G. Absolute iron deficiency is defined as ferritin <30 ng/mL and TSAT <20%. Functional iron deficiency in patients receiving ESAs is defined as ferritin 30-800 ng/mL and TSAT 20%-50%. No iron deficiency is defined as ferritin >800 ng/mL or TSAT greater or equal to 50%. [8]
H. Iron repletion needs to be verified before instituting Epo therapy. [4]
I. Detection of erythroid responses generally occurs within 6 to 8 weeks of treatment. If no response occurs in this time frame, this treatment should be considered a failure and discontinued. [4]
J. Iron stores evaluation is recommended to occur every month during initial erythropoietin treatment in adults with chronic kidney disease or at least every 3 months during stable ESA treatment or in patients with HD-CKD not treated with an erythropoietin. [7]
K. Anemia in HIV patients has been defined as hemoglobin less than 10 g/dL [11, 25-26], hemoglobin less than 11 g/dL [11, 27], or hemoglobin less than 12 g/dL. [17]
L. Although primarily used in patients with ESRD, ESAs such as erythropoietin and darbepoetin alfa also correct the anemia in those with CKD who do not yet require dialysis. [21, 32]
M. Examples of other anemias include: vitamin B12, folate or iron deficiency anemia, hemolysis, or gastrointestinal bleeding.
N. Data from a systematic review by the Agency for Healthcare Research and Quality (AHRQ) determined that delaying ESA treatment until hemoglobin is less than 10 g/dL resulted in fewer thromboembolic events and a reduced mortality. [8]
O. Per consult with hematologist/oncologist, if a patient does not respond to one short-acting ESA, switching to another short-acting agent would not provide any added benefit; instead, one would increase the dose or perhaps switch to a long-acting agent. [34]
P. Epoetin alfa was effective in maintaining the dose of rivabirin in anemic patients with chronic hepatitis C virus in patients with a baseline hemoglobin of 12 g/dL or less. [20]

4 . References

1. Aranesp prescribing information. Amgen Inc. Thousand Oaks, CA. January 2019.

2. Epogen prescribing information. Amgen Inc. Thousand Oaks, CA. July 2018.
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5 . Revision History

Date	Notes
5/22/2023	update guideline

Etoposide

Prior Authorization Guideline

Guideline ID	GL-116500
Guideline Name	Etoposide
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Etoposide capsules	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of small cell lung cancer (SCLC)

AND

2 - Prescribed by or in consultation with an oncologist

Product Name: Etoposide capsules

Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
9/24/2022	2023 New Implementation

Evenity (romosozumab-aqqg injection)

Prior Authorization Guideline

Guideline ID	GL-125513
Guideline Name	Evenity (romosozumab-aqqg injection)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	5/16/2019
P&T Revision Date:	05/14/2020 ; 06/16/2021 ; 6/21/2023

1 . Indications

Drug Name: Evenity (romosozumab-aqqg injection)
Postmenopausal women with osteoporosis at high risk of fracture Indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

2 . Criteria

Product Name: Evenity	
Approval Length	12 Months [A]
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of postmenopausal osteoporosis or osteopenia

AND

2 - One of the following:

2.1 For diagnosis of osteoporosis, both of the following:

2.1.1 Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.1.2 One of the following:

2.1.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.1.2.2 Trial and failure, contraindication, or intolerance to one anti-resorptive treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]) [B]

OR

2.2 For diagnosis of osteopenia, both of the following:

2.2.1 BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following:

2.2.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.2.2.2 Both of the following:

2.2.2.2.1 Trial and failure, contraindication, or intolerance to one anti-resorptive treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]) [B]

AND

2.2.2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: [C]

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

AND

3 - Trial of, contraindication, or intolerance to one of the following:

- Forteo (teriparatide)
- Tymlos (abaloparatide)

AND

4 - Treatment duration of Evenity (romosozumab-aqqg) has not exceeded a total of 12 months during the patient's lifetime [A]

Notes	Evenity (romosozumab-aqqg) not to exceed the FDA-recommended tre atment duration of 12 monthly doses.

3 . Endnotes

A. The anabolic effect of Evenity wanes after 12 monthly doses of therapy. Therefore, the duration of Evenity use should be limited to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered. [1]
B. Antiresorptive agents work by slowing the resorption or breakdown part of the remodeling cycle. Examples of antiresorptive agents include bisphosphonates (alendronate, ibandronate, risedronate, zoledronic acid), Prolia (denosumab), calcitonin, and selective estrogen receptor modulators (raloxifene). [2-4]
C. The WHO FRAX tool is available at www.shef.ac.uk/FRAX and incorporates multiple clinical factors that predict fracture risk, largely independent of BMD. [2]

4 . References

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3. National Osteoporosis Foundation. Treatment and Adherence. Available at: https://www.nof.org/patients/treatment/medicationadherence/. Accessed April 25, 2019.
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5 . Revision History

Date	Notes
5/9/2023	2023 UM Annual Review. Update criteria to say "For diagnosis of osteo porosis" and "For diagnosis of osteopenia" to align with Tymlos. No ch anges to clinical intent

Evkeeza (evinacumab-dgnb)

Prior Authorization Guideline

Guideline ID	GL-123203
Guideline Name	Evkeeza (evinacumab-dgnb)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	
P&T Revision Date:	04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Evkeeza (evinacumab-dgnb)
Homozygous Familial Hypercholesterolemia (HoFH) Indicated as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, aged 5 years and older, with homozygous familial hypercholesterolemia (HoFH). **Limitations of Use** The safety and effectiveness of Evkeeza have not been established in patients with other causes of hypercholesterolemia, including those with heterozygous familial hypercholesterolemia (HeFH). The effects of Evkeeza on cardiovascular morbidity and mortality have not been determined.

2 . Criteria

Product Name: Evkeeza	
Diagnosis	Homozygous Familial Hypercholesterolemia [HoFH]

Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 5 years of age or older

AND

2 - Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by one of the following: [2-4]

2.1 Genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus

OR

2.2 Both of the following:

2.2.1 One of the following:

- Untreated/pre-treatment LDL-C greater than 500 mg/dL
- Treated LDL-C greater than 300 mg/dL

AND

2.2.2 One of the following:

- Xanthoma before 10 years of age
- Evidence of heterozygous familial hypercholesterolemia in both parents

AND

3 - Patient has failed to achieve a low-density lipoprotein-cholesterol (LDL-C) goal of less than 100 mg/dL despite use of both of the following: [2,5-9]

3.1 One of the following:

3.1.1 Patient is currently treated with maximally tolerated statin therapy plus ezetimibe

OR

3.1.2 Patient is unable to tolerate statin therapy as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms: [B]

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

OR

3.1.3 Patient has a labeled contraindication to all statins

OR

3.1.4 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN

AND

3.2 One of the following:

- Patient has been treated with PCSK9 therapy or did not respond to PCSK9 therapy
- Physician attests that the patient is known to have two LDL-receptor negative alleles (little to no residual function) and therefore would not respond to PCSK9 therapy
- Patient has a history of intolerance or contraindication to PCSK9 therapy
- Patient has previously been treated with Juxtapid (lomitapide)
- Patient has previously been treated with lipoprotein apheresis

AND

4 - Patient will continue other traditional lipid-lowering therapies (e.g., maximally tolerated statins, ezetimibe) in combination with Evkeeza

AND

5 - Dose will not exceed 15 milligrams per kilogram of bodyweight infused once every 4 weeks

AND

6 - Prescribed by one of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

Product Name: Evkeeza	
Diagnosis	Homozygous Familial Hypercholesterolemia [HoFH]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of LDL-C reduction from baseline while on Evkeeza therapy

AND

2 - Patient will continue other traditional lipid-lowering therapies (e.g., maximally tolerated statins, ezetimibe) in combination with Evkeeza

AND

3 - Dose will not exceed 15 milligrams per kilogram of bodyweight infused once every 4 weeks

AND

4 - Prescribed by one of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

3 . Endnotes

A. Per the 2018 ACC/AHA national treatment guidelines, adherence, response to therapy, and adverse effects should be monitored within 4 -12 weeks following LDL-C lowering medication initiation or dose adjustment, repeated every 3 to 12 months as needed. Additionally, in the Evkeeza pivotal trial the primary outcome of change in LDL-C was evaluated at 24 weeks. [1,2,6]
B. In patients treated with statins, it is recommended to measure creatine kinase levels in individuals with severe statin-associated muscle symptoms. [6]

4 . References

1. Evkeeza Prescribing Information. Regeneron Pharmaceuticals, Inc. Tarrytown, NY. March 2023.
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3. Raal FJ, Santos RD. Homozygous familial hypercholesterolemia: current perspectives on diagnosis and treatment. Atherosclerosis. 2012;223:262-8.
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5 . Revision History

Date	Notes

3/27/2023	Annual review - submission of medical records removed. Age criteria u pdated to reflect label update

Excluded Drugs Administrative Policy - Commercial

Prior Authorization Guideline

Guideline ID	GL-126082
Guideline Name	Excluded Drugs Administrative Policy - Commercial
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Caverject, Muse, Edex, Kybella, Durolane, Euflexxa, Gel-One, Gelsyn-3. GenVisc, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz FX, Synojoynt, Synvisc, Synvisc-One, Triluron, Trivisc, Visco-3	
Approval Length	N/A - Requests should not be approved
Guideline Type	Prior Authorization
Approval Criteria **1** - Requests are not authorized and will not be approved. See Background Section for details.	

2 . Background

Benefit/Coverage/Program Information

Caverject, Muse, Edex

1. Is the requested medication being used to treat erectile dysfunction?
Yes = Deny. The plan does not cover medications for the treatment of erectile dysfunction as the excluded from coverage. No = Deny. The plan does not cover drugs that do not have clear information to prove it helps the problem. This should come from reliable medical sources. Samaritan uses these sources to def which treatments have been proven to work. The drug you have requested does not meet these requirements.

Kybella

1. Is the requested medication being used for cosmetic purposes?
Yes = Deny. The plan does not cover drugs used for cosmetic purposes. For this reason, Kybella requested for <diagnosis> is not covered. No = Deny. The plan does not cover drugs that do not have clear information to prove it helps the problem. This should come from reliable medical sources. Samaritan uses these sources to def which treatments have been proven to work. The drug you have requested does not meet these requirements.

Durolane, Euflexxa, Gel-One, Gelsyn-3, GenVisc, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz FX, Synojoynt, Synvisc, Synvisc-One, Triluron, Trivisc, Visco-3

1. Is the requested medication being used to treat osteoarthritis?
Yes = Deny. Samaritan Health Plan does not cover drugs that do not have clear information to pr they are effective. This should come from reliable medical sources. <drug> does not have clear documentation of efficacy, so it is not a covered service. No = Deny. The plan does not cover drugs that do not have clear information to prove it helps the problem. This should come from reliable medical sources. Samaritan uses these sources to def which treatments have been proven to work. The drug you have requested does not meet these requirements.

3 . Revision History

Date	Notes
6/5/2023	New program

Exkivity (mobocertinib)

Prior Authorization Guideline

Guideline ID	GL-116577
Guideline Name	Exkivity (mobocertinib)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Exkivity	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is one of the following:

- Locally advanced

- Metastatic

AND

3 - Disease is epidermal growth factor receptor (EGFR) exon 20 insertion mutation positive

AND

4 - Patient has progressed on or following prior treatment with a platinum-containing regimen (e.g., carboplatin, cisplatin)

AND

5 - Prescribed by or in consultation with an oncologist or hematologist

AND

6 - Patient is 18 years of age or older

AND

7 - Trial and failure, intolerance, or contraindication to Rybrevant (amivantamab)

Product Name: Exkivity	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/21/2022	2023 New Implementation

Exondys 51 (eteplirsen) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-124049
Guideline Name	Exondys 51 (eteplirsen) - PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	11/17/2016
P&T Revision Date:	02/13/2020 ; 05/14/2020 ; 05/20/2021 ; 06/16/2021 ; 12/15/2021 ; 05/19/2022 ; 06/15/2022 ; 5/18/2023

1 . Indications

Drug Name: Exondys 51 (eteplirsen)
Duchenne muscular dystrophy (DMD) Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping. This indication is approved under accelerated approval based on an increase in dystrophin in skeletal muscle observed in some patients treated with Exondys 51. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

2 . Criteria

Product Name: Exondys 51	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Duchenne muscular dystrophy (DMD)

AND

2 - Documentation of a confirmed mutation of the dystrophin gene amenable to exon 51 skipping

AND

3 - Patient is 7 years of age or older [2-4]

AND

4 - Prescribed by or in consultation with a neurologist who has experience treating children

AND

5 - Dose will not exceed 30 milligrams per kilogram of body weight infused once weekly

AND

6 - Patient is ambulatory, as evaluated via the 6-minute walk test (6MWT) or North Star ambulatory assessment (NSAA) [2-4]

Product Name: Exondys 51	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is tolerating therapy

AND

2 - Prescribed by or in consultation with a neurologist who has experience treating children

AND

3 - Dose will not exceed 30 milligrams per kilogram of body weight infused once weekly

AND

4 - Patient is maintaining ambulatory status, as evaluated via the 6-minute walk test (6MWT) or North Star ambulatory assessment (NSAA)

Product Name: Exondys 51	
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting both of the following:

1.1 Diagnosis of Duchenne muscular dystrophy (DMD)

AND

1.2 Documentation of a confirmed mutation of the dystrophin gene amenable to exon 51 skipping

AND

2 - Patient is 7 years of age or older [2-4]

AND

3 - Prescribed by or in consultation with a neurologist who has experience treating children

AND

4 - Dose will not exceed 30 milligrams per kilogram of body weight infused once weekly

AND

5 - Submission of medical records (e.g., chart notes, laboratory values) documenting the patient is ambulatory, as evaluated via the 6-minute walk test (6MWT) or North Star ambulatory assessment (NSAA) [2-4]

3 . References

1. Exondys 51 Prescribing Information. Sarepta Therapeutics, Inc. Cambridge, MA. January 2022.
2. Mendell JR, Goemans N, Lowes LP, et al. Longitudinal effect of eteplirsen versus historical control on ambulation in Duchenne muscular dystrophy. Ann Neurol. 2016;79(2):257-271. doi: 10.1002/ana.24555
3. Mendell JR, Rodino-Klapac LR, Sahenk Z, et al. Eteplirsen for the treatment of Duchenne muscular dystrophy. Ann Neurol. 2013;74(5):637-647.
4. Per Clinical Consultation with a Pediatrician, October 5, 2016 and January 22, 2020.

4 . Revision History

Date	Notes
5/4/2023	Annual review: Formatting updates.

Extavia (interferon beta-1b)

Prior Authorization Guideline

Guideline ID	GL-121386
Guideline Name	Extavia (interferon beta-1b)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name: Brand Extavia, Brand Betaseron	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsing forms of multiple sclerosis

AND

2 - Prescribed by or in consultation with neurologist

AND

3 - Trial and failure, contraindication, or intolerance to all of the following (New Starts Only):

- dimethyl fumarate
- fingolimod
- glatopa/glatiramer acetate

Product Name: Brand Extavia, Brand Betaseron	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy

2 . Revision History

Date	Notes
2/22/2023	New Program

Fabry Disease Agents

Prior Authorization Guideline

Guideline ID	GL-126824
Guideline Name	Fabry Disease Agents
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	
P&T Revision Date:	10/16/2019 ; 10/21/2020 ; 05/20/2021 ; 10/20/2021 ; 10/19/2022 ; 7/19/2023

1 . Indications

Drug Name: Fabrazyme (agalsidase beta)
Fabry disease Indicated for the treatment of adult and pediatric patients 2 years of age and older with confirmed Fabry disease.
Drug Name: Elfabrio (pegunigalsidase alfa-iwxj)
Fabry disease Indicated for the treatment of adults with confirmed Fabry disease.

2 . Criteria

Product Name: Fabrazyme	
Approval Length	60 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Fabry disease

AND

2 - Patient is 2 years of age or older

AND

3 - One of the following: [3, 4]

- Detection of pathogenic mutations in the GLA gene by molecular genetic testing
- Deficiency in α-galactosidase A (α-Gal A) enzyme activity in plasma, isolated leukocytes, or dried blood spots (DBS)
- Significant clinical manifestations (e.g., neuropathic pain, cardiomyopathy, renal insufficiency, angiokeratomas, cornea verticillata)

AND

4 - Will not be used in combination with Galafold (migalastat) [A]

Product Name: Elfabrio	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Fabry disease

AND

2 - Disease confirmed by one of the following: [3, 4]

- Detection of pathogenic mutations in the GLA gene by molecular genetic testing

- Deficiency in α-galactosidase A (α-Gal A) enzyme activity in plasma, isolated leukocytes, or dried blood spots (DBS)
- Significant clinical manifestations (e.g., neuropathic pain, cardiomyopathy, renal insufficiency, angiokeratomas, cornea verticillata)

AND

3 - Will not be used in combination with Galafold (migalastat) [A]

Product Name: Elfabrio	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . Endnotes

A. The safety and effectiveness of concomitant use of Galafold (migalastat) and Fabrazyme (agalsidase beta) has not been established. [2, 6]

4 . References

1. Fabrazyme prescribing information. Genzyme Corporation. Cambridge, MA. August 2021.
2. Per clinical consultation with geneticist. October 11, 2018.
3. Ortiz A, Germain DP, Desnick RJ, et al. Fabry disease revisited: Management and treatment recommendations for adult patients. Mol Genet Metab. 2018;123(4):416-427. doi:10.1016/j.ymgme.2018.02.014.
4. Michaud M, Mauhin W, Belmatoug N, et al. When and How to Diagnose Fabry Disease in Clinical Pratice. Am J Med Sci. 2020;360(6):641-649. doi:10.1016/j.amjms.2020.07.011.
5. Elfabrio prescribing information. Chiesi USA, Inc. Cary, NC. May 2023.
6. UptoDate. Fabry disease:Treatment and prognosis. Available at: https://www.uptodate.com/contents/fabry-disease-treatment-and-prognosis?search=fabry%20disease&source=search_result&selectedTitle=2~68&usage_type=default&display_rank=2. Accessed June 12, 2023.

5 . Revision History

Date	Notes
6/29/2023	New UM PA Criteria for Elfabrio

Fasenra (benralizumab)

Prior Authorization Guideline

Guideline ID	GL-124552
Guideline Name	Fasenra (benralizumab)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2024
P&T Approval Date:	1/24/2018
P&T Revision Date:	05/19/2022 ; 05/18/2023 ; 05/18/2023 ; 05/16/2024 ; 6/19/2024

1 . Indications

Drug Name: Fasenra (benralizumab)
Severe Eosinophilic Asthma Indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype. Limitations of use: Fasenra is not indicated for treatment of other eosinophilic conditions. Fasenra is not indicated for the relief of acute bronchospasm or status asthmaticus.

2 . Criteria

Product Name: Fasenra	
Approval Length	6 Months [F]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe asthma

AND

2 - Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter [6, C, G]

AND

3 - One of the following:

3.1 Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months [2, 3, C]

OR

3.2 Prior asthma-related hospitalization within the past 12 months [D]

AND

4 – One of the following:

4.1 Both of the following [4, 5, A, B]:

4.1.1 Patient is 6 years of age or older but less than 12 years of age

AND

4.1.2 Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

4.1.2.1 Both of the following [A, 4, 5]:

• Medium-dose inhaled corticosteroid (e.g., greater than 100 – 200 mcg fluticasone propionate equivalent/day)
• Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium])

OR

4.1.2.2 One medium dosed combination ICS/LABA product (e.g., Advair Diskus [fluticasone propionate 100mcg/ salmeterol 50mcg], Symbicort [budesonide 80mcg/ formoterol 4.5mcg] Breo Ellipta [fluticasone furoate 50 mcg/ vilanterol 25 mcg])

OR

4.2 – Both of the following:
- 4.2.1 Patient is 12 years of age or older

AND

4.2.2 Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

4.2.2.1 Both of the following [4, 5, A]:

• High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day)

• Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium])

OR

4.2.2.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate 500mcg/ salmeterol 50mcg], Symbicort [budesonide 160mcg/ formoterol 4.5mcg], Breo Ellipta [fluticasone 200mcg/ vilanterol 25mcg])

AND

5 - Prescribed by or in consultation with one of the following:

• Pulmonologist
• Allergist/Immunologist

Product Name: Fasenra	
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications)

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

3. Endnotes

A. The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention update lists anti-interleukin- 5 treatment or anti-interleukin 5 receptor treatment as an add on option for patients with severe eosinophilic asthma that is uncontrolled on two or more controllers plus as-needed reliever medication (Step 4-5 treatment). [5]

B. The SIROCCO and CALIMA trials evaluated the effect of benralizumab 30mg administered in 4 week and 8 week regimens as add on therapy to standard of care medicine. The trials enrolled patients 12 to 75 years of age with severe asthma defined as a history of two or more exacerbations in the previous year which needed systemic corticosteroids or a temporary increase in the patient's usual maintenance dose of oral corticosteroids. Patients were also required to have received treatment with a medium dose or high dose ICS plus LABA for at least one year before enrollment. Both trials confirmed benralizumab significantly reduced the annual exacerbation rates and was generally well tolerated in patients who were uncontrolled on high dose ICS plus LABA and had a baseline blood eosinophil count of 300 cells per microliter or greater [2, 3]. The baseline eosinophil level requirement of greater than or equal to 150 cells per microliter and the requirement for a history of one or more exacerbations listed in the criteria comes from the inclusion criteria allowed in the ZONDA trial. The ZONDA trial was a 28-week,

Phase 3, randomized, double blind, placebo controlled, multicenter, oral corticosteroid reduction trial [6].

C. Recommendation inferred from the national P&T committee meeting, December 2015, regarding similar agent first-in-class IL-5 antagonist Nucala (mepolizumab) in the use of severe eosinophilic asthma.

D. Asthma treatment can often be reduced, once good asthma control has been achieved and maintained for three months and lung function has hit a plateau. However, the approach to stepping down will depend on patient specific factors (e.g., current medications, risk factors). At this time evidence for optimal timing, sequence, and magnitude of treatment reductions is limited. It is feasible and safe for most patients to reduce the ICS dose by 25-50% at three month intervals, but complete cessation of ICS is associated with a significant risk of exacerbations [5].

E. The GINA Global Strategy for Asthma Management and Prevention update recommends that patients with asthma should be reviewed regularly to monitor their symptom control, risk factors and occurrence of exacerbations, as well as to document the response to any treatment changes. Ideally, response to Type 2-targeted therapy should be re-evaluated every 3-6 months, including re-evaluation of the need for ongoing biologic therapy for patients with good response to Type 2 targeted therapy. [5]

F. The Institute for Clinical and Economic Review (ICER) defines eosinophilic inflammation as a blood eosinophil level greater than or equal to 150 cells per microliter at initiation of therapy. This is the lowest measured threshold for eosinophilic asthma in pivotal trials. [7]

5 . References

1. Fasenra Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. April 2024.
2. FitzGerald JM, Bleecker ER, Nair P, et al. Benralizumab, an anti-interleukin-5 receptor α monoclonal antibody, as add-on treatment for patients with severe, uncontrolled, eosinophilic asthma (CALIMA): a randomised, double-blind, placebo-controlled phase 3 trial. Lancet. 2016 Oct 29;388(10056):2128-2141.
3. Bleecker ER, FitzGerald JM, Chanez P, et al. Efficacy and safety of benralizumab for patients with severe asthma uncontrolled with high-dosage inhaled corticosteroids and long-acting Beta two agonist (SIROCCO): a randomised, multicentre, placebo-controlled phase 3 trial. Lancet. 2016 Oct 29;388(10056):2115-2127.
4. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention (2022 update). 2022 www.ginasthma.org. Accessed April 2024.
5. Nair P, Wenzel S, Rabe KF, et al. ZONDA Trial Investigators. Oral glucocorticoid-sparing effect of benralizumab in severe asthma. N Engl J Med. 2017;376(25):2448-2458.
6. Institute for Clinical and Economic Review (ICER). Biologic therapies for treatment of asthma associated with type 2 inflammation: effectiveness, value, and value-based price benchmarks. https://icer.org/wp-content/uploads/2020/10/ICER_Asthma-Final-Report_Unredacted_08122020.pdf. Published December 20, 2018. Accessed April 15, 2022.
7. Wedner HJ, Fujisawa T, Guilbert TW, Ikeda M, Mehta V, Tam JS, Lukka PB, Asimus S, Durżyński T, Johnston J, White WI, Shah M, Werkström V, Jison ML; all TATE investigators. Benralizumab in children with severe eosinophilic asthma: Pharmacokinetics and long-term safety (TATE study). Pediatr Allergy Immunol. 2024 Mar;35(3):e14092.

6 . Revision History

Date	Notes
6/4/2024	Addition of new 10 mg/0.5mL prefilled syringe.

Fingolimod

Prior Authorization Guideline

Guideline ID	GL-121366
Guideline Name	Fingolimod
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name: Generic Fingolimod	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS)

AND

2 - Prescribed by or in consultation with a neurologist

Product Name: Generic Fingolimod

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
2/22/2023	Remove brand

Firmagon (degarelix)

Prior Authorization Guideline

Guideline ID	GL-112099
Guideline Name	Firmagon (degarelix)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	11/1/2022
P&T Approval Date:	5/18/2010
P&T Revision Date:	09/18/2019 ; 09/16/2020 ; 10/20/2021 ; 9/21/2022

1 . Indications

Drug Name: Firmagon (degarelix)
Advanced Prostate Cancer Indicated for treatment of patients with advanced prostate cancer.

2 . Criteria

Product Name: Firmagon	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of advanced prostate cancer [1-2]

AND

2 - Prescribed by or in consultation with an oncologist

Product Name: Firmagon	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Firmagon prescribing information. Ferring Pharmaceuticals Inc. Parsippany, NJ. March 2020.
2. Klotz L, Boccon-Gibod L, Shore ND, et al. The efficacy and safety of Firmagon: a 12-month, comparative, randomized, open-label, parallel-group phase III study in patients with prostate cancer. BJU Int. 2008;102:1531-1538.

4 . Revision History

Date	Notes
8/22/2022	2022 Annual Review

Flutamide- SAMLG

Prior Authorization Guideline

Guideline ID	GL-116502
Guideline Name	Flutamide- SAMLG
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Flutamide	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic prostate cancer

AND

2 - Disease is locally confined Stage B2 to C and Stage D2

AND

3 - Will be used in combination with Luteinizing Hormone-Releasing Hormone (LHRH) agonist (e.g., goserelin, leuprolide)

AND

4 - Submission of medical records (e.g., chart notes) confirming current liver function

AND

5 - Patient does not have severe hepatic impairment

AND

6 - Prescribed by or in consultation with an oncologist

Product Name: Flutamide	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/5/2022	2023 New Implementation

Fosrenol (lanthanum carbonate)

Prior Authorization Guideline

Guideline ID	GL-126335
Guideline Name	Fosrenol (lanthanum carbonate)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Generic Lanthanum	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hyperphosphatemia in chronic kidney disease (CKD)

AND

2 - Prescribed by or in consultation with nephrologist

AND

3 - Trial and failure, contraindication, or intolerance (at least 6 weeks) to both:

- maximally tolerated calcium acetate
- sevelamer carbonate

AND

4 - Member is 6 years old or older

Product Name: Generic Lanthanum	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy

2 . Revision History

Date	Notes
6/9/2023	New Program

Gamifant (emapalumab-lzsg)

Prior Authorization Guideline

Guideline ID	GL-120194
Guideline Name	Gamifant (emapalumab-lzsg)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	
P&T Revision Date:	02/13/2020 ; 02/18/2021 ; 02/17/2022 ; 2/16/2023

1 . Indications

Drug Name: Gamifant (emapalumab-lzsg)
Primary Hemophagocytic Lymphohistiocytosis (HLH) Indicated for the treatment of adult and pediatric (newborn and older) patients with primary HLH with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy.

2 . Criteria

Product Name: Gamifant	
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary hemophagocytic lymphohistiocytosis (HLH)

AND

2 - One of the following:

2.1 Disease is one of the following:

- Refractory
- Recurrent
- Progressive

OR

2.2 Trial and failure, contraindication, or intolerance to conventional HLH therapy (e.g., etoposide, dexamethasone, cyclosporine A, intrathecal methotrexate)

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

AND

4 - Patient has not received hematopoietic stem cell transplantation (HSCT)

Product Name: Gamifant	
Approval Length	6 Months [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., improvement in hemoglobin/lymphocyte/platelet counts, afebrile, normalization of inflammatory factors/markers)

AND **2** - Patient has not received HSCT

3 . Endnotes

A. Per clinical consultation, it is appropriate to limit authorization duration to no more than 6 months at a time, given that the ultimate goal in therapy is to receive HSCT and treatment with Gamifant should be viewed as bridge therapy to HSCT. Pivotal trial data duration was also less than 3 months. [2]

4 . References

1. Gamifant Prescribing Information. Sobi Inc. Waltham, MA. June 2020.
2. Per clinical consult with a pediatric hematologist/oncologist, January 18, 2019.

5 . Revision History

Date	Notes
1/15/2023	Annual Review - no criteria changes

Gaucher Disease Agents

Prior Authorization Guideline

Guideline ID	GL-118474
Guideline Name	Gaucher Disease Agents
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	11/20/2000
P&T Revision Date:	02/13/2020 ; 02/18/2021 ; 02/17/2022 ; 05/19/2022 ; 2/16/2023

1 . Indications

Drug Name: Cerezyme (imiglucerase for injection)
Type 1 Gaucher Disease Indicated for treatment of adults and pediatric patients 2 years of age and older with Type 1 Gaucher disease that results in one or more of the following conditions: - anemia - thrombocytopenia - bone disease - hepatomegaly or splenomegaly
Drug Name: Elelyso (taliglucerase alfa) for injection
Type 1 Gaucher Disease Indicated for the treatment of patients 4 years and older with a confirmed diagnosis of Type 1 Gaucher disease.
Drug Name: VPRIV (velaglucerase alfa for injection)
Type 1 Gaucher Disease Indicated for long-term enzyme replacement therapy (ERT) for patients with type 1 Gaucher disease.
Drug Name: Cerdelga (eliglustat)
Type 1 Gaucher Disease Indicated for the long-term treatment of adult patients with Gaucher disease type 1 (GD1) who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test. Limitations of Use: Patients who are CYP2D6 ultra-rapid metabolizers (URMs) may not achieve adequate

concentrations of CERDELGA to achieve a therapeutic effect. A specific dosage cannot be recommended for those patients whose CYP2D6 genotype cannot be determined (indeterminate metabolizers).
Drug Name: Zavesca (miglustat)
Type 1 Gaucher Disease Indicated as monotherapy for the treatment of adult patients with mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option (e.g., due to allergy, hypersensitivity, or poor venous access).

2 . Criteria

Product Name: Cerezyme, Elelyso, or VPRIV	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Type 1 Gaucher disease

AND

2 - Patient has evidence of symptomatic disease (e.g., moderate to severe anemia [A], thrombocytopenia [B], bone disease [C], hepatomegaly [D], or splenomegaly [D])

AND

3 - One of the following:

3.1 Patient is 4 years of age or older (applies to Elelyso and VPRIV only)

OR

3.2 Patient is 2 years of age or older (applies to Cerezyme only)

Product Name: Cerdelga	
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Type 1 Gaucher disease

AND

2 - Patient is an extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) of cytochrome P450 enzyme (CYP) 2D6 as detected by an FDA-cleared test

AND

3 - Patient is 18 years of age or older

Product Name: Generic miglustat or Brand Zavesca	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mild to moderate Type 1 Gaucher disease [E]

AND

2 - Patient is 18 years of age or older

3 . Endnotes

A. Goals of treatment with anemia are to increase hemoglobin to greater than or equal to 12.0 g/dL for males (greater than 12 years of age), and to greater than or equal to 11.0 g/dL for both children (less than or equal to 12 years of age) and females (greater than 12 years of age). [6, 8]
B. Moderate thrombocytopenia is defined as a platelet count of 60,000 to 120,000/microliter. A platelet count of 120,000/microliter to meet the criterion of thrombocytopenia is based on the upper end of the range that defines moderate thrombocytopenia. [6]

C. In bone disease, the goal is to lessen or eliminate bone pain and prevent bone crises. Bone disease can be diagnosed using MRI, bone scan, and X-ray. [6-8]
D. Hepatomegaly is defined as a liver mass of greater than 1.25 times normal value. Splenomegaly is defined as a splenic mass greater than the normal, and moderate splenomegaly is considered a spleen volume of greater than 5 and less than or equal to 15 times normal. [6]
E. Zavesca may be prescribed only by physicians knowledgeable in the management of Gaucher disease (GD). In order to prescribe Zavesca, physicians must read the letter to doctors from Actelion, then sign and fax the one-page physician statement affirming that they are qualified to manage patients with GD and that they have read the Zavesca review booklet containing the full prescribing information. Zavesca is dispensed exclusively by Accredo specialty pharmacy. [10]

4 . References

1. Cerezyme Prescribing Information. Genzyme Corporation. Cambridge, MA. December 2021.
2. Elelyso Prescribing Information. Pfizer, Inc. New York, NY. August 2022.
3. VPRIV Prescribing Information. Takeda Pharmaceuticals U.S.A., Inc. Lexington, MA. September 2021.
4. Cerdelga Prescribing Information. Genzyme Ireland, Ltd. Waterford, Ireland. July 2021.
5. Zavesca Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. August 2022.
6. Pastores GM, Weinreb NJ, Aerts H, et al. Therapeutic goals in the treatment of Gaucher disease. Semin Hematol. 2004;41(4 Suppl 5):4-14.
7. Weinreb NJ, Aggio MC, Andersson HC, et al. Gaucher disease type 1: revised recommendations on evaluations and monitoring for adult patients. Semin Hematol. 2004;41(suppl 5):15-22.
8. Weinreb N, Taylor J, Cox T, et al. A benchmark analysis of the achievement of therapeutic goals for type 1 Gaucher disease patients treated with imiglucerase. Am J Hematol. 2008;83:890-895.
9. Hollak CE, vom Dahl S, Aerts JM, et al. Force majeure: therapeutic measures in response to restricted supply of imiglucerase (Cerezyme) for patients with Gaucher disease. Blood Cells Mol Dis. 2010;44(1):41-7.
10. Actelion Pharmaceuticals US, Inc. Zavesca (miglustat). Available at: https://www.zavesca.com/hcp-home.html. Accessed on January 5, 2023.
11. Per clinical consult with geneticist, November 11, 2010.

5 . Revision History

Date	Notes
2/17/2023	Annual review - no criteria changes.

General Oncology

Prior Authorization Guideline

Guideline ID	GL-126339
Guideline Name	General Oncology
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Vonjo, Lynparza, Calquence, Ibrance, Lytgobi, Krazati, Generic Everolimus, Sprycel, Zolinza, Emcyt, Gleostine, Hycamtin, Generic Lenalidomide, Thalomid, Votrient, Generic Sorafenib, Leukeran, Retevmo, Tafinlar, Mekinist, Cotellic, Rezlidhia, Pemazyre, Ninlaro	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Medication is being used for an FDA approved age **AND** **2** - Prescribed by or in consultation with oncologist	

AND

3 - One of the following:

3.1 Medication is being used for FDA approved indication

OR

3.2 Diagnosis is supported as a use in the National Cancer network (NCCN) Drugs and Biologics Compendium with a category of Evidence and Consensus of 1, 2A, or 2B

Product Name: Vonjo, Lynparza, Calquence, Ibrance, Lytgobi, Krazati, Generic Everolimus, Sprycel, Zolinza, Emcyt, Gleostine, Hycamtin, Generic Lenalidomide, Thalomid, Votrient, Generic Sorafenib, Leukeran, Retevmo, Tafinlar, Mekinist, Cotellic, Rezlidhia, Pemazyre, Ninlaro	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Background

Benefit/Coverage/Program Information

Compendia Requirements

NCCN Categories of Evidence and Consensus:

Category	Level of Consensus
1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

3 . Revision History

Date	Notes
6/9/2023	Update program

Givlaari (givosiran)

Prior Authorization Guideline

Guideline ID	GL-118098
Guideline Name	Givlaari (givosiran)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	3/1/2023
P&T Approval Date:	1/15/2020
P&T Revision Date:	02/13/2020 ; 01/20/2021 ; 01/19/2022 ; 1/18/2023

1 . Indications

Drug Name: Givlaari (givosiran)
Acute Hepatic Porphyria Indicated for the treatment of adults with acute hepatic porphyria (AHP).

2 . Criteria

Product Name: Givlaari	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of acute hepatic porphyria (i.e., acute intermittent porphyria, hereditary coproporphyria, variegate porphyria, ALA dehydrase deficient porphyria)

AND

2 - Patient has active disease with at least two documented porphyria attacks within the past 6 months

AND

3 - Provider attestation documenting elevated urinary or plasma levels of one of the following within the past 12 months:

- Porphobilinogen (PBG)
- Delta-aminolevulinic acid (ALA)

AND

4 - Patient has not had a liver transplant

AND

5 - Prescribed by or in consultation with a gastroenterologist or a specialist with expertise in the diagnosis and management of acute hepatic porphyria

Product Name: Givlaari	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response while on therapy as demonstrated by both of the following:

- Reduction in hemin administration requirements
- Reduction in the rate or number of porphyria attacks

AND

2 - Patient has not had a liver transplant

AND

3 - Prescribed by or in consultation with a gastroenterologist or a specialist with expertise in the diagnosis and management of acute hepatic porphyria

3 . References

1. Givlaari Prescribing Information. Alnylam Pharmaceuticals, Inc. Cambridge, MA. October 2021.

4 . Revision History

Date	Notes
1/4/2023	Annual review - no changes.

Glatopa (glatiramer)

Prior Authorization Guideline

Guideline ID	GL-121385
Guideline Name	Glatopa (glatiramer)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name: Generic Glatopa, Generic Glatiramer	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsing forms of multiple sclerosis

AND

2 - Prescribed by or in consultation with a neurologist

Product Name: Generic Glatopa, Generic Glatiramer

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - For continuation of prior therapy	

2 . Revision History

Date	Notes
2/22/2023	New Program

Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist

Prior Authorization Guideline

Guideline ID	GL-116519
Guideline Name	Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Bydureon, Byetta, Trulicity, Victoza	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Type 2 Diabetes

AND

2 - Patient has had trial of, or contraindication to maximally tolerated dose of metformin

AND

3 - One of the following:

3.1 Both of the following:

- Patient has heart failure (HF) or high risk/established atherosclerotic cardiovascular disease (ASCVD)
- Trial of, or contraindication to an sodium-glucose cotransporter-2 (SGLT2) inhibitor (e.g., Farxiga, Jardiance)

OR

3.2 Both of the following:

- Patient does not have heart failure (HF) or high risk/established ASCVD
- Trial of, or contraindication to an dipeptidyl peptidase 4 (DPP-4) Inhibitor (e.g., Januvia, Onglyza)

Product Name: Bydureon, Byetta, Trulicity, Victoza	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/31/2022	New Implementation

Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist - SCP

Prior Authorization Guideline

Guideline ID	GL-116517
Guideline Name	Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist - SCP
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Bydureon Bcise, Byetta, Trulicity, Victoza	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Type 2 Diabetes

AND

2 - Patient has had trial of, or contraindication to maximally tolerated dose of metformin

AND

3 - One of the following:

3.1 Both of the following:

- Patient has heart failure (HF) or high risk/established ASCVD
- Trial of, or contraindication to an SGLT-2 Inhibitor

OR

3.2 Both of the following:

- Patient does not have heart failure (HF) or high risk/established ASCVD
- Trial of, or contraindication to an DPP-4 Inhibitor

Product Name: Bydureon Bcise, Byetta, Trulicity, Victoza	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/31/2022	2023 New Implementation

Gonadotropin-Releasing Hormone Agonists

Prior Authorization Guideline

Guideline ID	GL-126091
Guideline Name	Gonadotropin-Releasing Hormone Agonists
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	12/12/2005
P&T Revision Date:	12/18/2019 ; 02/13/2020 ; 07/15/2020 ; 09/16/2020 ; 01/20/2021 ; 09/15/2021 ; 06/15/2022 ; 08/18/2022 ; 09/21/2022 ; 01/18/2023 ; 6/21/2023

1 . Indications

Drug Name: Lupron Depot (leuprolide acetate) 1-Month 7.5 mg, Lupron Depot 3-Month 22.5 mg, Lupron Depot 4-Month 30 mg, Lupron Depot 6-Month 45 mg
Prostate Cancer Indicated for treatment of advanced prostatic cancer. **Off Label Uses: Gender Dysphoria [18, 19]** Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [18] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [19]
Drug Name: Lupron Depot 3.75 mg
Endometriosis Indicated for the management of endometriosis, including pain relief and reduction of endometriotic lesions. In combination with a norethindrone acetate, it is also indicated for initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms. Limitations of Use: The total duration of therapy with

LUPRON DEPOT 3.75 mg plus add-back therapy should not exceed 12 months due to concerns about adverse impact on bone mineral density.

Uterine Leiomyomata (Fibroids) Indicated for concomitant use with iron therapy for preoperative hematologic improvement of women with anemia caused by fibroids for whom three months of hormonal suppression is deemed necessary. Limitations of Use: Not indicated for combination use with norethindrone acetate add-back therapy for the preoperative hematologic improvement of women with anemia caused by heavy menstrual bleeding due to fibroids.

Off Label Uses: Gender Dysphoria [18, 19] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [18] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would.

Drug Name: Lupron Depot 3-Month 11.25 mg

Endometriosis Indicated for the management of endometriosis, including pain relief and reduction of endometriotic lesions. In combination with a norethindrone acetate, it is also indicated for initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms. Limitations of Use: The total duration of therapy with LUPRON DEPOT 11.25 mg plus add-back therapy should not exceed 12 months due to concerns about adverse impact on bone mineral density.

Uterine Leiomyomata (Fibroids) Indicated for concomitant use with iron therapy for preoperative hematologic improvement of women with anemia caused by fibroids for whom three months of hormonal suppression is deemed necessary. Limitations of Use: Not indicated for combination use with norethindrone acetate add-back therapy for the preoperative hematologic improvement of women with anemia caused by heavy menstrual bleeding due to fibroids.

Off Label Uses: Gender Dysphoria [18, 19] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [18] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would.

Drug Name: Leuprolide Acetate

Prostate Cancer Indicated for the palliative treatment of advanced prostatic cancer.

Off Label Uses: Infertility Used for controlled ovarian hyperstimulation to enhance the in vitro fertilization-embryo transfer (IVF-ET) procedure. [6]

Gender Dysphoria [18, 19] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing

hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [18] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [19]

Drug Name: Leuprolide Acetate Depot

Prostate Cancer Indicated for the palliative treatment of advanced prostate cancer.

Off Label Uses: Gender Dysphoria [18, 19] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [18] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [19]

Drug Name: Lupron Depot-PED (leuprolide acetate)

Central Precocious Puberty (CPP) Indicated in the treatment of pediatric patients with central precocious puberty (CPP).

Off Label Uses: Gender Dysphoria [18, 19] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [18] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [19]

Drug Name: Lupaneta Pack (leuprolide acetate inj; norethindrone acetate tablets) 1-Month 3.75mg, 3-Month 11.25 mg

Endometriosis Indicated for initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms. Limitation of use: Duration of use is limited due to concerns about adverse impact on bone mineral density. The initial treatment course of Lupaneta Pack is limited to 6 months. A single retreatment course of not more than 6 months may be administered after the initial course of treatment if symptoms recur. Use of Lupaneta for longer than a total of 12 months is not recommended.

Drug Name: Camcevi (leuprolide)

Prostate Cancer Indicated for the treatment of adult patients with advanced prostate cancer.

Drug Name: Eligard (leuprolide acetate)

Prostate Cancer Indicated for the palliative treatment of advanced prostate cancer.

Gender Dysphoria [18, 19] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [18] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [19]

Drug Name: Fensolvi (leuprolide acetate)

Central Precocious Puberty (CPP) Indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP).

Drug Name: Supprelin LA (histrelin acetate)

Central Precocious Puberty (CPP) Indicated for the treatment of children with CPP. Children with CPP (neurogenic or idiopathic) have an early onset of secondary sexual characteristics (earlier than 8 years of age in females and 9 years of age in males). They also show a significantly advanced bone age that can result in diminished adult height attainment. Prior to initiation of treatment a clinical diagnosis of CPP should be confirmed by measurement of blood concentrations of total sex steroids, luteinizing hormone (LH) and follicle stimulating hormone (FSH) following stimulation with a GnRH analog, and assessment of bone age versus chronological age. Baseline evaluations should include height and weight measurements, diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor), and adrenal steroids to exclude congenital adrenal hyperplasia.

Gender Dysphoria [18, 19] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [18] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [19]

Drug Name: Trelstar (triptorelin pamoate)

Prostate Cancer Indicated for the palliative treatment of advanced prostate cancer.

Gender Dysphoria [18, 19] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [18] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [19]

Drug Name: Triptodur (triptorelin)

Central Precocious Puberty (CPP) Indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP).

Gender Dysphoria [18, 19] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [18] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [19]

Drug Name: Vantas (histrelin acetate)
Prostate Cancer Indicated for the palliative treatment of advanced prostate cancer.

2 . Criteria

Product Name: Lupron Depot (3.75 mg and 11.25 mg)	
Diagnosis	Endometriosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endometriosis

AND

2 - One of the following: [9, 13]

2.1 History of inadequate pain control response following a trial of at least 6 months, or history of intolerance or contraindication to one of the following:

- Danazol
- Combination (estrogen/progestin) oral contraceptive
- Progestins

OR

2.2 Patient has had surgical ablation to prevent recurrence

Product Name: Lupron Depot (3.75 mg and 11.25 mg)	
Diagnosis	Endometriosis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Recurrence of symptoms following a trial of at least 6 months with leuprolide acetate

AND

2 - Used in combination with one of the following:

- Norethindrone 5 mg daily
- Other "add-back" sex-hormones (e.g., estrogen, medroxyprogesterone)
- Other bone-sparing agents (e.g., bisphosphonates)

Product Name: Lupron Depot (3.75 mg and 11.25 mg)	
Diagnosis	Uterine Leiomyomata (Fibroids) - For the reduction of the size of fibroids [off-label]
Approval Length	4 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For use prior to surgery to reduce the size of fibroids to facilitate a surgical procedure (e.g., myomectomy, hysterectomy) [6]

Product Name: Lupron Depot (3.75 mg and 11.25 mg)	
Diagnosis	Uterine Leiomyomata (Fibroids) - Anemia [5,7]

Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For the treatment of anemia

AND

2 - Anemia is caused by uterine leiomyomata (fibroids)

AND

3 - Patient has tried and had an inadequate response to at least 1 month of monotherapy with iron

AND

4 - Used in combination with iron therapy

AND

5 - For use prior to surgery

Product Name: Fensolvi, Lupron Depot-PED, Supprelin LA, Triptodur	
Diagnosis	Central Precocious Puberty (CPP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of central precocious puberty (idiopathic or neurogenic)

AND

2 - Early onset of secondary sexual characteristics in one of the following:

- Females less than 8 years of age
- Males less than 9 years of age

AND

3 - Advanced bone age of at least one year compared with chronological age

AND

4 - One of the following:

4.1 Both of the following:

- Patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing
- Peak luteinizing hormone (LH) level above pre-pubertal range

OR

4.2 Patient has a random LH level in the pubertal range

AND

5 - One of the following:

5.1 Patient had one of the following diagnostic evaluations to rule out tumors, when suspected:

- Diagnostic imaging of the brain (MRI or CT scan) (in patients with symptoms suggestive of a brain tumor or in those 6 years of age or younger)
- Pelvic/testicular/adrenal ultrasound (if steroid levels suggest suspicion)
- Adrenal steroids to rule out congenital adrenal hyperplasia (when pubarche precedes thelarche or gonadarche)

OR

5.2 Patient has no suspected tumors

AND

6 - Prescribed by or in consultation with a pediatric endocrinologist

Product Name: Fensolvi, Lupron Depot-PED, Supprelin LA, Triptodur	
Diagnosis	Central Precocious Puberty (CPP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - LH levels have been suppressed to pre-pubertal levels

AND

2 - Prescribed by or in consultation with a pediatric endocrinologist

Product Name: Generic leuprolide acetate*	
Diagnosis	Treatment of Infertility (off-label) [6]
Approval Length	2 Month [A] (or per plan benefit design)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of infertility

AND

2 - Used as part of an assisted reproductive technology (ART) protocol

Notes	*Please consult client-specific resources to confirm whether benefit ex clusions should be reviewed for medical necessity.

Product Name: Eligard, Leuprolide Acetate, generic leuprolide acetate, Trelstar, Vantas	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced or metastatic prostate cancer [6, 16]

AND

2 - Trial and failure, contraindication, or intolerance to any brand Lupron formulation

Product Name: Camcevi, Lupron Depot (7.5 mg, 22.5 mg, 30 mg and 45 mg)	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced or metastatic prostate cancer [6, 16]

Product Name: Camcevi, Eligard, Leuprolide Acetate, generic leuprolide acetate, Lupron Depot (7.5 mg, 22.5 mg, 30 mg and 45 mg), Trelstar, Vantas	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Lupaneta Pack	
Diagnosis	Endometriosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endometriosis

AND

2 - One of the following: [9, 13]

2.1 History of inadequate pain control response following a trial of at least 6 months, or history of intolerance or contraindication to one of the following:

- Danazol
- Combination (estrogen/progestin) oral contraceptive
- Progestins

OR

2.2 Patient has had surgical ablation to prevent recurrence

Product Name: Lupaneta Pack	
Diagnosis	Endometriosis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Recurrence of symptoms following a trial of at least 6 months with leuprolide therapy

Product Name: Lupron Depot, Lupron Depot-PED, Leuprolide Acetate, generic leuprolide acetate, Eligard, Supprelin LA, Trelstar, Triptodur	
Diagnosis	Gender Dysphoria/Gender Incongruence (off-label) [18, 19]
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Using gonadotropin for suppression of puberty [18,19]

AND

2 - Diagnosis of gender dysphoria/gender incongruence

3 . Endnotes

A. Sixty days would be a reasonable length of authorization for the treatment of infertility. [14]

4 . References

1. Leuprolide acetate prescribing information. Sandoz Inc. Princeton, NJ. June 2020.
2. Vantas prescribing information. Endo Pharmaceuticals Solutions Inc. Malvern, PA. December 2020.
3. Lupron Depot (3.75 mg) prescribing information. AbbVie Inc. North Chicago, IL. July 2022.
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15. Lupaneta Pack prescribing information. AbbVie Inc. North Chicago, IL. October 2019.
16. National Comprehensive Cancer Network Drugs and Biologics Compendium (NCCN Compendium). Available at: http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed August 31, 2022.
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19. Coleman E, Bockting W, Botzer M et al. Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7. International Journal of Transgenderism. 13:165-232, 2011.
20. Triptodur prescribing information. Arbor Pharmaceuticals, LLC. Atlanta, GA. April 2022.
21. Fensolvi prescribing information. Tolmar Pharmaceuticals, Inc. Fort Collins, CO. April 2022.
22. Camcevi Prescriber Information. Accord BioPharma, Inc. Durham, NC. May 2021.
23. Leuprolide Acetate Depot Prescribing Information. Cipla USA, Inc. Warren, NJ. May 2022.

5 . Revision History

Date	Notes
5/26/2023	Addition of new Lupron Depot 45 mg pediatric kit as target for the exis ting CPP indication

Grastek (Timothy Grass)

Prior Authorization Guideline

Guideline ID	GL-116509
Guideline Name	Grastek (Timothy Grass)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Grastek	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of grass pollen-induced allergies

AND

2 - Prescribed by or in consultation with one of the following:

- Allergist

- Immunologist

Product Name: Grastek	
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/10/2022	2023 New Implementation

Growth Hormones

Prior Authorization Guideline

Guideline ID	GL-116599
Guideline Name	Growth Hormones
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 One of the following: [12]

1.1.1 Both of the following: [24-26]

- Infant is < 4 months of age

- Infant has suspected GH deficiency based on clinical presentation (e.g., persistent neonatal hypoglycemia, persistent or prolonged neonatal jaundice/elevated bilirubin, male infant with microgenitalia, midline anatomical defects, failure to thrive, etc.)

OR

1.1.2 History of neonatal hypoglycemia associated with pituitary disease

OR

1.1.3 Diagnosis of panhypopituitarism

OR

1.2 All of the following:

1.2.1 Diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]

1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]

- Height is > 2.0 standard deviations [SD] below midparental height
- Height is > 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is > 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of > 2 SD below mean for age and gender (e.g., delayed > 2 years compared with chronological age)

AND

1.2.2 Documentation of one of the following: [22]

1.2.2.1 Both of the following:

- Patient is male

- Bone age < 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

1.2.3 One of the following:

1.2.3.1 Both of the following: [10, 11, 12]

1.2.3.1.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa

AND

1.2.3.1.2 Both GH response values are < 10 mcg/L

OR

1.2.3.2 Both of the following: [11]

1.2.3.2.1 Patient is < 1 year of age

AND

1.2.3.2.2 One of the following is below the age and gender adjusted normal range as provided by the physician's lab: [A, 13, 14]

- Insulin-like Growth Factor 1 (IGF-1/Somatomedin-C)
- Insulin Growth Factor Binding Protein-3 (IGFBP-3)

AND

2 - Prescribed by or in consultation with an endocrinologist

Notes	Includes children who have undergone brain radiation. If patient is a Transition Phase Adolescent or Adult who had childhood onset GH deficiency, utilize criteria for Transition Phase Adolescent or Adult GH Deficiency. NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	Includes children who have undergone brain radiation. If patient is a Transition Phase Adolescent or Adult who had childhood onset GH deficiency, utilize criteria for Transition Phase Adolescent or Adult GH Deficiency.

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin [off-label] [B, 11]	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Prader-Willi Syndrome [10, 11]

AND

2 - Prescribed by or in consultation with an endocrinologist

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin [off-label] [B, 11]	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Evidence of positive response to therapy (e.g., increase in total lean body mass, decrease in fat mass)

OR

1.2 Both of the following:

1.2.1 Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

1.2.2 Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

2 - Prescribed by or in consultation with an endocrinologist

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin [off-label] [B, 11]	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of SGA based on demonstration of catch up growth failure in the first 24 months of life using a 0-36 month growth chart as confirmed by the following criterion: [10]

1.1 One of the following is below the 3rd percentile for gestational age (more than 2 SD below population mean):

- Birth weight
- Birth length

AND

2 - Height remains less than or equal to 3rd percentile (more than 2 SD below population mean) [10]

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	NOTE: Documentation of previous height, current height and goal expec ted adult height will be required for renewal.

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin [off-label] [B, 11]	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Turner Syndrome or Noonan Syndrome [off-label except for Norditropin] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with one of the following: [10, 22]

1.1 Both of the following:

1.1.1 Turner Syndrome (Gonadal Dysgenesis)

AND

1.1.2 Documentation of both of the following:

- Patient is female
- Bone age < 14 years

OR

1.2 Both of the following:

1.2.1 Noonan Syndrome

AND

1.2.2 Documentation of one of the following:

1.2.2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

2 - Height is below the 5th percentile on growth charts for age and gender [10]

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	NOTE: Documentation of previous height, current height and goal expec ted adult height will be required for renewal

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Turner Syndrome or Noonan Syndrome [off-label except for Norditropin] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure with short stature homeobox (SHOX) gene deficiency as confirmed by genetic testing [2]

AND

2 - Documentation of one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	NOTE: Documentation of previous height, current height and goal expec ted adult height will be required for renewal.

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

Product Name: Norditropin Flexpro [off-label] [B, 11] or Nutropin AQ NuSpin	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with chronic renal insufficiency [10]

AND

2 - Documentation of one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Nephrologist

Notes	NOTE: Documentation of previous height, current height and goal expec ted adult height will be required for renewal.

Product Name: Norditropin Flexpro [off-label] [B, 11] or Nutropin AQ NuSpin	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Nephrologist

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of adult GH deficiency as a result of one of the following: [10, 12, 21]

1.1 Clinical records supporting a diagnosis of childhood-onset GHD

OR

1.2 Both of the following:

1.2.1 Adult-onset GHD

AND

1.2.2 Clinical records documenting that hormone deficiency is a result of hypothalamic-pituitary disease from organic or known causes (e.g., damage from surgery, cranial irradiation, head trauma, or subarachnoid hemorrhage)

AND

2 - One of the following: [10, 12, 20-21]

2.1 Both of the following:

2.1.1 Patient has undergone one of the following GH stimulation tests to confirm adult GH deficiency:

- Insulin tolerance test (ITT)
- Glucagon
- Macimorelin

AND

2.1.2 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 Both of the following:

2.2.1 Documented deficiency of three of the following anterior pituitary hormones:

- Prolactin
- Adrenocorticotropic hormone (ACTH)
- Thyroid stimulating hormone (TSH)
- Follicle-stimulating hormone/luteinizing hormone (FSH/LH)

AND

2.2.2 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	Use the following criteria for child- and adult-onset with pituitary disease; use Isolated GHD in Adult criteria for patients without pituitary disease.

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Evidence of ongoing monitoring as demonstrated by documentation within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]

AND

2 - Prescribed by or in consultation with an endocrinologist

Notes	Use the following criteria for child- and adult-onset with pituitary disease; use Isolated GHD in Adult criteria for patients without pituitary disease.

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Transition Phase Adolescent Patients
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following: [21]

- Attained expected adult height
- Closed epiphyses on bone radiograph

AND

2 - One of the following: [20, 21]

2.1 Both of the following:

2.1.1 Documentation of high risk of GH deficiency due to GH deficiency in childhood from one of the following:

2.1.1.1 Embryopathic/congenital defects

OR

2.1.1.2 Genetic mutations

OR

2.1.1.3 Irreversible structural hypothalamic-pituitary disease

OR

2.1.1.4 Panhypopituitarism

OR

2.1.1.5 Deficiency of three of the following anterior pituitary hormones:

- ACTH
- TSH
- Prolactin
- FSH/LH

AND

2.1.2 One of the following:

2.1.2.1 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

OR

2.1.2.2 All of the following:

2.1.2.2.1 Patient does not have a low IGF-1/Somatomedin C level

AND

2.1.2.2.2 Discontinued GH therapy for at least 1 month

AND

2.1.2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon

- Macimorelin

AND

2.1.2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 All of the following:

2.2.1 At low risk of severe GH deficiency (e.g., due to isolated and/or idiopathic GH deficiency)

AND

2.2.2 Discontinued GH therapy for at least 1 month

AND

2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon
- Macimorelin

AND

2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

3 - Prescribed by or in consultation with an endocrinologist

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Transition Phase Adolescent Patients
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Evidence of positive response to therapy (e.g., increase in total lean body mass, exercise capacity or IGF-1 and IGFBP-3 levels)

AND

2 - Prescribed by or in consultation with an endocrinologist

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Isolated Growth Hormone Deficiency in Adults
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documented deficiency of GH as demonstrated by both of the following: [20-21]

1.1 Patient has undergone two of the following GH stimulation tests:

- ITT
- Glucagon
- Macimorelin

AND

1.2 Patient has two of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

2 - Prescribed by or in consultation with an endocrinologist

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Isolated Growth Hormone Deficiency in Adults
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Evidence of ongoing monitoring as demonstrated by documentation within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]

AND

2 - Prescribed by or in consultation with an endocrinologist

Product Name: All Products	
Guideline Type	Prior Authorization

Approval Criteria

1 - Requests for coverage of growth hormone for the diagnosis of Idiopathic Short Stature (ISS) are not authorized and will not be approved. There is no consensus in current peer-reviewed

medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. [E]	
Notes	Approval Length: N/A - Requests for non-approvable diagnoses should not be approved

2 . Endnotes

A. Several recent review articles in the literature have suggested that GH stimulation tests should no longer be used to diagnose GHD. [13,14] The authors argue that GH stimulation test may have side effects, lack precision, accuracy, and do not predict response to GH therapy. It has been suggested that newer diagnostic procedures such as serum IGF-1, IGFBP-3 concentrations, genetic testing and neuroimaging could provide an alternative approach to the diagnosis of GHD in childhood.
B. Overall, there are no observable differences in the results obtained among the different preparations as long as the regimen follows currently approved daily injections. Many of the products are available in a variety of injection devices that are meant to make administration more appealing and easier. Currently, there is no evidence that clinical outcome differs among the various injection systems, although there may be patient and parent preferences for some of these devices. [11, 21]
C. Even a 5% weight loss in persons with HIV infection indicates a poor prognosis. [2]
D. Patients with HIV-associated wasting may begin an initial 12-week course of therapy with Serostim, 6 mg/day s.c. The clinician should monitor treatment responses by obtaining serial body weights and BCM measurements by BIA. A positive response to therapy probably should be considered as a 2% increase in body weight and/or BCM. Maintenance therapy may continue on a monthly basis as long as wasting is still evident. Once BCM has normalized, therapy can be stopped, with the patient being observed for an 8-week period. Over these 8 weeks, body weight, BCM, and any appearance of wasting symptoms can be monitored. If wasting reappears, therapy can be restarted. [17]
E. Guidelines for idiopathic short stature recommend against the routine use of GH in every child with height standard deviation score ≤ - 2.25. [23]

3 . References

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4 . Revision History

Date	Notes
10/31/2022	2023 New Implementation

Growth Hormones - PA, NF

Prior Authorization Guideline

Guideline ID	GL-127046
Guideline Name	Growth Hormones - PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	3/17/2000
P&T Revision Date:	08/15/2019 ; 05/14/2020 ; 08/13/2020 ; 08/19/2021 ; 12/15/2021 ; 06/15/2022 ; 08/18/2022 ; 01/18/2023 ; 7/19/2023

1 . Indications

Drug Name: Genotropin, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, and Zomacton
Pediatric Growth Hormone Deficiency Indicated for the treatment of pediatric patients with growth failure due to inadequate secretion of endogenous growth hormone.
Drug Name: Skytrofa
Pediatric Growth Hormone Deficiency Indicated for the treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone (GH).
Drug Name: Genotropin and Omnitrope
Prader-Willi Syndrome (PWS) Indicated for the treatment of pediatric patients who have growth failure due to Prader-Willi Syndrome (PWS). The diagnosis of PWS should be confirmed by appropriate genetic testing. **Small for Gestational Age (SGA)** Indicated for the treatment of growth failure in children born small for gestational age (SGA) who fail to manifest catch-up growth by age 2.

Drug Name: Norditropin Flexpro, Humatrope, and Zomacton
Small for Gestational Age (SGA) Indicated for the treatment of pediatric patients with short stature born small for gestational age (SGA) with no catch-up growth by 2 years to 4 years of age.
Drug Name: Genotropin, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, and Zomacton
Turner Syndrome Indicated for the treatment of pediatric patients with short stature associated with Turner syndrome.
Drug Name: Humatrope and Zomacton
SHOX Deficiency Indicated for the treatment of pediatric patients with short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency.
Drug Name: Nutropin AQ NuSpin
Growth Failure Secondary to Chronic Kidney Disease (CKD) Indicated for the treatment of growth failure associated with CKD up to the time of renal transplantation. Nutropin AQ therapy should be used in conjunction with optimal management of CKD.
Drug Name: Norditropin Flexpro
Noonan Syndrome Indicated for the treatment of pediatric patients with short stature associated with Noonan Syndrome. **Prader-Willi Syndrome** Indicated for the treatment of pediatric patients with growth failure due to Prader-Willi syndrome (PWS).
Drug Name: Genotropin, Nutropin AQ NuSpin, and Omnitrope
[Non-Approvable Use] Idiopathic Short Stature (ISS) [E] Indicated for the treatment of idiopathic short stature, also called non-growth hormone-deficient short stature, defined by height SDS less than or equal to -2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range, in pediatric patients whose epiphyses are not closed and for whom diagnostic evaluation excludes other causes associated with short stature that should be observed or treated by other means. **Please Note: The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy.
Drug Name: Norditropin Flexpro and Humatrope
[Non-Approvable Use] Idiopathic Short Stature (ISS) [E] Indicated for the treatment of pediatric patients with Idiopathic Short Stature (ISS), height standard deviation score (SDS) less than -2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range. **Please Note: The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy.

Drug Name: Genotropin, Nutropin AQ NuSpin, Omnitrope, and Saizen
Adult Growth Hormone Deficiency Indicated for replacement of endogenous growth hormone in adults with growth hormone deficiency who meet either of the following two criteria: Adult-Onset: Patients who have growth hormone deficiency, either alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma; or Childhood-Onset: Patients who were growth hormone deficient during childhood as a result of congenital, genetic, acquired, or idiopathic causes. Patients who were treated with somatropin for growth hormone deficiency in childhood and whose epiphyses are closed should be reevaluated before continuation of somatropin therapy at the reduced dose level recommended for growth hormone deficient adults. Confirmation of the diagnosis of adult growth hormone deficiency in both groups involves an appropriate growth hormone provocative test with two exceptions: (1) patients with multiple other pituitary hormone deficiencies due to organic disease; and (2) patients with congenital/genetic growth hormone deficiency.
Drug Name: Norditropin Flexpro, Humatrope, and Zomacton
Adult Growth Hormone Deficiency Indicated for the replacement of endogenous GH in adults with GH deficiency.
Drug Name: Serostim
AIDS Wasting or Cachexia Indicated for the treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance. Concomitant antiretroviral therapy is necessary.
Drug Name: Zorbtive
Short Bowel Syndrome Indicated for the treatment of short bowel syndrome in adult patients receiving specialized nutritional support.
Drug Name: Zomacton
[Non-Approvable Use] Idiopathic Short Stature (ISS) [E] Indicated for the treatment of pediatric patients with Idiopathic Short Stature (ISS), height standard deviation score (SDS) less than or equal to -2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range. **Please Note: The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy.
Drug Name: Sogroya
Pediatric Growth Hormone Deficiency Indicated for the treatment of pediatric patients 2.5 years of age or older with growth failure due to inadequate secretion of endogenous growth hormone. **Adult Growth Hormone Deficiency** Indicated for the replacement of endogenous GH in adults with GH deficiency.

2 . Criteria

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 One of the following: [12]

1.1.1 Both of the following: [24-26]

- Infant is < 4 months of age
- Infant has suspected GH deficiency based on clinical presentation (e.g., persistent neonatal hypoglycemia, persistent or prolonged neonatal jaundice/elevated bilirubin, male infant with microgenitalia, midline anatomical defects, failure to thrive, etc.)

OR

1.1.2 History of neonatal hypoglycemia associated with pituitary disease

OR

1.1.3 Diagnosis of panhypopituitarism

OR

1.2 All of the following:

1.2.1 Diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]

1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]

- Height is > 2.0 standard deviations [SD] below midparental height
- Height is > 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is > 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of > 2 SD below mean for age and gender (e.g., delayed > 2 years compared with chronological age)

AND

1.2.2 Documentation of one of the following: [22]

1.2.2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

1.2.3 One of the following:

1.2.3.1 Both of the following: [10, 11, 12]

1.2.3.1.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa

AND

1.2.3.1.2 Both GH response values are < 10 mcg/L

OR

1.2.3.2 Both of the following: [11]

1.2.3.2.1 Patient is < 1 year of age

AND

1.2.3.2.2 One of the following is below the age and gender adjusted normal range as provided by the physician's lab: [A, 13, 14]

- Insulin-like Growth Factor 1 (IGF-1/Somatomedin-C)
- Insulin Growth Factor Binding Protein-3 (IGFBP-3)

AND

2 - Prescribed by or in consultation with an endocrinologist

Notes	Includes children who have undergone brain radiation. If patient is a Transition Phase Adolescent or Adult who had childhood onset GH deficiency, utilize criteria for Transition Phase Adolescent or Adult GH Deficiency. NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]

- Previous height and date obtained

- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	Includes children who have undergone brain radiation. If patient is a Transition Phase Adolescent or Adult who had childhood onset GH deficiency, utilize criteria for Transition Phase Adolescent or Adult GH Deficiency.

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 One of the following: [12]

1.1.1 Both of the following: [24-26]

- Infant is < 4 months of age
- Suspected GHD based on clinical presentation (e.g., persistent neonatal hypoglycemia that is not responsive to treatment, persistent or prolonged neonatal jaundice/elevated bilirubin, male infant with microgenitalia, midline anatomical defects, etc.)

OR

1.1.2 History of neonatal hypoglycemia associated with pituitary disease

OR

1.1.3 Diagnosis of panhypopituitarism

OR

1.2 All of the following:

1.2.1 Diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]

1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]

- Height is > 2.0 standard deviations [SD] below midparental height
- Height is > 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is > 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of > 2 SD below mean for age and gender (e.g., delayed > 2 years compared with chronological age)

AND

1.2.2 Documentation of one of the following: [22]

1.2.2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

1.2.2.2 Both of the following:

- Patient is female

- Bone age < 14 years

AND

1.2.3 One of the following:

1.2.3.1 Both of the following: [10, 11, 12]

1.2.3.1.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa

AND

1.2.3.1.2 Both GH response values are < 10 mcg/L

OR

1.2.3.2 Both of the following: [11]

1.2.3.2.1 Patient is < 1 year of age

AND

1.2.3.2.2 One of the following is below the age and gender adjusted normal range as provided by the physician's lab: [A, 13, 14]

- Insulin-like Growth Factor 1 (IGF-1/Somatomedin-C)
- Insulin Growth Factor Binding Protein-3 (IGFBP-3)

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	Includes children who have undergone brain radiation. If patient is a Transition Phase Adolescent or Adult who had childhood onset GH deficiency, utilize criteria for Transition Phase Adolescent or Adult GH Deficiency. NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 One of the following: [12]

1.1.1 Both of the following: [24-26]

- Infant is < 4 months of age
- Suspected GHD based on clinical presentation (e.g., persistent neonatal hypoglycemia that is not responsive to treatment, persistent or prolonged neonatal jaundice/elevated bilirubin, male infant with microgenitalia, midline anatomical defects, etc.)

OR

1.1.2 History of neonatal hypoglycemia associated with pituitary disease

OR

1.1.3 Diagnosis of panhypopituitarism

OR

1.2 Submission of medical records (e.g., chart notes) documenting all of the following:

1.2.1 Diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]

1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]

- Height is > 2.0 standard deviations [SD] below midparental height
- Height is > 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is > 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of > 2 SD below mean for age and gender (e.g., delayed > 2 years compared with chronological age)

AND

1.2.2 One of the following: [22]

1.2.2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

1.2.3 One of the following:

1.2.3.1 Both of the following: [10, 11, 12]

1.2.3.1.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine
- Clonidine

- Glucagon
- Insulin
- Levodopa

AND

1.2.3.1.2 Both GH response values are < 10 mcg/L

OR

1.2.3.2 Both of the following: [11]

1.2.3.2.1 Patient is < 1 year of age

AND

1.2.3.2.2 One of the following is below the age and gender adjusted normal range as provided by the physician's lab: [A, 13, 14]

- Insulin-like Growth Factor 1 (IGF-1/Somatomedin-C)
- Insulin Growth Factor Binding Protein-3 (IGFBP-3)

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	Includes children who have undergone brain radiation. If patient is a Transition Phase Adolescent or Adult who had childhood onset GH deficiency, utilize criteria for Transition Phase Adolescent or Adult GH Deficiency.

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope

Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Submission of medical records (e.g., chart notes) documenting both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Skytrofa	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 One of the following: [12]

1.1.1 History of neonatal hypoglycemia associated with pituitary disease

OR

1.1.2 Diagnosis of panhypopituitarism

OR

1.2 All of the following:

1.2.1 Diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]

1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]

- Height is > 2.0 standard deviations [SD] below midparental height
- Height is > 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is > 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of > 2 SD below mean for age and gender (e.g., delayed > 2 years compared with chronological age)

AND

1.2.2 Documentation of one of the following: [22]

1.2.2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

1.2.3 Both of the following: [10, 11, 12]

1.2.3.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa

AND

1.2.3.2 Both GH response values are < 10 mcg/L

AND

2 - Patient is 1 year of age or older

AND

3 - Patient weight is 11.5 kg or greater

AND

4 - Prescribed by or in consultation with an endocrinologist

AND

5 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	NOTE: Documentation of previous height, current height and goal expec ted adult height will be required for renewal.

Product Name: Skytrofa	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Skytrofa	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 One of the following: [12]

1.1.1 History of neonatal hypoglycemia associated with pituitary disease

OR

1.1.2 Diagnosis of panhypopituitarism

OR

1.2 All of the following:

1.2.1 Submission of medical records (e.g., chart notes) documenting diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]

1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]

- Height is > 2.0 standard deviations [SD] below midparental height
- Height is > 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is > 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of > 2 SD below mean for age and gender (e.g., delayed > 2 years compared with chronological age)

AND

1.2.2 One of the following: [22]

1.2.2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

1.2.3 Both of the following: [10, 11, 12]

1.2.3.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa

AND

1.2.3.2 Both GH response values are < 10 mcg/L

AND

2 - Patient is 1 year of age or older

AND

3 - Patient weight is 11.5 kg or greater

AND

4 - Prescribed by or in consultation with an endocrinologist

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	NOTE: Documentation of previous height, current height and goal expec ted adult height will be required for renewal.

Product Name: Skytrofa	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Submission of medical records (e.g., chart notes) documenting both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin [off-label] [B, 11]	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Prader-Willi Syndrome [10, 11]

AND

2 - Prescribed by or in consultation with an endocrinologist

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin [off-label] [B, 11]	
Diagnosis	Prader-Willi Syndrome

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Evidence of positive response to therapy (e.g., increase in total lean body mass, decrease in fat mass)

OR

1.2 Both of the following:

1.2.1 Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

1.2.2 Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

2 - Prescribed by or in consultation with an endocrinologist

Product Name: Genotropin, Humatrope [off-label], Saizen [off-label], Zomacton [off-label] [B, 11], or Omnitrope	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Prader-Willi Syndrome [10, 11]

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope [off-label], Saizen [off-label], Zomacton [off-label] [B, 11], or Omnitrope	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Evidence of positive response to therapy (e.g., increase in total lean body mass, decrease in fat mass)

OR

1.2 Both of the following:

1.2.1 Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained

- Current height and date obtained

AND

1.2.2 Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope [off-label], Saizen [off-label], Zomacton [off-label] [B, 11], or Omnitrope	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Prader-Willi Syndrome [10, 11]

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope [off-label], Saizen [off-label], Zomacton [off-label] [B, 11], or Omnitrope	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 Evidence of positive response to therapy (e.g., increase in total lean body mass, decrease in fat mass)

OR

1.2 Submission of medical records (e.g., chart notes) documenting both of the following:

1.2.1 Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

1.2.2 Both of the following:

- Expected adult height not attained

- Documentation of expected adult height goal

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin [off-label] [B, 11]	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of SGA based on demonstration of catch up growth failure in the first 24 months of life using a 0-36 month growth chart as confirmed by the following criterion: [10]

1.1 One of the following is below the 3rd percentile for gestational age (more than 2 SD below population mean):

- Birth weight
- Birth length

AND

2 - Height remains less than or equal to 3rd percentile (more than 2 SD below population mean) [10]

AND

3 - Prescribed by or in consultation with an endocrinologist	
Notes	NOTE: Documentation of previous height, current height and goal expec ted adult height will be required for renewal.

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin [off-label] [B, 11]	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

Product Name: Genotropin, Humatrope, Saizen [off-label] [B, 11], Zomacton, or Omnitrope	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of SGA based on demonstration of catch up growth failure in the first 24 months of life using a 0-36 month growth chart as confirmed by the following criterion: [10]

1.1 One of the following is below the 3rd percentile for gestational age (more than 2 SD below the population mean):

- Birth weight
- Birth length

AND

2 - Height remains less than or equal to 3rd percentile (more than 2 SD below population mean) [10]

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	NOTE: Documentation of previous height, current height and goal expec ted adult height will be required for renewal.

Product Name: Genotropin, Humatrope, Saizen [off-label] [B, 11], Zomacton, or Omnitrope	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [28]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope, Saizen [off-label] [B, 11], Zomacton, or Omnitrope	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of SGA based on demonstration of catch up growth failure in the first 24 months of life using a 0-36 month growth chart as confirmed by the following criterion: [10]

1.1 Submission of medical records (e.g., chart notes) documenting one of the following is below the 3rd percentile for gestational age (more than 2 SD below the population mean):

- Birth weight
- Birth length

AND

2 - Submission of medical records (e.g., chart notes) documenting height remains less than or equal to 3rd percentile (more than 2 SD below population mean) [10]

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope, Saizen [off-label] [B, 11], Zomacton, or Omnitrope	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [28]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Submission of medical records (e.g., chart notes) documenting both of the following:

- Expected adult height not attained

- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Turner Syndrome or Noonan Syndrome [off-label except for Norditropin] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with one of the following: [10, 22]

1.1 Both of the following:

1.1.1 Turner Syndrome (Gonadal Dysgenesis)

AND

1.1.2 Documentation of both of the following:

- Patient is female
- Bone age < 14 years

OR

1.2 Both of the following:

1.2.1 Noonan Syndrome

AND

1.2.2 Documentation of one of the following:

1.2.2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

2 - Height is below the 5th percentile on growth charts for age and gender [10]

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Turner Syndrome or Noonan Syndrome [off-label except for Norditropin] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Turner Syndrome [off-label for Saizen] or Noonan Syndrome [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with one of the following: [10, 22]

1.1 Both of the following:

1.1.1 Turner Syndrome (Gonadal Dysgenesis)

AND

1.1.2 Documentation of both of the following:

- Patient is female

- Bone age < 14 years

OR

1.2 Both of the following:

1.2.1 Noonan Syndrome

AND

1.2.2 Documentation of one of the following:

1.2.2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

2 - Height is below the 5th percentile on growth charts for age and gender [10]

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	NOTE: Documentation of previous height, current height and goal expec ted adult height will be required for renewal.

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Turner Syndrome [off-label for Saizen] or Noonan Syndrome [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope

Diagnosis	Turner Syndrome [off-label for Saizen] or Noonan Syndrome [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with one of the following: [10, 22]

1.1 Both of the following:

1.1.1 Turner Syndrome (Gonadal Dysgenesis)

AND

1.1.2 Submission of medical records (e.g., chart notes) documenting both of the following:

- Patient is female
- Bone age < 14 years

OR

1.2 Both of the following:

1.2.1 Noonan Syndrome

AND

1.2.2 Submission of medical records (e.g., chart notes) documenting one of the following:

1.2.2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

2 - Submission of medical records (e.g., chart notes) documenting height below the 5th percentile on growth charts for age and gender [10]

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Turner Syndrome [off-label for Saizen] or Noonan Syndrome [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Submission of medical records (e.g., chart notes) documenting both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claim or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure with short stature homeobox (SHOX) gene deficiency as confirmed by genetic testing [2]

AND

2 - Documentation of one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	NOTE: Documentation of previous height, current height and goal expec ted adult height will be required for renewal.

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

Product Name: Genotropin [off-label], Humatrope, Saizen [off-label], Zomacton, or Omnitrope [off-label] [B, 11]	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure with short stature homeobox (SHOX) gene deficiency as confirmed by genetic testing [2]

AND

2 - Documentation of one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	NOTE: Documentation of previous height, current height and goal expec ted adult height will be required for renewal.

Product Name: Genotropin [off-label], Humatrope, Saizen [off-label], Zomacton, or Omnitrope [off-label] [B, 11]	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin [off-label], Humatrope, Saizen [off-label], Zomacton, or Omnitrope [off-label] [B, 11]

Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of pediatric growth failure with short stature homeobox (SHOX) gene deficiency as confirmed by genetic testing [2]

AND

2 - Submission of medical records (e.g., chart notes) documenting one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin [off-label], Humatrope, Saizen [off-label], Zomacton, or Omnitrope [off-label] [B, 11]	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Submission of medical records (e.g., chart notes) documenting both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Norditropin Flexpro [off-label] [B, 11] or Nutropin AQ NuSpin	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with chronic renal insufficiency [10]

AND

2 - Documentation of one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Nephrologist

Notes	NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Norditropin Flexpro [off-label] [B, 11] or Nutropin AQ NuSpin	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Nephrologist

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with chronic renal insufficiency [10]

AND

2 - Documentation of one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Nephrologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	NOTE: Documentation of previous height, current height and goal expec ted adult height will be required for renewal.

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Nephrologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with chronic renal insufficiency [10]

AND

2 - Submission of medical records (e.g., chart notes) documenting one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age < 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age < 14 years

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Nephrologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Submission of medical records (e.g., chart notes) documenting both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Nephrologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of adult GH deficiency as a result of one of the following: [10, 12, 21]

1.1 Clinical records supporting a diagnosis of childhood-onset GHD

OR

1.2 Both of the following:

1.2.1 Adult-onset GHD

AND

1.2.2 Clinical records documenting that hormone deficiency is a result of hypothalamic-pituitary disease from organic or known causes (e.g., damage from surgery, cranial irradiation, head trauma, or subarachnoid hemorrhage)

AND

2 - One of the following: [10, 12, 20-21]

2.1 Both of the following:

2.1.1 Patient has undergone one of the following GH stimulation tests to confirm adult GH deficiency:

- Insulin tolerance test (ITT)
- Glucagon
- Macimorelin

AND

2.1.2 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 Both of the following:

2.2.1 Documented deficiency of three of the following anterior pituitary hormones:

- Prolactin
- Adrenocorticotropic hormone (ACTH)
- Thyroid stimulating hormone (TSH)
- Follicle-stimulating hormone/luteinizing hormone (FSH/LH)

AND

2.2.2 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	Use the following criteria for child- and adult-onset with pituitary disease; use Isolated GHD in Adult criteria for patients without pituitary disease.

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Evidence of ongoing monitoring as demonstrated by documentation within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]

AND

2 - Prescribed by or in consultation with an endocrinologist

Notes	Use the following criteria for child- and adult-onset with pituitary disease; use Isolated GHD in Adult criteria for patients without pituitary disease.

Product Name: Genotropin, Humatrope, Saizen, Sogroya, Zomacton [B, 21], or Omnitrope	
Diagnosis	Adult Growth Hormone Deficiency

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of adult GH deficiency as a result of one of the following: [10, 12, 21]

1.1 Clinical records supporting a diagnosis of childhood-onset GHD

OR

1.2 Both of the following:

1.2.1 Adult-onset GHD

AND

1.2.2 Clinical records documenting that hormone deficiency is a result of hypothalamic-pituitary disease from organic or known causes (e.g., damage from surgery, cranial irradiation, head trauma, or subarachnoid hemorrhage)

AND

2 - One of the following: [10, 12, 21]

2.1 Both of the following:

2.1.1 Patient has undergone one of the following GH stimulation tests to confirm adult GH deficiency:

- Insulin tolerance test (ITT)
- Glucagon
- Macimorelin

AND

2.1.2 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L

- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 Both of the following:

2.2.1 Documented deficiency of three of the following anterior pituitary hormones:

- Prolactin
- ACTH
- TSH
- FSH/LH

AND

2.2.2 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	Use the following criteria for child- and adult-onset with pituitary disease; use Isolated GHD in Adult criteria for patients without pituitary disease.

Product Name: Genotropin, Humatrope, Saizen, Sogroya, Zomacton [B, 21], or Omnitrope	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Evidence of ongoing monitoring as demonstrated by documentation within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	Use the following criteria for child- and adult-onset with pituitary diseas e; use Isolated GHD in Adult criteria for patients without pituitary diseas e.

Product Name: Genotropin, Humatrope, Saizen, Zomacton [B, 21], or Omnitrope	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of adult GH deficiency as a result of one of the following: [10, 12, 21]

1.1 Submission of medical records (e.g., chart notes) supporting a diagnosis of childhood-onset GHD

OR

1.2 Both of the following:

1.2.1 Adult-onset GHD

AND

1.2.2 Submission of medical records (e.g., chart notes) documenting that hormone deficiency is a result of hypothalamic-pituitary disease from organic or known causes (e.g., damage from surgery, cranial irradiation, head trauma, or subarachnoid hemorrhage)

AND

2 - One of the following: [10, 12, 21]

2.1 Both of the following:

2.1.1 Patient has undergone one of the following GH stimulation tests to confirm adult GH deficiency:

- Insulin tolerance test (ITT)
- Glucagon
- Macimorelin

AND

2.1.2 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 Both of the following:

2.2.1 Submission of medical records (e.g., chart notes) documenting deficiency of three of the following anterior pituitary hormones:

- Prolactin
- ACTH
- TSH
- FSH/LH

AND

2.2.2 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	Use the following criteria for child- and adult-onset with pituitary disease; use Isolated GHD in Adult criteria for patients without pituitary disease.

Product Name: Genotropin, Humatrope, Saizen, Zomacton [B, 21], or Omnitrope	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting evidence of ongoing monitoring within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	Use the following criteria for child- and adult-onset with pituitary disease; use Isolated GHD in Adult criteria for patients without pituitary disease.

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Transition Phase Adolescent Patients
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following: [21]

- Attained expected adult height
- Closed epiphyses on bone radiograph

AND

2 - One of the following: [20, 21]

2.1 Both of the following:

2.1.1 Documentation of high risk of GH deficiency due to GH deficiency in childhood from one of the following:

2.1.1.1 Embryopathic/congenital defects

OR

2.1.1.2 Genetic mutations

OR

2.1.1.3 Irreversible structural hypothalamic-pituitary disease

OR

2.1.1.4 Panhypopituitarism

OR

2.1.1.5 Deficiency of three of the following anterior pituitary hormones:

- ACTH
- TSH
- Prolactin
- FSH/LH

AND

2.1.2 One of the following:

2.1.2.1 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

OR

2.1.2.2 All of the following:

2.1.2.2.1 Patient does not have a low IGF-1/Somatomedin C level

AND

2.1.2.2.2 Discontinued GH therapy for at least 1 month

AND

2.1.2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon
- Macimorelin

AND

2.1.2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 All of the following:

2.2.1 At low risk of severe GH deficiency (e.g., due to isolated and/or idiopathic GH deficiency)

AND

2.2.2 Discontinued GH therapy for at least 1 month

AND

2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon
- Macimorelin

AND

2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L

- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

3 - Prescribed by or in consultation with an endocrinologist

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Transition Phase Adolescent Patients
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Evidence of positive response to therapy (e.g., increase in total lean body mass, exercise capacity or IGF-1 and IGFBP-3 levels)

AND

2 - Prescribed by or in consultation with an endocrinologist

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Transition Phase Adolescent Patients [off-label] [B]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following: [21]

- Attained expected adult height
- Closed epiphyses on bone radiograph

AND

2 - One of the following: [20, 21]

2.1 Both of the following:

2.1.1 Documentation of high risk of GH deficiency due to GH deficiency in childhood from one of the following:

2.1.1.1 Embryopathic/congenital defects

OR

2.1.1.2 Genetic mutations

OR

2.1.1.3 Irreversible structural hypothalamic-pituitary disease

OR

2.1.1.4 Panhypopituitarism

OR

2.1.1.5 Deficiency of three of the following anterior pituitary hormones:

- ACTH
- TSH
- Prolactin
- FSH/LH

AND

2.1.2 One of the following:

2.1.2.1 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

OR

2.1.2.2 All of the following:

2.1.2.2.1 Patient does not have a low IGF-1/Somatomedin C level

AND

2.1.2.2.2 Discontinued GH therapy for at least 1 month

AND

2.1.2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon
- Macimorelin

AND

2.1.2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 All of the following:

2.2.1 At low risk of severe GH deficiency (e.g., due to isolated and/or idiopathic GH deficiency)

AND

2.2.2 Discontinued GH therapy for at least 1 month

AND

2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon
- Macimorelin

AND

2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Transition Phase Adolescent Patients [off-label] [B]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Evidence of positive response to therapy (e.g., increase in total lean body mass, exercise capacity or IGF-1 and IGFBP-3 levels)

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton, or Omnitrope	
Diagnosis	Transition Phase Adolescent Patients [off-label] [B]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting one of the following: [21]

- Attained expected adult height
- Closed epiphyses on bone radiograph

AND

2 - Submission of medical records (e.g., chart notes) documenting one of the following: [20, 21]

2.1 Both of the following:

2.1.1 Documentation of high risk of GH deficiency due to GH deficiency in childhood from one of the following:

2.1.1.1 Embryopathic/congenital defects

OR

2.1.1.2 Genetic mutations

OR

2.1.1.3 Irreversible structural hypothalamic-pituitary disease

OR

2.1.1.4 Panhypopituitarism

OR

2.1.1.5 Deficiency of three of the following anterior pituitary hormones:

- ACTH
- TSH
- Prolactin
- FSH/LH

AND

2.1.2 One of the following:

2.1.2.1 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

OR

2.1.2.2 All of the following:

2.1.2.2.1 Patient does not have a low IGF-1/Somatomedin C level

AND

2.1.2.2.2 Discontinued GH therapy for at least 1 month

AND

2.1.2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon
- Macimorelin

AND

2.1.2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 All of the following:

2.2.1 At low risk of severe GH deficiency (e.g., due to isolated and/or idiopathic GH deficiency)

AND

2.2.2 Discontinued GH therapy for at least 1 month

AND

2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon
- Macimorelin

AND

2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Serostim	
Diagnosis	Human Immunodeficiency Virus (HIV)-Associated Cachexia
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HIV-associated wasting syndrome or cachexia [7, 15, 18, 19]

AND

2 - One of the following: [7, 15, 18, 19, C]

2.1 Unintentional weight loss of > 10% over the last 12 months

OR

2.2 Unintentional weight loss of > 7.5% over the last 6 months

OR

2.3 Loss of 5% body cell mass (BCM) within 6 months

OR

2.4 Body mass index (BMI) < 20 kg/m^2

OR

2.5 All of the following

- Patient is male
- BCM < 35% of total body weight
- BMI < 27 kg/m^2

OR

2.6 All of the following

- Patient is female
- BCM < 23% of total body weight
- BMI < 27 kg/m^2

AND

3 - Nutritional evaluation since onset of wasting first occurred [7, 15, 18, 19]

AND

4 - Patient has not had weight loss as a result of other underlying treatable conditions (e.g., depression, mycobacterium avium complex, chronic infectious diarrhea, or malignancy with the exception of Kaposi's sarcoma limited to skin or mucous membranes) [7, 15, 18, 19]

AND

5 - Anti-retroviral therapy has been optimized to decrease the viral load [7, 15, 18, 19]

Product Name: Serostim	
Diagnosis	Human Immunodeficiency Virus (HIV)-Associated Cachexia
Approval Length	6 months [D]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Evidence of positive response to therapy (i.e., greater than or equal to 2% increase in body weight and/or BCM) [17, 18]

AND

2 - One of the following targets or goals has not been achieved: [17, 18]

- Weight
- BCM
- BMI

Product Name: Zorbtive	
Diagnosis	Short Bowel Syndrome
Approval Length	4 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Short Bowel Syndrome [9, 16]

AND

2 - Patient is currently receiving specialized nutritional support (e.g., intravenous parenteral nutrition, fluid, and micronutrient supplements) [9, 16]

AND

3 - Patient has not previously received 4 weeks of treatment with Zorbtive [9, 16]

Notes	NOTE: Treatment with Zorbtive will not be authorized beyond 4 weeks. Administration for more than 4 weeks has not been adequately studied.

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Isolated Growth Hormone Deficiency in Adults
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documented deficiency of GH as demonstrated by both of the following: [20-21]

1.1 Patient has undergone two of the following GH stimulation tests:

- ITT
- Glucagon
- Macimorelin

AND

1.2 Patient has two of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

2 - Prescribed by or in consultation with an endocrinologist

Product Name: Norditropin Flexpro or Nutropin AQ NuSpin	
Diagnosis	Isolated Growth Hormone Deficiency in Adults

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Evidence of ongoing monitoring as demonstrated by documentation within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]

AND

2 - Prescribed by or in consultation with an endocrinologist

Product Name: Genotropin, Humatrope, Saizen, Sogroya, Zomacton [off-label] [B, 21], or Omnitrope	
Diagnosis	Isolated Growth Hormone Deficiency in Adults
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documented deficiency of GH as demonstrated by both of the following: [20-21]

1.1 Patient has undergone two of the following GH stimulation tests:

- ITT
- Glucagon
- Macimorelin

AND

1.2 Patient has two of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Sogroya, Zomacton [off-label] [B, 21], or Omnitrope	
Diagnosis	Isolated Growth Hormone Deficiency in Adults
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Evidence of ongoing monitoring as demonstrated by documentation within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton [off-label] [B, 21], or Omnitrope

Diagnosis	Isolated Growth Hormone Deficiency in Adults
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting deficiency of GH as demonstrated by both of the following: [20-21]

1.1 Patient has undergone two of the following GH stimulation tests:

- ITT
- Glucagon
- Macimorelin

AND

1.2 Patient has two of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton [off-label] [B, 21], or Omnitrope	
Diagnosis	Isolated Growth Hormone Deficiency in Adults

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting evidence of ongoing monitoring within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Product Name: All Products	
Guideline Type	Prior Authorization, Non Formulary

Approval Criteria

1 - Requests for coverage of growth hormone for the diagnosis of Idiopathic Short Stature (ISS) are not authorized and will not be approved. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. [E]

Notes	Approval Length: N/A - Requests for non-approvable diagnoses should not be approved

Product Name: Sogroya	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 One of the following: [12]

1.1.1 History of neonatal hypoglycemia associated with pituitary disease

OR

1.1.2 Diagnosis of panhypopituitarism

OR

1.2 All of the following:

1.2.1 Diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]

1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]

- Height is greater than 2.0 standard deviations [SD] below midparental height
- Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is greater than 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of greater than 2 SD below mean for age and gender (e.g., delayed greater than 2 years compared with chronological age)

AND

1.2.2 Documentation of one of the following: [22]

1.2.2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

1.2.3 Both of the following: [10, 11, 12]

1.2.3.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa

AND

1.2.3.2 Both GH response values are less than 10 mcg/L

AND

2 - Patient is 2.5 years of age or older

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)

Notes	NOTE: Documentation of previous height, current height and goal expec ted adult height will be required for renewal.

Product Name: Sogroya	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)

- Nutropin (somatropin)

3 . Endnotes

A. Several recent review articles in the literature have suggested that GH stimulation tests should no longer be used to diagnose GHD. [13,14] The authors argue that GH stimulation test may have side effects, lack precision, accuracy, and do not predict response to GH therapy. It has been suggested that newer diagnostic procedures such as serum IGF-1, IGFBP-3 concentrations, genetic testing and neuroimaging could provide an alternative approach to the diagnosis of GHD in childhood.
B. Overall, there are no observable differences in the results obtained among the different preparations as long as the regimen follows currently approved daily injections. Many of the products are available in a variety of injection devices that are meant to make administration more appealing and easier. Currently, there is no evidence that clinical outcome differs among the various injection systems, although there may be patient and parent preferences for some of these devices. [11, 21]
C. Even a 5% weight loss in persons with HIV infection indicates a poor prognosis. [2]
D. Patients with HIV-associated wasting may begin an initial 12-week course of therapy with Serostim, 6 mg/day s.c. The clinician should monitor treatment responses by obtaining serial body weights and BCM measurements by BIA. A positive response to therapy probably should be considered as a 2% increase in body weight and/or BCM. Maintenance therapy may continue on a monthly basis as long as wasting is still evident. Once BCM has normalized, therapy can be stopped, with the patient being observed for an 8-week period. Over these 8 weeks, body weight, BCM, and any appearance of wasting symptoms can be monitored. If wasting reappears, therapy can be restarted. [17]
E. Guidelines for idiopathic short stature recommend against the routine use of GH in every child with height standard deviation score ≤ - 2.25. [23]
F. When GHD is congenital and near complete, the diagnosis is relatively easy to confirm because affected children present with severe growth failure, delayed bone age, and very low serum concentrations of GH, IGF-1, and IGFBP-3 [8]. For patients with all of these clinical characteristics, it is reasonable to make the diagnosis of GHD without performing GH stimulation testing. [29]
G. Measurements of IGF-1 and IGFBP-3 have shown comparable diagnostic performance with growth hormone stimulation tests and are valuable for patient`s convenience and ease of performance and can be useful in the workup of growth hormone deficiency. [30]

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5 . Revision History

Date	Notes
7/20/2023	update guideline

Hereditary Angioedema Agents

Prior Authorization Guideline

Guideline ID	GL-124256
Guideline Name	Hereditary Angioedema Agents
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	3/6/2024
P&T Approval Date:	2/17/2009
P&T Revision Date:	09/18/2019 ; 03/18/2020 ; 07/15/2020 ; 12/16/2020 ; 02/18/2021 ; 04/21/2021 ; 08/19/2021 ; 10/20/2021 ; 10/20/2021 ; 04/20/2022 ; 4/19/2023 ; 06/21/2023 ; 11/16/2023 ; 02/15/2024 ; 03/20/2024

1 . Indications

Drug Name: Berinert (C1 esterase inhibitor [Human])
Acute treatment of Hereditary Angioedema (HAE) Indicated for the treatment of acute abdominal, facial, or laryngeal attacks of HAE in adult and adolescent patients. The safety and efficacy of Berinert for prophylactic therapy have not been established.
Drug Name: Cinryze (C1 esterase inhibitor [Human])
Prophylaxis of Hereditary Angioedema (HAE) Indicated for routine prophylaxis against angioedema attacks in adults, adolescents and pediatric patients (6 years old and above) with HAE. **Off Label Uses: Acute treatment of Hereditary Angioedema (HAE)** Following treatment with nanofiltered C1 inhibitor concentrate (Cinryze) for an acute attack, the median time to response was 30 minutes in 82 patients with HAE. [3]
Drug Name: Firazyr (icatibant)

Acute treatment of Hereditary Angioedema (HAE) Indicated for the treatment of acute attacks of HAE in adults 18 years of age and older.
Drug Name: Haegarda (C1 esterase inhibitor [Human])
Prophylaxis of Hereditary Angioedema (HAE) Indicated for routine prophylaxis to prevent HAE attacks in patients 6 years of age and older.
Drug Name: Kalbitor (ecallantide)
Acute treatment of Hereditary Angioedema (HAE) Indicated for treatment of acute attacks of HAE in patients 12 years of age and older.
Drug Name: Orladeyo (berotralstat)
Prophylaxis of Hereditary Angioedema (HAE) Indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years of age and older. Limitations of Use: The safety and effectiveness of ORLADEYO for the treatment of acute HAE attacks have not been established. ORLADEYO should not be used for treatment of acute HAE attacks. Additional doses or doses of ORLADEYO higher than 150 mg once daily are not recommended due to the potential for QT prolongation.
Drug Name: Ruconest (C1 esterase inhibitor [Recombinant])
Acute treatment of Hereditary Angioedema (HAE) Indicated for the treatment of acute attacks in adult and adolescent patients with HAE. Limitation of Use: Effectiveness was not established in HAE patients with laryngeal attacks.
Drug Name: Takhzyro (lanadelumab-flyo)
Prophylaxis of Hereditary Angioedema (HAE) Indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 2 years and older.
Drug Name: Sajazir (icatibant)
Acute treatment of Hereditary Angioedema (HAE) Indicated for the treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older.

2 . Criteria

Product Name: Cinryze, Haegarda, Orladeyo or Takhzyro	
Diagnosis	Prophylaxis of HAE attacks
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of hereditary angioedema (HAE) [A]

AND

2 – One of the following:

2.1 Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following:

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

2.2 DIAGNOSIS HAS BEEN CONFIRMED BY BOTH OF THE FOLLOWING:

2.2.1 PATIENT HAS NORMAL C1-INH LEVELS (HAE-N1-C1INH PREVIOUSLY REFERRED TO AS HAE TYPE 3)

AND

2.2.2 One of the following:

Confirmed presence of a FXII, plasminogen gene mutation, angiopoietin-1 mutation, or kininogen mutation

Patient has recurrent angioedema attacks that are refractory to high-dose antihistamines (e.g., cetirizine) with a confirmed family history of recurrent angioedema

3 - For prophylaxis against HAE attacks [3]

AND

4 – NOT USED IN COMBINATION WITH OTHER APPROVED TREATMENTS FOR PROPHYLAXIS AGAINST HAE ATTACKS

5 - One of the following:

- Patient is 6 years of age or older (applies to Cinryze and Haegarda only)
- Patient is 12 years of age or older (applies to Orladeyo only)
- Patient is 2 years of age or older (applies to Takhzyro only)

AND

6 - One of the following:

6.1 Trial and failure, contraindication or intolerance to one of the following: (applies to Cinryze only)

- Orladeyo
- Haegarda
- Takhzyro

OR

6.2 For continuation of prior therapy (applies to Cinryze only)

AND

5 - Prescribed by or in consultation with one of the following: [B]

- Immunologist
- Allergist

Product Name: Cinryze, Haegarda, Orladeyo or Takhzyro	
Diagnosis	Prophylaxis of HAE attacks
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in the number or rate of HAE attacks while on therapy)

AND

2 - Not used in combination with other approved treatments for prophylaxis against HAE attacks

Product Name: Cinryze [off-label], Brand Firazyr, Generic icatibant, Sajazir, or Ruconest	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) [3, A]

AND

2 – One of the following:
2.1 Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by one of the following:

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

2.2 Diagnosis has been confirmed by both of the following:

2.2.1 Patient has normal C1-INH levels (HAE-n1-C1INH previously referred to as HAE Type 3)

AND

2.2.2 One of the following:
- Confirmed presence of a FXII, plasminogen gene mutation, angiopoietin-1 mutation, or kininogen mutation
- Patient has recurrent angioedema attacks that are refractory to high-dose antihistamines (e.g., cetirizine) with a confirmed family history of recurrent angioedema

AND

3 - For the treatment of acute HAE attacks [3, C]

AND

4 - Not used in combination with other approved treatments for acute HAE attacks

AND

5 - One of the following:

- Patient is 6 years of age or older (applies to Cinryze only)
- Patient is 18 years of age or older (applies to Brand Firazyr, generic icatibant, and Sajazir only)

AND

6 - Prescribed by or in consultation with one of the following: [B]

- Immunologist
- Allergist

AND

7 - Trial and failure or intolerance to generic icatibant (applies to brand Firazyr only):

Product Name: Cinryze [off-label], Brand Firazyr, Generic icatibant, Sajazir, or Ruconest	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Not used in combination with other approved treatments for prophylaxis against HAE attacks

Product Name: Kalbitor	
Diagnosis	Treatment of acute HAE attacks

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) [A]

AND

2 – One of the following

2.1 Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by one of the following:

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

2.2 Diagnosis has been confirmed by both of the following:

2.2.1 Patient has normal C1-INH levels (HAE-n1-C1INH previously referred to as HAE Type 3)

AND

2.2.2 One of the following:

- Confirmed presence of a FXII, plasminogen gene mutation, angiopoietin-1 mutation, or kininogen mutation
- Patient has recurrent angioedema attacks that are refractory to high-dose antihistamines (e.g., cetirizine) with a confirmed family history of recurrent angioedema

AND

3 - For the treatment of acute HAE attacks

AND

4 - Patient is greater than or equal to 12 years of age [D]

AND

5 - Not used in combination with other approved treatments for acute HAE attacks

AND

6 - Prescribed by or in consultation with one of the following: [B]

- Immunologist
- Allergist

Product Name: Kalbitor	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Not used in combination with other approved treatments for acute HAE attacks

Product Name: Berinert	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) [3, A]

AND

2 – One of the following:

2.1 Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by one of the following:

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

2.2 Diagnosis has been confirmed by both of the following:
2.2.1 Patient has normal C1-INH levels (HAE-n1-C1INH previously referred to as HAE Type 3)

AND

2.2.2 One of the following:

- Confirmed presence of a FXII, plasminogen gene mutation, angiopoietin-1 mutation, or kininogen mutation
- Patient has recurrent angioedema attacks that are refractory to high-dose antihistamines (e.g., cetirizine) with a confirmed family history of recurrent angioedema

AND

3 - For the treatment of acute HAE attacks [3, C]

AND

4 - Not used in combination with other approved treatments for acute HAE attacks

AND

5 - One of the following:

5.1 Trial and failure, contraindication, or intolerance to Ruconest

OR

5.2 One of the following:

- Patient is 12 years of age or younger
- Documentation that patient has history of laryngeal attacks

AND

6 - Prescribed by or in consultation with one of the following: [B]

- Immunologist
- Allergist

Product Name: Berinert	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Not used in combination with other approved treatments for acute HAE attacks

Product Name: Cinryze	
Diagnosis	Prophylaxis of HAE attacks
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) [A]

AND

2 - One of the following [A]:

2.1 Submission of medical records (e.g., chart notes) documenting diagnosis has been confirmed by C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following:

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

OR

2.2 Submission of medical records (e.g., chart notes) documenting diagnosis has been confirmed by both of the following:
2.2.1 Patient has normal C1-INH levels (HAE-n1-C1INH previously referred to as HAE Type 3)

AND

2.2.2 One of the following:

- Confirmed presence of a FXII, plasminogen gene mutation, angiopoietin-1 mutation, or kininogen mutation
- Patient has recurrent angioedema attacks that are refractory to high-dose antihistamines (e.g., cetirizine) with a confirmed family history of recurrent angioedema

AND

3- For prophylaxis against HAE attacks [3]

AND

4 - Not used in combination with other approved treatments for prophylaxis against HAE attacks

AND

5 - Patient is 6 years of age or older

AND

6 - One of the following:
6.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication or intolerance to one of the following:

- Orladeyo
- Haegarda
- Takhzyro

OR

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

AND

7 - Prescribed by or in consultation with one of the following: [B]
- Immunologist
- Allergist

3 . Endnotes

A. HAE is a rare genetic disorder caused by a deficiency of C1-inhibitor and is inherited in an autosomal dominant manner. This condition is characterized by recurrent episodes of angioedema, without urticaria or pruritus, which most often affect the skin or mucosal tissues of the upper respiratory and gastrointestinal tracts. Diagnosis of HAE requires a blood test to confirm low or abnormal levels of C1-inhibitor. [10]

B. Includes immunologist and allergist specialties to ensure the requirement for proper diagnosing and assessing the severity of the symptoms. In the pivotal Cinryze trial, criteria for participation of long term prophylaxis included patients 9 years and older with documented HAE (based on: a low C4 level plus low C1 inhibitor antigenic level/or low C1 inhibitor functional level OR a known HAE causing mutation) AND a history of at least two HAE attack per month. [1, 8] Berinert is approved for the treatment of acute attacks in patients who are 13 years and older. In the pivotal Berinert trial patients had laboratory-confirmed C1-inhibitor deficiency (type I or II HAE). [9]

C. Following treatment with nanofiltered C1 inhibitor concentrate (Cinryze) for an acute attack, the median time to response was 30 minutes in 82 patients with hereditary angioedema (median number of attacks per patient, 3; range, 1 to 57 attacks) in an open-label extension trial (median follow-up of 11 months). Additionally, 93% of attacks responded within 4 hr after C1 inhibitor concentrate treatment. [3]

D. Kalbitor carries a black box warning that states the following: "Anaphylaxis has been reported after administration of Kalbitor. Because of the risk of anaphylaxis, Kalbitor should only be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and hereditary angioedema (HAE). Healthcare professionals should be aware of the similarity of symptoms between hypersensitivity reactions and hereditary angioedema and patients should be monitored closely. Do not administer Kalbitor to patients with known clinical hypersensitivity to Kalbitor." In 255 HAE patients treated with intravenous or subcutaneous Kalbitor in clinical studies, 10 patients (3.9%) experienced anaphylaxis. For the subgroup of 187 patients treated with subcutaneous Kalbitor, 5 patients (2.7%) experienced anaphylaxis. Symptoms associated with these reactions have included chest discomfort, flushing, pharyngeal edema, pruritus, rhinorrhea, sneezing, nasal congestion, throat irritation, urticaria, wheezing, and hypotension. These reactions occurred within the first hour after dosing. Other adverse reactions indicative of hypersensitivity reactions included the following: pruritus (5.1%), rash (3.1%), and urticaria (2.0%). Patients should be observed for an appropriate period of

time after administration of Kalbitor, taking into account the time to onset of anaphylaxis seen in clinical trials. In the Kalbitor HAE program, patients developed antibodies to ecallantide. Rates of seroconversion increased with exposure to ecallantide over time. Overall, 7.4% of patients seroconverted to anti-ecallantide antibodies. Neutralizing antibodies to ecallantide were determined in vitro to be present in 4.7% of patients. Anti-ecallantide and anti-Po pastoris IgE antibodies were also detected. While the long-term effects of antibodies to Kalbitor are not known, patients who seroconvert may be at a higher risk of a hypersensitivity reaction. The manufacturer developed a Risk Evaluation and Mitigation Strategy (REMS) program consisting of a Medication Guide and Communication Plan to notify healthcare professionals of the risk of anaphylaxis and the need to distinguish signs and symptoms of anaphylaxis and HAE attack as they may overlap. The presence of the black box warning necessitating administration by a healthcare professional; development of antibodies to ecallantide that may predispose patients to higher risks of hypersensitivity reactions; and the requirement for a REMS program offer compelling evidence to warrant the continued inclusion of an age criterion. [7]

4 . References

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3. Micromedex Healthcare Series [internet database]. Greenwood Village (CO): Thomson Reuters (Healthcare) Inc. Updated periodically. Available at: http://www.thomsonhc.com/. Accessed July 30, 2019.
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5. Ruconest Prescribing Information. Pharming Healthcare Inc. Bridgewater, NJ. April 2020.
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7. Kalbitor Prescribing Information. Dyax Corp. Lexington, MA. November 2021.
8. FDA/CDER. Briefing Document for Blood products Advisory Committee. Presented May 2, 2008. Available at: http://www.fda.gov/. Accessed July 30, 2019.
9. Craig TJ, Levy RJ, Wasserman RL. Efficacy of human C1 esterase inhibitor concentrate compared with placebo in acute hereditary angioedema attacks. J Allergy Clin Immunol. Oct 2009;124(4):801-8.
10. Cicardi M, Zura B. Hereditary angioedema: Pathogenesis and diagnosis. UpToDate Web site. Available at: http://www.uptodate.com/. Accessed July 30, 2019.
11. Takhzyro Prescribing Information. Dyax Corp. Lexington, MA. February 2023.
12. Orladeyo Prescribing Information. BioCryst Pharmaceuticals, Inc. Durham, NC. March 2022.
13. Sajazir Prescribing Information. Cipla Ltd., India. May 2022.
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5 . Revision History

Date	Notes
3/5/2024	Update guideline

Ilaris (canakinumab injection)

Prior Authorization Guideline

Guideline ID	GL-115159
Guideline Name	Ilaris (canakinumab injection)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	10/1/2023
P&T Approval Date:	11/17/2009
P&T Revision Date:	08/15/2019 ; 08/13/2020 ; 08/19/2021 ; 08/18/2022 ; 10/19/2022, 8/17/2023

1 . Indications

Drug Name: Ilaris (canakinumab injection)
Periodic Fever Syndromes: Cryopyrin-Associated Periodic Syndromes (CAPS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), Familial Mediterranean Fever(FMF) Indicated for the treatment of the following autoinflammatory Periodic Fever Syndromes: Cryopyrin-Associated Periodic Syndromes (CAPS), in adults and children 4 years of age and older including, Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS); Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) in adult and pediatric patients; Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) in adult and pediatric patients; Familial Mediterranean Fever (FMF) in adult and pediatric patients. **Systemic Juvenile Idiopathic Arthritis (SJIA)** Indicated for the treatment of active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older. **Still's disease (Adult-Onset Still's Disease [AOSD])** Indicated for the treatment of active Still's disease, including Adult-Onset Still's Disease (AOSD) in patients aged 2 years and older.

2 . Criteria

Product Name: Ilaris	
Diagnosis	Periodic Fever Syndromes [Cryopyrin-Associated Periodic Syndromes (CAPS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency(MKD), Familial Mediterranean Fever(FMF)]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following periodic fever syndromes:

- cryopyrin-associated periodic syndromes (CAPS), including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS)
- tumor necrosis factor (TNF) receptor associated periodic syndrome (TRAPS)
- hyperimmunoglobulin D (Hyper-IgD) syndrome (HIDS/mevalonate kinase deficiency (MKD)
- familial mediterranean fever (FMF)

AND

2 - Prescribed by or in consultation with one of the following:

- Immunologist
- Allergist
- Dermatologist
- Rheumatologist
- Neurologist

AND

3 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Adalimumab, Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

Product Name: Ilaris	
Diagnosis	Periodic Fever Syndrome [CAPS, TRAPS, HIDS/MKD, FMF]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Adalimumab, Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

Product Name: Ilaris	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active systemic juvenile idiopathic arthritis (SJIA)

AND

2 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [1, 2]:

- Minimum duration of a 3-month trial and failure of methotrexate
- Minimum duration of a 1-month trial of a nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen)
- Minimum duration of a 2-week trial of a systemic glucocorticoid (e.g., prednisone)

AND

3 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Adalimumab, Remicade [infliximab])

- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name: Ilaris	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 2]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in clinical features or symptoms (e.g., pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline

AND

2 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Adalimumab, Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

Product Name: Ilaris	
Diagnosis	Still's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Still's Disease, including Adult-Onset Still's Disease (AOSD)

AND

2 - Trial and failure, contraindication, or intolerance to one of the following: [1-3]

- Corticosteroids (e.g., prednisone)
- Methotrexate
- Nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen)

AND

3 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Adalimumab, Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name: Ilaris	
Diagnosis	Still's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Adalimumab, Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

3 . Definitions

Definition	Description
Cryopyrin-Associated Periodic Syndromes (CAPS):	A group of rare, autosomal dominantly inherited auto-inflammatory conditions comprising of Familial-Cold Auto-inflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), Neonatal-Onset Multisystem Inflammatory Disease (NOMID) or also known as Chronic Infantile Neurologic Cutaneous Articular Syndrome (CINCA), which are caused by the CIAS1 gene mutation and characterized by recurrent symptoms (urticaria-like skin lesions, fever chills, arthralgia, profuse sweating, sensorineural hearing/vision loss, and increased inflammation markers the blood). Approximately 300 people in the United States are affected by CAPS. [1, 4, 5]
Familial Cold Autoinflammatory Syndrome (FCAS):	The mildest form of CAPS, is characterized by cold-induced, daylong episodes of fever associated with rash, arthralgia, headaches and less frequently conjunctivitis, but without other signs of CNS inflammation. Symptoms usually begin during the first 6 months of life and are predominantly triggered by cold exposure. Duration of episodes usually is less than 24 hours. [5]
Muckle-Wells Syndrome (MWS):	A subtype of CAPS, which is characterized by episodic attacks of inflammation associated with a generalized urticaria-like rash, fever, malaise, arthralgia, and progressive hearing loss. Duration of symptoms usually lasts from 24-48 hours. [5]

4 . References

1. Ilaris Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. September 2020.
2. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. Arthritis Rheumatol. 2022;74(4):553-569.
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5. Aksentijevich I, Putnam CD, Remmers EF, et al. Clinical continuum of cryopyrinopathies: novel CIAS1 mutations in North-American patients and a new cryopyrin model. Arthritis Rheum. 2007;56(4):1273-85.

5 . Revision History

Date	Notes
8/1/2023	2023 UM Annual Review. Removal of "Other medical specialist" r equirement. Removed Ilaris 180mg as it is discontinued.

Ilumya (tildrakizumab-asmn)

Prior Authorization Guideline

Guideline ID	GL-127355
Guideline Name	Ilumya (tildrakizumab-asmn)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	5/17/2018
P&T Revision Date:	11/14/2019 ; 07/15/2020 ; 09/16/2020 ; 07/21/2021 ; 07/20/2022 ; 10/19/2022 ; 12/14/2022 ; 7/19/2023

1 . Indications

Drug Name: Ilumya (tildrakizumab-asmn)
Plaque Psoriasis Indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

2 . Criteria

Product Name: Ilumya	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate-to-severe plaque psoriasis

AND

2 - One of the following [2]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - One of the following:

5.1 Both of the following:

5.1.1 Trial and failure, contraindication, or intolerance to THREE of the following:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- One formulary adalimumab product
- Skyrizi (risankizumab)
- One formulary ustekinumab product

- Tremfya (guselkumab)

AND

5.1.2 Trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

OR

5.2 For continuation of prior Ilumya therapy, defined as no more than a 45-day gap in therapy

Product Name: Ilumya	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1-3]:

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

3 . References

1. Ilumya prescribing information. Merck & Co., Inc. Whitehouse Station, NJ. July 2020.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
3. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

4 . Revision History

Date	Notes
7/4/2023	Addition of Cyltezo, Hyrimoz, and brand Adalimumab-adaz as preferred step options; Annual review - no criteria changes

Imbruvica (ibrutinib)

Prior Authorization Guideline

Guideline ID	GL-116536
Guideline Name	Imbruvica (ibrutinib)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Imbruvica	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming one of the following:

1.1 One of the following diagnoses:

- Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)
- Waldenstrom's Macroglobulinemia (WM) or Waldenstrom's Macroglobulinemia/lymphoplasmacytic lymphoma

OR

1.2 Both of the following:

- Diagnosis of Mantle Cell Lymphoma (MCL)
- Patient is relapsed or refractory to at least one NCCN preferred therapy (e.g., RDHA, RCHOP, HyperCVAD, bendamustine+rituximab) or other NCCN recommended first line treatment of MCL

OR

1.3 Both of the following:

- Diagnosis of Marginal Zone Lymphoma (MZL)
- Patient has received at least one prior anti-CD20- based therapy (e.g., rituximab)

AND

2 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hematologist

Product Name: Imbruvica	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/24/2022	2023 New Implementation

Imiquimod

Prior Authorization Guideline

Guideline ID	GL-116552
Guideline Name	Imiquimod
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Imiquimod	
Diagnosis	Actinic keratosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of clinically typical (nonhyperkeratotic, nonhypertrophic, visible or palpable) actinic keratosis

AND

2 - Disease involves the face or scalp

AND

3 - Patient is immunocompetent

Product Name: Imiquimod	
Diagnosis	Genital and perianal warts
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of external genital and perianal warts (condyloma acuminata)

Product Name: Imiquimod	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/5/2022	2023 New Implementation

Immune Globulins - PA, NF

Prior Authorization Guideline

Guideline ID	GL-121785
Guideline Name	Immune Globulins - PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	6/1/2024
P&T Approval Date:	9/5/2000
P&T Revision Date:	07/17/2019 ; 09/18/2019 ; 08/15/2019 ; 10/16/2019 ; 11/14/2019 ; 12/18/2019 ; 04/15/2020 ; 05/14/2020 ; 04/21/2021 ; 09/15/2021 ; 12/15/2021 ; 01/19/2022 ; 02/17/2022 ; 04/20/2022 ; 04/19/2023 ; 04/19/2023 ; 12/13/2023 ; 02/15/2024 ; 03/20/2024 ; 04/17/2024 ; 5/16/2024

1 . Indications

Drug Name: Bivigam and Octagam 5% (immune globulin [Human])
Primary Immunodeficiency Disorders Indicated for the treatment of primary immunodeficiency disorders associated with defects in humoral immunity. These include, but are not limited to: congenital agammaglobulinemia, X-linked agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.
Drug Name: Flebogamma 5% (immune globulin [Human])
Primary Immunodeficiency Disorders Indicated in adults and pediatric patients 2 years of age and older for the treatment of primary immunodeficiency (PI), including the humoral immune defects in common variable immunodeficiency, x-linked agammaglobulinemia, severe combined immunodeficiency, and Wiskott-Aldrich syndrome.
Drug Name: Flebogamma 10% (immune globulin [Human])
Primary Immunodeficiency Disorders Indicated as replacement therapy in primary immunodeficiency (PI) including the humoral immune defects in common variable immunodeficiency, xlinked agammaglobulinemia, severe combined immunodeficiency, and Wiskott-Aldrich syndrome.

Chronic Primary Immune Thrombocytopenia (ITP) Indicated for the treatment of patients 2 years of age and older with chronic primary ITP to raise platelet count.

Drug Name: Gamastan (immune globulin [Human])

Measles (Rubeola) Indicated to prevent or modify measles in a susceptible person exposed fewer than 6 days previously. A susceptible person is one who has not been vaccinated and has not had measles previously. Gamastan may be especially indicated for susceptible household contacts of measles patients, particularly contacts under 1 year of age, for whom the risk of complications is highest. Gamastan is also indicated for pregnant women without evidence of immunity. Gamastan and measles vaccine should not be given at the same time. If a child is older than 12 months and has received Gamastan, he should be given measles vaccine about 5 months later when the measles antibody titer will have disappeared. If a susceptible child exposed to measles is immunocompromised, give Gamastan immediately.

Rubella Indicated to modify rubella in exposed women who will not consider a therapeutic abortion. Some studies suggest that the use of Gamastan in exposed, susceptible women can lessen the likelihood of infection and fetal damage; therefore, Gamastan may benefit those women who will not consider a therapeutic abortion. Do not give Gamastan for routine prophylaxis of rubella in early pregnancy to an unexposed woman.

Hepatitis A Indicated for prophylaxis following exposure to hepatitis A. The prophylactic value of Gamastan is greatest when given before or soon after exposure to hepatitis A. Gamastan is not indicated in persons with clinical manifestations of hepatitis A or in those exposed more than 2 weeks previously.

Varicella Indicated to modify varicella. Passive immunization against varicella in immunosuppressed patients is best accomplished by use of Varicella Zoster Immune globulin (Human) [VZIG]. If VZIG is unavailable, Gamastan, promptly given, may also modify varicella.

Drug Name: Privigen (immune globulin [Human])

Chronic Immune Thrombocytopenic Purpura (ITP) Indicated for the treatment of patients age 15 years and older with chronic ITP to raise platelet counts.

Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI). This includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Indicated for the treatment of adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment. Limitation of Use: Privigen maintenance therapy in CIDP has not been studied for periods longer than 6 months. After responding during an initial treatment period, not all patients require indefinite maintenance therapy with Privigen in order to remain free of CIDP symptoms. Individualize the duration of any treatment beyond 6 months based upon the patient's response and demonstrated need for continued therapy.

Drug Name: Gammagard S/D (immune globulin [Human])

Kawasaki Disease Indicated for the prevention of coronary artery aneurysms associated with Kawasaki syndrome in pediatric patients.

B-cell Chronic Lymphocytic Leukemia (CLL) Indicated for prevention of bacterial infections in hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell Chronic Lymphocytic Leukemia (CLL).

Idiopathic Thrombocytopenic Purpura (ITP) Indicated for the treatment of adult chronic idiopathic thrombocytopenic purpura to increase platelet count and to prevent and/or to control bleeding.

Primary Immunodeficiency Disorders Indicated for the treatment of primary immunodeficiency (PI) associated with defects in humoral immunity, in adults and children two years and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Drug Name: Gammaked and Gamunex-C (immune globulin [Human])

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Indicated for the treatment of CIDP in adults to improve neuromuscular disability and impairment and for maintenance therapy to prevent relapse.

Idiopathic Thrombocytopenic Purpura (ITP) Indicated for the treatment of adults and children with idiopathic thrombocytopenic purpura to raise platelet counts to prevent bleeding or to allow a patient with ITP to undergo surgery.

Primary Immunodeficiency Disorders Indicated for treatment of primary humoral immunodeficiency in patients 2 years of age and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Drug Name: Immune globulin products (IVIG)

Off Label Uses: Bone Marrow Transplant (BMT) [6, 21-24] Has been used to decrease the incidence of infections and graft versus host disease (GVHD) in patients 20 years of age and older who underwent bone marrow transplantation.

Dermatomyositis [6, 25-29] In patients with treatment-resistant dermatomyositis, IVIG therapy resulted in improvements in muscle strength and neuromuscular symptoms.

Multifocal Motor Neuropathy (MMN) [6, 30, 34] In placebo-controlled trials, IVIG has been shown to improve strength and reduce disability and conduction block in patients with MMN.

Pediatric HIV [6, 35-37, 75] Used to decrease the frequency of serious and minor bacterial infections; the frequency of hospitalization; and to increase the time free of serious bacterial infections in patients with HIV.

Guillain-Barre Syndrome [6, 38-40] Considered to be equally effective as plasma exchange for the treatment of Guillain-Barre Syndrome.

Lambert-Eaton Myasthenic Syndrome [6, 41] Shown to produce short-term improvement in strength in patients with Lambert-Eaton Myasthenic Syndrome.

Myasthenia Gravis [6, 72, 74] A clinical study comparing IVIG with plasma exchange did not show a significant difference between the two treatments in patients with myasthenia gravis

exacerbation. Several open studies support beneficial effects of IVIG in treating myasthenia gravis.

Relapsing Remitting Multiple Sclerosis [6, 50, 52] Published studies indicate that IVIG may reduce the frequency of acute exacerbations and provide symptomatic relief in patients with relapsing-remitting forms of multiple sclerosis.

Stiff-Person Syndrome [6, 83, 84] The efficacy of IVIG for the treatment of stiff-person syndrome was demonstrated in a randomized, double-blind, placebo-controlled, crossover trial.

Polymyositis [6, 64] Found to be effective in reversing chronic polymyositis previously unresponsive to immunosuppressive therapy.

Drug Name: Gammagard liquid (immune globulin [Human])

Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age or older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Multifocal Motor Neuropathy (MMN) Indicated as a maintenance therapy to improve muscle strength and disability in adult patients with Multifocal Motor Neuropathy (MMN).

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Indicated as a therapy to improve neuromuscular disability and impairment in adult patients with Chronic Inflammatory Demyelinating Polyneuropathy (CIDP). Limitation of Use: Gammagard Liquid has not been studied in immunoglobulin-naive patients with CIDP. Gammagard Liquid maintenance therapy in CIDP has not been studied for periods longer than 6 months. After responding during an initial treatment period, not all patients require indefinite maintenance therapy with Gammagard Liquid in order to remain free of CIDP symptoms. Individualize the duration of any treatment beyond 6 months based upon the patient's response and demonstrated need for continued therapy.

Drug Name: Gammaplex (immune globulin [Human])

Primary Immunodeficiency Disorders Indicated for replacement therapy in primary humoral immunodeficiency (PI) in adults and pediatric patients two years of age and older. This includes, but is not limited to, the humoral immune defect in common variable immunodeficiency, X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Chronic Immune Thrombocytopenic Purpura (ITP) Indicated for the treatment of adults with chronic immune thrombocytopenic purpura (ITP) to raise platelet counts.

Drug Name: Octagam 10% (immune globulin [Human])

Chronic Immune Thrombocytopenic Purpura Indicated in chronic immune thrombocytopenic purpura to rapidly raise platelet counts to control or prevent bleeding in adults.

Dermatomyositis Indicated for the treatment of dermatomyositis in adults.

Drug Name: Octagam 5% (immune globulin [Human])
Primary Immunodeficiency Disorders Indicated for the treatment of primary immunodeficiency disorders associated with defects in humoral immunity. These include, but are not limited to: congenital agammaglobulinemia, X-linked agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.
Drug Name: Cytogam (human cytomegalovirus immune globulin liquid)
Cytomegalovirus Indicated for the prophylaxis of cytomegalovirus disease associated with transplantation of kidney, lung, liver, pancreas and heart. In transplants of these organs other than kidney from CMV seropositive donors into seronegative recipients, prophylactic CMV-IGIV should be considered in combination with ganciclovir.
Drug Name: Varizig (varicella zoster immune globulin [Human] solution)
Post-exposure prophylaxis of varicella Indicated for post-exposure prophylaxis of varicella in high risk individuals. High risk groups include: immunocompromised children and adults, newborns of mothers with varicella shortly before or after delivery, premature infants, neonates and infants less than one year of age, adults without evidence of immunity, pregnant women. Limitations of Use: There is no convincing evidence that Varizig reduces the incidence of chickenpox infection after exposure to VZV. There is no convincing evidence that established infections with VZV can be modified by Varizig administration. There is no indication for the prophylactic use of Varizig in immunodeficient children or adults when there is a past history of varicella, unless the patient is undergoing bone marrow transplantation.
Drug Name: Hizentra (immune globulin [Human] liquid)
Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older. This includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies. **Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)** Indicated for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy to prevent relapse of neuromuscular disability and impairment. Limitations of Use: Hizentra maintenance therapy in CIDP has been systematically studied for 6 months and for a further 12 months in a follow-up study. Maintenance therapy beyond these periods should be individualized based upon the patient's response and need for continued therapy.
Drug Name: Panzyga (immune globulin intravenous [Human] - ifas)
Primary Immunodeficiency Disorders Indicated for treatment of primary humoral immunodeficiency (PI) in patients 2 years of age and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies. **Chronic Immune Thrombocytopenia (ITP)** Indicated for the treatment of adult patients with ITP to raise platelet counts to control or prevent bleeding. **Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)** Indicated for the treatment of

adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment.
Drug Name: Cuvitru (immune globulin [Human])
Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age and older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.
Drug Name: Cutaquig (Immune globulin subcutaneous [Human] - hipp)
Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.
Drug Name: Xembify (immune globulin subcutaneous, human - klhw)
Primary Immunodeficiency Disorders Indicated for treatment of primary humoral immunodeficiency (PI) in patients 2 years of age and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.
Drug Name: Asceniv (immune globulin intravenous, human - slra)
Primary Immunodeficiency Disorders Indicated for the treatment of primary humoral immunodeficiency (PI) in adults and adolescents (12 to 17 years of age). PI includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies (SCID).
Drug Name: HyQvia (immune globulin with recombinant human hyaluronidase) for subcutaneous administration
Primary Immunodeficiency Indicated for the treatment of Primary Immunodeficiency (PI) in adults and pediatric patients two years of age and older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies. **Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)** Indicated for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy to prevent relapse of neuromuscular disability and impairment in adults.
Drug Name: Alyglo (immune globulin intravenous, human-stwk)
Primary Immunodeficiency Disorders Indicated for the treatment of primary humoral immunodeficiency (PI) in adults. This includes, but is not limited to, the humoral immune defect

in congenital agammaglobulinemia, common variable immunodeficiency (CVID), X- linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiency (SCID).

2 . Criteria

Product Name: Intravenous or subcutaneous immune globulins (IVIG or SCIG)	
Diagnosis	Primary Immunodeficiency Syndrome
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For patients with a primary immunodeficiency syndrome [1, 3, 5, 6, 57, 61, 65-71, I, J]

AND

2 - Clinically significant functional deficiency of humoral immunity as evidenced by one of the following: [73]

2.1 Documented failure to produce antibodies to specific antigens

OR

2.2 History of significant recurrent infections

AND

3 - One of the following:

3.1 Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo, Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

OR

3.2 Trial and failure, contraindication, or intolerance to two of the following (applies to Cutaquig only):

- Cuvitru
- Hizentra
- Xembify

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Asceniv, Cutaquig, Panzyga	
Diagnosis	Primary Immunodeficiency Syndrome
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - For patients with a primary immunodeficiency syndrome [1, 3, 5, 6, 57, 61, 65-71, I, J]

AND

2 - Clinically significant functional deficiency of humoral immunity as evidenced by one of the following: [73]

2.1 Documented failure to produce antibodies to specific antigens

OR

2.2 History of significant recurrent infections

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo, Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following (applies to Cutaquig only):

- Cuvitru
- Hizentra
- Xembify

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: HyQvia	
Diagnosis	Primary Immunodeficiency Syndrome
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For patients with a primary immunodeficiency syndrome

AND

2 - Patient is 2 years of age or older

AND

3 - Clinically significant functional deficiency of humoral immunity as evidenced by one of the following: [73]

3.1 Documented failure to produce antibodies to specific antigens

OR

3.2 History of significant recurrent infections

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulins (IVIG)	
Diagnosis	Idiopathic Thrombocytopenic Purpura (ITP)
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of idiopathic thrombocytopenic purpura (ITP) [3, 5, 62, 68-70, 88]

AND

2 - Documented platelet count of less than 50 x 10^9 / L [85]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo, Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Alyglo, Asceniv, Panzyga	
Diagnosis	Idiopathic Thrombocytopenic Purpura (ITP)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of idiopathic thrombocytopenic purpura (ITP) [3, 5, 62, 68-70, 88]

AND

2 - Documented platelet count of less than 50 x 10^9 / L [85]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulins (IVIG)	
Diagnosis	Kawasaki Disease (KD) [5, 7-9]
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Kawasaki Disease [5]

AND

2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo, Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Alyglo, Asceniv, Panzyga	
Diagnosis	Kawasaki Disease (KD) [5, 7-9]
Approval Length	1 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Kawasaki Disease [5]

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulins (IVIG)	
Diagnosis	B-cell Chronic Lymphocytic Leukemia (CLL) [5, 10-14]
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of B-cell chronic lymphocytic leukemia (CLL) [5]

AND

2 - One of the following:

2.1 Documented hypogammaglobulinemia (IgG less than 500 mg/dL) [13, 14, 78, B]

OR

2.2 History of bacterial infection(s) associated with B-cell CLL [13-15, 78, A]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo, Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Alyglo, Asceniv, Panzyga	
Diagnosis	B-cell Chronic Lymphocytic Leukemia (CLL) [5, 10-14]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of B-cell chronic lymphocytic leukemia (CLL) [5]

AND

2 - One of the following:

2.1 Documented hypogammaglobulinemia (IgG less than 500 mg/dL) [13, 14, 78, B]

OR

2.2 History of bacterial infection(s) associated with B-cell CLL [13-15, 78, A]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG), Hizentra	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [15-20, 55, 58, 62, C, H]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) as confirmed by all of the following [77, C]:

1.1 Progressive symptoms present for at least 2 months

AND

1.2 Symptomatic polyradiculoneuropathy as indicated by one of the following:

1.2.1 Progressive or relapsing motor impairment of more than one limb

OR

1.2.2 Progressive or relapsing sensory impairment of more than one limb

AND

1.3 Electrophysiologic findings when three of the following four criteria are present:

- Partial conduction block of 1 or more motor nerve
- Reduced conduction velocity of 2 or more motor nerves
- Prolonged distal latency of 2 or more motor nerves
- Prolonged F-wave latencies of 2 or more motor nerves or the absence of F waves

AND

2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo, Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG), Hizentra	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [15-20, 55, 58, 62, C, H]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as measured by an objective scale (e.g., Rankin, Modified Rankin, Medical Research Council [MRC] scale) [77, H, P]

AND

2 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect [P]

AND

3- Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo, Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Alyglo, Asceniv, Panzyga	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [15-20, 55, 58, 62, C, H]
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) as confirmed by all of the following [77, C]:

1.1 Progressive symptoms present for at least 2 months

AND

1.2 Symptomatic polyradiculoneuropathy as indicated by one of the following:

1.2.1 Progressive or relapsing motor impairment of more than one limb

OR

1.2.2 Progressive or relapsing sensory impairment of more than one limb

AND

1.3 Electrophysiologic findings when three of the following four criteria are present:

- Partial conduction block of 1 or more motor nerve

- Reduced conduction velocity of 2 or more motor nerves
- Prolonged distal latency of 2 or more motor nerves
- Prolonged F-wave latencies of 2 or more motor nerves or the absence of F waves

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

3- Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Gamastan	
Diagnosis	Hepatitis A
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For prophylaxis of Hepatitis A before or soon after exposure [57, 93]

AND

2 - Patient does not have clinical manifestations of hepatitis A [57, 93]

AND

3 - Patient does not have exposure to hepatitis A for more than 2 weeks previously [57, 93]

Product Name: Gamastan	
Diagnosis	Measles (Rubeola)

Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For use in susceptible individuals exposed to measles fewer than 6 days previously [57, 93]

AND

2 - Patient is not receiving measles vaccine at the same time [57, 93]

Product Name: Gamastan	
Diagnosis	Varicella
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For passive immunization against varicella [57, 93]

AND

2 - Patient is immunosuppressed [57, 93]

AND

3 - Varicella Zoster Immune Globulin (Human) vaccine is not available

Product Name: Gamastan	
Diagnosis	Rubella
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For pregnant women who are exposed or susceptible to Rubella [57, 93]

AND

2 - Patient will not consider a therapeutic abortion [57, 93]

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Bone Marrow Transplantation (off-label) [21-24]
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Confirmed allogeneic bone marrow transplant within the last 100 days [21-23, D]

AND

2 - Documented severe hypogammaglobulinemia (IgG less than 400 mg/dL) [21, D]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo, Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Alyglo, Asceniv, Panzyga	
Diagnosis	Bone Marrow Transplantation (off-label) [21-24]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Confirmed allogeneic bone marrow transplant within the last 100 days [21-23, D]

AND

2 - Documented severe hypogammaglobulinemia (IgG less than 400 mg/dL) [21, D]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist,neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	HIV (off-label) [35-37, 75, 79, 80]
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HIV disease [35, 75, K]

AND

2 - Patient is less than or equal to 13 years of age [75, 80]

AND

3 - One of the following:

3.1 Documented hypogammaglobulinemia (IgG less than 400 mg/dL) [75, L]

OR

3.2 Functional antibody deficiency as demonstrated by one of the following: [79]

- Poor specific antibody titers
- Recurrent bacterial infections

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo, Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist,neurologist)

Product Name: Alyglo, Asceniv, Panzyga	
Diagnosis	HIV (off-label) [35-37, 75, 79, 80]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of HIV disease [35, 75, K]

AND

2 - Patient is less than or equal to 13 years of age [75, 80]

AND

3 - One of the following:

3.1 Documented hypogammaglobulinemia (IgG less than 400 mg/dL) [75, L]

OR

3.2 Functional antibody deficiency as demonstrated by one of the following: [79]

- Poor specific antibody titers
- Recurrent bacterial infections

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Multifocal Motor Neuropathy (off-label) [30-34]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multifocal motor neuropathy (MMN) as confirmed by all of the following [76, 86, 87, N]:

1.1 Weakness with slowly progressive or stepwise progressive course over at least one month

AND

1.2 Asymmetric involvement of two or more nerves

AND

1.3 Absence of both of the following:

1.3.1 Motor neuron signs

AND

1.3.2 Bulbar signs

AND

2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo, Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Multifocal Motor Neuropathy (off-label) [30-34]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale] [76, 87]

AND

2 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

3- Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo, Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Alyglo, Asceniv, Panzyga	
Diagnosis	Multifocal Motor Neuropathy (off-label) [30-34]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of multifocal motor neuropathy (MMN) as confirmed by all of the following [76, 86, 87, N]:

1.1 Weakness with slowly progressive or stepwise progressive course over at least one month

AND

1.2 Asymmetric involvement of two or more nerves

AND

1.3 Absence of both of the following:

1.3.1 Motor neuron signs

AND

1.3.2 Bulbar signs

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Relapsing-Remitting Multiple Sclerosis (off-label) [50-52]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsing remitting multiple sclerosis (RRMS)) [6, 50, 52, 75, G]

AND

2 - Documentation of an MS exacerbation or progression (worsening) of the patient's clinical status from the visit prior to the one prompting the decision to initiate immune globulin therapy [6, 50, 52, 75, G, M, O]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following agents: [52, G, M, O]

- Aubagio (teriflunomide)*
- Avonex (interferon beta-1a)*
- Betaseron (interferon beta-1b)*
- Copaxone/Glatopa (glatiramer acetate)*
- Extavia (interferon beta-1b)*
- Gilenya (Fingolimod)*
- Lemtrada (alemtuzumab)*
- Plegridy (peginterferon beta-1a)*
- Rebif (interferon beta-1a)*
- Tecfidera (dimethyl fumarate)*
- Tysabri (natalizumab)*

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo, Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Notes	*This agent may require prior authorization.

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Relapsing-Remitting Multiple Sclerosis (off-label) [50-52]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - The prescriber maintains and provides chart documentation of the patient's evaluation, including both of the following [6, 50, 52, 75, O]:

1.1 Findings of interval examination including neurological deficits incurred

AND

1.2 Assessment of disability (e.g., Expanded Disability Status Score [EDSS], Functional Systems Score [FSS], Multiple Sclerosis Functional Composie [MSFC], Disease Steps [DS])

AND

2 - Stable or improved disability score (e.g., EDSS, FSS, MSFC, DS) [6, 50, 52, 75]

AND

3 - Documentation of decreased number of relapses since starting immune globulin therapy [6, 50, 52, 75]

AND

4 - Diagnosis continues to be the relapsing-remitting form of MS (RRMS)

AND

5 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

6- Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo, Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

7- Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Alyglo, Asceniv, Panzyga	
Diagnosis	Relapsing-Remitting Multiple Sclerosis (off-label) [50-52]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of relapsing remitting multiple sclerosis (RRMS)) [6, 50, 52, 75, G]

AND

2 - Documentation of an MS exacerbation or progression (worsening) of the patient's clinical status from the visit prior to the one prompting the decision to initiate immune globulin therapy [6, 50, 52, 75, G, M, O]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following agents: [52, G, M, O]

- Aubagio (teriflunomide)*
- Avonex (interferon beta-1a)*
- Betaseron (interferon beta-1b)*
- Copaxone/Glatopa (glatiramer acetate)*
- Generic dimethyl fumarate
- Gilenya (Fingolimod)*
- Lemtrada (alemtuzumab)*
- Tysabri (natalizumab)*

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Notes	*This agent may require prior authorization.

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Myasthenia Gravis Exacerbation (off-label) [45-49]
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis [45, 72, 74, F, R]

AND

2 - Evidence of myasthenic exacerbation, defined by one of the following symptoms in the last month: [45, 72, 74, F, R]

2.1 Difficulty swallowing

OR

2.2 Acute respiratory failure

OR

2.3 Major functional disability responsible for the discontinuation of physical activity

AND

3 - Concomitant immunomodulator therapy (e.g., azathioprine, mycophenolate mofetil, cyclosporine), unless contraindicated, will be used for long-term management of myasthenia gravis [45, 72, 74, F, R]

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo, Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

5- Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Alyglo, Asceniv, Panzyga	
Diagnosis	Myasthenia Gravis Exacerbation (off-label) [45-49]
Approval Length	3 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis [45, 72, 74, F, R]

AND

2 - Evidence of myasthenic exacerbation, defined by one of the following symptoms in the last month: [45, 72, 74, F, R]

2.1 Difficulty swallowing

OR

2.2 Acute respiratory failure

OR

2.3 Major functional disability responsible for the discontinuation of physical activity

AND

3 - Concomitant immunomodulator therapy (e.g., azathioprine, mycophenolate mofetil, cyclosporine), unless contraindicated, will be used for long-term management of myasthenia gravis [45, 72, 74, F, R]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist,neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Stiff Person Syndrome (off-label) [53]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of stiff-person syndrome [55, 83, 84]

AND

2 - Trial and failure, contraindication or intolerance to GABAergic medication (e.g., baclofen, benzodiazepines) [55, 83, 84]

AND

3 - Trial and failure, contraindication or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids) [55, 83, 84]

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo, Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Stiff Person Syndrome (off-label) [53]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo, Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

3- Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Alyglo, Asceniv, Panzyga	
Diagnosis	Stiff Person Syndrome (off-label) [53]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of stiff-person syndrome [55, 83, 84]

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication or intolerance to GABAergic medication (e.g., baclofen, benzodiazepines) [55, 83, 84]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids) [55, 83, 84]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Dermatomyositis and Polymyositis (off-label) [6, 25-29, 64]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses [29]:

- Dermatomyositis
- Polymyositis

AND

2 - Trial and failure, contraindication, or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids, cyclophosphamide, methotrexate) [29, Q]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo, Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Dermatomyositis and Polymyositis (off-label) [6, 25-29, 64]

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

2- Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo, Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Alyglo, Asceniv, Panzyga	
Diagnosis	Dermatomyositis and Polymyositis (off-label) [6, 25-29, 64]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following diagnoses [29]:

- Dermatomyositis
- Polymyositis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids, cyclophosphamide, methotrexate) [29, Q]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Guillain-Barre Syndrome (off-label) [38-40]
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Guillain-Barre Syndrome

AND

2 - Patients with severe disease requiring aid to walk [40, E]

AND

3 - Onset of neuropathic symptoms within the last four weeks [40, E]

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo, Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Guillain-Barre Syndrome (off-label) [38-40]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

2- Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo, Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Alyglo, Asceniv, Panzyga	
Diagnosis	Guillain-Barre Syndrome (off-label) [38-40]
Approval Length	3 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Guillain-Barre Syndrome

AND

2 - Patients with severe disease requiring aid to walk [40, E]

AND

3 - Onset of neuropathic symptoms within the last four weeks [40, E]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist,neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Lambert-Eaton Myasthenic Syndrome (off-label) [41]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Lambert-Eaton Myasthenic Syndrome (LEMS) [41]

AND

2 - History of failure, contraindication, or intolerance to immunomodulator monotherapy (e.g., azathioprine, corticosteroids) [81, 82]

AND

3 - Concomitant immunomodulator therapy (eg, azathioprine, corticosteroids), unless contraindicated, will be used for long-term management of LEMS [81, 82]

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo, Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Lambert-Eaton Myasthenic Syndrome (off-label) [41]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

AND

2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo, Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

3 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist,neurologist)

Product Name: Alyglo, Asceniv, Panzyga	
Diagnosis	Lambert-Eaton Myasthenic Syndrome (off-label) [41]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Lambert-Eaton Myasthenic Syndrome (LEMS) [41]

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming history of failure, contraindication, or intolerance to immunomodulator monotherapy (e.g., azathioprine, corticosteroids) [81, 82]

AND

3 - Concomitant immunomodulator therapy (e.g., azathioprine, corticosteroids), unless contraindicated, will be used for long-term management of LEMS [81, 82]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C

- Privigen

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Cytogam	
Diagnosis	Prophylaxis for CMV Infection
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Patient requires prophylaxis for CMV infection following kidney transplantation

AND

1.1.2 Patient is CMV- seronegative and organ donor is CMV-seropositive

OR

1.2 All of the following:

1.2.1 Patient requires prophylaxis for CMV infection following liver, heart, lung, or pancreas transplantation

AND

1.2.2 Patient is CMV- seronegative and organ donor is CMV-seropositive

AND

1.2.3 Used in combination with ganciclovir or valganciclovir unless the patient has a hypersensitivity to, is intolerant of, or therapy is deemed inappropriate

Product Name: Varizig	
Diagnosis	Varicella
Approval Length	1 Dose
Guideline Type	Prior Authorization

Approval Criteria

1 - For passive immunization or post exposure-prophylaxis of varicella

AND

2 - Patient is considered a high risk individual (e.g., immune compromised, pregnant woman, newborn of mother with varicella, premature infant, and infant less than 1 year old)

AND

3 - Prescribed immune globulin is being used intramuscularly

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Pediatric Acute-Onset Neuropsychiatric Syndrome/Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANS/PANDAS) (off-label)
Approval Length	3 Month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Pediatric Acute-onset Neuropsychiatric Syndrome (PANS)
- Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS)

AND

2 - Trial and failure of at least two clinically appropriate trials of less intensive treatments which were not effective, not tolerated, or did not result in sustained improvement. Trials may be done concurrently:

- Short course antibiotic therapy
- Corticosteroids (e.g., prednisone, dexamethasone, methylprednisolone)
- NSAIDs (e.g., Ibuprofen, naproxen, celecoxib)
- SSRI therapy
- Behavior therapy

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Alyglo, Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

AND

4 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Pediatric Acute-Onset Neuropsychiatric Syndrome/Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANS/PANDAS) (off-label)
Approval Length	12 Month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 – Documentation of reevaluation at 3 months by the specialist

AND

2 - Clinical testing with a validated instrument (must be performed pretreatment and posttreatment to demonstrate clinically meaningful improvement)

3 . Endnotes

A. Guidelines from the British Committee for Standards in Haematology [11] and the National Comprehensive Cancer Network [16] state that IVIG therapy may be beneficial in patients with recurrent infections. Clinical studies show that IVIG reduces the number of bacterial infections, but not viral or fungal infections. [24]
B. Based on inclusion criteria from Molica et al. [14]
C. According to published data, there appears to be no difference in efficacy among IVIG, plasma exchange, and corticosteroids. [15, 17, 20]
D. A controlled trial indicated that treatment with IVIG beyond three months was associated with a delayed recovery of humoral immunity, and the rate of infections after two years of treatment was increased significantly in IVIG recipients. [25] Centers for Disease Control and Prevention, Infectious Disease Society of America, and American Society of Blood and Marrow Transplantation guidelines recommended routine IVIG use to prevent bacterial infections among BMT recipients with unrelated marrow grafts who experience severe hypogammaglobulinemia (e.g., IgG < 400 mg/dl) within the first 100 days after transplant. [21]
E. The American Academy of Neurology recommends that IVIG is for patients with GBS who require aid to walk within 2 weeks from the onset of neuropathic symptoms. [40]
F. The effectiveness of IVIG for moderate-to-severe but stable myasthenia gravis, or for moderate exacerbations of myasthenia gravis have not been demonstrated in adequately controlled trials. [48] IVIG may be as effective as plasma exchange for patients with acute exacerbations of myasthenia gravis. [45] The indications for the use of IVIG are the same as those for plasma exchange: to produce rapid improvement to help the patient through a difficult period of myasthenic weakness. It has the advantages of not requiring special equipment or large-bore vascular access. [59] The usual dose of immune globulin is 400 mg per kilogram per day for five successive days. The improvement rate after immune globulin treatment, calculated from eight published reports, was 73 percent, but this figure is likely to be biased by selective reporting of positive uncontrolled trials. In patients who respond, improvement begins within four to five days. The effect is temporary but may be sustained for weeks to months, allowing intermittent long-term therapy in patients with otherwise refractory disease.
G. Guidelines from the American Academy of Neurology [42] state that interferon Beta or glatirimer are appropriate treatments for patients who have relapsing-remitting multiple sclerosis. The guidelines state that it is only possible that IVIG reduces the attack rate in RRMS, and that current evidence suggests IVIG is of little benefit with regard to slowing disease progression.
H. Treatment for CIDP includes corticosteroids such as prednisone, which may be prescribed alone or in combination with immunosuppressant drugs. [58] Plasmapheresis and intravenous immunoglobulin (IVIG) therapy are effective. IVIG may be used even as a first-line therapy. Physiotherapy may improve muscle strength, function and mobility, and minimize the shrinkage of muscles and tendons and distortions of the joints.
I. Subcutaneous formulations of immune globulin are available for the treatment of patients with primary immune deficiency. Subcutaneous infusions may be an alternative for patients with adverse effects to intravenous infusions of immune globulin or with poor venous access. Other advantages include decreased cost of administration, independence

from scheduled home nursing visits, better maintenance of intravenous immune globulin trough levels, and a serum IgG profile (smaller variation in the peak and trough IgG concentrations compared to intravenous administration) that is similar to that in a normal population. Disadvantages include more frequent infusions and local reactions. [6]

J. There are good data to show that all immune globulins (IVIG/SCIG) are effective for primary immunodeficiency. There are no data for SCIG for indications other than PI. Efficacy is a class effect for all immune globulins products. It is appropriate to combine all IVIG/SCIG products as they are used interchangeably for PI; can combine all IVIG for other indications. Gamastan S/D (IMIG) has unique indications and should be available on the formulary. [74]
K. IVIG has been used in children with symptomatic human immunodeficiency virus (HIV) infection who are immunosuppressed in association with acquired immunodeficiency syndrome (AIDS) or AIDS-related complex (ARC) in an attempt to control or prevent infections and improve immunologic parameters. Results of studies in adults and children with symptomatic HIV infection indicate that IVIG, used in dosages similar to those used for replacement therapy in patients with primary immunodeficiencies, reduces the incidence of recurrent bacterial infections and sepsis, including upper respiratory tract infections. [75]
L. The ACIP, American Academy of Pediatrics (AAP), Centers for Disease Control (CDC), National Institutes of Health (NIH), HIV Medicine Association of the Infectious Diseases Society of America (IDSA), Pediatric Infectious Diseases Society, and other experts state that HIV-infected infants and children who have hypogammaglobulinemia (IgG less than 400 mg/dL) should receive IVIG (400 mg/kg once every 2-4 weeks) to prevent serious bacterial infections. [75]
M. Per expert consultant regarding MS: IVIG is only used in acute, severe MS. IVIG is used for bad relapses of MS with significant neurological dysfunction when a patient is breaking through their regular maintenance medications. It takes about 3 months to see if there is improvement in MS and one cannot say a patient has failed a medication if they have a breakthrough episode of MS within this 3 month period [86].
N. Per expert consultant regarding multifocal motor neuropathy: the European Federation of Neurological Societies (EFNS) guidelines [88] as outlined on page 344 and in the table are fairly reasonable: 1. Weakness with slowly progressive or stepwise progressive course 2. Asymmetric involvement of two or more nerves 3. Absence of upper motor neuron signs and bulbar signs [87].
O. Per expert consultant regarding MS: there are no data to support the initial length of IVIG treatment in MS. I would suggest 3 months and then reevaluate. An appropriate length of time for reauthorization of IVIG is 12 months. Patients who receive IVIG for RRMS should be in acute exacerbation, should have tried steroids, have documentation of inability to tolerate other disease modifying drugs, as well as show progression of disease. IVIG should be used 2nd or 3rd line if other injectable disease modifying drugs are not tolerated. Guidelines do not support IVIG as first line treatment for MS [87].
P. Per expert consultant regarding CIDP: It is important to reevaluate a patient after initial treatment. Some patients may need changes in dosing intervals due to wearing off of a dose within 2-3 weeks. Treatment can be lifelong for some patient [87].
Q. Per expert consultant regarding dermatomyositis: It is reasonable to ask a patient to try steroids prior to treatment with IVIG. [87]
R. Per expert consultant regarding MG: IVIG should be used in patients with moderate to severe myasthenia gravis with acute exacerbation. Most MDs favor plasma exchange for maintenance therapy in MG patients. Myasthenic exacerbation = myasthenic crisis. [87]

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5 . Revision History

Date	Notes
5/2/2024	Added Alyglo as target to guideline. Background updates.

Increlex (mecasermin [rDNA origin])

Prior Authorization Guideline

Guideline ID	GL-116419
Guideline Name	Increlex (mecasermin [rDNA origin])
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	4/4/2006
P&T Revision Date:	11/14/2019 ; 11/12/2020 ; 11/18/2021 ; 11/17/2022

1 . Indications

Drug Name: Increlex (mecasermin [rDNA origin]) injection
Severe Primary IGF-1 deficiency (Primary IGFD) Indicated for the treatment of growth failure in pediatric patients 2 years of age and older with severe primary IGF-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH. Severe Primary IGFD is defined by: height standard deviation score less than or equal to -3.0, basal IGF-1 standard deviation score less than or equal to -3.0, and normal or elevated GH. Limitations of use: Increlex is not a substitute to GH for approved GH indications. Increlex is not indicated for use in patients with secondary forms of IGF-1 deficiency, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacological doses of anti-inflammatory corticosteroids.

2 . Criteria

Product Name: Increlex	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following: [A]

1.1 All of the following:

1.1.1 Diagnosis of severe primary IGF-1 deficiency [3]

AND

1.1.2 Height standard deviation score less than or equal to -3.0

AND

1.1.3 Basal IGF-1 standard deviation score less than or equal to -3.0

AND

1.1.4 Normal or elevated growth hormone

AND

1.1.5 Prescribed by or in consultation with a pediatric endocrinologist

OR

1.2 Both of the following:

1.2.1 Diagnosis of growth hormone (GH) gene deletion in patients who have developed neutralizing antibodies to GH

AND

1.2.2 Prescribed by or in consultation with a pediatric endocrinologist

Notes	NOTE: Documentation of previous height, current height and goal expec ted adult height will be required for renewal. Increlex is not a substitute for GH for approved GH indications.

Product Name: Increlex	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Growth increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [2, B]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height is not obtained
- Documentation of expected adult height goal

Notes	NOTE: Increlex is not a substitute for GH for approved GH indications.

3 . Endnotes

A. Growth Hormone Deficiency (GHD) and severe Primary IGF-1 Deficiency (IGFD) are two distinct hormone disorders. Patients with severe Primary IGFD are not GH deficient, and therefore, exogenous GH treatment cannot be expected to resolve the patient's growth deficiency. [1]
B. Typically near-adult height is defined as bone age of 16 years or more for males and 14 years or more for females and a growth rate less than 2 cm/year for 1 year. [2]

4 . References

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5 . Revision History

Date	Notes
11/2/2022	2022 Annual Review

Infliximab – PA, NF

Prior Authorization Guideline

Guideline ID	GL-115152
Guideline Name	Infliximab – PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	12/15/2009
P&T Revision Date:	07/15/2020 ; 08/13/2020 ; 12/16/2020 ; 05/20/2021 ; 08/19/2021 ; 02/17/2022 ; 08/18/2022 ; 10/19/2022

1 . Indications

Drug Name: Remicade (infliximab), Infliximab, Avsola (infliximab-axxq), Inflectra (infliximab-dyyb), Renflexis (Infliximab-abda)
Rheumatoid Arthritis (RA) Indicated in combination with methotrexate, for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis. **Psoriatic Arthritis (PsA)** Indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis. **Plaque Psoriasis (PsO)** Indicated for the treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate. Therapy should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician. **Ankylosing Spondylitis (AS)** Indicated for reducing signs and symptoms in patients with active ankylosing spondylitis. **Crohn's Disease (CD)** Indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have

had an inadequate response to conventional therapy. Also indicated for reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn's disease.

Pediatric Crohn's Disease Indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy.

Ulcerative Colitis (UC) Indicated for reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

Pediatric Ulcerative Colitis Indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

Off Label Uses: **Sarcoidosis** Has been used for the treatment of refractory sarcoidosis. [5-7]

2 . Criteria

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active RA

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

AND

4 - Used in combination with methotrexate

AND

5 - Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderately to severely active RA

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

AND

4 - Used in combination with methotrexate

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Psoriatic Arthritis (PsA)

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active PsA

AND

2 - One of the following [4]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

AND

4 - Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of active PsA

AND

2 - One of the following [4]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic severe (i.e., extensive and/or disabling) plaque psoriasis

AND

2 - One of the following [5]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [6]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

- anthralin
- coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to infliximab therapy as evidenced by ONE of the following [1, 5]

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of chronic severe (i.e., extensive and/or disabling) plaque psoriasis

AND

2 - One of the following [5]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [6]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [7]

AND

4 - Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following [1, 7]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [7]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola

• Inflectra	
Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Crohn's Disease (CD) or Fistulizing Crohn's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Moderately to severely active Crohn's disease
- Fistulizing Crohn's disease

AND

2 - One of the following [8, 9]:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CDAI) greater than 220

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies [8, 9]:

- 6-mercaptopurine
- Azathioprine

- Corticosteroids (e.g., prednisone)
- Methotrexate

AND

5 - Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Crohn's Disease (CD) or Fistulizing Crohn's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 8, 9]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Crohn's Disease (CD) or Fistulizing Crohn's Disease
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following diagnoses:

- Moderately to severely active Crohn's disease
- Fistulizing Crohn's disease

AND

2 - One of the following [8, 9]:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CDAI) greater than 220

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one of the following conventional therapies [8, 9]:

- 6-mercaptopurine
- Azathioprine
- Corticosteroids (e.g., prednisone)
- Methotrexate

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [10, 11]:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, ESR, CRP)
- Dependent on, or refractory to, corticosteroids

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies [10, 11]:

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND

5 - Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 10, 11]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [10, 11]:

- Greater than 6 stools per day

- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, ESR, CRP)
- Dependent on, or refractory to, corticosteroids

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one of the following conventional therapies [10, 11]:

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Sarcoidosis [Off-label] [12-15]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of sarcoidosis

AND

2 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Dermatologist
- Ophthalmologist

AND

3 - Trial and failure, contraindication, or intolerance to one corticosteroid (e.g., prednisone)

AND

4 - Trial and failure, contraindication, or intolerance to one immunosuppressant (e.g., methotrexate, cyclophosphamide, or azathioprine)

AND

5 - Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Sarcoidosis [Off-label] [12-15]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to infliximab therapy

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Sarcoidosis [Off-label] [12-15]
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of sarcoidosis

AND

2 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Dermatologist
- Ophthalmologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one corticosteroid (e.g., prednisone)

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one immunosuppressant (e.g., methotrexate, cyclophosphamide, or azathioprine)

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola

• Inflectra	
Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

3 . References

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14. Rossman M, Newman LS, Baughman RP, et al. A double-blinded, randomized, placebo-controlled trial of infliximab in subjects with active pulmonary sarcoidosis. Sarcoidosis Vasc Diffuse Lung Dis. 2006;23(3):201-8.
15. Per clinical consult with dermatologist. June 26, 2019.
16. Inflectra prescribing information. Hospira. Lake Forest, IL. March 2022.
17. Renflexis Prescribing Information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. January 2022.
18. Avsola Prescribing Information. Amgen Inc. Thousand Oaks, CA. September 2021.
19. Infliximab Prescribing Information. Janssen Biotech, Inc. Horsham, PA. October 2021.

4 . Revision History

Date	Notes
10/23/2022	Further clinical detail and criteria added

Injectable Iron Products

Prior Authorization Guideline

Guideline ID	GL-103641
Guideline Name	Injectable Iron Products
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2022
P&T Approval Date:	10/20/2021
P&T Revision Date:	3/16/2022

1 . Indications

Drug Name: Accrufer (ferric maltol)
Iron deficiency Indicated for the treatment of iron deficiency in adults
Drug Name: Feraheme (ferumoxytol injection)
Iron deficiency Indicated for the treatment of iron deficiency anemia (IDA) in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron or who have chronic kidney disease (CKD).
Drug Name: Injectafer (ferric carboxymaltose injection)
Iron deficiency Indicated for the treatment of iron deficiency anemia (IDA) in adult and pediatric patients 1 year of age and older who have either intolerance to oral iron or an unsatisfactory response to oral iron or adult patients who have non-dialysis dependent chronic kidney disease (CKD).
Drug Name: Monoferric (ferric derisomaltose injection)

Iron deficiency Indicated for the treatment of iron deficiency anemia (IDA) in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron or who have non-hemodialysis dependent chronic kidney disease (CKD).

2 . Criteria

Product Name: Accrufer, Feraheme, Injectafer, and Monoferric	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure of a minimum 30-day supply or intolerance to one of the following generics:

- ferrous sulfate
- ferrous gluconate
- ferrous fumarate

3 . References

1. Accrufer Prescribing Information. Shield Therapeutics Inc. October 2020.
2. Feraheme Prescribing Information. AMAG Pharmaceuticals, Inc. Waltham, MA. September 2020.
3. Injectafer Prescribing Information. American Regent, Inc. Shirley, NY. November 2021.
4. Monoferric Prescribing Information. Pharmacosmos Therapeutics, Inc. Morristown, NJ. September 2020.

4 . Revision History

Date	Notes
3/3/2022	Updated to add Feraheme, Injectafer, and Monoferric as targets

Intron A (interferon Alfa-2b)

Prior Authorization Guideline

Guideline ID	GL-116582
Guideline Name	Intron A (interferon Alfa-2b)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Intron A	
Diagnosis	Chronic Hepatitis B
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Chronic hepatitis B infection

AND

2 - Patient is without decompensated liver disease

AND

3 - Patient does not have autoimmune hepatitis

AND

4 - Patient is 18 years of age or older

AND

5 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hematologist
- Infectious disease specialist

Product Name: Intron A	
Diagnosis	Chronic Hepatitis C
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Chronic hepatitis C infection

AND

2 - Patient is without decompensated liver disease

AND

3 - Patient does not have autoimmune hepatitis

AND

4 - Patient is 18 years of age or older

AND

5 - Patient has not previously been treated with interferon

AND

6 - One of the following:

- Medication is prescribed for use with ribavirin
- Patient has intolerance or contraindication to ribavirin.

AND

7 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hematologist
- Infectious disease specialist

Product Name: Intron A	
Diagnosis	Metastatic Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic renal cell carcinoma (RCC)

AND

2 - Patient is without decompensated liver disease

AND

3 - Patient does not have autoimmune hepatitis

AND

4 - Patient is 18 years of age or older

AND

5 - Prescribed in combination with Avastin (bevacizumab)

AND

6 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hematologist
- Infectious disease specialist

Product Name: Intron A	
Diagnosis	AIDS-Related Kaposi Sarcoma (KS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of AIDS-related Kaposi sarcoma (KS)

AND

2 - Patient is without decompensated liver disease

AND

3 - Patient does not have autoimmune hepatitis

AND

4 - Patient is 18 years of age or older

AND

5 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hematologist
- Infectious disease specialist

Product Name: Intron A	
Diagnosis	Condylomata Acuminata (CA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of condylomata acuminata (CA) (genital or perianal)

AND

2 - Patient is without decompensated liver disease

AND

3 - Patient does not have autoimmune hepatitis

AND

4 - Patient is 18 years of age or older

AND

5 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hematologist
- Infectious disease specialist

Product Name: Intron A	
Diagnosis	Follicular Lymphoma (FL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of clinically aggressive follicular non-Hodgkin lymphoma

AND

2 - Patient is without decompensated liver disease

AND

3 - Patient does not have autoimmune hepatitis

AND

4 - Patient is 18 years of age or older

AND

5 - Prescribed in conjunction with anthracycline-containing combination chemotherapy

AND

6 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hematologist
- Infectious disease specialist

Product Name: Intron A	
Diagnosis	Hairy Cell Leukemia (HCL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hairy cell leukemia (HCL)

AND

2 - Patient is without decompensated liver disease

AND

3 - Patient does not have autoimmune hepatitis

AND

4 - Patient is 18 years of age or older

AND

5 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hematologist
- Infectious disease specialist

Product Name: Intron A	
Diagnosis	Malignant Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of malignant melanoma

AND

2 - Patient is without decompensated liver disease

AND

3 - Patient does not have autoimmune hepatitis

AND

4 - Patient is 18 years of age or older

AND

5 - Prescribed as adjuvant to surgical treatment who are free of disease but at high risk for systemic recurrence

AND

6 - Must be administered within 56 days of surgery.

AND

7 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hematologist
- Infectious disease specialist

Product Name: Intron A	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/27/2022	2023 New Implementation

Intron A (interferon Alfa-2b)

Prior Authorization Guideline

Guideline ID	GL-116570
Guideline Name	Intron A (interferon Alfa-2b)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Intron A	
Diagnosis	Chronic Hepatitis B
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Chronic hepatitis B infection

AND

2 - Patient is without decompensated liver disease

AND

3 - Patient does not have autoimmune hepatitis

AND

4 - Patient is 18 years of age or older

AND

5 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hematologist
- Infectious disease specialist

Product Name: Intron A	
Diagnosis	Chronic Hepatitis C
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Chronic hepatitis C infection

AND

2 - Patient is without decompensated liver disease

AND

3 - Patient does not have autoimmune hepatitis

AND

4 - Patient is 18 years of age or older

AND

5 - Patient has not previously been treated with interferon

AND

6 - One of the following:

- Medication is prescribed for use with ribavirin
- Patient has intolerance or contraindication to ribavirin.

AND

7 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hematologist
- Infectious disease specialist

Product Name: Intron A	
Diagnosis	Metastatic Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic renal cell carcinoma (RCC)

AND

2 - Patient is without decompensated liver disease

AND

3 - Patient does not have autoimmune hepatitis

AND

4 - Patient is 18 years of age or older

AND

5 - Prescribed in combination with Avastin (bevacizumab)

AND

6 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hematologist
- Infectious disease specialist

Product Name: Intron A	
Diagnosis	AIDS-Related Kaposi Sarcoma (KS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of AIDS-related Kaposi sarcoma (KS)

AND

2 - Patient is without decompensated liver disease

AND

3 - Patient does not have autoimmune hepatitis

AND

4 - Patient is 18 years of age or older

AND

5 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hematologist
- Infectious disease specialist

Product Name: Intron A	
Diagnosis	Condylomata Acuminata (CA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of condylomata acuminata (CA) (genital or perianal)

AND

2 - Patient is without decompensated liver disease

AND

3 - Patient does not have autoimmune hepatitis

AND

4 - Patient is 18 years of age or older

AND

5 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hematologist
- Infectious disease specialist

Product Name: Intron A	
Diagnosis	Follicular Lymphoma (FL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of clinically aggressive follicular non-Hodgkin lymphoma

AND

2 - Patient is without decompensated liver disease

AND

3 - Patient does not have autoimmune hepatitis

AND

4 - Patient is 18 years of age or older

AND

5 - Prescribed in conjunction with anthracycline-containing combination chemotherapy

AND

6 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hematologist
- Infectious disease specialist

Product Name: Intron A	
Diagnosis	Hairy Cell Leukemia (HCL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hairy cell leukemia (HCL)

AND

2 - Patient is without decompensated liver disease

AND

3 - Patient does not have autoimmune hepatitis

AND

4 - Patient is 18 years of age or older

AND

5 - Prescribed by or in consultation with one of the following:

- Oncolgist
- Hematologist
- Infectious disease specialist

Product Name: Intron A	
Diagnosis	Malignant Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of malignant melanoma

AND

2 - Patient is without decompensated liver disease

AND

3 - Patient does not have autoimmune hepatitis

AND

4 - Patient is 18 years of age or older

AND

5 - Prescribed as adjuvant to surgical treatment who are free of disease but at high risk for systemic recurrence

AND

6 - Must be administered within 56 days of surgery.

AND

7 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hematologist
- Infectious disease specialist

Product Name: Intron A	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/26/2022	2023 New Implementation

Invega Hafyera (paliperidone palmitate)

Prior Authorization Guideline

Guideline ID	GL-116578
Guideline Name	Invega Hafyera (paliperidone palmitate)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Invega Hafyera	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of schizophrenia

AND

2 - Trial and failure (defined by at least 6 months of treatment) of one of the following:

- Invega Trinza

- Invega Sustenna

AND

3 - Clinical need or concern for adherence which could be improved upon with twice yearly dosing

Product Name: Invega Hafyera	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/21/2022	2023 New Implementation

Izervay (avacincaptad pegol)

Prior Authorization Guideline

Guideline ID	GL-124083
Guideline Name	Izervay (avacincaptad pegol)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	10/18/2023
P&T Revision Date:	11/16/2023

1 . Indications

Drug Name: Izervay (avacincaptad pegol)
Geographic Atrophy (GA) Indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

2 . Criteria

Product Name: Izervay	
Approval Length	6 months [A, 1]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration

AND

2 - Disease is confirmed by one of the following:

- Fundus photography (e.g. fundus autofluorescence [FAF])
- Optical coherence tomography (OCT)
- Fluorescein angiography

AND

3 - GA is not secondary to any other conditions (e.g., Stargardt disease, cone rod dystrophy, toxic maculopathies)

AND

4 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name: Izervay	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in growth rate of GA lesion)

AND

2 - Patient has not exceeded a total of 12 months treatment [B, 1]

3. End Notes

A. In GATHER1 and GATHER2, the mean rate of GA growth (slope) from baseline to Month 12, measured by Fundus Autofluorescence (FAF) was evaluated at 3 time points: baseline, Month 6, and Month 12. [1]
B. The recommended dose for Izervay is 2 mg (0.1 mL of 20 mg/mL solution) administered by intravitreal injection to each affected eye once monthly (approximately 28 ± 7 days) for up to 12 months. [1]

4 References

1. Izervay Precribing Information. Iveric Bio, Inc. Parsippany, NJ. August 2023.
2. FDA Product Review. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/217225Orig1s000TOC.cfm. Accessed September 11, 2023.
3. Lexicomp. Izervay. Available at: https://www.uptodate.com/contents/avacincaptad-pegol- drug-information?search=geotrophic%20atropgy%20secondary%20to%20amd&source=search_result&selectedTitle=5~150&usage_type=default&display_rank=5. Accessed September 11, 2023.

5 . Revision History

Date	Notes
11/20/2023	Updated guideline

Jakafi (ruxolitinib)

Prior Authorization Guideline

Guideline ID	GL-121959
Guideline Name	Jakafi (ruxolitinib)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	2/21/2012
P&T Revision Date:	08/15/2019 ; 03/18/2020 ; 03/17/2021 ; 11/18/2021 ; 03/16/2022 ; 05/19/2022 ; 3/15/2023

1 . Indications

Drug Name: Jakafi (ruxolitinib)
Myelofibrosis Indicated for treatment of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis in adults. **Polycythemia Vera** Indicated for treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea. **Acute Graft Versus Host Disease** Indicated for treatment of steroid-refractory acute graft-versus-host disease (GVHD) in adult and pediatric patients 12 years and older. **Chronic Graft Versus Host Disease** Indicated for treatment of chronic graft-versus-host disease (cGVHD) after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

2 . Criteria

Product Name: Jakafi	
Diagnosis	Myelofibrosis
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Primary myelofibrosis
- Post-polycythemia vera myelofibrosis
- Post-essential thrombocythemia myelofibrosis

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Jakafi	
Diagnosis	Polycythemia Vera
Approval Length	8 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of polycythemia vera [1]

AND

2 - Trial and failure, contraindication, or intolerance to hydroxyurea [1]

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Jakafi	
Diagnosis	Myelofibrosis, Polycythemia Vera
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Jakafi therapy (e.g., spleen volume reduction, symptom improvement, hematocrit control)

Notes	If the member does not meet the medical necessity reauthorization criteria requirements, a denial should be issued and a 2-month authorization should be issued one time for Jakafi gradual therapy discontinuation.

Product Name: Jakafi	
Diagnosis	Acute Graft Versus Host Disease
Approval Length	6 Month(s) [C]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute graft-versus-host disease

AND

2 - Disease is steroid-refractory

AND

3 - Patient is 12 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist
- Physician experienced in the management of transplant patients

Product Name: Jakafi	
Diagnosis	Chronic Graft Versus Host Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic graft-versus-host disease

AND

2 - Patient is 12 years of age or older

AND

3 - Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.)

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist
- Physician experienced in the management of transplant patients

Product Name: Jakafi	
Diagnosis	Chronic Graft Versus Host Disease

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

A. Jakafi should be discontinued after 6 months if there is no spleen size reduction or symptom improvement since initiation of therapy. [1]
B. The initial authorization duration of 8 months is based on clinical trials (primary endpoint of hematocrit control and spleen volume reduction was evaluated at 32 weeks). [1]
C. Authorization duration of 6 months is based median time from response to death or need for new therapy for acute GVHD in clinical trials (173 days). Additionally, tapering of Jakafi may be considered after 6 months of treatment in patients with response who have discontinued therapeutic doses of corticosteroids. [1]

4 . References

1. Jakafi Prescribing Information. Incyte Corp. Wilmington, DE. January 2023.

5 . Revision History

Date	Notes
3/2/2023	2023 Annual Review

Kalydeco (ivacaftor)

Prior Authorization Guideline

Guideline ID	GL-129493
Guideline Name	Kalydeco (ivacaftor)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/7/2023

1 . Indications

Drug Name: Kalydeco (ivacaftor)
Cystic fibrosis Indicated for the treatment of cystic fibrosis (CF) in patients age 1 month and older who have one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use.

2 . Criteria

Product Name: Kalydeco	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Patient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data* as detected by an FDA-cleared cystic fibrosis mutation test or a test performed at a Clinical Laboratory Improvement Amendments (CLIA)-approved facility

AND

3 - Patient is 1 month of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist affiliated with a CF care center
- Pulmonologist

Notes	*Please consult Background section for table of CFTR gene mutations r esponsive to Kalydeco.

Product Name: Kalydeco	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response (i.e., improvement in lung function [percent predicted forced expiratory volume in one second {PPFEV1}], decreased number of pulmonary exacerbations) to therapy [A]

3 . Background

Clinical Practice Guidelines

CFTR Gene Mutations that are Responsive to Kalydeco [1]

*Intent of table is to provide a quick reference; PA team members should still review at point of request for clinical appropriateness as off label support continuously evolves. [Last Reviewed: 1/6/23]

List of *CFTR* Gene Mutations that Produce CFTR Protein and are Responsive to KALYDECO

*711+3A→G *	*F311del*	*I148T*	*R75Q*	*S589N*
*2789+5G→A *	*F311L*	*I175V*	*R117C *	*S737F*
*3272-26A→G *	*F508C*	*I807M*	*R117G*	*S945L *
*3849+10kbC→T *	*F508C;S1251N † *	*I1027T*	*R117H *	*S977F *
A120T	*F1052V*	*I1139V*	*R117L*	*S1159F*
A234D	*F1074L*	*K1060T*	*R117P*	*S1159P*
A349V	*G178E*	*L206W *	*R170H*	*S1251N *
*A455E *	*G178R *	*L320V*	*R347H *	*S1255P *
A1067T	*G194R*	*L967S*	*R347L*	*T338I*
D110E	*G314E*	*L997F*	*R352Q *	*T1053I*
D110H	*G551D *	*L1480P*	*R553Q*	*V232D*
D192G	*G551S *	*M152V*	*R668C*	*V562I*
*D579G *	*G576A*	*M952I*	*R792G*	*V754M*
D924N	*G970D*	*M952T*	*R933G*	*V1293G*
*D1152H *	*G1069R*	*P67L *	*R1070Q*	*W1282R*
D1270N	*G1244E *	*Q237E*	*R1070W *	*Y1014C*
E56K	*G1249R*	*Q237H*	*R1162L*	*Y1032C*
E193K	*G1349D *	*Q359R*	*R1283M*	
E822K	*H939R*	*Q1291R*	*S549N *	
*E831X *	*H1375P*	*R74W*	*S549R *	

** Clinical data exist for these mutations.*

† Complex/compound mutations where a single allele of the CFTR gene has multiple mutations; these exist independent of the presence of mutations on the other allele.

4 . Endnotes

A. The primary efficacy endpoint in both Kalydeco pivotal trials was improvement in lung function as determined by the mean absolute change from baseline in percent predicted pre-dose FEV1 through 24 weeks of treatment. [2]

5 . References

1. Kalydeco Prescribing Information. Vertex Pharmaceuticals Incorporated. Boston, MA. May 2023.
2. Ramsey BW, Davies J, McElvaney G, et al. A CFTR potentiator in patients with cystic fibrosis and the G551D mutation. N Engl J Med. 2011;365:1663-1672.

Kanuma (sebelipase alfa)

Prior Authorization Guideline

Guideline ID	GL-108422
Guideline Name	Kanuma (sebelipase alfa)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	9/1/2022
P&T Approval Date:	2/25/2016
P&T Revision Date:	07/15/2020 ; 07/21/2021 ; 7/20/2022

1 . Indications

Drug Name: Kanuma (sebelipase alfa)
Lysosomal Acid Lipase (LAL) deficiency Indicated for the treatment of patients with a diagnosis of Lysosomal Acid Lipase (LAL) deficiency.

2 . Criteria

Product Name: Kanuma	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of lysosomal acid lipase deficiency (LAL-D, Wolman Disease, Cholesteryl ester storage disease) [B]

AND

2 - Diagnosis was confirmed by one of the following: [A]

2.1 Enzymatic blood test (e.g., dried blood spot test) demonstrating a deficiency of LAL enzyme activity

OR

2.2 Genetic testing for mutations in the lipase A, lysosomal acid type (LIPA) gene

AND

3 - Prescribed by or in consultation with one of the following:

- A specialist experienced in the treatment of inborn errors of metabolism
- Gastroenterologist
- Lipidologist

Product Name: Kanuma	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction in LDL, triglycerides, AST or ALT, increase in HDL, reduction in liver fat content)

AND

2 - Prescribed by or in consultation with one of the following:

- A specialist experienced in the treatment of inborn errors of metabolism

- Gastroenterologist
- Lipidologist

3 . Endnotes

A. Due to similar clinical presentations, LAL-D is often misdiagnosed as familial defective apolipoprotein B (ApoB) deficiency, heterozygous familial hypercholesterolemia (HeFH), familial combined hyperlipidemia (FCH), or polygenic hypercholesterolaemia [3]. A diagnosis of LAL-D can be confirmed by identification of a LIPA mutation or a deficient LAL enzyme in peripheral blood leukocytes, fibroblasts, or dried blood spots. A biopsy and/or radiographic findings may help support a LAL-D diagnosis, however these are not considered diagnostic. [2,3]
B. LAL deficiency is sub-classified as Wolman disease in infants and cholesteryl ester storage disease (CESD) in children and adults. [4]

4 . References

1. Kanuma prescribing information, Alexion Pharmaceuticals. Cheshire, CT. December 2015.
2. Burton BK, Balwani M, Feillet F, et al. A Phase 3 Trial of Sebelipase Alfa in Lysosomal Acid Lipase Deficiency. N Engl J Med. 2015;373(11):1010-20.
3. Reiner, Guardamagna, Nair, et al. Lysosomal acid lipase deficiency - an under-recognized cause of dyslipidaemia and liver dysfunction. Atherosclerosis. 2014;235(1): 21-30.
4. Strebinger G, Müller E, Feldman A, Aigner E. Lysosomal acid lipase deficiency - early diagnosis is the key. Hepat Med. 2019 May 23;11:79-88.

5 . Revision History

Date	Notes
7/1/2022	Annual Review - criteria updated to have initial and reauth criteria and r espective approval lengths updated; specialist requirement options ex panded

Kimyrsa

Prior Authorization Guideline

Guideline ID	GL-126049
Guideline Name	Kimyrsa
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Kimyrsa	
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of an FDA-approved indication

OR

1.2 If requested for an off-label diagnosis, the off-label guideline approval criteria have been met

AND **2** - Prescribed by or in consultation with an infectious disease specialist **AND** **3** - Trial and failure of, or clinical rationale why Orbactiv (oritavancin) can't be used

2 . Revision History

Date	Notes
6/5/2023	New program

Kineret (anakinra)

Prior Authorization Guideline

Guideline ID	GL-127337
Guideline Name	Kineret (anakinra)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	1/28/2002
P&T Revision Date:	09/18/2019 ; 10/16/2019 ; 03/18/2020 ; 09/16/2020 ; 02/18/2021 ; 02/17/2022 ; 10/19/2022 ; 12/14/2022 ; 02/16/2023 ; 7/19/2023

1 . Indications

Drug Name: Kineret (anakinra)
Rheumatoid Arthritis (RA) Indicated for the reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis (RA), in patients 18 years of age or older who have failed 1 or more disease modifying antirheumatic drugs (DMARDs). Kineret can be used alone or in combination with DMARDs other than tumor necrosis factor (TNF) blocking agents. **Cryopyrin-Associated Periodic Syndromes (CAPS): Neonatal-Onset Multisystem Inflammatory Disease (NOMID) [A]** Indicated for the treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID). **Deficiency of Interleukin-1 Receptor Antagonist (DIRA)** Indicated for the treatment of Deficiency of Interleukin-1 Receptor Antagonist (DIRA). **Off Label Uses: Systemic Juvenile Idiopathic Arthritis (SJIA)** Has been used for the treatment of systemic juvenile idiopathic arthritis. [7]

2 . Criteria

Product Name: Kineret	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

AND

4 - One of the following:

4.1 All of the following:

4.1.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- One formulary adalimumab product
- Rinvoq (upadacitinib)
- Simponi (golimumab)
- Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)

AND

4.1.2 Trial and failure, contraindication, or intolerance to BOTH of the following:

- Actemra (tocilizumab)
- Orencia (abatacept)

OR

4.2 For continuation of prior Kineret therapy, defined as no more than a 45-day gap in therapy

Notes	*Includes attestation that a total of two TNF inhibitors have already bee n tried in the past, and the patient should not be made to try a third TNF inhibitor.

Product Name: Kineret	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Kineret	
Diagnosis	Neonatal-Onset Multisystem Inflammatory Disease (NOMID) [A]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neonatal-onset multisystem inflammatory disease (NOMID)

AND

2 - Diagnosis of NOMID has been confirmed by one of the following: [5-6, B]

2.1 NLRP-3 (nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3-gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]) mutation

OR

2.2 Both of the following:

2.2.1 Two of the following clinical symptoms:

- Urticaria-like rash
- Cold/stress triggered episodes
- Sensorineural hearing loss
- Musculoskeletal symptoms (e.g., arthralgia, arthritis, myalgia)
- Chronic aseptic meningitis
- Skeletal abnormalities (e.g., epiphyseal overgrowth, frontal bossing)

AND

2.2.2 Elevated acute phase reactants (e.g., erythrocyte sedimentation rate [ESR], C-reactive protein [CRP], serum amyloid A [SAA])

AND

3 - Prescribed by or in consultation with one of the following

- Allergist/Immunologist
- Rheumatologist
- Pediatrician

Product Name: Kineret	
Diagnosis	Neonatal-Onset Multisystem Inflammatory Disease (NOMID) [A]
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Kineret	
Diagnosis	Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA)

Product Name: Kineret	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA) (Off-Label)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active systemic juvenile idiopathic arthritis [7]

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [7]:

- Minimum duration of a 3-month trial and failure of methotrexate

- Minimum duration of a 1-month trial of a nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen)
- Minimum duration of a 2-week trial of a systemic glucocorticoid (e.g., prednisone)

Product Name: Kineret	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA) (Off-Label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [7]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in clinical features or symptoms (e.g., pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline

3 . Endnotes

A. Three clinically overlapping, interleukin-1-associated, autoinflammatory disorders are known collectively as the cryopyrin-associated periodic syndromes (CAPS) or cryopyrinopathies: familial cold autoinflammatory syndrome (FCAS), Muckle-Wells syndrome (MWS), and neonatal onset multisystem inflammatory disorder (NOMID, also known as chronic infantile neurological cutaneous and articular [CINCA] syndrome). [4]

B. In addition to clinical symptoms, a diagnosis should be made using a combination of procedures including laboratory assessments, skin biopsy, and genetic testing. [5] Diagnostic criteria developed by a multidisciplinary team of international experts in the care of children and adults with CAPS found that the best diagnosis criteria model included: raised inflammatory markers (CRP/SAA) plus two or more of six CAPS-typical signs/symptoms including (1) urticaria-like rash, (2) cold-triggered episodes, (3) sensorineural hearing loss, (4) musculoskeletal symptoms (arthralgia/arthritis/myalgia), (5) chronic aseptic meningitis, and (6) skeletal abnormalities (epiphyseal overgrowth/frontal bossing). This proposed model had a sensitivity of 81% and a specificity of 94%. It performed equally well for all CAPS subtypes and in subgroups with and without evidence of NLRP3 mutation ($p < 0.001$). [4, 6]

4 . References

1. Kineret Prescribing Information. Swedish Orphan Biovitrum. Stockholm, Sweden. December 2020.
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. Arthritis Rheumatol. 2021;73(7):1108-23.
3. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.
4. Nigrovic PA. Cryopyrin-associated periodic syndromes and related disorders. UpToDate. Updated June 6, 2017. http:www.uptodate.com. Accessed March 19, 2019.
5. Yu JR and Leslie KS. Cryopyrin-associated periodic syndrome: an update on diagnosis and treatment response. Curr Allergy Asthma Rep. 2011;11(1):12-20
6. Kuemmerle-Deschner JB, Ozen S, Tyrrell PN, et al. Diagnostic criteria for cryopyrin-associated periodic syndrome (CAPS). Ann Rheum Dis. 2017 Jun;76(6):942-947.
7. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. Arthritis Rheumatol. 2022;74(4):553-569.

5 . Revision History

Date	Notes
6/30/2023	Addition of Cyltezo, Hyrimoz, and brand Adalimumab-adaz as preferre d step options for RA

Kisqali (ribociclib)

Prior Authorization Guideline

Guideline ID	GL-116993
Guideline Name	Kisqali (ribociclib)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Kisqali	
Diagnosis	Breast Cancer in Women
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent or metastatic breast cancer

AND

2 - Patient has hormone receptor positive (HR+)

AND

3 - Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer

AND

4 - One of the following:

4.1 Patient is post-menopausal

OR

4.2 Both of the following:

- Patient is pre/perimenopausal and is receiving gonadotropin-releasing hormone agonist
- Patient has had bilateral oophorectomy or ovarian irradiation

AND

5 - One of the following:

5.1 Medication will be used in combination one of the following:

- anastrozole
- exemestane
- letrozole

OR

5.2 Medication will be used in combination with fulvestrant

AND

6 - Patient is 18 years of age or older

AND

7 - Prescribed by or in consultations with an oncologist

Product Name: Kisqali	
Diagnosis	Breast Cancer in Men
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent or metastatic breast cancer

AND

2 - Patient has hormone receptor positive (HR+)

AND

3 - Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer

AND

4 - Patient is receiving gonadotropin-releasing hormone analog

AND

5 - One of the following:

5.1 Medication will be used in combination with one of the following:

- anastrozole
- exemestane
- letrozole

OR

5.2 Medication will be used in combination with fulvestrant

AND

6 - Patient is 18 years of age or older

AND

7 - Prescribed by or in consultations with an oncologist

Product Name: Kisqali	
Diagnosis	All indications
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive response to therapy

2 . Revision History

Date	Notes
11/16/2022	Update guideline

Korsuva (difelikefalin)

Prior Authorization Guideline

Guideline ID	GL-124264
Guideline Name	Korsuva (difelikefalin)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	5/19/2022
P&T Revision Date:	5/18/2023

1 . Indications

Drug Name: Korsuva (difelikefalin) injection
Chronic kidney disease (CKD) Indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis (HD). Limitations of use: Korsuva has not been studied in patients on peritoneal dialysis and is not recommended for use in this population.

2 . Criteria

Product Name: Korsuva	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Patient is currently undergoing hemodialysis (HD) at an optimal dialysis dose (e.g., Kt/V greater than or equal to 1.2) [A, B, 4]

AND

3 - Patient is experiencing moderate to severe pruritus associated with CKD (CKD-aP)

AND

4 - Exclusion of other causes of pruritus (e. g., eczema, infections, drug-induced skin dryness) [C, 3]

AND

5 - Trial and failure, contraindication, or intolerance to ONE topical anti-pruritic treatment: [2,3]

- emollient cream
- analgesics (e.g., pramoxine lotion, capsaicin)
- corticosteroids (e.g., hydrocortisone, triamcinolone)

AND

6 - Trial and failure, contraindication, or intolerance to ONE oral treatment: [2,3]

- antihistamine (e.g., diphenhydramine, hydroxyzine, loratadine)
- gabapentin
- pregabalin

AND

7 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Dermatologist

Product Name: Korsuva	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is currently undergoing hemodialysis [A]

AND

2 - Documentation of positive clinical response to therapy (e.g., improved quality of life, improved worst itching intensity numerical rating score from baseline)

3 . Endnotes

A. Korsuva is administered by intravenous bolus injection into the venous line of the dialysis circuit at the end of each HD treatment. [1]
B. On average, a Kt/V of 1.2 is roughly equivalent to a URR of about 63 percent. Thus, another standard of adequate dialysis is a minimum Kt/V of 1.2. The Kidney Disease Outcomes Quality Initiative (KDOQI) group has adopted the Kt/V of 1.2 as the standard for dialysis adequacy. [4]
C. Pruritus associated with Chronic Kidney Disease (CKD-aP), previously known as uremic pruritus, may vary from a localized itch, commonly in the back, face, and arms, to a generalized itch involving the entire body. Primary skin lesions may present with similar symptoms, and any suspicion of an underlying primary lesion should be first evaluated by dermatology. [3]

4 . References

1. Korsuva Prescribing Information. Cara Therapeutics, Inc. Stamford, CT. August 2021.
2. Davison SN, Levin A, Moss AH, et al. Executive summary of the KDIGO Controversies Conference on Supportive Care in Chronic Kidney Disease: developing a roadmap to improving quality care. Kidney International. 2015;88(3):447-459.

3. Ragazzo J, Cesta A, Jassal SV, Chiang N, Battistella M. Development and Validation of a Uremic Pruritus Treatment Algorithm and Patient Information Toolkit in Patients With Chronic Kidney Disease and End Stage Kidney Disease. Journal of Pain and Symptom Management. 2020;59(2):279-292.e5.
4. Hemodialysis: Dose & Adequacy | NIDDK. National Institute of Diabetes and Digestive and Kidney Diseases. Accessed April 4, 2022.

5 . Revision History

Date	Notes
5/3/2023	2023 Annual Review - no changes

Krystexxa (pegloticase)

Prior Authorization Guideline

Guideline ID	GL-108900
Guideline Name	Krystexxa (pegloticase)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	9/1/2022
P&T Approval Date:	2/15/2011
P&T Revision Date:	07/15/2020 ; 07/21/2021 ; 7/20/2022

1 . Indications

Drug Name: Krystexxa (pegloticase)
Refractory gout Indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. Gout refractory to conventional therapy occurs in patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these drugs are contraindicated. Important Limitations of Use: Krystexxa is not recommended for the treatment of asymptomatic hyperuricemia.

2 . Criteria

Product Name: Krystexxa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gout

AND

2 - Trial and failure, contraindication, or intolerance to maximum recommended doses to both of the following conventional therapies: [A]

- Xanthine oxidase inhibitor (i.e., allopurinol, febuxostat)
- Uricosuric agent (e.g., probenecid)

AND

3 - One of the following:

- History of at least two gout flares in the previous 12 months
- At least 1 gouty tophus

AND

4 - Prescribed by or in consultation with a rheumatologist or nephrologist

Product Name: Krystexxa	
Approval Length	12 Months [B]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Krystexxa therapy demonstrated by both of the following:

- Serum urate level has decreased since initiating therapy
- Clinical improvement in the signs and symptoms of gout (e.g., decrease in tophi size or frequency of gouty flares per year from baseline or improvement in chronic arthropathy or quality of life)

3 . Endnotes

A. Additional inclusion criteria in pivotal trials were as follows: Contraindication to treatment with allopurinol or history of failure to normalize serum uric acid despite 3 or more months of treatment with the maximum medically appropriate allopurinol dose (determined by the treating physician) [2]. Febuxostat is another first-line pharmacologic agent for the treatment of gout [3]
B. The efficacy and safety profile of long-term pegloticase treatment (mean follow-up of 2.5 years) has been shown to be consistent with that observed in the 6 month pivotal trials. [4]

4 . References

1. Krystexxa Prescribing Information. Horizon Therapeutics, Inc. Deerfield, IL. March 2021.
2. Sundy JS, Baraf HS, Yood RA, et al. Efficacy and tolerability of pegloticase for the treatment of chronic gout in patients refractory to conventional treatment: two randomized controlled trials. JAMA. 2011;306(7):711-20.
3. Fitzgerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for Management of Gout. Arthritis Care Res (Hoboken). 2020 Jun;72(6):774-60.
4. Becker MA, Baraf HS, Yood RA. Long-term safety of pegloticase in chronic gout refractory to conventional treatment. Ann Rheum Dis. 2013;72(9):1469-74.

5 . Revision History

Date	Notes
7/22/2022	Annual review: no criteria changes.

Ledipasvir/Sofosbuvir

Prior Authorization Guideline

Guideline ID	GL-116583
Guideline Name	Ledipasvir/Sofosbuvir
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1 - Treatment Naive without Cirrhosis - Pre-Treatment HCV RNA less than 6 Million IU/mL
Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient is without cirrhosis

AND

3 - Patient is treatment-naive

AND

4 - Pre-treatment HCV RNA less than 6 million IU/mL

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

Product Name: Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1 - Treatment Naive without Cirrhosis - Pre-Treatment HCV RNA greater than or equal to 6 Million IU/mL
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient is without cirrhosis

AND

3 - Patient is treatment-naive

AND

4 - Pre-treatment HCV RNA greater than or equal to 6 million IU/mL

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

Product Name: Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Treatment-Naive or PegIFN/RBV-experienced or PegIFN/RBV/protease inhibitor-experienced (No Decompensated Cirrhosis)
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 4, 5, or 6

AND

2 - One of the following:

- Patient is treatment-naive
- Patient has prior failure to peginterferon alfa plus ribavirin treatment
- Patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir)

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

Product Name: Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Post-Liver Transplant
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6

AND

2 - Patient is a liver transplant recipient

AND

3 - One of the following:

3.1 Patient is without cirrhosis or has compensated cirrhosis (Child-Pugh Class A)

OR

3.2 Both of the following:

- Patient has decompensated cirrhosis (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

Product Name: Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Decompensated Cirrhosis - Ribavirin Eligible
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6

AND

2 - Patient has decompensated cirrhosis (e.g., Child-Pugh Class B or C)

AND

3 - Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

Product Name: Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Decompensated Cirrhosis; Ribavirin Ineligible OR Prior Sovaldi or NS5A-Based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6

AND

2 - Patient has decompensated cirrhosis (e.g., Child-Pugh Class B or C)

AND

3 - One of the following:

3.1 Patient is ribavirin ineligible

OR

3.2 Both of the following:

- Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based therapy
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

2 . Revision History

Date	Notes
10/28/2022	2023 New Implementation

Lenvima (lenvatinib)

Prior Authorization Guideline

Guideline ID	GL-117534
Guideline Name	Lenvima (lenvatinib)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Lenvima	
Diagnosis	Endometrial Carcinoma (EC)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Endometrial Carcinoma (EC)

AND

2 - Patient has advanced EC that is not microsatellite instability-high (MIS-H) or mismatch repair deficient (dMMR)

AND

3 - Patient has tried at least one NCCN recommended systemic therapy (e.g., carboplatin, paclitaxel, cisplatin, carboplatin/paclitaxel, cisplatin/doxorubicin, etc.)

AND

4 - Patient is not a candidate for curative therapy

AND

5 - Patient is 18 years of age or older

AND

6 - Prescribed by or in consultation with an oncologist

Product Name: Lenvima	
Diagnosis	Hepatocellular Cancer (HCC)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Hepatocellular Cancer (HCC)

AND

2 - Patient has unresectable or metastatic disease

AND

3 - Patient is 18 years of age or older

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Lenvima	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Renal Cell Carcinoma (RCC)

AND

2 - Patient has advanced disease

AND

3 - One of the following:

- Used in combination with Keytruda
- Used in combination with everolimus

AND

4 - Patient is 18 years of age or older

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Lenvima	
Diagnosis	Differentiated Thyroid Carcinoma (DTC)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Differentiated Thyroid Carcinoma (DTC)

AND

2 - Disease is refractory to radioactive iodine therapy

AND

3 - Patient is 18 years of age or older

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Lenvima	
Diagnosis	All indications listed above
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
11/30/2022	Update guideline

Leqvio (inclisiran) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-127651
Guideline Name	Leqvio (inclisiran) - PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	
P&T Revision Date:	06/15/2022 ; 03/15/2023 ; 7/19/2023

1 . Indications

Drug Name: Leqvio (inclisiran) injection, for subcutaneous use
Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD) Indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C). Limitations of Use: The effect of Leqvio on cardiovascular morbidity and mortality has not been determined.

2 . Criteria

Product Name: Leqvio	
Diagnosis	Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

1.1 Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following:

1.1.1 Both of the following: [5]

1.1.1.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL

AND

1.1.1.2 One of the following:

- Family history of myocardial infarction in first-degree relative less than 60 years of age
- Family history of myocardial infarction in second-degree relative less than 50 years of age
- Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
- Family history of familial hypercholesterolemia in first- or second-degree relative
- Family history of tendinous xanthomata and/or arcus cornealis in first- or second-degree relative

OR

1.1.2 Both of the following: [5]

1.1.2.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL

AND

1.1.2.2 One of the following:

- Functional mutation in the LDL receptor, ApoB, or PCSK9 gene
- Tendinous xanthomata
- Arcus cornealis before age 45

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD) as confirmed by one of the following: [2,4]

- Acute coronary syndromes
- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization
- Stroke
- Transient ischemic attack
- Peripheral arterial disease presumed to be of atherosclerotic origin

AND

2 - One of the following: [4]

2.1 Patient has been receiving at least 12 consecutive weeks of HIGH-INTENSITY statin therapy [i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a HIGH-INTENSITY statin at maximally tolerated dose

OR

2.2 Both of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 One of the following:

- Patient has been receiving at least 12 consecutive weeks of MODERATE-INTENSITY statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 20-40 mg, pravastatin 40-80 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily, or Livalo (pitavastatin) 2-4 mg] and will continue to receive a MODERATE-INTENSITY statin at maximally tolerated dose
- Patient has been receiving at least 12 consecutive weeks of LOW-INTENSITY statin therapy [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, Livalo (pitavastatin) 1 mg] and will continue to receive a LOW-INTENSITY statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low- or moderate-, and high-intensity statins as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low- or moderate-, and high-intensity statins:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times ULN)

OR

2.4 Patient has a labeled contraindication to all statins

OR

2.5 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN [4]

AND

3 - One of the following:

3.1 Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy

OR

3.2 Patient has a history of contraindication or intolerance to ezetimibe

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Patient has been receiving at least 12 consecutive weeks of Repatha therapy as adjunct to maximally tolerated lipid lowering therapy (e.g., statins, ezetimibe)

AND

4.1.2 Despite adherence to Repatha therapy, patient has been unable to achieve LDL-C goal as evidenced by one of the following within the last 120 days:

- LDL-C greater than or equal to 55 mg/dL for diagnosis of ASCVD [2]
- LDL-C greater than or equal to 100 mg/dL for diagnosis of HeFH [3]

OR

4.2 Patient is unable to maintain adherence to Repatha therapy due to one of the following:

- Manual dexterity problems (e.g., tremors, arthritis)
- Visual impairment (e.g., best-corrected visual acuity of 20/200 or worse) [6]

OR

4.3 Patient has experienced a hypersensitivity reaction, defined as angioedema, vasculitis, urticaria, to Repatha therapy

AND

5 - Prescribed by or in consultation with one of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

6 - Medication will not be used in combination with PCSK9 inhibitor therapy [2,3]

Product Name: Leqvio	
Diagnosis	Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of LDL-C reduction from baseline while on therapy

AND

2 - One of the following:

2.1 Patient continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at the maximally tolerated dose

OR

2.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statins, ezetimibe)

AND

3 - Medication will not be used in combination with PCSK9 inhibitor therapy [2,3]

Product Name: Leqvio	
Diagnosis	Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following diagnoses:

1.1 Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following:

1.1.1 Both of the following: [5]

1.1.1.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL

AND

1.1.1.2 One of the following:

- Family history of myocardial infarction in first-degree relative less than 60 years of age
- Family history of myocardial infarction in second-degree relative less than 50 years of age
- Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
- Family history of familial hypercholesterolemia in first- or second-degree relative
- Family history of tendinous xanthomata and/or arcus cornealis in first- or second-degree relative

OR

1.1.2 Both of the following: [5]

1.1.2.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL

AND

1.1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting one of the following:

- Functional mutation in the LDL receptor, ApoB, or PCSK9 gene
- Tendinous xanthomata
- Arcus cornealis before age 45

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD) as confirmed by one of the following: [2,4]

- Acute coronary syndromes
- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization
- Stroke
- Transient ischemic attack
- Peripheral arterial disease presumed to be of atherosclerotic origin

AND

2 - One of the following: [4]

2.1 Patient has been receiving at least 12 consecutive weeks of HIGH-INTENSITY statin

therapy [i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a HIGH-INTENSITY statin at maximally tolerated dose

OR

2.2 Both of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 One of the following:

- Patient has been receiving at least 12 consecutive weeks of MODERATE-INTENSITY statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 20-40 mg, pravastatin 40-80 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily, or Livalo (pitavastatin) 2-4 mg] and will continue to receive a MODERATE-INTENSITY statin at maximally tolerated dose
- Patient has been receiving at least 12 consecutive weeks of LOW-INTENSITY statin therapy [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, Livalo (pitavastatin) 1 mg] and will continue to receive a LOW-INTENSITY statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low- or moderate-, and high-intensity statins as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low- or moderate-, and high-intensity statins:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times ULN)

OR

2.4 Patient has a labeled contraindication to all statins

OR

2.5 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN [4]

AND

3 - One of the following:

3.1 Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy

OR

3.2 Patient has a history of contraindication or intolerance to ezetimibe

AND

4 - Submission of medical records (e.g., chart notes, laboratory values) documenting one of the following:

4.1 Both of the following:

4.1.1 Patient has been receiving at least 12 consecutive weeks of Repatha therapy as adjunct to maximally tolerated lipid lowering therapy (e.g., statins, ezetimibe)

AND

4.1.2 Despite adherence to Repatha therapy, patient has been unable to achieve LDL-C goal as evidenced by one of the following within the last 120 days:

- LDL-C greater than or equal to 55 mg/dL for diagnosis of ASCVD [2]
- LDL-C greater than or equal to 100 mg/dL for diagnosis of HeFH [3]

OR

4.2 Patient is unable to maintain adherence to Repatha therapy due to one of the following:

- Manual dexterity problems (e.g., tremors, arthritis)
- Visual impairment (e.g., best-corrected visual acuity of 20/200 or worse) [6]

OR

4.3 Patient has experienced a hypersensitivity reaction, defined as angioedema, vasculitis, urticaria, to Repatha therapy

AND

5 - Prescribed by or in consultation with one of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

6 - Medication will not be used in combination with PCSK9 inhibitor therapy [2,3]

Product Name: Leqvio	
Diagnosis	Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting LDL-C reduction from baseline while on therapy

AND

2 - One of the following:

2.1 Patient continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at the maximally tolerated dose

OR

2.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statins, ezetimibe)

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting one of the following:

3.1 Both of the following:

3.1.1 Patient has previously received at least 12 consecutive weeks of Repatha therapy as adjunct to maximally tolerated lipid lowering therapy (e.g., statins, ezetimibe)

AND

3.1.2 Despite adherence to Repatha therapy, patient was unable to achieve LDL-C goal as evidenced by one of the following:

- LDL-C greater than or equal to 55 mg/dL for diagnosis of ASCVD [2]
- LDL-C greater than or equal to 100 mg/dL for diagnosis of HeFH [3]

OR

3.2 Patient continues to be unable to maintain adherence to Repatha therapy due to one of the following:

- Manual dexterity problems (e.g., tremors, arthritis)
- Visual impairment (e.g., best-corrected visual acuity of 20/200 or worse) [6]

OR

3.3 Patient has experienced a hypersensitivity reaction, defined as angioedema, vasculitis, urticaria, to Repatha therapy

AND

4 - Medication will not be used in combination with PCSK9 inhibitor therapy [2,3]

3 . References

1. Leqvio prescribing information. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2021.
2. Ray KK, Wright RS, Kallend D, et al. Two phase 3 trials of inclisiran in patients with elevated LDL cholesterol. N Engl J Med. 2020;382(16):1507-1519.
3. Raal FJ, Kallend D, Ray KK, et al. Inclisiran for the Treatment of Heterozygous Familial Hypercholesterolemia. N Engl J Med. 2020;382(16):1520-1530.
4. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2019; 73:e285-e350.
5. Scientific Steering Committee on behalf of the Simon Broome Register Group. Risk of fatal coronary heart disease in familial hypercholesterolaemia. BMJ. 1991;303:893-6.
6. Vision Impairment and Blindness | Examination-Based Studies | Information on Data Sources | Vision and Eye Health Surveillance System | Vision Health Initiative (VHI) | CDC. www.cdc.gov. Published February 27, 2019. Accessed April 5, 2022.

4 . Revision History

Date	Notes
7/6/2023	Update to account for 2022 ACC recommendations of a lower LDL thre shold of 55mg/dl for patients with ASCVD at very high risk.

Leukine

Prior Authorization Guideline

Guideline ID	GL-117929
Guideline Name	Leukine
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Leukine	
Diagnosis	Acute myelogenous leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myelogenous leukemia (AML)

AND

2 - Leukine will be used to shorten time to neutrophil recovery and to reduce the incidence of severe and life-threatening infections

AND

3 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Leukine	
Diagnosis	Bone marrow transplant (allogeneic or autologous)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of bone marrow transplant (allogeneic or autologous)

AND

2 - Patient has graft failure or engraftment delay

AND

3 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Leukine	
Diagnosis	Myeloid reconstitution after allogeneic bone marrow transplantation
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient will use drug to accelerate myeloid recovery following transplantation in one of the following conditions:

- Non-Hodgkin lymphoma (NHL)

- Hodgkin lymphoma
- Acute lymphoblastic leukemia (ALL)

AND

2 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Leukine	
Diagnosis	Febrile neutropenia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following

1.1 Patient will use as primary prophylaxis of neutropenia in patients receiving chemotherapy

OR

1.2 Patient is at high risk for neutropenic fever

AND

2 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Leukine	
Diagnosis	Peripheral stem cell transplantation
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient will use for mobilization of hematopoietic progenitor cells for leukapheresis

AND

2 - Patient will use for myeloid reconstitution following autologous peripheral stem cell transplantation

AND

3 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Leukine	
Diagnosis	Acute Radiation Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute radiation syndrome

AND

2 - Patient will use for the treatment of radiation-induced myelosuppression of the bone marrow

AND

3 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Leukine	
Diagnosis	All indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
12/6/2022	Update guideline

Linezolid

Prior Authorization Guideline

Guideline ID	GL-117564
Guideline Name	Linezolid
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Generic linezolid	
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 One of the following diagnoses:

- Nosocomial pneumonia
- Community-acquired pneumonia
- Skin and skin structure infections (complicated and uncomplicated)

AND

1.1.2 Submission of medical records (e.g., chart notes) confirming infection is susceptible to linezolid

AND

1.1.3 One of the following:

1.1.3.1 Patient has a severe allergy to beta lactamase inhibitors or any antibiotic that the organism is susceptible to

OR

1.1.3.2 Patient has failed treatment with antibiotics that the organism is susceptible to

OR

1.2 Both of the following:

1.2.1 Submission of medical records (e.g., chart notes) confirming one of the following:

- Vancomycin-Resistant Enterococcus faecium infection
- Methicillin-resistant Staphylococcus aureus (MRSA) infection

AND

1.2.2 Patient has failed or is intolerant to Vancomycin if the organism is susceptible to Vancomycin.

AND

2 - Prescribed by or in consultation with an infectious disease specialist

Notes	*Approval Duration: For vancomycin-resistant Enterococcus faecium, authorization will be issued for 28 days. For osteomyelitis, authorization will be issued for the requested duration, not to exceed 6 weeks. All other approvals will be issued for 14 days.

Product Name: Generic linezolid	
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - One of the following diagnoses: • Nosocomial pneumonia • Community-acquired pneumonia • Skin and skin structure infections (complicated and uncomplicated) • Vancomycin-Resistant Enterococcus faecium infection • Methicillin-resistant Staphylococcus aureus (MRSA) infection **AND** **2** - Documentation of positive clinical response to therapy	
Notes	*Approval Duration: For vancomycin-resistant Enterococcus faecium, a uthorization will be issued for 28 days. For osteomyelitis, authorization will be issued for the requested duration, not to exceed 6 weeks. All oth er approvals will be issued for 14 days.

2 . Revision History

Date	Notes
12/12/2022	New Implementation

Lorbrena (lorlatinib)

Prior Authorization Guideline

Guideline ID	GL-116560
Guideline Name	Lorbrena (lorlatinib)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Lorbrena	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient has had no prior treatment for ALK-positive arrangement-positive NSCLC

AND

2.1.2 Trial and failure, contraindication, or intolerance to one of the following:

- Alecensa (alectinib)
- Alunbrig (brigatinib)

OR

2.2 Both of the following:

2.2.1 For diagnosis of ALK-positive arrangement-positive NSCLC when the ALK-rearrangement is discovered during first-line systemic therapy

AND

2.2.2 Trial and failure, contraindication, or intolerance to one of the following:

- Alunbrig (brigatnib)
- Zykadia (ceritinib)

AND

3 - Patient is 18 years of age or older

AND

4 - Prescribed by or in consultation with an oncologist or hematologist

Product Name: Lorbrena	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria
1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/20/2022	2023 New Implementation

Lumizyme (alglucosidase alfa)

Prior Authorization Guideline

Guideline ID	GL-125299
Guideline Name	Lumizyme (alglucosidase alfa)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	12/5/2006
P&T Revision Date:	06/17/2020 ; 05/20/2021 ; 11/18/2021 ; 05/19/2022 ; 5/18/2023

1 . Indications

Drug Name: Lumizyme (alglucosidase alfa)
Pompe Disease Indicated for patients with Pompe disease [acid alpha-glucosidase (GAA) deficiency].

2 . Criteria

Product Name: Lumizyme	
Diagnosis	Infantile Onset Pompe Disease (IOPD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of infantile-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) as confirmed by one of the following: [3]

1.1 Absence or deficiency (less than 1% of the lab specific normal mean) of GAA enzyme activity in lymphocytes, fibroblasts, or muscle tissues as confirmed by an enzymatic assay

OR

1.2 Molecular genetic testing confirms mutations in the GAA gene

AND

2 - Presence of clinical signs and symptoms of the disease (e.g., cardiomegaly, hypotonia, etc.)

AND

3 - Patient is less than or equal to 12 months of age

Product Name: Lumizyme	
Diagnosis	Infantile Onset Pompe Disease (IOPD)
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Lumizyme	
Diagnosis	Late Onset Pompe Disease (LOPD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) as confirmed by one of the following: [3, 5]

1.1 Absence or deficiency (less than 40% of the lab specific normal mean) of GAA enzyme activity in lymphocytes, fibroblasts, or muscle tissues as confirmed by an enzymatic assay

OR

1.2 Molecular genetic testing confirms mutations in the GAA gene

AND

2 - Presence of clinical signs and symptoms of the disease (e.g., respiratory distress, skeletal muscle weakness, etc.) [A]

AND

3 - Patient is 1 year of age or older

Product Name: Lumizyme	
Diagnosis	Late Onset Pompe Disease (LOPD)
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . Endnotes

A. Consensus recommendation based on current clinical guidelines indicate that treatment should be started in patients with late onset Pompe disease when they become symptomatic and/or show signs of disease progression [3, 5].

4 . References

1. Lumizyme Prescribing Information. Genzyme Corporation. Cambridge, MA. May 2022.
2. Kronn DF, Day-Salvatore D, Hwu WL, et al. Management of Confirmed Newborn- Screened Patients With Pompe Disease Across the Disease Spectrum.
3. Kishani PS, Steiner RD, Bali, D. ACMG Practice Guideline. Pompe disease diagnosis and management guideline. Genet Med. 2006;8(5):267-88.
4. Diagnosing Pompe Disease (also known as Acid Maltase Deficiency). Available at: https://www.pompe.com/-/media/EMS/Conditions/RareDiseases/Brands/pompe-us/hcp/PDF/SAUSPD18042050bk1vFinal10.pdf?la=en-US and https://www.pompe.com/-/media/EMS/Conditions/RareDiseases/Brands/pompe-us/hcp/PDF/SAUSPD18042050bj1vFinal10.pdf?la=en-US. Accessed May 12, 2020.
5. Barba-Romero MA, Barrot E, Bautista-Lorite J, et al. Clinical guidelines for late-onset Pompe disease. Rev Neurol 2012; 54 (8): 497-507.

5 . Revision History

Date	Notes
5/5/2023	Annual review: No criteria changes. Updated reauthorization criteria ap proval length to 24 months for both indications. Updated references.

Luxturna (voretigene neparvovec)

Prior Authorization Guideline

Guideline ID	GL-126108
Guideline Name	Luxturna (voretigene neparvovec)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	11/16/2017
P&T Revision Date:	06/17/2020 ; 06/16/2021 ; 06/15/2022 ; 6/21/2023

1 . Indications

Drug Name: Luxturna (voretigene neparvovec)
RPE65 Mutation-Associated Retinal Dystrophy Indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Patients must have viable retinal cells as determined by the treating physician(s).

2 . Criteria

Product Name: Luxturna	
Approval Length	1 time for each eye [D]
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of confirmed biallelic RPE65 mutation-associated retinal dystrophy (e.g., Leber's congenital amaurosis [LCA], retinitis pigmentosa [RP], early onset severe retinal dystrophy [EOSRD], etc.) [1-6]

AND

2 - Patient is 12 months of age or older [6, A]

AND

3 - Used for the treatment of vision loss defined by one of the following: [1]

- Visual acuity worse than 20/60 in both eyes
- Visual field less than 20 degrees in any meridian as measured by III4e isopter or equivalent in both eyes

AND

4 - Patient has sufficient viable retinal cells as determined by optical coherence tomography (OCT) demonstrating an area of retina within the posterior pole of greater than 100 micron thickness [1, 6, C]

AND

5 - Prescribed by or in consultation with one of the following physicians associated with an ocular gene therapy treatment Center of Excellence: [B]

- Ophthalmologist
- Retinal specialist/surgeon

AND

6 - Administered by a retinal specialist/surgeon experienced in performing intraocular surgery [2-6, B]

AND

7 - Patient has not previously received RPE65 gene therapy in the intended eye [2-5, D, E]

3 . Endnotes

A. Per Luxturna Prescribing Information (PI), treatment with Luxturna is not recommended for patients younger than 12 months of age, because the retinal cells are still undergoing cell proliferation, and Luxturna would potentially be diluted or lost during cell proliferation. [6] This is consistent with the Samaritan Large Group age policy, as there is a specific efficacy concern when using the medication in patients of a certain age.
B. Voretigene neparvovec will be administered solely through a small number of Centers of Excellence associated with an active ophthalmology practice that treats patients with inherited retinal diseases including RPE65 mutation-associated retinal dystrophy. Voretigene neparvovec will only be prepared and administered by surgeons who have completed the in-person training programs. [5, 6]
C. According to the FDA Advisory Committee discussions and PI, voretigene neparvovec should only be administered to patients with sufficient viable retinal cells. Treatment failure may occur if patients do not have enough viable retinal cells for exposure to the vector. The injection is also only targeted at 1/5 of the retina, and if not delivered to the appropriate location, may not be able to exert action or may be degraded by other precipitants within the eye (i.e., enzymes). [2-6]
D. The recommended voretigene neparvovec administration regimen consists of sequential, bilateral subretinal injections of 1.5E11 (or 150 billion) vg delivered in a total subretinal volume of 0.3 mL per eye per lifetime (total of 2 injections per lifetime). The individual administration procedures to each eye are to be performed on separate days no more than 6 to 18 days apart. This interval between administrations was used in the pivotal trial to afford an opportunity for identification of early-emergent potential surgical complications prior to a patient undergoing the second procedure, and to reduce the risk of a deleterious immune response by carrying out the two administration procedures in a near-simultaneous fashion, rather than a more widely spaced interval that could facilitate a prime boost response. [5, 6]
E. Since there are other RPE65 gene therapies in the pipeline that will also be administered once per lifetime, voretigene neparvovec was not specified in this criterion to concede the possibility that patients may have already received RPE65 gene therapy through participation in clinical trials.

4 . References

1. Russell S, Bennett J, Wellman JA, et al. Efficacy and safety of voretigene neparvovec (AAV2-hRPE65v2) in patients with RPE65-mediated inherited retinal dystrophy: a randomised, controlled, open-label, phase 3 trial. Lancet. 2017;390:849-60.
2. Food and Drug Administration (FDA) Advisory Committee. Cellular, Tissue and Gene Therapies Advisory Committee Meeting Announcement. Website. October 12, 2017. https://www.fda.gov/advisorycommittees/calendar/ucm574394.htm. June 1, 2022.
3. FDA. Voretigene briefing information. Website. October 12, 2017. https://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/bloodvaccinesandotherbiologics/cellulartissueandgenetherapiesadvisorycommittee/ucm579290.pdf. Accessed June 1, 2022.
4. FDA. Voretigene briefing information. [errata]. Website. October 12, 2017. https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Blo

odVaccinesandOtherBiologics/CellularTissueandGeneTherapiesAdvisoryCommittee/UCM579307.pdf. Accessed June 1, 2022.
5. Spark Therapeutics. Voretigene briefing information. Website. October 12, 2017. https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/CellularTissueandGeneTherapiesAdvisoryCommittee/UCM579300.pdf. Accessed June 1, 2022.
6. Luxturna Prescribing Information. Spark Therapeutics, Inc. Philadelphia, PA. May 2022.

5 . Revision History

Date	Notes
6/12/2023	Annual review - updated references.

Lysodren (mitotane)

Prior Authorization Guideline

Guideline ID	GL-116494
Guideline Name	Lysodren (mitotane)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Lysodren	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inoperable (functional or nonfunctional) adrenocortical carcinoma

AND

2 - Prescribed by or in consultation with an oncologist

Product Name: Lysodren

Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
9/29/2022	2023 New Implementation

Matulane (procarbazine)

Prior Authorization Guideline

Guideline ID	GL-116558
Guideline Name	Matulane (procarbazine)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Matulane	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Hodgkin lymphoma

AND

2 - Prescribed by or in consultation with an oncologist

Product Name: Matulane

Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/4/2022	2023 New Implementation

Mavyret (glecaprevir/pibrentasvir)

Prior Authorization Guideline

Guideline ID	GL-116588
Guideline Name	Mavyret (glecaprevir/pibrentasvir)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Indications

Drug Name: Mavyret (glecaprevir/pibrentasvir)
Chronic Hepatitis C (CHC) Indicated for the treatment of adult and pediatric patients 3 years and older with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A). Indicated for the treatment of adult and pediatric patients 3 years and older with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor (PI), but not both.

2 . Criteria

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; Treatment-Naïve; without Decompensated Cirrhosis
Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient is treatment-naive

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, or 4; Treatment-Naive; Coinfection with HIV; with Compensated Cirrhosis*
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, or 4

AND

2 - Patient is coinfected with human immunodeficiency virus (HIV) [2]

AND

2 - Patient is treatment-naive for chronic hepatitis C

AND

3 - Patient has compensated cirrhosis (e.g., Child-Pugh Class A) [2]

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Notes	*Patients with chronic hepatitis C Genotype 1, 2, 3, or 4 who are treatme nt-naive, coinfected with HIV, and do NOT have cirrhosis can follow the standard 8-week treatment regimen for patients without HIV infection

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 5, or 6; Treatment-Naive; Coinfection with HIV; without Decompensated Cirrhosis
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 5 or 6

AND

2 - Patient is coinfected with human immunodeficiency virus (HIV) [2]

AND

3 - Patient is treatment-naive for chronic hepatitis C

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C) [2]

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1; Treatment-Experienced (Prior failure to an NS3/4A Protease Inhibitor); without Decompensated Cirrhosis
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient has experienced failure with a previous treatment regimen that included a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)]

AND

3 - Patient has had no previous treatment experience with a treatment regimen that included an NS5A inhibitor (e.g., Daklinza [daclatasvir])

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1; Treatment-Experienced (Prior failure to an NS5A Inhibitor); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient has experienced failure with a previous treatment regimen that included an NS5A inhibitor (e.g., Daklinza [daclatasvir])

AND

3 - Patient has had no previous treatment experience with a treatment regimen that included a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)]

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 3; Treatment-Experienced (Interferon- or Sovaldi-based Regimen); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 3

AND

2 - Patient has experienced treatment failure with a previous treatment regimen that included interferon, peginterferon, ribavirin, and/or Sovaldi (sofosbuvir)

AND

3 - Patient has had no previous treatment experience with a treatment regimen that included a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)] or an NS5A inhibitor (e.g., Daklinza [daclatasvir])

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 4, 5, or 6; Treatment-Experienced (Interferon-based Regimen); without Cirrhosis
Approval Length	8 Week(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with a previous interferon-based treatment regimen

AND

3 - Patient has had no previous treatment experience with a treatment regimen that included a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)] or an NS5A inhibitor (e.g., Daklinza [daclatasvir])

AND

4 - Patient is without cirrhosis

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 4, 5, or 6; Treatment-Experienced (Interferon-based Regimen); with Compensated Cirrhosis

Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with a previous interferon-based treatment regimen

AND

3 - Patient has had no previous treatment experience with a treatment regimen that included a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)] or an NS5A inhibitor (e.g., Daklinza [daclatasvir])

AND

4 - Patient has compensated cirrhosis (e.g., Child-Pugh Class A)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)

Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 4, 5, or 6; Treatment-Experienced (Sovaldi-based regimen); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with a previous treatment regimen that included Sovaldi (sofosbuvir)

AND

3 - Patient has had no previous treatment experience with an HCV NS3/4A protease inhibitor inclusive combination direct acting antiviral regimen (e.g., Zepatier [elbasvir/grazoprevir])

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; Treatment-Experienced (Prior failure of Mavyret); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with Mavyret (glecaprevir/pibrentasvir) [2]

AND

3 - Used in combination with Sovaldi (sofosbuvir) and ribavirin [2]

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)

Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; Treatment-Experienced (Prior failure of Vosevi); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with Vosevi (sofosbuvir/velpatasvir/voxilaprevir) [2]

AND

3 - Used in combination with Sovaldi (sofosbuvir) and ribavirin [2]

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)

Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; HCV-Uninfected Recipients of a Liver Transplant from HCV-Viremic Donors; without Decompensated Cirrhosis
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

- Patient was not infected with HCV prior to receiving a liver transplant
- Patient received a liver transplant from a donor with a diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

3 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

4 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6 Post-Liver or Kidney Transplant; without Decompensated Cirrhosis
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient has had a liver or kidney transplant

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

3 . References

1. Mavyret Prescribing Information. Abbvie Inc. North Chicago, IL. September 2021.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. September 2021. http://www.hcvguidelines.org/full-report-view. Accessed May 16, 2022.

4 . Revision History

Date	Notes
10/28/2022	Bulk copy OptumRx SP to Samaritan SP for 1/1/2023 Implementation

Melphalan

Prior Authorization Guideline

Guideline ID	GL-116555
Guideline Name	Melphalan
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Melphalan	
Diagnosis	Multiple Myeloma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - Used for palliative treatment

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Melphalan	
Diagnosis	Ovarian cancer
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ovarian cancer

AND

2 - Used for palliative treatment of nonresectable epithelial ovarian carcinoma

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Melphalan	
Diagnosis	All indications listed above
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/14/2022	2023 New Implementation

Mepsevii (vestronidase alfa-vjbk)

Prior Authorization Guideline

Guideline ID	GL-125304
Guideline Name	Mepsevii (vestronidase alfa-vjbk)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	2/15/2018
P&T Revision Date:	06/17/2020 ; 05/20/2021 ; 04/20/2022 ; 5/18/2023

1 . Indications

Drug Name: Mepsevii (vestronidase alfa-vjbk)
Mucopolysaccharidosis (MPS VII, Sly Syndrome) Indicated for the treatment of Mucopolysaccharidosis (MPS VII, Sly Syndrome) in pediatric and adult patients. Limitations of use: The effect of Mepsevii on the central nervous system manifestations of MPS VII has not been determined.

2 . Criteria

Product Name: Mepsevii	
Diagnosis	Mucopolysaccharidosis (MPS VII, Sly Syndrome)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Mucopolysaccharidosis VII (MPS VII, Sly syndrome)

Product Name: Mepsevii	
Diagnosis	Mucopolysaccharidosis (MPS VII, Sly Syndrome)
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . References

1. Mepsevii Prescribing Information. Ultragenyx Pharmaceutical Inc. Novato CA. December 2020.

4 . Revision History

Date	Notes
5/3/2023	Annual review: Initial authorization approval duration updated to 12 m onths. New reauthorization section added.

Mesnex (mesna)

Prior Authorization Guideline

Guideline ID	GL-116540
Guideline Name	Mesnex (mesna)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Mesnex tablet	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Used for the prevention of ifosfamide-induced hemorrhagic cystitis

AND

2 - Patient is receiving ifosfamide therapy

AND

3 - Prescribed to follow IV Mesna administration for ifosfamide doses less than or equal to 2g/m2/day

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Mesnex tablet	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
9/29/2022	2023 New Implementation

Methylphenidate solution and chewable tablet

Prior Authorization Guideline

Guideline ID	GL-116503
Guideline Name	Methylphenidate solution and chewable tablet
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Generic methylphenidate solution/chewable tablet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Submission of medical records (e.g., chart notes) confirming the member has difficulty swallowing pills and/or has tried and failed methylphenidate tablets	

Product Name: Generic methylphenidate solution/chewable tablet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/20/2022	2023 New Implementation

Mitoxantrone

Prior Authorization Guideline

Guideline ID	GL-125170
Guideline Name	Mitoxantrone
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	5/18/2001
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 05/19/2022 ; 5/18/2023

1 . Indications

Drug Name: Mitoxantrone
Multiple Sclerosis Indicated for reducing neurologic disability and/or the frequency of clinical relapses in patients with secondary (chronic) progressive, progressive relapsing, or worsening relapsing-remitting multiple sclerosis (i.e., patients whose neurologic status is significantly abnormal between relapses). It is not indicated in the treatment of patients with primary progressive multiple sclerosis. **Prostate Cancer** Indicated, in combination with corticosteroids, as initial chemotherapy for the treatment of patients with pain related to advanced hormone-refractory prostate cancer. **Acute Non-Lymphocytic Leukemia (ANLL)** Indicated, in combination with other approved drug(s), in the initial therapy of ANLL in adults. This category includes myelogenous, promyelocytic, monocytic, and erythroid acute leukemias.

2 . Criteria

Product Name: Generic mitoxantrone	
Diagnosis	Multiple Sclerosis
Approval Length	6 Months [5-6, A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

1.1 Secondary progressive multiple sclerosis: gradually worsening disability with or without superimposed relapses [2]

OR

1.2 Progressive relapsing multiple sclerosis: progression of disability from the onset with superimposed relapses [2]

OR

1.3 Worsening relapsing-remitting multiple sclerosis: neurological status remains significantly abnormal in between multiple sclerosis relapses [3]

AND

2 - Trial and failure, contraindication, or intolerance to two of the following disease-modifying therapies for MS: [B, 3, 11]

- Aubagio (teriflunomide)
- Lemtrada (alemtuzumab)
- Mavenclad (cladribine)
- Plegridy (peginterferon beta-1a)
- Tysabri (natalizumab)
- Any one of the interferon beta-1a injections (e.g., Avonex)
- Any one of the interferon beta-1b injections (e.g., Betaseron)
- Any one of the glatiramer acetate injections (e.g., Copaxone, Glatopa, generic glatiramer acetate)
- Any one of the oral fumarates (e.g., generic dimethyl fumarate)
- Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (e.g., Gilenya, Mayzent, Zeposia)
- Any one of the B-cell targeted therapies (e.g., Kesimpta)

AND

3 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

4 - Neutrophil count greater than or equal to 1,500 cell/mm^3

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Generic mitoxantrone	
Diagnosis	Multiple Sclerosis
Approval Length	6 Months [5-6, A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

3 - A lifetime cumulative dose less than 140 mg/m^2 [1]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Generic mitoxantrone	
Diagnosis	Prostate Cancer
Approval Length	6 Months [5-6, A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced hormone-refractory (castration-resistant) prostate cancer

AND

2 - Used in combination with corticosteroids (e.g., prednisone, methylprednisolone) [7, 8, 10]

AND

3 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

4 - Neutrophil count greater than or equal to 1,500 cell/mm^3

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Generic mitoxantrone	
Diagnosis	Prostate Cancer
Approval Length	6 Months [5-6, A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

3 - A lifetime cumulative dose less than 140mg/m^2 [1]

Product Name: Generic mitoxantrone	
Diagnosis	Acute Non-Lymphocytic Leukemia (ANLL)
Approval Length	6 Months [5-6, A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute non-lymphocytic leukemia (ANLL) (e.g., myelogenous, promyelocytic, monocytic, and erythroid)

AND

2 - Used in combination with other medications used for the treatment of ANLL [9, 10]

AND

3 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Generic mitoxantrone

Diagnosis	Acute Non-Lymphocytic Leukemia (ANLL)
Approval Length	6 Months [5-6, A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

3 - A lifetime cumulative dose less than 140mg/m^2 [1]

3 . Endnotes

A. All patients should be carefully assessed for cardiac signs and symptoms by history and physical examination prior to start of Novantrone therapy. Left ventricular ejection fraction (LVEF) should be evaluated prior to administration of the initial dose of mitoxantrone and all subsequent doses. Mitoxantrone is recommended to be dosed once every three months. Additional doses of mitoxantrone should not be administered to multiple sclerosis patients who have experienced either a drop in LVEF to below 50% or a clinically significant reduction in LVEF during mitoxantrone therapy. [1]
B. Per 2018 American Academy of Neurology (AAN) Multiple Sclerosis (MS) guideline, mitoxantrone should not be prescribed to people with MS due to the high frequency of severe adverse effects unless the potential benefit greatly outweighs the risk. Another MS agent that has relatively more side effects include Lemtrada and its prescribing information recommends reserving use after two prior lines of therapies have been tried. Due to this, a requirement of two prior agents for Mitoxantrone would be more appropriate to align with other MS agents that have more risks than benefit. [11]

4 . References

1. Mitoxantrone Prescribing Information. Fresenius Kabi USA, LLC. Lake Zurich, IL. December 2019.
2. Hartung HP, Gonsette R, Konig N, et al. Mitoxantrone in progressive multiple sclerosis: a placebo-controlled, double-blind, randomized, mulitcentre trial. Lancet 2002;360:2018-25.

3. Marriott JJ, Miyasaki JM, Gronseth G, O'Connor PW. Evidence Report: The efficacy and safety of mitoxantrone (Novantrone) in the treatment of multiple sclerosis: Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology. 2010;74:1463-70.
4. Avasarala JR, Cross AH, Clifford DB, Singer BA, Siegal BA, Abbey EE. Rapid onset mitoxantrone-induced cardiotoxicity in secondary progressive multiple sclerosis. Mult Scler. 2003;9:59-62.
5. Ghalie RG, Edan G, Laurent M, et al. Cardiac adverse effects associated with mitoxantrone (Novantrone) therapy in patients with MS. Neurology. 2002;59:909-13.
6. Bastianello S, Pozzilli C, D'Andrea F, et al. A controlled trial of mitoxantrone in multiple sclerosis: serial MRI evaluation at one year. Can J Neurol Sci. 1994;21:266-70.
7. Petrylak DP, Tangen CM, Hussain MH, et al. Docetaxel and estramustine compared with mitoxantrone and prednisone for advanced refractory prostate cancer. N Engl J Med. 2004;351:1513-20.
8. Tannock IF, de Wit R, Berry WR, et al. Investigators. Docetaxel plus prednisone or mitoxantrone plus prednisone for advanced prostate cancer. N Engl J Med. 2004;351:1502-12.
9. Anderson JE, Kopecky KJ, Willman CL, et al. Outcome after induction chemotherapy for older patients with acute myeloid leukemia is not improved with mitoxantrone and etoposide compared to cytarabine and daunorubicin: a Southwest Oncology Group study. Blood. 2002;100:3869-76. Epub 2002 Aug 1.
10. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at www.nccn.org. Accessed May 3, 2023.
11. Rae-Grant, A., Day, G., Marrie, R., Rabinstein, A., Cree, B., Gronseth, G., Haboubi, M., Halper, J., Hosey, J., Jones, D., Lisak, R., Pelletier, D., Potrebic, S., Sitcov, C., Sommers, R., Stachowiak, J., Getchius, T., Merillat, S. and Pringsheim, T., 2018. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis. Neurology, 90(17), pp.777-788.

5 . Revision History

Date	Notes
5/3/2023	Annual Review, no changes.

Mometasone Nasal Implant

Prior Authorization Guideline

Guideline ID	GL-125932
Guideline Name	Mometasone Nasal Implant
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Sinuva, Propel, Propel Mini SDS, Propel Mini	
Approval Length	One time approval per nare (30 days)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Polyp of nasal cavity and/or nasal sinus

AND

2 - Patient is 18 years of age or older

AND

3 - Documentation of prior ethmoid sinus surgery and patient is at risk of needing a repeat surgery in the same sinus

AND

4 - Patient has tried and had an inadequate response or intolerance at least TWO nasal steroids at maximum FDA recommended dosing

AND

5 - Patient has not previously received the requested implant in the same sinus

2 . Revision History

Date	Notes
5/22/2023	New program

Monoclonal Antibody Agents for Alzheimer’s Disease

Prior Authorization Guideline

Guideline Name	Monoclonal Antibody Agents for Alzheimer’s Disease
Formulary	Samaritan Large Group

Guideline Note:

Effective Date:	8/16/2024
P&T Approval Date:	2/18/2021
P&T Revision Date:	8/15/2024

1 . Indications

Drug Name: Aduhelm (aducanumab-avwa)
Alzheimer's Disease Indicated for the treatment of Alzheimer's disease. Treatment with Aduhelm should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with Aduhelm. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s)**.**
Drug Name: Kisunla (donanemab-azbt)
Alzheimer's Disease Indicated for the treatment of Alzheimer’s disease. Treatment with Kisunla should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials.
Drug Name: Leqembi (lecanemab-irmb)
Alzheimer's Disease Indicated for the treatment of Alzheimer’s disease. Treatment with Leqembi should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials.

2 . Criteria

Product Name: Aduhelm	
Diagnosis	Alzheimer's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization, Non-Formulary

Approval Criteria

1.- Both of the following:

1. Based on the National Institute on Aging and the Alzheimer's Association (NIA-AA) criteria, one of the following: [16,17,24]

    1. Diagnosis of mild cognitive impairment due to Alzheimer's disease
    2. Diagnosis of probable Alzheimer's disease dementia

AND

2. Submission of medical records (e.g., chart notes) confirming both of the following: [18- 19]

    1. Clinical Dementia Rating-Global (CDR-G) score of 0.5 or Clinical Dementia Rating Sum of Boxes (CDR-SB) score of 0.5-4
    2. Mini-Mental State Examination score of 24-30

AND

2.- Submission of medical records (e.g., chart notes) confirming the presence of beta-amyloid protein deposition, as evidenced by one of the following:

2.1 Positive amyloid positron emission tomography (PET) scan

OR

2.2 Both of the following:

• Attestation that the patient does not have access to amyloid PET scanning
• Cerebrospinal fluid (CSF) biomarker or blood testing documents abnormalities suggestive of beta-amyloid accumulation (e.g., Aβ42 level, Aβ42:Aβ40 ratio)

AND

3 - Provider attests that the patient's ApoE e4 carrier status is known prior to initiating treatment and a shared decision-making conversation regarding the results has been completed

AND

4 - Other differential diagnoses (e.g., dementia with Lewy bodies (DLB), frontotemporal dementia (FTD), vascular dementia, pseudodementia due to mood disorder, vitamin B12 deficiency, encephalopathy, etc.) have been ruled out

AND

5 - Both of the following: [18-19]

- Patient is not currently taking an anticoagulant or antiplatelet agent (unless aspirin 325 mg/day or less)
- Patient has no history of transient ischemic attack (TIA) or stroke within previous year prior to initiating treatment

AND

- Counseling has been provided on the risk of amyloid-related imaging abnormalities (ARIA-E and ARIA-H) and patient and/or caregiver are aware to monitor for headache, dizziness, visual disturbances, nausea, and vomiting [20]

AND

1. - Submission of medical records (e.g., chart notes) confirming a baseline brain magnetic resonance imaging (MRI) has been completed within 12 months prior to initiating treatment

AND

2. - Not used in combination with other Aβ monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Leqembi)

AND

3.- Prescribed by a neurologist, geriatrician, or geriatric psychiatrist

Product Name: Aduhelm	
Diagnosis	Alzheimer's Disease
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization, Non-Formulary

Approval Criteria

1 - Patient is benefitting from therapy as defined by both of the following:

1.1 Based on the National Institute on Aging and the Alzheimer's Association (NIA-AA) criteria, one of the following: [16,17,24]

- Patient continues to have a diagnosis of mild cognitive impairment due to Alzheimer's disease
- Patient continues to have a diagnosis of probable Alzheimer's disease dementia

AND

2 Submission of medical records (e.g., chart notes) confirming both of the following: [18- 19]
3 Clinical Dementia Rating-Global (CDR-G) score of 0.5 or Clinical Dementia Rating Sum of Boxes (CDR-SB) score of 0.5-4

- Mini-Mental State Examination score of 24-30

AND

2 - Submission of medical records (e.g., chart notes) confirming follow-up brain magnetic resonance imaging (MRI) has been completed after the initiation of therapy prior to the 5th infusion treatment to show one of the following:

2.1 Both of the following:

- Less than 10 new incident microhemorrhages
- 2 or less focal areas of superficial siderosis

OR

2.2 If 10 or more new incident microhemorrhages or greater than 2 focal areas of superficial siderosis are present then both of the following:

- Patient has been clinically evaluated for ARIA related signs or symptoms (e.g., dizziness, visual disturbances)
- Follow-up MRI demonstrates radiographic stabilization (i.e., no increase in size or

number of ARIA-H)

AND

3 - Not used in combination with other Aβ monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Leqembi)

AND

4 - Prescribed by a neurologist, geriatrician, or geriatric psychiatrist

Product Name: Kisunla	
Diagnosis	Alzheimer’s Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization, Non-Formulary

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of one of the following, based on the National Institute on Aging and the Alzheimer's Association (NIA-AA) criteria:

- Mild cognitive impairment due to Alzheimer's disease
- Mild dementia due to Alzheimer's disease

AND

1.2 Submission of medical records (e.g., chart notes) confirming Mini-Mental State Examination score of 20-28

AND

2 Submission of medical records (e.g., chart notes) confirming the presence of beta-amyloid protein deposition, as evidenced by one of the following:

- Positive amyloid positron emission tomography (PET) scan
- Attestation that patient does not have access to amyloid PET scanning and cerebrospinal fluid (CSF) biomarker testing documents abnormalities suggestive of beta-amyloid accumulation (e.g., Aβ42 level, Aβ42:Aβ40 ratio, Tau, p-Tau)

AND

3 - Both of the following:

- Provider attests that testing regarding the patient's ApoE e4 carrier status has been performed prior to initiating treatment
- Prior to testing, a shared decision-making conversation has occurred, regarding the risk of amyloid-related imaging abnormalities (ARIA), across genotypes, and the implications of genetic testing results

AND

4 Submission of medical records (e.g., chart notes) confirming a baseline brain magnetic resonance imaging (MRI) has been completed within 12 months prior to initiating treatment

AND

5 - Other differential diagnoses (e.g., dementia with Lewy bodies (DLB), frontotemporal dementia (FTD), vascular dementia, pseudodementia due to mood disorder, vitamin B12 deficiency, encephalopathy) have been ruled out

AND

6 - Both of the following:

- Patient is not currently taking an anticoagulant (e.g., warfarin, dabigatran)
- Patient has no history of intracerebral hemorrhage (e.g., transient ischemic attack [TIA], stroke) prior to initiating treatment

AND

7 - Not used in combination with other Aβ monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Aduhelm, Leqembi)

AND

8 - Counseling has been provided on the risk of amyloid-related imaging abnormalities (ARIA- E and ARIA-H) and patient and/or caregiver are aware to monitor for headache, dizziness, visual disturbances, nausea, and vomiting

AND

9 - Provider will enroll patient in a registry [e.g., Alzheimer's Network for Treatment and Diagnostics (ALZ-Net)]

AND

10 - Patient is not being treated with Kisunla as part of a clinical trial

AND

11 - Prescribed by a neurologist, geriatrician, or geriatric psychiatrist

Product Name: Kisunla	
Diagnosis	Alzheimer’s Disease
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization, Non-Formulary

Approval Criteria

1 - Both of the following:

1.1 Patient continues to have one of the following diagnoses based on the National Institute on Aging and the Alzheimer's Association (NIA-AA) criteria:

- Mild cognitive impairment due to Alzheimer's disease
- Mild dementia due to Alzheimer's disease

AND

1.2 Submission of medical records (e.g., chart notes) confirming Mini-Mental State Examination score of 20-28

AND

2 **-** Submission of medical records (e.g., chart notes) confirming that at least one amyloid PET brain scan is performed every 6 months and the result is positive for amyloid based on visual read [A]

AND

3 - Submission of medical records (e.g., chart notes) confirming follow-up brain magnetic resonance imaging (MRI) has been completed after the initiation of therapy prior to the 5th and 7th infusion treatment to show one of the following radiographic evidence of amyloid related imaging abnormalities (i.e, ARIA-E, ARIA-H):

- Patient has mild radiographic severity of Aria – E on MRI and is asymptomatic
- Patient has mild radiographic severity of Aria – E on MRI and has mild clinical symptoms
- Patient has mild radiographic severity of Aria-H on MRI and is asymptomatic
- ARIA (i.e. ARIA E, ARIA H) has not been observed on MRI

AND

4 - Not used in combination with other Aβ monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Aduhelm, Leqembi)

AND

5 - Patient is not being treated with Kisunla as part of a clinical trial

AND

6 - Prescribed by a neurologist, geriatrician, or geriatric psychiatrist

Product Name: Legembi	
Disease	Alzheimer's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization, Non-Formulary

Approval Criteria

1 **-** Both of the following:

1.1 Diagnosis of one of the following, based on the National Institute on Aging and the Alzheimer's Association (NIA-AA) criteria:

- Mild cognitive impairment due to Alzheimer's disease
- Mild dementia due to Alzheimer's disease

AND

1.2 Submission of medical records (e.g., chart notes) confirming all of the following [12-13]:

- Global Clinical Dementia Rating (CDR) score of 0.5 or 1.0
- CDR Memory Box score of 0.5 or greater
- Mini-Mental State Examination score of 22 or greater

AND

2 - Submission of medical records (e.g., chart notes) confirming the presence of beta-amyloid protein deposition, as evidenced by one of the following:

- Positive amyloid positron emission tomography (PET) scan
- Attestation that patient does not have access to amyloid PET scanning and cerebrospinal fluid (CSF) biomarker testing documents abnormalities suggestive of beta-amyloid accumulation (e.g., Aβ42 level, Aβ42:Aβ40 ratio, Tau, p-Tau)

AND

3 - Both of the following:

- Provider attests that testing regarding the patient's ApoE e4 carrier status has been performed prior to initiating treatment
- Prior to testing, a shared decision-making conversation has occurred, regarding the risk of amyloid-related imaging abnormalities (ARIA), across genotypes, and the implications of genetic testing results

AND

4 **-** Submission of medical records (e.g., chart notes) confirming a baseline brain magnetic resonance imaging (MRI) has been completed within 12 months prior to initiating treatment

AND

5 **-** Other differential diagnoses (e.g., dementia with Lewy bodies (DLB), frontotemporal dementia (FTD), vascular dementia, pseudodementia due to mood disorder, vitamin B12 deficiency, encephalopathy) have been ruled out

AND

6 **-** Both of the following [9, 12-13]:

- Patient is not currently taking an anticoagulant (e.g., warfarin, dabigatran)
- Patient has no history of intracerebral hemorrhage (e.g., transient ischemic attack [TIA], stroke) prior to initiating treatment

AND

7 **-** Not used in combination with other Aβ monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Aduhelm, Kisunla)

AND

8 - Counseling has been provided on the risk of amyloid-related imaging abnormalities (ARIA- E and ARIA-H) and patient and/or caregiver are aware to monitor for headache, dizziness, visual disturbances, nausea, and vomiting

AND

9 - Provider will enroll patient in a registry [e.g., Alzheimer's Network for Treatment and Diagnostics (ALZ-Net)]

AND

10 - Patient is not being treated with Leqembi as part of a clinical trial

AND

11 - Prescribed by a neurologist, geriatrician, or geriatric psychiatrist

Product Name: Legembi	
Diagnosis	Alzheimer’s Disease
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization, Non-Formulary

Approval Criteria

1 - Both of the following:

1.1 Patient continues to have one of the following diagnoses based on the National Institute on Aging and the Alzheimer's Association (NIA-AA) criteria:

- Mild cognitive impairment due to Alzheimer's disease
- Mild dementia due to Alzheimer's disease

AND

1.2 Submission of medical records (e.g., chart notes) confirming all of the following [12-13]:

- Global Clinical Dementia Rating (CDR) score of 0.5 or 1.0
- CDR Memory Box score of 0.5 or greater
- Mini-Mental State Examination score of 22 or greater

AND

2 - Submission of medical records (e.g., chart notes) confirming follow-up brain magnetic resonance imaging (MRI) has been completed after the initiation of therapy prior to the 5th and 7th infusion treatment to show one of the following radiographic evidence of amyloid related imaging abnormalities (i.e, ARIA-E, ARIA-H):

- Patient has mild radiographic severity of Aria – E on MRI and is asymptomatic
- Patient has mild radiographic severity of Aria – E on MRI and has mild clinical symptoms
- Patient has mild radiographic severity of Aria-H on MRI and is asymptomatic
- ARIA (i.e. ARIA E, ARIA H) has not been observed on MRI

AND

3- Not used in combination with other Aβ monoclonal antibodies (mAbs) for Alzheimer's Disease (e.g., Aduhelm, Kisunla)

AND

4 - Patient is not being treated with Leqembi as part of a clinical trial

AND

5 - Prescribed by a neurologist, geriatrician, or geriatric psychiatrist

3 . Definitions

Definition	Description
ARIA-E	Amyloid related imaging abnormality due to edema/effusion
ARIA-H	Amyloid related imaging abnormality due to micro hemorrhages and hemosiderin deposits

4 . Endnotes

A. In clinical trials, completion of active treatment was based on amyloid PET levels measured at week 24, week 52, and week 76. [1,7]
B. In the TrailBlazer -ALZ 2 people were able to complete treatment and switch to placebo at 6, 12, or 18 months after they achieved one of the study's treatment goals, minimal levels of amyloid plaque, consistent with a visually negative amyloid PET scan. In the overall population of people receiving Kisunla, 17% completed treatment at 6 months, 47% at 12 months, and 69% at 18 months based on assessment of amyloid levels via a amyloid PET scan. Kisunla dosing can be stopped based on reduction of amyloid plaques to minimal levels on amyloid PET imaging. Amyloid positron emission tomography (PET) levels were measured at weeks 24, 52, and 76. Amyloid PET values may increase after treatment with donanemab is stopped. [1]
C. Core CSF biomarker assessment is defined as a combination of amyloid-β 1-42 peptide (Aβ42, which is correlated with APP metabolism and amyloid deposition), Total Tau protein (T-Tau) which reflects neurodegeneration, and phosphorylated Tau protein (P-Tau181) which reflects tangle pathology measurement. According to the literature, these core biomarkers have a high specificity and sensitivity for discriminating AD from other dementias The typical CSF biomarker profile in AD associates increased T-Tau and P-Tau181 concentrations and decreased Aβ42 peptide concentration. It has been clearly demonstrated that a combination of CSF biomarkers that includes Aβ42/Aβ40 ratio calculation, significantly improves the discriminatory capacity in the diagnosis of AD [6]

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6Revision History

Date	Notes
8/1/2024	Update guideline

Multiple Sclerosis (MS) Agents - PA, NF

Prior Authorization Guideline

Guideline ID	GL-125951
Guideline Name	Multiple Sclerosis (MS) Agents - PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	11/20/2000
P&T Revision Date:	09/18/2019 ; 01/15/2020 ; 03/18/2020 ; 05/14/2020 ; 07/15/2020 ; 07/15/2020 ; 08/13/2020 ; 09/16/2020 ; 11/12/2020 ; 12/16/2020 ; 01/20/2021 ; 03/17/2021 ; 05/20/2021 ; 06/16/2021 ; 08/19/2021 ; 08/19/2021 ; 12/15/2021 ; 12/15/2021 ; 03/16/2022 ; 04/20/2022 ; 05/19/2022 ; 11/17/2022 ; 12/14/2022 ; 02/16/2023 ; 03/15/2023 ; 04/19/2023 ; 04/19/2023 ; 05/18/2023 ; 5/18/2023

1 . Indications

Drug Name: Aubagio (teriflunomide)
Relapsing forms of multiple sclerosis (MS) Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Avonex (interferon beta-1a)

Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Bafiertam (monomethyl fumarate)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Betaseron (interferon beta-1b)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Briumvi (ublituximab-xiiy)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Copaxone (glatiramer acetate), Glatopa (glatiramer acetate)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Extavia (interferon beta-1b)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Kesimpta (ofatumumab)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Lemtrada (alemtuzumab)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in

adults. Because of its safety profile, the use of Lemtrada should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS. Limitations of Use: Lemtrada is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.
Drug Name: Mavenclad (cladribine)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, use of Mavenclad is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternate drug indicated for the treatment of MS. Limitations of Use: Mavenclad is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.
Drug Name: Mayzent (siponimod)
Relapsing forms of MS Indicated for the treatment of relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Ocrevus (ocrelizumab)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. **Primary Progressive Forms of Multiple Sclerosis (PPMS)** Indicated for the treatment of primary progressive MS, in adults.
Drug Name: Plegridy (peginterferon beta-1a)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Ponvory (ponesimod)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Rebif (interferon beta-1a)

Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Vumerity (diroximel fumarate)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Tascenso ODT (fingolimod)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older.

2 . Criteria

Product Name: Brand Aubagio, Avonex, Bafiertam, Betaseron, Brand Copaxone, Generic glatiramer acetate, Glatopa, Kesimpta*, Mayzent, Generic Teriflunomide, Vumerity	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A-D]

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - For Brand Aubagio, trial and failure or intolerance to generic teriflunomide

Notes	*For Kesimpta, there is a QL Override (For new starts only): Please enter 2 PAs as follows with the same start date: First PA: Approve 3 syringes or pens per 28 days for the first month (Loading dose has a MDD of 0.05); Second PA: Approve 1 syringe or pen per 28 days (no overrides needed) for 12 months. (Kesimpta is hard-coded with a quantity of 1 syringe or pen per 28 days; 0.4 mL per 20 mg pen or syringe. Maintenance dose has a MDD of 0.02)

Product Name: Extavia, Plegridy, Ponvory, Rebif	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 For continuation of therapy

OR

2.2 Failure after a trial of at least 4 weeks, contraindication, or intolerance to at least two of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Bafiertam (monomethyl fumarate)
- Copaxone/Glatopa (glatiramer acetate)
- Kesimpta (ofatumumab)
- Dimethyl fumarate
- Vumerity (diroximel fumarate)

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Tascenso ODT	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - Patient is 10 years of age or older

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Patient is 18 years of age or older

AND

3.1.2 One of the following:

3.1.2.1 For continuation of therapy

OR

3.1.2.2 Failure after a trial of at least 4 weeks, contraindication, or intolerance to at least two of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Bafiertam (monomethyl fumarate)
- Copaxone/Glatopa (glatiramer acetate)
- Kesimpta (ofatumumab)
- Dimethyl fumarate
- Vumerity (diroximel fumarate)

OR

3.2 Both of the following:

- Patient is younger than 18 years of age
- Failure after a trial of at least 4 weeks or intolerance to Gilenya (fingolimod)

AND

4 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Brand Aubagio, Avonex, Bafiertam, Betaseron, Brand Copaxone, Extavia, Generic glatiramer acetate, Glatopa, Kesimpta, Mayzent, Plegridy, Ponvory, Rebif, Tascenso ODT, Generic Teriflunomide, Vumerity	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - For Brand Aubagio, trial and failure or intolerance to generic teriflunomide

Product Name: Extavia, Plegridy, Ponvory, Rebif	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy for continuation of therapy

AND

2.1.2 Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming failure after a trial of at least 4 weeks, contraindication, or intolerance to at least two of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Bafiertam (monomethyl fumarate)
- Copaxone/Glatopa (glatiramer acetate)
- Kesimpta (ofatumumab)
- Dimethyl fumarate
- Vumerity (diroximel fumarate)

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Briumvi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Failure after a trial of at least 4 weeks, contraindication, or intolerance of at least two of the following disease-modifying therapies for MS:

- Aubagio (teriflunomide)
- Kesimpta (ofatumumab)
- Lemtrada (alemtuzumab)
- Mavenclad (cladribine)
- Plegridy (peginterferon beta-1a)
- Tysabri (natalizumab)
- Any one of the interferon beta-1a injections (e.g., Avonex)
- Any one of the interferon beta-1b injections (e.g., Betaseron)
- Any one of the glatiramer acetate injections (e.g., Copaxone, Glatopa, generic glatiramer acetate)
- Any one of the oral fumarates (e.g., generic dimethyl fumarate)
- Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (e.g., Gilenya, Mayzent, Zeposia)

OR

2.2 For continuation of prior therapy

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [16]

AND

5 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

6 - Prescribed by or in consultation with a neurologist

Product Name: Briumvi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [16]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Lemtrada	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient has not been previously treated with alemtuzumab

AND

2.1.2 Failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS:

- Aubagio (teriflunomide)
- Mavenclad (cladribine)
- Plegridy (peginterferon beta-1a)
- Tysabri (natalizumab)
- Any one of the interferon beta-1a injections (e.g., Avonex)
- Any one of the interferon beta-1b injections (e.g., Betaseron)
- Any one of the glatiramer acetate injections (e.g., Copaxone, Glatopa, generic glatiramer acetate)
- Any one of the B-cell targeted therapies (e.g., Kesimpta)
- Any one of the oral fumarates (e.g., generic dimethyl fumarate)
- Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (e.g., Gilenya, Mayzent, Zeposia)

OR

2.2 Both of the following: [E]

2.2.1 Patient has previously received treatment with alemtuzumab

AND

2.2.2 At least 12 months have or will have elapsed since the most recent treatment course with alemtuzumab

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Mavenclad	
Approval Length	2 Month(s) [H]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a relapsing form of MS (e.g., relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient has not been previously treated with cladribine

AND

2.1.2 Failure after a trial of at least 4 weeks, contraindication, or intolerance to one of the following disease-modifying therapies for MS:

- Aubagio (teriflunomide)
- Lemtrada (alemtuzumab)
- Plegridy (peginterferon beta-1a)
- Tysabri (natalizumab)
- Any one of the interferon beta-1a injections (e.g., Avonex)
- Any one of the interferon beta-1b injections (e.g., Betaseron)
- Any one of the glatiramer acetate injections (e.g., Copaxone, Glatopa, generic glatiramer acetate)
- Any one of the B-cell targeted therapies (e.g., Kesimpta)
- Any one of the oral fumarates (e.g., generic dimethyl fumarate)

- Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (e.g., Gilenya, Mayzent, Zeposia)

OR

2.2 Both of the following:

2.2.1 Patient has previously received treatment with cladribine

AND

2.2.2 Patient has not already received the FDA-recommended lifetime limit of 2 treatment courses (or 4 treatment cycles total) of cladribine

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Ocrevus	
Diagnosis	Relapsing Forms of MS
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Failure after a trial of at least 4 weeks, contraindication, or intolerance to one of the following disease-modifying therapies for MS:

- Aubagio (teriflunomide)
- Kesimpta (ofatumumab)
- Lemtrada (alemtuzumab)
- Mavenclad (cladribine)
- Plegridy (peginterferon beta-1a)
- Tysabri (natalizumab)
- Any one of the interferon beta-1a injections (e.g., Avonex)
- Any one of the interferon beta-1b injections (e.g., Betaseron)
- Any one of the glatiramer acetate injections (e.g., Copaxone, Glatopa, generic glatiramer acetate)
- Any one of the oral fumarates (e.g., generic dimethyl fumarate)
- Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (e.g., Gilenya, Mayzent, Zeposia)

OR

2.2 For continuation of prior therapy

AND

3 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

4 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [14]

AND

5 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

6 - Prescribed by or in consultation with a neurologist

Product Name: Ocrevus	
Diagnosis	Relapsing Forms of MS
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [14]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Ocrevus	
Diagnosis	Primary Progressive Multiple Sclerosis (PPMS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Primary Progressive Multiple Sclerosis (PPMS)

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [14]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Ocrevus	
Diagnosis	Primary Progressive Multiple Sclerosis (PPMS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS [G, 22, 23]

AND

3 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [14]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

3 . Endnotes

A. According to the National MS Society, of the four disease courses that have been identified in MS, relapsing-remitting MS (RRMS) is characterized primarily by relapses, and secondary-progressive MS (SPMS) has both relapsing and progressive characteristics. These two constitute “relapsing forms of MS” if they describe a disease course that is characterized by the occurrence of relapses. [7] The effectiveness of interferon beta in SPMS patients without relapses is uncertain. [6]
B. Initiation of treatment with an interferon beta medication or glatiramer acetate should be considered as soon as possible following a definite diagnosis of MS with active, relapsing disease, and may also be considered for selected patients with a first attack who are at high risk of MS. [6]
C. Based on several years of experience with glatiramer acetate and interferon beta 1a and 1b, it is the consensus of researchers and clinicians with expertise in MS that these agents are likely to reduce future disease activity and improve quality of life for many individuals with relapsing forms of MS, including those with secondary progressive disease who continue to have relapses. For those who are appropriate candidates for one of these drugs, treatment must be sustained for years. Cessation of treatment may result in a resumption of pre-treatment disease activity. [6]
D. MS specialists will use Copaxone in relapsing forms of disease, including SPMS with relapses. While there have been no trials of Copaxone in SPMS (so we have no evidenced-based data upon which to make decisions or recommendations), it's clear that where there are relapses, the injectable therapies are partially effective – they reduce relapses and new lesions on MRI. In SPMS, the trials suggest that the interferons

work better in earlier, more inflammatory (i.e. those with relapses prior to the trial and with gadolinium-enhancing lesions, which is the MRI equivalent of active inflammation). Since Copaxone and the interferons appear to have rather similar efficacy in the head-to-head trials, most assume that Copaxone has a similar efficacy in SPMS: where there are relapses or active inflammation on MRI, it will likely have some benefit. Thus, most MS specialists will use Copaxone in patients with SPMS who have persistent relapses. [8]

E. According to Prescribing Information, the recommended dosage of Lemtrada is 12 mg/day administered by intravenous infusion for 2 treatment courses (first treatment course: 12 mg/day on 5 consecutive days; second treatment course: 12 mg/day on 3 consecutive days administered 12 months after the first treatment course). Following the second treatment course, subsequent treatment courses of 12 mg per day on 3 consecutive days (36 mg total dose) may be administered, as needed, at least 12 months after the last dose of any prior treatment courses. [11]
F. Not to exceed the FDA-recommended dosage of 2 treatment courses (with the second course administered 43 weeks following the last dose of the first course). According to Prescribing Information, the recommended cumulative dosage of Mavenclad is 3.5 mg per kg body weight administered orally and divided into 2 yearly treatment courses (1.75 mg per kg per treatment course). Each treatment course is divided into 2 treatment cycles with the second cycle of each course administered 23 to 27 days after the last dose of the first cycle. Following the administration of 2 treatment courses, do not administer additional Mavenclad treatment during the next 2 years. Treatment during these 2 years may further increase the risk of malignancy. The safety and efficacy of reinitiating Mavenclad more than 2 years after completing 2 treatment courses has not been studied. [16]
G. The advantage of using combination disease-modifying therapy (DMT) compared to monotherapy DMT use has not been demonstrated, but there are safety concerns, such as reduced efficacy or disease aggravation, with combination use. [22, 23]
H. Due to the unique dosing regimen of Mavenclad, a two-month PA approval length is implemented to ensure medication for the second cycle of the same treatment course is accessible to patients before the auth expires. [16]

4 . References

1. Avonex Prescribing Information. Biogen Inc. Cambridge, MA. November 2021.
2. Betaseron Prescribing Information. Bayer. Whippany, NJ. November 2021
3. Copaxone Prescribing Information. Teva Pharmaceuticals. North Wales, PA. February 2023.
4. Extavia Prescribing Information. Novartis. East Hanover, NJ. November 2021.
5. Rebif Prescribing Information. Serono Inc. Rockland, MA. November 2021.
6. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline: Disease-modifying therapies for adults with multiple sclerosis. Neurology 2018;90:777-788.

7. National Multiple Sclerosis Society. Types of MS. Available at: https://www.nationalmssociety.org/What-is-MS/Types-of-MS. Accessed March 29, 2019.
8. Per clinical consultation with MS specialist, December 29, 2010.
9. Plegridy Prescribing Information. Biogen Idec Inc. Cambridge, MA. March 2022.
10. Aubagio Prescribing Information. Genzyme Corporation. Cambridge, MA. December 2022.
11. Lemtrada Prescribing Information. Genzyme Corporation. Cambridge, MA. January 2023.
12. Glatopa Prescribing Information. Sandoz Inc. Princeton, NJ. April 2022.
13. Hawker K, O'Connor P, Freedman MS, et al. Rituximab in patients with primary progressive multiple sclerosis: results of a randomized double-blind placebo-controlled multicenter trial. Ann Neurol. 2009; Oct;66(4):460-71.
14. Ocrevus Prescribing Information. Genentech, Inc. San Francisco, CA. August 2022.
15. Mayzent Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. January 2023.
16. Mavenclad Prescribing Information. EMD Serono, Inc. Rockland, MA. September 2022.
17. Vumerity Prescribing Information. Biogen Inc. Cambridge, MA. February 2023.
18. Bafiertam Prescribing Information. Banner Life Sciences. High Point, NC. January 2023.
19. Kesimpta Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. September 2022.
20. Hauser S, Bar-Or A, Cohen J et al. Ofatumumab versus Teriflunomide in Multiple Sclerosis. New England Journal of Medicine. 2020;383(6):546-557.
21. Ponvory Prescribing Information. Janssen Pharmaceuticals Inc. Titusville, NJ. September 2022.
22. Wingerchuk, D., & Carter, J. (2014). Multiple Sclerosis: Current and Emerging Disease-Modifying Therapies and Treatment Strategies. Mayo Clinic Proceedings, 89(2), 225-240.
23. Sorensen, P., Lycke, J., Erälinna, J., Edland, A., Wu, X., & Frederiksen, J. et al. (2011). Simvastatin as add-on therapy to interferon beta-1a for relapsing-remitting multiple sclerosis (SIMCOMBIN study): a placebo-controlled randomised phase 4 trial. The Lancet Neurology, 10(8), 691-701.
24. Tascenso ODT Prescribing Information. Cycle Pharmaceuticals Ltd. Cambridge, United Kingdom. December 2022.
25. Briumvi Prescribing Information. TG Therapeutics, Inc. Morrisville, NC. December 2022.

5 . Revision History

Date	Notes
5/23/2023	For brand Aubagio, requiring trial and failure or intolerance of generic teriflunomide

Myalept (metreleptin for injection)

Prior Authorization Guideline

Guideline ID	GL-109361
Guideline Name	Myalept (metreleptin for injection)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	5/21/2014
P&T Revision Date:	08/13/2020 ; 08/19/2021 ; 8/18/2022

Note:

2021 Annual Review

1 . Indications

Drug Name: Myalept (metreleptin for injection)
Congenital or acquired generalized lipodystrophy Indicated as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy

2 . Criteria

Product Name: Myalept	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of congenital or acquired generalized lipodystrophy

AND

2 - Patient is refractory to current standards of care for lipid and diabetic management

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Documentation demonstrates that patient has at least one of the following metabolic abnormalities: [2]

- Insulin resistance (defined as requiring more than 200 units per day)
- Hypertriglyceridemia
- Diabetes

Product Name: Myalept	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy, such as one of the following:

- Sustained reduction in hemoglobin A1c level from baseline
- Sustained reduction in triglyceride levels from baseline

3 . References

1. Myalept Prescribing Information. Amryt Pharmaceuticals DAC. Dublin, Ireland. February 2022.
2. Handelsman Y, Oral EA, Bloomgarden ZT, et al. The clinical approach to the detection of lipodystrophy – an AACE consensus statement. Endocrine Practice 2013;19(1):107-116.
3. Araujo-Vilar, D., Santini, F. Diagnosis and Treatment of Lipodystrophy: A Step-by-Step Approach. Journal of Endocrinological Investigation volume 42, pages61–73 (2019). Available at https://link.springer.com/article/10.1007/s40618-018-0887-z. Accessed July 13, 2022.

4 . Revision History

Date	Notes
7/13/2022	2022 Annual Review

Myobloc (rimabotulinumtoxin B)

Prior Authorization Guideline

Guideline ID	GL-108278
Guideline Name	Myobloc (rimabotulinumtoxin B)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	9/1/2022
P&T Approval Date:	4/20/2001
P&T Revision Date:	10/16/2019 ; 07/15/2020 ; 04/21/2021 ; 07/21/2021 ; 7/20/2022

1 . Indications

Drug Name: Myobloc (rimabotulinumtoxin B)
Cervical Dystonia (CD) Indicated for the treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia. **Chronic Sialorrhea** Indicated for the treatment of chronic sialorrhea in adults.

2 . Criteria

Product Name: Myobloc	
Diagnosis	Cervical Dystonia (also known as spasmodic torticollis)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cervical dystonia (also known as spasmodic torticollis) [2]

Product Name: Myobloc	
Diagnosis	Cervical Dystonia (also known as spasmodic torticollis)
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - At least 3 months have elapsed since the last treatment [A]

Product Name: Myobloc	
Diagnosis	Chronic Sialorrhea
Approval Length	3 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic sialorrhea

Product Name: Myobloc	
Diagnosis	Chronic Sialorrhea
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - At least 3 months have elapsed since the last treatment [B]

3 . Endnotes

A. The duration of effect in patients responding to Myobloc treatment has been observed in studies to be between 12 and 16 weeks at doses of 5,000 Units or 10,000 Units. [1]
B. The typical duration of effect of each treatment is up to 3 months with the repeat of treatments should be determined by clinical response but should generally be no frequent than every 12 weeks.

4 . References

1. Myobloc Prescribing Information. Solstice Neurosciences, LLC. Louisville, KY. March 2021.
2. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016 May;86(19):1818-26.

5 . Revision History

Date	Notes
7/21/2022	Annual review - no changes.

Naglazyme (galsulfase injection)

Prior Authorization Guideline

Guideline ID	GL-125185
Guideline Name	Naglazyme (galsulfase injection)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	8/1/2006
P&T Revision Date:	06/17/2020 ; 06/16/2021 ; 06/15/2022 ; 6/21/2023

1 . Indications

Drug Name: Naglazyme (galsulfase injection)
Mucopolysaccharidosis (MPS VI) Indicated for patients with Mucopolysaccharidosis VI (MPS VI). Naglazyme has been shown to improve walking and stair-climbing capacity.

2 . Criteria

Product Name: Naglazyme

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Mucopolysaccharidosis VI (MPS VI, Maroteaux-Lamy Syndrome)	

Product Name: Naglazyme	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	

3 . References

1. Naglazyme Prescribing Information. BioMarin Pharmaceuticals Inc. April 2020.

4 . Revision History

Date	Notes
6/6/2023	Initial auth shortened to 12 months. Reauth criteria created with 24 month approval.

Natpara (parathyroid hormone)

Prior Authorization Guideline

Guideline ID	GL-110058
Guideline Name	Natpara (parathyroid hormone)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	4/14/2015
P&T Revision Date:	08/15/2019 ; 08/13/2020 ; 08/19/2021 ; 10/1/2022

1 . Indications

Drug Name: Natpara (parathyroid hormone)
Hypoparathyroidism Indicated as an adjunct to calcium and vitamin D to control hypocalcemia in patients with hypoparathyroidism. Limitations of Use: (1) Because of the potential risk of osteosarcoma, Natpara is recommended only for patients who cannot be well-controlled on calcium supplements and active forms of vitamin D alone; (2) Natpara was not studied in patients with hypoparathyroidism caused by calcium-sensing receptor mutations; and (3) Natpara was not studied in patients with acute post-surgical hypoparathyroidism.

2 . Criteria

Product Name: Natpara	
Approval Length	6 Month [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hypocalcemia due to chronic hypoparathyroidism

AND

2 - Natpara is not being used in the setting of acute post-surgical hypoparathyroidism

AND

3 - Patient does not have a known calcium-sensing receptor mutation

AND

4 - Patient has a documented parathyroid hormone concentration that is inappropriately low for the level of calcium, recorded on at least two occasions within the previous 12 months

AND

5 - Patient has been optimized on adequate doses of both of the following supplements [B]:

- Calcium (greater than or equal to 2,000 mg daily)

- Vitamin D (calcitriol greater than or equal to 1 mcg/day)

AND

6 - One of the following:

6.1 Patient has normal thyroid-stimulating hormone concentrations if not on thyroid hormone replacement therapy

OR

6.2 The dose has been stable for greater than or equal to 3 months for patients on thyroid hormone replacement therapy

AND

7 - Patient has normal serum magnesium and 25-hydroxyvitamin D concentrations

AND

8 - Used as an adjunct to calcium and vitamin D

AND

9 - Prescribed by or in consultation with an endocrinologist [D]

Product Name: Natpara	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient has achieved and maintained serum calcium levels in the ideal range (8 - 9 mg/dL)

OR

1.2 Patient has experienced a 50% or greater reduction from baseline in oral calcium intake

OR

1.3 Patient has experienced a 50% or greater reduction from baseline in oral vitamin D intake

3 . Endnotes

A. Patients randomized to Natpara therapy in the REPLACE pivotal trial were given therapy for 24 weeks duration. [2]
B. Due to a potential risk of osteosarcoma, Natpara use should be limited to those who do not respond to standard of care therapy with calcium and active vitamin D supplementation. [3]
C. In the REPLACE trial, patients were initiated on Natpara therapy with both calcium supplements and active vitamin D. During the 12-week titration phase, the doses of active vitamin D were reduced and, if possible, eliminated, followed by a reduction in oral calcium doses, while maintaining serum calcium at or above the concentration recorded at baseline. [2]
D. Prescriber certification is required through the Natpara REMS program. [1]

4 . References

1. Natpara Prescribing Information. Shire-NPS Pharmaceuticals, Inc. Lexington, MA. July 2020
2. Mannstadt M, Clarke BL, Vokes T, et al. Efficacy and safety of recombinant human parathyroid hormone (1-84) in hypoparathyroidism (REPLACE): a double blind, placebo-controlled, randomized phase 3 study. Lancet. 2013; 1:275-83.
3. FDA Summary Review: Natpara. Food and Drug Administration Web Site. 2015. http://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/125511Orig1s000SumR.pdf. Accessed July 9, 2019.

5 . Revision History

Date	Notes
8/3/2022	Annual Review Update to Reauth - addition of "from baseline"

Neulasta (pegfilgrastim)

Prior Authorization Guideline

Guideline ID	GL-116557
Guideline Name	Neulasta (pegfilgrastim)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Neulasta/Neulasta Onpro	
Diagnosis	Primary Prophylaxis of Chemotherapy-Induced Febrile Neutropenia (CFN)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - One of the following:

1.1 Patient is receiving chemotherapy associated with greater than 20% incidence of febrile neutropenia

OR

1.2 Both of the following:

- Patient is receiving selected chemotherapy regimen associated with 10-20% incidence of febrile neutropenia
- One or more risk factors associated with chemotherapy-induced infection, febrile neutropenia, or neutropenia

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Neulasta/Neulasta Onpro	
Diagnosis	Secondary Prophylaxis of Febrile Neutropenia
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a history of febrile neutropenia with previous chemotherapy

AND

2 - Patient is receiving myelosuppressive chemotherapy associated with neutropenia (ANC less than 500 cells/mm^3)

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Neulasta/Neulasta Onpro	
Diagnosis	Neutropenia associated with Dose Dense Chemotherapy (NDDC)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen and the incidence of febrile neutropenia is unknown

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Neulasta/Neulasta Onpro

Diagnosis	Primary Prophylaxis of Chemotherapy-Induced Febrile Neutropenia (CFN),Secondary Prophylaxis of Febrile Neutropenia, Neutropenia associated with Dose Dense Chemotherapy (NDDC)
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Neulasta/Neulasta Onpro	
Diagnosis	Febrile Neutropenia (FN)
Approval Length	1 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving myelosuppressive chemotherapy associated with neutropenia (ANC less than or equal to 500 cells/mm^3)

AND

2 - Patient is at high risk for infection-associated complications

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Neulasta/Neulasta Onpro	
Diagnosis	Acute Radiation Syndrome (ARS)
Approval Length	1 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is/was acutely exposed to myelosuppressive doses of radiation

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Neulasta/Neulasta Onpro	
Diagnosis	Febrile Neutropenia (FN), Acute Radiation Syndrome (ARS)
Approval Length	1 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/4/2022	2023 New Implementation

Neupogen (filgrastim)

Prior Authorization Guideline

Guideline ID	GL-116548
Guideline Name	Neupogen (filgrastim)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Neupogen	
Diagnosis	Bone Marrow/Stem Cell Transplant (BMSCT)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - One of the following:

1.1 Patient has non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT)

OR

1.2 Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

OR

1.3 Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Neupogen	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - Patient has completed induction or consolidation chemotherapy

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Neupogen	
Diagnosis	Primary Prophylaxis of Chemotherapy-Induced Febrile Neutropenia (CFN)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient is receiving chemotherapy associated with greater than 20% incidence of febrile neutropenia

OR

1.2 Both of the following:

- Patient is receiving selected chemotherapy regimen associated with 10-20% incidence of febrile neutropenia
- One or more risk factors associated with chemotherapy-induced infection, febrile neutropenia, or neutropenia

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Neupogen	
Diagnosis	Secondary Prophylaxis of Febrile Neutropenia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has a history of febrile neutropenia with previous chemotherapy

AND

2 - Patient is receiving myelosuppressive chemotherapy associated with neutropenia (ANC less than 500 cells/mm^3)

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Neupogen	
Diagnosis	Neutropenia associated with Dose Dense Chemotherapy (NDDC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen and the incidence of febrile neutropenia is unknown

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Neupogen	
Diagnosis	Severe Chronic Neutropenia (SCN)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - For patients with severe chronic neutropenia (SCN) (i.e., congenital, cyclic, and idiopathic neutropenias with chronic absolute neutrophil count [ANC] less than or equal to 500 cells/mm^3)

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Neupogen	
Diagnosis	Febrile Neutropenia (FN)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving myelosuppressive chemotherapy associated with neutropenia (ANC less than or equal to 500 cells/mm^3)

AND

2 - Patient is at high risk for infection-associated complications

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Neupogen	
Diagnosis	Acute Radiation Syndrome (ARS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Patient is/was acutely exposed to myelosuppressive doses of radiation **AND** **2** - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Neupogen	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	

2 . Revision History

Date	Notes
9/24/2022	2023 New Implementation

Nexviazyme (avalglucosidase alfa-ngpt)

Prior Authorization Guideline

Guideline ID	GL-113432
Guideline Name	Nexviazyme (avalglucosidase alfa-ngpt)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	11/1/2022
P&T Approval Date:	10/21/2021
P&T Revision Date:	11/18/2021 ; 02/17/2022 ; 9/21/2022

1 . Indications

Drug Name: Nexviazyme (avalglucosidase alfa-ngpt)
Pompe Disease Indicated for the treatment of patients 1 year of age and older with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency).

2 . Criteria

Product Name: Nexviazyme

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) as confirmed by one of the following: [2, 3]

1.1 Absence or deficiency (less than 40% of the lab specific normal mean) of GAA enzyme activity in lymphocytes, fibroblasts, or muscle tissues as confirmed by an enzymatic assay

OR

1.2 Molecular genetic testing confirms mutations in the GAA gene

AND

2 - Presence of clinical signs and symptoms of the disease (e.g., respiratory distress, skeletal muscle weakness, etc.) [A]

AND

3 - Patient is 1 year of age or older

AND

4 - Trial and failure, contraindication, or intolerance to Lumizyme

Product Name: Nexviazyme

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . Endnotes

A. Consensus recommendation based on current clinical guidelines indicate that treatment should be started in patients when they become symptomatic and/or show signs of disease progression [2, 3].

4 . References

1. Nexviazyme Prescribing Information. Genzyme Corporation. Cambridge, MA. August 2021.
2. Barba-Romero MA, Barrot E, Bautista-Lorite J, et al. Clinical guidelines for late-onset Pompe disease. Rev Neurol 2012; 54 (8): 497-507.
3. Kishnani PS, Steiner RD, Bali D, et al. Pompe disease diagnosis and management guideline. Genet Med. May 2006; 8(5): 267–288.

5 . Revision History

Date	Notes
9/7/2022	Annual review: No criteria changes.

Nilutamide

Prior Authorization Guideline

Guideline ID	GL-116541
Guideline Name	Nilutamide
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Generic nilutamide	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of metastatic prostate cancer	

AND

2 - Prescribed in combination with surgical castration

AND

3 - Submission of medical records (e.g., chart notes) confirming current liver function

AND

4 - Patient does not have severe hepatic impairment

AND

5 - Patient does not have severe respiratory insufficiency

AND

6 - Prescribed by or in consultation with an oncologist

Product Name: Generic nilutamide	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of no disease progression

2 . Revision History

Date	Notes
9/29/2022	2023 New Implementation

Nplate (romiplostim)

Prior Authorization Guideline

Guideline ID	GL-118126
Guideline Name	Nplate (romiplostim)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	4/7/2009
P&T Revision Date:	02/13/2020 ; 02/18/2021 ; 04/21/2021 ; 02/17/2022 ; 2/16/2023

1 . Indications

Drug Name: Nplate (romiplostim)
Immune Thrombocytopenia (ITP) Indicated for the treatment of thrombocytopenia in adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy and in pediatric patients 1 year of age and older with ITP for at least 6 months who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Limitations of Use: - Nplate is not indicated for the treatment of thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than ITP. - Nplate should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increases the risk for bleeding. - Nplate should not be used in an attempt to normalize platelet counts. **Hematopoietic Syndrome of Acute Radiation Syndrome** Indicated to increase survival in

adults and in pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation.

2 . Criteria

Product Name: Nplate	
Diagnosis	Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Immune thrombocytopenia (ITP) [A]
- Relapsed/refractory ITP [4]

AND

2 - Baseline platelet count is less than 30,000/mcL [2-4]

AND

3 - Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding

AND

4 - Trial and failure, contraindication, or intolerance to one of the following: [2]

- Corticosteroids (e.g., dexamethasone, prednisone)
- Immune globulins (e.g., Gammaplex, Gammagard S/D)
- Splenectomy

AND

5 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Nplate	
Diagnosis	Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding

Product Name: Nplate	
Diagnosis	Hematopoietic Syndrome of Acute Radiation Syndrome
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hematopoietic syndrome of acute radiation syndrome

AND

2 - Patient is acutely exposed to myelosuppressive doses of radiation

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

3 . Endnotes

A. ITP has previously been called idiopathic thrombocytopenic purpura, immune thrombocytopenic purpura, or autoimmune thrombocytopenic purpura (AITP). These terms have been replaced by "immune thrombocytopenia" to reflect the known autoantibody mechanism and the absence of purpura in some patients. [5]

4 . References

1. Nplate Prescribing Information. Amgen Inc. Thousand Oaks, CA. February 2022.
2. Kuter DJ, Bussel JB, Lyons RM, et al. Efficacy of romiplostim in patients with chronic immume thrombocytopenic purpura: a double-blind randomised controlled trial. Lancet. 2008; 371:395-403.
3. American Society of Hematology 2019 guidelines for immune thrombocytopenia. Available at: https://ashpublications.org/bloodadvances/article/3/23/3829/429213/American-Society-of-Hematology-2019-guidelines-for. Accessed December 9, 2022.
4. Per clinical consult with hematologist/oncologist, June 20, 2018.
5. Immune thrombocytopenia (ITP) in adults: Clinical manifestations and diagnosis. UpToDate Website. Available at: www.uptodate.com. Accessed December 9, 2022.

5 . Revision History

Date	Notes
2/1/2023	Annual review: Background updates.

Nucala (mepolizumab)

Prior Authorization Guideline

Guideline ID	GL-124557
Guideline Name	Nucala (mepolizumab)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	11/17/2015
P&T Revision Date:	08/15/2019 ; 11/14/2019 ; 02/13/2020 ; 12/16/2020 ; 03/17/2021 ; 09/15/2021 ; 03/16/2022 ; 07/20/2022 ; 05/19/2022 ; 5/18/2023

1 . Indications

Drug Name: Nucala (mepolizumab)
Severe Eosinophilic Asthma Indicated for the add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype. Limitations of Use: Nucala is not indicated for the relief of acute bronchospasm or status asthmaticus. **Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)** Indicated for the add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids. **Eosinophilic Granulomatosis with Polyangiitis** Indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

Hypereosinophilic Syndrome Indicated for the treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for greater than or equal to 6 months without an identifiable non-hematologic secondary cause.

2 . Criteria

Product Name: Nucala	
Diagnosis	Severe Asthma
Approval Length	6 Months [G]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe asthma [1, A]

AND

2 - Asthma is an eosinophilic phenotype as defined by one of the following [1, 3, B]:

- Baseline (pre-treatment) peripheral blood eosinophil level is greater than or equal to 150 cells/microliter
- Peripheral blood eosinophil levels were greater than or equal to 300 cells/microliter within the past 12 months

AND

3 - One of the following:

3.1 Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months [2-4, H]

OR

3.2 Prior asthma-related hospitalization within the past 12 months

AND

4 - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications [2-4, D]:

4.1 Both of the following:

- High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium)

OR

4.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol], Breo Ellipta [fluticasone/vilanterol])

AND

5 - Age greater than or equal to 6 years [1]

AND

6 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name: Nucala	
Diagnosis	Severe Asthma
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications) [C]

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name: Nucala	
Diagnosis	Chronic rhinosinusitis with nasal polyps (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP)

AND

2 - Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone) [10, 11]

AND

3 - Used in combination with another agent for CRSwNP [J]

AND

4 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Otolaryngologist
- Pulmonologist

Product Name: Nucala	
Diagnosis	Chronic rhinosinusitis with nasal polyps (CRSwNP)
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS; 0-8 scale], improvement in nasal obstruction symptoms via visual analog scale [VAS; 0-10 scale])

AND

2 - Used in combination with another agent for CRSwNP [J]

AND

3 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Otolaryngologist
- Pulmonologist

Product Name: Nucala	
Diagnosis	Eosinophilic Granulomatosis with Polyangiitis (EGPA)
Approval Length	12 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA)

AND

2 - Patient's disease has relapsed or is refractory to standard of care therapy (i.e., corticosteroid treatment with or without immunosuppressive therapy) [F, 7]

AND

3 - Patient is currently receiving corticosteroid therapy (e.g., prednisolone, prednisone) [F, 7]

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Rheumatologist
- Allergist/Immunologist

Product Name: Nucala	
Diagnosis	Eosinophilic Granulomatosis with Polyangiitis (EGPA)
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., increase in remission time)

Product Name: Nucala

Diagnosis	Hypereosinophilic Syndrome (HES)
Approval Length	12 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hypereosinophilic syndrome (HES)

AND

2 - Patient has been diagnosed for at least 6 months

AND

3 - Verification that other non-hematologic secondary causes have been ruled out (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy)

AND

4 - Patient is Fip1-like1-platelet-derived growth factor receptor alpha (FIP1L1-PDGFRA)-negative

AND

5 - Patient has uncontrolled HES defined as both of the following:

- History of 2 or more flares within the past 12 months [I]
- Pre-treatment blood eosinophil count greater than or equal to 1000 cells/microliter

AND

6 - Trial and failure, contraindication, or intolerance to one of the following:

- Corticosteroid therapy (e.g., prednisone)
- Cytotoxic/immunosuppressive therapy (e.g., hydroxyurea, cyclosporine, imatinib)

AND

7 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Hematologist

Product Name: Nucala	
Diagnosis	Hypereosinophilic Syndrome (HES)
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction in flares, decreased blood eosinophil count, reduction in corticosteroid dose)

3 . Background

Clinical Practice Guidelines

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 1. Low, medium and high daily doses of inhaled corticosteroids in adolescents and adults 12 years and older [6]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	> 500-1000	> 1000
Beclometasone dipropionate (DPI or pMDI, extrafine particle*, HFA)	100-200	> 200-400	> 400
Budesonide (DPI, or pMDI, standard particle, HFA)	200-400	> 400-800	> 800
Ciclesonide (pMDI, extrafine particle*, HFA)	80-160	> 160-320	> 320
Fluticasone furoate (DPI)	100		200
Fluticasone propionate (DPI)	100-250	> 250-500	> 500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	> 250-500	> 500
Mometasone furoate (DPI)	Depends on DPI device – see product information		
Mometasone furoate (pMDI, standard particle, HFA)	200-400		> 400

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

This is not a table of equivalence, but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

4 . Endnotes

A. Patients included across the 3 pivotal studies (DREAM, MENSA, and SIRIUS) [2-4] were characterized with clinical features of severe refractory asthma per American Thoracic Society (ATS) criteria [5]. Per the ATS: "Severe asthma is defined as asthma which requires treatment with high dose inhaled corticosteroids (ICS) plus a second controller (and/or systemic corticosteroids) to prevent it from becoming 'uncontrolled' or which remains 'uncontrolled' despite this therapy.'' This definition includes patients who received an adequate trial of these therapies in whom treatment was stopped due to lack of response. In patients greater than 6 years of age, ''Gold Standard/International Guidelines treatment'' is high dose ICS plus a long-acting beta 2-agonist (LABA), leukotriene modifier or theophylline and/or continuous or near continuous systemic corticosteroids as background therapy."
B. Inclusion criteria was modified from the DREAM study to the MENSA study to be limited to patients with eosinophils greater than or equal to 150 cells/mcL in the peripheral blood at screening or greater than or equal to 300 cells/mcL at some time during the previous year [3].
C. The primary endpoint for the DREAM and MENSA studies was the annual rate of clinically significant asthma exacerbations as a composite of the required use of systemic corticosteroids for at least 3 days, admission, or ED visit. Both studies showed mepolizumab-treated patients experienced a significant improvement in exacerbation rates compared with baseline and compared with placebo. [2, 3]
D. The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention update lists anti-interleukin- 5 treatment or anti-interleukin 5 receptor treatment as an add on option for patients with severe eosinophilic asthma that is uncontrolled on two or more controllers plus as-needed reliever medication (Step 4-5 treatment). [6]
E. Asthma treatment can often be reduced, once good asthma control has been achieved and maintained for three months and lung function has hit a plateau. However the approach to stepping down will depend on patient specific factors (e.g., current medications, risk factors). At this time evidence for optimal timing, sequence and magnitude of treatment reductions is limited. It is feasible and safe for most patients to reduce the ICS dose by 25-50% at three month intervals, but complete cessation of ICS is associated with a significant risk of exacerbations [6].
F. Nucala was approved for Eosinophilic Granulomatosis with Polyangiitis (EGPA) based on the results from the pivotal, 52-week, Phase III MIRRA study. MIRRA looked at the

efficacy and safety of 300 mg of mepolizumab administered SQ every four weeks versus placebo as add-on therapy to standard of care (corticosteroids plus or minus immunosuppressants) in 136 patients with relapsing and/or refractory EGPA. MIRRA reported statistically significant outcomes with both co-primary endpoints (i.e., accrued time in remission and proportion of patients achieving remission) in favor of the treatment group [7, 8].

G. The GINA Global Strategy for Asthma Management and Prevention update recommends that patients with asthma should be reviewed regularly to monitor their symptom control, risk factors and occurrence of exacerbations, as well as to document the response to any treatment changes. Ideally, response to Type 2-targeted therapy should be re-evaluated every 3-6 months, including re-evaluation of the need for ongoing biologic therapy for patients with good response to Type 2 targeted therapy. [6]
H. Per P&T Committee, February 2019, revised exacerbation requirement to mirror other IL-5 antagonists.
I. Historical flares were defined as a worsening of HES-related clinical symptoms or a blood eosinophil count requiring an escalation in therapy. [1]
J. Other agents used for CRSwNP include intranasal corticosteroids and nasal saline.

5 . References

1. Nucala prescribing information. GlaxoSmithKline LLC. Philadelphia, PA. March 2023.
2. Pavord ID, Korn S, Howarth P, et al. Mepolizumab for severe eosinophilic asthma (DREAM): a multicentre, double-blind, placebo-controlled trial. Lancet. 2012;380: 651-59.
3. Ortega HG, Liu MC, Pavord ID, et al. Mepolizumab treatment in patients with severe eosinophilic asthma. N Engl J Med. 2014;371(13):1198-1207.
4. Bel EH, Wenzel SE, Thompson PJ, et al. Oral Glucocorticoid-Sparing Effect of Mepolizumab in Eosinophilic Asthma. N Engl J Med. 2014;371:1189-1197.
5. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. Eur Respir J. 2014;43:343-373.
6. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention (2022 update). 2022 www.ginasthma.org. Accessed April 2023.
7. Wechsler ME, Akuthota P, Jayne D, et al. Mepolizumab or Placebo for Eosinophilic Granulomatosis with Polyangiitis. N Engl J Med. 2017;376(20):1921-1932.
8. GlaxoSmithKline Press Release. GSK achieves approval for Nucala (mepolizumab) for the treatment of eosinophilic granulomatosis with polyangiitis (EGPA) for adults in the US. Website. Available from: https://www.gsk.com/en-gb/media/press-releases/gsk-achieves-approval-for-nucala-mepolizumab-for-the-treatment-of-eosinophilic-granulomatosis-with-polyangiitis-egpa-for-adults-in-the-us/. Accessed March 11, 2021.
9. ClinicalTrials.gov Web site. https://clinicaltrials.gov/ct2/show/NCT03085797. Accessed August 15, 2021.
10. Peters AT, Spector S, Hsu J, et al. Diagnosis and management of rhinosinusitis: a practice parameter update. Ann Allergy Asthma Immunol. 2014;113(4):347-85.

11. Orlandi RR, Kingdom TT, Hwang PH, et al. International consensus statement on allergy and rhinology: rhinosinusitis. Int Forum Allergy Rhinol. 2016 Feb; Suppl 1:S22-209.

6 . Revision History

Date	Notes
4/24/2023	2023 UM Annual Review. No criteria changes. Background updates

Nulibry (fosdenopterin)

Prior Authorization Guideline

Guideline ID	GL-123199
Guideline Name	Nulibry (fosdenopterin)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	
P&T Revision Date:	04/20/2022 ; 06/15/2022 ; 4/19/2023

1 . Indications

Drug Name: Nulibry (fosdenopterin)
Molybdenum cofactor deficiency (MoCD) Type A Indicated to reduce the risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A.

2 . Criteria

Product Name: Nulibry

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

- Diagnosis of molybdenum cofactor deficiency (MoCD) Type A
- Genetic mutation in the MOCS1 gene

AND

2 - Patient has clinical and/or laboratory signs and symptoms consistent with MOCD Type A (e.g., seizures, limb/axial hypertonia, elevated levels of urinary sulfite/SSC [s-sulfocysteine] or xanthine in blood/urine, low uric acid in blood/urine)

AND

3 - Prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders

Product Name: Nulibry	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders

AND

2 - Patient continues to benefit from medication

3 . References

1. Nulibry Prescribing Information. Origin Biosciences, Inc. Boston, MA. March 2021.
2. Study of ORGN001 (formerly ALXN1101) in neonates, infants and children with molybdenum cofactor deficiency (MOCD) type A. ClinicalTrials.gov identifier: NCT02629393. Updated February 26, 2021. Accessed April 12, 2021. https://www.clinicaltrials.gov/ct2/show/study/NCT02629393.
3. Per clinical consultation with pediatrician, April 30, 2021.
4. Mechler, K., Mountford, W., Hoffmann, G. et al. Ultra-orphan diseases: a quantitative analysis of the natural history of molybdenum cofactor deficiency. Genet Med 17, 965–970 (2015). https://doi.org/10.1038/gim.2015.12

4 . Revision History

Date	Notes
3/13/2023	Annual review - no criteria changes

Octreotide Products - PA, NF

Prior Authorization Guideline

Guideline ID	GL-116110
Guideline Name	Octreotide Products - PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2025
P&T Approval Date:	1/19/2001
P&T Revision Date:	11/14/2019 ; 07/15/2020 ; 09/16/2020 ; 12/16/2020 ; 11/18/2021 ; 01/19/2022 ; 11/17/2022 ; 12/13/2023 ; 11/21/2024 ; 12/15/2024

1 . Indications

Drug Name: Sandostatin (octreotide acetate)
Acromegaly Indicated to reduce blood levels of growth hormone and IGF-1 (somatomedin C) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses. **Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing** Indicated for the treatment of severe diarrhea and flushing episodes associated with metastatic carcinoid tumors. Limitations of Use: Improvement in clinical signs and symptoms, or reduction in tumor size or rate of growth, were not shown in clinical trials performed

with Sandostatin Injection; these trials were not optimally designed to detect such effects.

Vasoactive Intestinal Peptide Tumors (VIPomas), for Symptomatic Treatment of Diarrhea Indicated for the treatment of the profuse watery diarrhea associated with VIP-secreting tumors. Limitations of Use: Improvement in clinical signs and symptoms, or reduction in tumor size or rate of growth, were not shown in clinical trials performed with Sandostatin Injection; these trials were not optimally designed to detect such effects.

Drug Name: Sandostatin LAR Depot (octreotide acetate)

General Indicated in patients in whom initial treatment with Sandostatin Injection has been shown to be effective and tolerated.

Acromegaly Indicated for long-term maintenance therapy in acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. The goal of treatment in acromegaly is to reduce GH and IGF-1 levels to normal.

Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing Indicated for long-term treatment of the severe diarrhea and flushing episodes associated with metastatic carcinoid tumors. Limitation of Use: The effect of Sandostatin LAR on tumor size, rate of growth and development of metastases, has not been determined.

Vasoactive Intestinal Peptide Tumors (VIPomas), for Symptomatic Treatment of Diarrhea Indicated for long-term treatment of the profuse watery diarrhea associated with VIP-secreting tumors. Limitation of Use: The effect of Sandostatin LAR on tumor size, rate of growth and development of metastases, has not been determined.

Drug Name: Mycapssa (octreotide capsule, delayed release)

Acromegaly Indicated for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide.

2 . Criteria

Product Name: Brand Sandostatin, Generic octreotide, Brand Sandostatin LAR, Generic octreotide LAR	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - One of the following:

2.1 Inadequate response to one of the following:

- Surgery
- Pituitary irradiation

OR

2.2 Not a candidate for surgical resection or pituitary irradiation

AND

3 - Trial and failure, contraindication, or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses

AND

4 - One of the following:

4.1 Patient has had a trial of short-acting generic octreotide and responded to and tolerated therapy (Applies to Sandostatin LAR and generic octreotide LAR only)

OR

4.2 Trial and failure, or intolerance to generic octreotide (Applies to Brand Sandostatin only)

Product Name: Mycapssa	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - One of the following:

2.1 Inadequate response to one of the following:

- Surgery
- Pituitary irradiation

OR

2.2 Not a candidate for surgical resection or pituitary irradiation

AND

3 - Patient has responded to and tolerated treatment with generic octreotide or lanreotide

AND

4 - Patient requires long-term maintenance treatment

Product Name: Brand Sandostatin, Generic octreotide, Brand Sandostatin LAR, Generic octreotide LAR, Mycapssa	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size)

Product Name: Brand Sandostatin, Generic octreotide

Diagnosis	Acromegaly
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - One of the following:

2.1 Inadequate response to one of the following:

- Surgery
- Pituitary irradiation

OR

2.2 Not a candidate for surgical resection or pituitary irradiation

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses

AND

4 - Both of the following (Applies to Brand Sandostatin only):

4.1 - Paid claims or submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) with generic octreotide

AND

4.2 - Submission of medical records confirming generic octreotide has not been effective AND valid clinical justification provided explaining how Brand Sandostatin is expected to provide benefit when generic octreotide has not been shown to be effective despite having the same active ingredient

Product Name: Mycapssa	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - Submission of medical records (e.g., chart notes) of one of the following to confirm diagnosis of acromegaly:

2.1 Serum GH level greater than 1 ng/mL after a 2-hour oral glucose tolerance test (OGTT) at the time of diagnosis:

OR

2.2 Elevated serum IGF-1 levels (above the age and gender adjusted normal range as provided by the physician's lab) at the time of diagnosis

AND

3 – One of the following:

3.1 Inadequate response to one of the following:

- Surgery
- Pituitary irradiation

OR

3.2 Not a candidate for surgical resection or pituitary irradiation

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming patient has responded to and tolerated treatment with generic octreotide or lanreotide

AND

5 - Patient requires long-term maintenance treatment

Product Name: Brand Sandostatin, Generic octreotide,Brand Sandostatin LAR, Generic octreotide LAR	
Diagnosis	Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes

AND

2 - One of the following:

2.1 Patient has had a trial of short-acting generic octreotide and responded to and tolerated therapy (Applies to Sandostatin LAR and generic octreotide LAR only)

OR

2.2 Trial and failure, or intolerance to generic octreotide (Applies to Brand Sandostatin only)

Product Name: Brand Sandostatin, Generic octreotide, Brand Sandostatin LAR, Generic octreotide LAR	
Diagnosis	Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of an improvement in the number of diarrhea or flushing episodes

Product Name: Brand Sandostatin	
Diagnosis	Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes

AND

2 - Both of the following:
2.1 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) with generic octreotide

AND

2.2 Submission of medical records confirming generic octreotide has not been effective AND valid clinical justification provided explaining how Brand Sandostatin is expected to provide benefit when generic octreotide has not been shown to be effective despite having the same active ingredient

Product Name: Brand Sandostatin, Generic octreotide, Brand Sandostatin LAR, Generic octreotide LAR	
Diagnosis	Vasoactive Intestinal Peptide Tumors, for Symptomatic Treatment of Diarrhea
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea

AND

2 - One of the following:

2.1 Patient has had a trial of short-acting generic octreotide and responded to and tolerated therapy (Applies to Sandostatin LAR only)

OR

2.2 Trial and failure, or intolerance to generic octreotide (Applies to Brand Sandostatin only)

Product Name: Brand Sandostatin, Generic octreotide, Brand Sandostatin LAR, Generic Sandostatin LAR	
Diagnosis	Vasoactive Intestinal Peptide Tumors, for Symptomatic Treatment of Diarrhea
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of an improvement in the number of diarrhea episodes

Product Name: Brand Sandostatin, generic octreotide	
Diagnosis	Vasoactive Intestinal Peptide Tumors, for Symptomatic Treatment of Diarrhea
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea

AND

2 - Both of the following (Applies to Brand Sandostatin only):
2.1 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) with generic octreotide

AND

2.2 Submission of medical records confirming generic octreotide has not been effective AND valid clinical justification provided explaining how Brand Sandostatin is expected to provide benefit when generic octreotide has not been shown to be effective despite having the same active ingredient

3 . References

1. Sandostatin Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. November 2023.
2. Sandostatin LAR Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. July 2023.
3. Octreotide Prescribing Information. Mylan Institutional LLC. Morgantown, WV. November 2022.
4. Mycapssa Prescribing Information. MW Encap Ltd. Scotland, UK. June 2020.

4 . Revision History

Date	Notes

12/19/2024	Drug-specific NF criteria will apply for Sandostatin LAR and generic. Criteria will align with ORx Commercial criteria except submission of medical records will apply to confirm diagnosis check. Paid claims or submission of medical records will apply to confirm trial requirements. Submission of medical records will also be required for justification of how Brand Sandostatin is expected to provide benefit when generic octreotide has not been effective.

Onpattro (patisiran) & Tegsedi (inotersen)

Prior Authorization Guideline

Guideline ID	GL-122099
Guideline Name	Onpattro (patisiran) & Tegsedi (inotersen)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	10/17/2018
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Onpattro (patisiran), Tegsedi (inotersen)
Hereditary transthyretin-mediated amyloidosis Indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

2 . Criteria

Product Name: Onpattro or Tegsedi

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) with polyneuropathy

AND

2 - Patient has a transthyretin (TTR) mutation (e.g., V30M) [1-4]

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - One of the following [2, 4]:

- Patient has a baseline polyneuropathy disability (PND) score ≤ IIIb
- Patient has a baseline familial amyloidotic polyneuropathy (FAP) stage of 1 or 2
- Patient has a baseline neuropathy impairment score (NIS) between 5 and 130 for Onpattro or a baseline neuropathy impairment score (NIS) between 10 and 130 for Tegsedi

AND

5 - Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy) [2, 4]

Product Name: Onpattro or Tegsedi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has demonstrated a benefit from therapy (e.g., improved neurologic impairment, slowing of disease progression, quality of life assessment)

AND

2 - One of the following [2, 4]:

- Patient continues to have a polyneuropathy disability (PND) score ≤ IIIb
- Patient continues to have a familial amyloidotic polyneuropathy (FAP) stage of 1 or 2
- Patient continues to have a neuropathy impairment score (NIS) between 5 and 130 for Onpattro or a neuropathy impairment score (NIS) between 10 and 130 for Tegsedi

3 . References

1. Onpattro Prescribing Information. Alnylam Pharmaceuticals, Inc. Cambridge, MA. January 2023.
2. Adams D, Suhr OB, Dyck PJ, et al. Trial design and rationale for APOLLO, a phase 3, placebo-controlled study of patisiran in patients with hereditary ATTR amyloidosis with polyneuropathy. BMC Neurol. 2017;17:181.
3. Tegsedi Prescribing Information. Akcea Therapeutics, Inc. Boston, MA. June 2022.
4. Benson MD, Waddington-Cruz M, Berk JL, et al. Inotersen treatment for patients with hereditary transthyretin amyloidosis. N Engl J Med. 2018;379(1):22-31.

4 . Revision History

Date	Notes
3/6/2023	2023 Annual Review.

Opioid Risk Management

Prior Authorization Guideline

Guideline ID	GL-116507
Guideline Name	Opioid Risk Management
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Short-Acting Opioids	
Diagnosis	Cancer or end-of-life care
Approval Length	12 month(s)
Guideline Type	Quantity Limit
Approval Criteria **1** - Diagnosis of cancer or end of life care	

Notes	Note: Patients with a cancer drug in their prescription claims history within the previous 365 days will not be subject to a max daily dose, day supply, or fill restriction. Additionally, if criteria is approved patients will not be subject to a max daily dose, day supply, or fill restriction.

Product Name: Short-Acting Opioids	
Diagnosis	Postoperative Pain Management
Approval Length	14 Day(s)
Guideline Type	Quantity Limit
Approval Criteria **1** - Medication is being used to treat postoperative pain **AND** **2** - Medication is not being prescribed for pain related to a dental procedure **AND** **3** - The dose being prescribed is the dose that the patient was stable on prior to discharge	
Notes	*Patients with a cancer drug in their prescription claims history within the previous 365 days will not be subject to a max daily dose, day supply, or fill restriction. Additionally, if criteria is approved patients will not be subject to a max daily dose, day supply, or fill restriction.

Product Name: Short-Acting Opioids	
Diagnosis	All Other Diagnoses
Approval Length	6 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Prescriber certifies that there is an active treatment plan that includes but is not limited to a specific treatment objective and the use of other pharmacological and non-pharmacological agents for pain relief as appropriate

AND

2 - Prescriber certifies that there has been an informed consent document signed and an addiction risk assessment has been performed

AND

3 - Prescriber certifies that a written/signed agreement between prescriber and patient addressing issues of prescription management, diversion, and the use of other substances exists

Notes	Note: Patients with a cancer drug in their prescription claims history within the previous 365 days will not be subject to a max daily dose, day supply, or fill restriction. Additionally, if criteria is approved patients will not be subject to a max daily dose, day supply, or fill restriction. If the prescriber is unable to certify written documentation to meet criterion (2) and/or (3), written or verbal attestation from the provider may be accepted confirming that the prescriber (or prescriber's representative) has verbally addressed criterion (2) and/or (3) with the patient.

Product Name: Opioid Cough Medications	
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 18 years of age or older

Product Name: Opioid Cough Medications*	
Diagnosis	Greater than the maximum dose as specified in the product prescribing information OR compendia for off-label uses (in the absence of a drug-specific guideline)*
Approval Length	60 Day(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - One of the following:

1.1 Quantity limit override requests must involve an FDA-approved indication

OR

1.2 Quantity limit override requests involving off-label indications must meet off-label guideline approval criteria

AND

2 - One of the following:

2.1 The maximum doses specified under the quantity restriction have been tried for an adequate period of time and been deemed ineffective in the treatment of the member's disease or medical condition

OR

2.2 If lower doses have not been tried, there is clinical support (i.e., clinical literature, patient attributes, or characteristics of the drug) that the number of doses available under the quantity restriction will be ineffective in the treatment of the member's disease or medical condition

AND

3 - One of the following:**

3.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

3.2 Higher dose or quantity is supported by one of following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

Notes	*This guideline only applies in the absence of a drug-specific quantity limit override guideline. No override requests will be permitted for ace taminophen, alone or in combination with other agents, which will exc eed a total of 4 grams of acetaminophen per day. **NOTE: Published biomedical literature may be used as evidence to support safety and a dditional efficacy at higher than maximum doses for the diagnosis pro vided.

Product Name: Long Acting Opioids: Arymo ER, brand Kadian, Morphabond ER, Nucynta ER, Brand Zohydro ER	
Diagnosis	Cancer or End-of-Life Care
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of cancer

OR

1.2 Patient is receiving opioids as part of end-of-life care

AND

2 - Trial and failure, contraindication or intolerance to at least two of the following preferred products

- Hydromorphone ER
- Morphine sulfate ER
- Oxymorphone ER
- Embeda
- Hysingla ER
- Oxycontin
- Xtampza ER

Notes	If the member does not meet the medical necessity reauthorization au thorization criteria requirements, a denial should be issued and a maxi mum 30-day authorization may be authorized one time for the request ed drug/strength combination up to the requested quantity and/or M ME for transition to an alternative treatment.

Product Name: Long Acting Opioids: Arymo ER, brand Kadian, Morphabond ER, Nucynta ER, Brand Zohydro ER	
Diagnosis	Non-Cancer/End-of-Life Care Diagnosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Patient has moderate to severe chronic pain that is non-neuropathic

AND

1.1.2 One of the following:

1.1.2.1 For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]

OR

1.1.2.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy

OR

1.2 All of the following:

1.2.1 Patient has moderate to severe neuropathic pain or fibromyalgia

AND

1.2.2 Unless contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

1.2.3 Unless contraindicated, the patient has not exhibited an adequate response to at least 6-8 weeks of treatment with a tricyclic antidepressant (e.g., amitriptyline, nortriptyline, imipramine) titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

1.2.4 One of the following:

1.2.4.1 For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]

OR

1.2.4.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy

AND

2 - None of the following:

- For use as an as-needed PRN analgesic
- For pain that is mild or not expected to persist for an extended period of time
- For acute pain
- For postoperative pain, unless the patient is already receiving chronic opioid therapy prior to surgery, or if postoperative pain is expected to be moderate to severe and persist for an extended period of time

AND

3 - Trial and failure, contraindication or intolerance to at least two of the following preferred products

- Hydromorphone ER

• Morphine sulfate ER • Oxymorphone ER • Embeda • Hysingla ER • Oxycontin • Xtampza ER	
Notes	If the member does not meet the medical necessity reauthorization au thorization criteria requirements, a denial should be issued and a maxi mum 30-day authorization may be authorized one time for the request ed drug/strength combination up to the requested quantity and/or M ME for transition to an alternative treatment.

Product Name: Long Acting Opioids: Arymo ER, brand Kadian, Morphabond ER, Nucynta ER, Brand Zohydro ER	
Diagnosis	Non-Cancer/End-of-Life Care Diagnosis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation has been provided addressing ALL of the following

- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a nonopioid analgesic and/or nonpharmacologic intervention
- Patient demonstrates meaningful improvement in pain and function using a validated instrument (e.g., Brief Pain Inventory)
- Patient has been screened for substance abuse/opioid dependence using a validated instrument (e.g., DAST-10)
- Rationale for not tapering and discontinuing
- Patient has been screened for comorbid mental health
- If a state prescription drug monitoring program (PDMP) is available, the prescriber has identified there are no concurrently prescribed controlled substances from PDMP
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the

prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression • Total daily morphine equivalent dose	
Notes	If the member does not meet the medical necessity reauthorization au thorization criteria requirements, a denial should be issued and a maxi mum 30-day authorization may be authorized one time for the request ed drug/strength combination up to the requested quantity and/or M ME for transition to an alternative treatment.

Product Name: Long Acting Opioids: brand DURAGESIC, generic transdermal fentanyl patches, brand DOLOPHINE 5 mg tablets, brand DOLOPHINE 10 mg tablets, generic methadone 5 mg tablets, generic methadone 10 mg tablets, brand EXALGO, generic hydromorphone ER, brand MS CONTIN, generic morphine sulfate ER, generic oxymorphone ER, EMBEDA, Brand HYSINGLA ER, OXYCONTIN, generic oxycodone ER, Xtampza ER, generic hydrocodone ER	
Diagnosis	Cancer or End-of-Life Care
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of cancer

OR

1.2 Patient is receiving opioids as part of end-of-life care

Product Name: Long Acting Opioids: brand DURAGESIC, generic transdermal fentanyl patches, brand DOLOPHINE 5 mg tablets, brand DOLOPHINE 10 mg tablets, generic methadone 5 mg tablets, generic methadone 10 mg tablets, brand EXALGO, generic hydromorphone ER, brand MS CONTIN, generic morphine sulfate ER, generic oxymorphone

ER, EMBEDA, Brand HYSINGLA ER, OXYCONTIN, generic oxycodone ER, Xtampza ER, generic hydrocodone ER	
Diagnosis	Non-Cancer/End of Life Care Diagnosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Patient has moderate to severe chronic pain that is non-neuropathic

AND

1.1.2 One of the following:

1.1.2.1 For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]

OR

1.1.2.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy

OR

1.2 All of the following:

1.2.1 Patient has moderate to severe neuropathic pain or fibromyalgia

AND

1.2.2 Unless contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

1.2.3 Unless contraindicated, the patient has not exhibited an adequate response to at least 6-8 weeks of treatment with a tricyclic antidepressant (e.g., amitriptyline, nortriptyline, imipramine) titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

1.2.4 One of the following:

1.2.4.1 For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]

OR

1.2.4.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy

AND

2 - None of the following:

- For use as an as-needed PRN analgesic
- For pain that is mild or not expected to persist for an extended period of time
- For acute pain

• For postoperative pain, unless the patient is already receiving chronic opioid therapy prior to surgery, or if postoperative pain is expected to be moderate to severe and persist for an extended period of time	
Notes	If the member is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity initial authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may b e authorized one time for the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative t reatment.

Product Name: Long Acting Opioids: brand DURAGESIC, generic transdermal fentanyl patches, brand DOLOPHINE 5 mg tablets, brand DOLOPHINE 10 mg tablets, generic methadone 5 mg tablets, generic methadone 10 mg tablets, brand EXALGO, generic hydromorphone ER, brand MS CONTIN, generic morphine sulfate ER, generic oxymorphone ER, EMBEDA, Brand HYSINGLA ER, OXYCONTIN, generic oxycodone ER, Xtampza ER, generic hydrocodone ER	
Diagnosis	Non-Cancer/End-of-Life Care Diagnosis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation has been provided addressing ALL of the following:

- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a nonopioid analgesic and/or nonpharmacologic intervention
- Patient demonstrates meaningful improvement in pain and function using a validated instrument (e.g. Brief Pain Inventory)
- Patient has been screened for substance abuse/opioid dependence using a validated instrument (e.g. DAST-10)
- Rationale for not tapering and discontinuing opioid
- Patient has been screened for comorbid mental health conditions
- If a state prescription drug monitoring program (PDMP) is available, the prescriber has identified there are no concurrently prescribed controlled substances from PDMP

• If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression • Total daily morphine equivalent dose	
Notes	If the member does not meet the medical necessity reauthorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative treatment.

Product Name: Brand Butrans, generic buprenorphine patch, Brand Belbuca*	
Diagnosis	Cancer or End-of-Life Care
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient is being treated for cancer related pain or pain associated with end-of-life	
Notes	*Prior authorization may not apply depending on the plan

Product Name: Brand Butrans, generic buprenorphine patch, Brand Belbuca*	
Diagnosis	Non- Cancer Pain
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - The patient is being treated for pain severe enough to require daily, around-the-clock, longer-term opioid treatment	

AND

2 - None of the following:

- For use as an as-needed PRN analgesic
- For pain that is mild or not expected to persist for an extended period of time
- For acute pain
- For opioid dependence

AND

3 - The patient is not receiving other long-acting opioids concurrently

Notes	*Prior authorization may not apply depending on the plan. If the member is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity initial authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative treatment.

Product Name: Brand Butrans, generic buprenorphine patch, Brand Belbuca*,	
Diagnosis	Non-Cancer Pain
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation has been provided addressing ALL of the following

- Treatment goals are defined, including estimated duration of treatment

• Treatment plan includes the use of a nonopioid analgesic and/or nonpharmacologic intervention • Patient demonstrates meaningful improvement in pain and function using a validated instrument (e.g. Brief Pain Inventory) • Patient has been screened for substance abuse/opioid dependence using a validated instrument (e.g. DAST-10) • Rationale for not tapering and discontinuing opioid • Patient has been screened for comorbid mental health conditions • If a state prescription drug monitoring program (PDMP) is available, the prescriber has identified there are no concurrently prescribed controlled substances from PDMP • If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression • Total daily morphine equivalent dose	
Notes	*Prior authorization may not apply depending on the plan. If the memb er does not meet the medical necessity reauthorization authorization criteria requirements, a denial should be issued and a maximum 30-da y authorization may be authorized one time for the requested drug/str ength combination up to the requested quantity and/or MME for trans ition to an alternative treatment.

2 . References

1. Zohydro ER Prescribing Information.Currax Pharmaceuticals LLC. October 2019.

3 . Revision History

Date	Notes
10/26/2022	New Implementation

Orencia (abatacept)

Prior Authorization Guideline

Guideline ID	GL-116589
Guideline Name	Orencia (abatacept)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Indications

Drug Name: Orencia (abatacept) IV and SC
Rheumatoid Arthritis (RA) Indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis. Limitations of Use: The concomitant use of Orencia with other potent immunosuppressants (e.g., biologic disease-modifying antirheumatic drugs [DMARDs], Janus kinase [JAK] inhibitors) is not recommended. **Polyarticular Juvenile Idiopathic Arthritis (PJIA)** Indicated for the treatment of patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA). Limitations of Use: The concomitant use of Orencia with other potent immunosuppressants (e.g., biologic DMARDs, JAK inhibitors) is not recommended. **Psoriatic Arthritis (PsA)** Indicated for the treatment of adult patients with active psoriatic arthritis (PsA). Limitations of Use: The concomitant use of Orencia with other potent immunosuppressants (e.g., biologic DMARDs, JAK inhibitors) is not recommended.

Drug Name: Orencia (abatacept) IV
Prophylaxis for Acute Graft versus Host Disease (aGVHD) Indicated for the prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor. Limitations of Use: The concomitant use of Orencia with other potent immunosuppressants (e.g., biologic DMARDs, JAK inhibitors) is not recommended.

2 . Criteria

Product Name: Orencia IV or Orencia SC	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate

- leflunomide
- sulfasalazine

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- One formulary adalimumab product
- Rinvoq (upadacitinib)
- Simponi (golimumab)
- Xeljanz/XR (tofacitinib/ER)

OR

4.2 For continuation of prior Orencia therapy, defined as no more than a 45-day gap in therapy

Notes	*Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Orencia IV or Orencia SC	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Orencia IV or Orencia SC	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:

- leflunomide
- methotrexate

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Enbrel (etanercept)
- One formulary adalimumab product
- Xeljanz (tofacitinib)

OR

4.2 For continuation of prior Orencia therapy, defined as no more than a 45-day gap in therapy

Notes	* Includes attestation that a total of two TNF inhibitors have already b een tried in the past, and the patient should not be made to try a third TNF inhibitor.

Product Name: Orencia IV or Orencia SC	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Orencia IV or Orencia SC

Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis (PsA)

AND

2 - One of the following [5]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following:

- Cimzia (certolizumab pegol)

- Enbrel (etanercept)
- One formulary adalimumab product
- Simponi (golimumab)
- One formulary ustekinumab product
- Skyrizi (risankizumab-rzaa)
- Tremfya (guselkumab)
- Rinvoq (upadacitinib)
- Xeljanz/XR (tofacitinib/ER)

OR

4.2 For continuation of prior Orencia therapy, defined as no more than a 45-day gap in therapy

Product Name: Orencia IV or Orencia SC	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 5]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name: Orencia IV	
Diagnosis	Prophylaxis for Acute Graft versus Host Disease (aGVHD)
Approval Length	2 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Used for prophylaxis of acute graft versus host disease (aGVHD)

AND

2 - Patient is 2 years of age or older

AND

3 - Patient will receive hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor

AND

4 - Recommended antiviral prophylactic treatment for Epstein-Barr Virus (EBV) reactivation (e.g., acyclovir) will be administered prior to Orencia and continued for six months after HSCT

AND

5 - Used in combination with both of the following:

- calcineurin inhibitor (e.g., cyclosporine, tacrolimus)
- methotrexate

3 . References

1. Orencia prescribing information. Bristol-Myers Squibb Company. Princeton, NJ. December 2021.

2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.
3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
4. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Rheumatol. 2019;71(6):846-863.
5. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.

4 . Revision History

Date	Notes
10/28/2022	Bulk copy OptumRx SP to Samaritan SP for 1/1/2023 Implementation

Orilissa (elagolix)

Prior Authorization Guideline

Guideline ID	GL-121371
Guideline Name	Orilissa (elagolix)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name: Orilissa 200mg	
Approval Length	6 Month (s)*
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of moderate to severe pain associated with endometriosis	

AND

2 - Trial and failure, contraindication, or intolerance to a 3-month trial of prescription strength NSAIDs

AND

3 - Trial and failure, contraindication, or intolerance to two 3-month trials of hormonal therapies (eg combined oral contraceptives, progestins, or levonorgestrel IUD, etc.)

AND

4 - At least 18 years old but not yet through menopause

AND

5 - Prescribed by or in consultation with obstetrician or gynecologist

AND

6 - Request is for one 200mg tablet twice daily with documentation of coexisting dyspareunia

Notes	*No renewals allowed due to maximum duration of use is 6 months fo r 200 mg twice daily dose.

Product Name: Orilissa 150mg	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe pain associated with endometriosis

AND

2 - Trial and failure, contraindication, or intolerance to a 3-month trial of prescription strength NSAIDs

AND

3 - Trial and failure, contraindication, or intolerance to two 3-month trials of hormonal therapies (eg combined oral contraceptives, progestins, or levonorgestrel IUD, etc.)

AND

4 - At least 18 years old but not yet through menopause

AND

5 - Prescribed by or in consultation with obstetrician or gynecologist

AND

6 - Request is for one 150mg tablet once daily

Product Name: Orilissa 150mg	
Approval Length	18 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy of the 150mg once daily dose

AND

2 - Total duration of therapy on the requested medication is less than 24 months

AND

3 - Documentation of symptom improvement on the requested medication

2 . Revision History

Date	Notes
2/22/2023	New Program

Orkambi (lumacaftor/ivacaftor)

Prior Authorization Guideline

Guideline ID	GL-124331
Guideline Name	Orkambi (lumacaftor/ivacaftor)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	6/10/2015
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 10/19/2022 ; 4/19/2023

1 . Indications

Drug Name: Orkambi (lumacaftor/ivacaftor)
Cystic fibrosis (CF) Indicated for the treatment of cystic fibrosis (CF) in patients age 1 years and older who are homozygous for the F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene. Limitations of Use: The efficacy and safety of Orkambi have not been established in patients with CF other than those homozygous for the F508del mutation.

2 . Criteria

Product Name: Orkambi (100 mg - 125 mg) tablet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments (CLIA)-approved facility

AND

3 - Patient is 6 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist affiliated with a cystic fibrosis care center
- Pulmonologist

Product Name: Orkambi (200 mg - 125 mg) tablet	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments (CLIA)-approved facility

AND

3 - Patient is 12 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist affiliated with a cystic fibrosis care center
- Pulmonologist

Product Name: Orkambi (100 mg - 125 mg) tablet, Orkambi (200 mg - 125 mg) tablet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (i.e., improvement in lung function [forced expiratory volume in one second {FEV1}], decreased number of pulmonary exacerbations)

Product Name: Orkambi (100 mg - 125 mg) granules packet, Orkambi (150 mg - 188 mg) granules packet, Orkambi (75 mg - 94 mg) granules packet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments (CLIA)-approved facility

AND

3 - One of the following:

3.1 Patient is 1 through 5 years of age

OR

3.2 Both of the following:

- Patient is 6 years of age or greater
- Patient is unable to swallow oral tablets

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist affiliated with a cystic fibrosis care center
- Pulmonologist

Product Name: Orkambi (100 mg - 125 mg) granules packet, Orkambi (150 mg - 188 mg) granules packet, Orkambi (75 mg - 94 mg) granules packet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (i.e., improvement in lung function [forced expiratory volume in one second {FEV1}], decreased number of pulmonary exacerbations)

AND

2 - One of the following:

2.1 Patient is 1 through 5 years of age

OR

2.2 Both of the following:

- Patient is 6 years of age or greater
- Patient is unable to swallow oral tablets

3 . References

1. Orkambi Prescribing Information. Vertex Pharmaceuticals Incorporated. Boston, MA. February 2023.

4 . Revision History

Date	Notes
4/6/2023	Annual review: No criteria changes. Updated references.

Otezla (apremilast)

Prior Authorization Guideline

Guideline ID	GL-116590
Guideline Name	Otezla (apremilast)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Indications

Drug Name: Otezla (apremilast)
Psoriatic Arthritis (PsA) Indicated for the treatment of adult patients with active psoriatic arthritis. **Plaque Psoriasis (PsO)** Indicated for the treatment of adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy. **Oral Ulcers Associated with Behçet's Disease** Indicated for the treatment of adult patients with oral ulcers associated with Behçet's Disease.

2 . Criteria

Product Name: Otezla	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [2]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Product Name: Otezla	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 2]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name: Otezla	
Diagnosis	Plaque psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of plaque psoriasis

AND

2 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name: Otezla	
Diagnosis	Plaque psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1, 4]:

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name: Otezla	
Diagnosis	Oral Ulcers Associated with Behçet's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Behçet's Disease

AND

2 - Patient has active oral ulcers

Product Name: Otezla	
Diagnosis	Oral Ulcers Associated with Behçet's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction in pain from oral ulcers or reduction in number of oral ulcers)

3 . References

1. Otezla Prescribing Information. Celgene Corp. Summit, NJ. December 2021.
2. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
3. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
4. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.

4 . Revision History

Date	Notes
10/28/2022	Bulk copy OptumRx SP to Samaritan SP for 1/1/2023 Implementation

Oxervate (cenegermin-bkbj) - PA, QL

Prior Authorization Guideline

Guideline ID	GL-125314
Guideline Name	Oxervate (cenegermin-bkbj) - PA, QL
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	1/16/2019
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 12/15/2021 ; 05/19/2022 ; 09/21/2022 ; 09/21/2022 ; 5/18/2023

1 . Indications

Drug Name: Oxervate (cenegermin-bkbj)
Neurotrophic Keratitis (NK) Indicated for the treatment of neurotrophic keratitis (NK).

2 . Criteria

Product Name: Oxervate

Approval Length	8 weeks*
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neurotrophic keratitis

AND

2 - Trial and failure or intolerance to at least one over-the-counter ocular lubricant used at an optimal dose and frequency for at least two weeks (e.g., artificial tears, lubricating gels/ointments, etc.) [3]

AND

3 - Prescribed by or in consultation with an ophthalmologist

Notes	*Initial authorization maximum coverage is limited to one 8-week approval. Oxervate is hard-coded with a quantity limit of 112 mL per lifetime.

Product Name: Oxervate	
Approval Length	One 8-Week Approval*
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Provider attests patient is being treated for disease recurrence (e.g., new corneal damage following prior corneal healing) **AND** **1.1.2** Provider attests patient has not experienced treatment failure (e.g., patient has not experienced corneal healing after a previous course of Oxervate) **OR** **1.2** Provider attests treatment is for an eye that has not previously been treated with Oxervate	
Notes	*Reauthorization maximum coverage is limited to one 8-week approval. Oxervate is hard-coded with a quantity limit of 112 mL per lifetime. Subsequent request will be denied for off-label

Product Name: Oxervate	
Guideline Type	Quantity Limit*
Approval Criteria **1** - Requests for additional quantity will not be approved	
Notes	*Requests will be denied off-label.

3 . References

1. Oxervate Prescribing Information. Dompe U.S. Inc. Boston, MA. October 2019.
2. FDA Medical Review: Oxervate. Drugs at FDA Web site. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/761094Orig1s000MedR.pdf. Accessed April 1, 2021.
3. Per clinical consult with ophthalmologist, December 12, 2018.

4 . Revision History

Date	Notes
5/3/2023	Annual review: No criteria changes. Updated operational notes.

Oxlumo (lumasiran)

Prior Authorization Guideline

Guideline ID	GL-118914
Guideline Name	Oxlumo (lumasiran)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	2/18/2021
P&T Revision Date:	02/17/2022 ; 11/17/2022 ; 2/16/2023

1 . Indications

Drug Name: Oxlumo (lumasiran) injection
Primary Hyperoxaluria Type 1 Indicated for the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary and plasma oxalate levels in pediatric and adult patients.

2 . Criteria

Product Name: Oxlumo

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary hyperoxaluria type 1 (PH1)

AND

2 - Diagnosis has been confirmed by both of the following:

2.1 One of the following:

- Elevated urinary oxalate excretion
- Elevated plasma oxalate concentration
- Spot urinary oxalate to creatinine molar ratio greater than normal for age

AND

2.2 One of the following:

- Genetic testing demonstrating a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene
- Liver biopsy demonstrating absence or reduced alanine:glyoxylate aminotransferase (AGT) activity

AND

3 - Patient has not received a liver transplant

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Nephrologist
- Urologist
- Geneticist
- Specialist with expertise in the treatment of PH1

Product Name: Oxlumo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., decreased urinary oxalate excretion, decreased plasma oxalate concentration)

AND

2 - Patient has not received a liver transplant

AND

3 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Nephrologist
- Urologist
- Geneticist
- Specialist with expertise in the treatment of PH1

3 . References

1. Oxlumo prescribing information. Alnylam Pharmaceuticals, Inc. Cambridge, MA. October 2022.
2. UptoDate: Primary hyperoxaluria. Available at https://www.uptodate.com/contents/primary-hyperoxaluria?search=primary%20hyperoxaluria%20type%201&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1. Accessed October 19, 2022.

4 . Revision History

Date	Notes
1/1/2023	2023 Annual Review.

Palforzia (peanut allergen powder-dnfp)

Prior Authorization Guideline

Guideline ID	GL-116572
Guideline Name	Palforzia (peanut allergen powder-dnfp)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Palforzia	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis and clinical history of peanut allergy as documented by one of the following:

- Confirmed positive skin test
- Peanut-specific serum IgE greater than 0.35 kUA/L

AND

2 - Patient is 4 to 17 years of age

AND

3 - One of the following:

3.1 Reason is provided to support medical necessity for oral immunotherapy despite peanut avoidance with injectable epinephrine

OR

3.2 Patient will not be prescribed with concurrent injectable epinephrine

AND

4 - Patient does not have a history of severe or poorly controlled asthma

AND

5 - Prescribed by or in consultation with an allergist/immunologist

AND

6 - Prescriber is certified/enrolled in the Palforzia REMS Program

Product Name: Palforzia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - For patients who required use of injectable epinephrine while on therapy, reason must be provided to support continued need for Palforzia

AND

2 - One of the following:

2.1 All of the following:

2.1.1 Patient is 18 years of age or older

AND

2.1.2 Reason is provided that supports continued need for oral immunotherapy despite peanut avoidance

AND

2.1.3 Documentation that initial dose escalation occurred between the age of 4 and 17

OR

2.2 Patient is less than 18 years of age

2 . Revision History

Date	Notes
10/20/2022	2023 New Implementation

Palynziq (pegvaliase-pqpz) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-123742
Guideline Name	Palynziq (pegvaliase-pqpz) - PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	8/16/2018
P&T Revision Date:	10/21/2020 ; 10/20/2021 ; 10/19/2022 ; 2/16/2023

1 . Indications

Drug Name: Palynziq (pegvaliase-pqpz)
Phenylketonuria (PKU) Indicated to reduce blood phenylalanine concentrations in adult patients with phenylketonuria (PKU) who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management.

2 . Criteria

Product Name: Palynziq	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of phenylketonuria (PKU)

AND

2 - Patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management (e.g., phenylalanine restricted diet, Kuvan [sapropterin])

AND

3 - One of the following:

3.1 Patient has had a trial and failure or intolerance to generic sapropterin

OR

3.2 Patient is not a candidate for generic sapropterin) therapy due to the presence of two null mutations in trans

AND

4 - Patient will have phenylalanine blood levels measured every 4 weeks until a maintenance dose is established and periodically thereafter [A]

Product Name: Palynziq	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced an objective response to therapy, defined by one of the following [B, C]:

1.1 At least a 20% reduction in blood phenylalanine concentrations from pre-treatment baseline

OR

1.2 Blood phenylalanine concentrations less than or equal to 600 micromol/L

AND

2 - Patient will continue to have phenylalanine blood levels measured periodically during therapy [A]

Product Name: Palynziq	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of phenylketonuria (PKU)

AND

2 - Patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management (e.g., phenylalanine restricted diet, Kuvan [sapropterin])

AND

3 - Submission of medical records (e.g., chart notes) or paid claims for one of the following:

3.1 Patient has had a trial and failure or intolerance to generic sapropterin

OR

3.2 Patient is not a candidate for generic sapropterin therapy due to the presence of two null mutations in trans

AND

4 - Patient will have phenylalanine blood levels measured every 4 weeks until a maintenance dose is established and periodically thereafter [A]

3 . Endnotes

A. Patients should have blood phenylalanine (Phe) concentrations measured every 4 weeks after initiation of Palynziq (pegvaliase-pqpz), until a maintenance dosage is established. Periodic monitoring should continue after a maintenance dose is established [1].
B. Therapy should be discontinued in patients who do not achieve at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration less than or equal to 600 micromol/L after 16 weeks of continuous treatment with the maximum dosage of 40 mg once daily. Based on the recommended dosing regimen, patients could be evaluated for discontinuation after 49

weeks of therapy. This would allow for induction, titration, maintenance on 20 mg for 24 weeks, and maintenance on 40mg for 16 weeks.

C. The American College of Medical Genetics and Genomics guideline suggests blood Phe levels should be maintained in the range of 120–360 micromol/L for all patients [2].

4 . References

1. Palynziq prescribing information. BioMarin Pharmaceutical Inc. Novato, CA. November 2020.
2. Vockley J, Andersson HC, Antshel KM, et al. Phenylalanine hydroxylase deficiency: diagnosis and management guideline. Genet Med. 2014 Feb;16(2):188-200.

5 . Revision History

Date	Notes
4/6/2023	update guideline

Pancrelipase

Prior Authorization Guideline

Guideline ID	GL-116489
Guideline Name	Pancrelipase
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Creon, Pancreaze	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Submission of medical records (e.g., chart notes) confirming one of the following:	

1.1 Cystic Fibrosis

OR

1.2 History of pancreatectomy

OR

1.3 Exocrine pancreatic cancer

OR

1.4 Chronic pancreatitis confirmed by imaging

OR

1.5 Pancreatic insufficiency confirmed with one of the following methods:

- Steatorrhea with fecal fat determination
- Secretin
- CCK pancreatic function testing
- Two of the following CFTR mutations (G542X, W1282X, R553X, 621+1G>T, 1717-1G>A, 3120+1G>A , R1162X, 3659delC, 1898+1G>A, 2184delA, 711+1G>T, F508del, I507del, G551D, N1303K, R560T).

Product Name: Creon, Pancreaze	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
9/26/2022	New Implementation

PCSK9 Inhibitors

Prior Authorization Guideline

Guideline ID	GL-116544
Guideline Name	PCSK9 Inhibitors
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Praluent, Repatha	
Diagnosis	Atherosclerotic Cardiovascular Disease (ASCVD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Submission of medical records (e.g., chart notes) confirming all of the following:

1.1 One of the following:

1.1.1 Diagnosis of clinical Atherosclerotic Cardiovascular Disease (ASCVD)

OR

1.1.2 Patient has experienced a CV event

AND

1.2 Current low-density lipoprotein (LDL) is greater than or equal to 70 mg/dL

AND

2 - Submission of medical records (e.g., chart notes) confirming both of the following:

2.1 Patient is receiving maximally tolerated statin therapy (e.g. atorvastatin 40-80 mg, rosuvastatin 20-40 mg) or is statin intolerant

AND

2.2 Patient is receiving ezetimibe or has a documented intolerance to ezetimibe

AND

3 - Patient is 18 years of age or older

AND

4 - Prescribed by or in consultation with a cardiologist

Product Name: Praluent, Repatha	
Diagnosis	Primary or Familial Hyperlipidemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Primary or Familial Hyperlipidemia

AND

2 - Submission of medical records (e.g., chart notes) confirming an untreated (i.e., prior to lipid lowering therapy) low-density lipoprotein (LDL) greater than 190 mg/dL

AND

3 - Submission of medical records (e.g., chart notes) confirming current LDL is greater than 100 mg/dL

AND

4 - Submission of medical records (e.g., chart notes) confirming both of the following:

4.1 Patient is receiving maximally tolerated statin therapy (e.g. atorvastatin 40-80 mg, rosuvastatin 20-40 mg) or is statin intolerant

AND

4.2 Patient is receiving ezetimibe or has a documented intolerance to ezetimibe

AND

5 - Patient is 18 years of age or older

AND

6 - Prescribed by or in consultation with a cardiologist

Product Name: Praluent, Repatha	
Diagnosis	Homozygous Familial Hyperlipidemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Homozygous Familial Hyperlipidemia

AND

2 - Submission of medical records (e.g., chart notes) confirming an untreated (i.e., prior to lipid lowering therapy) low-density lipoprotein (LDL) greater than 190 mg/dL

AND

3 - Submission of medical records (e.g., chart notes) confirming current LDL is greater than 100 mg/dL

AND

4 - Submission of medical records (e.g., chart notes) confirming both of the following:

4.1 Patient is receiving maximally tolerated statin therapy (e.g. atorvastatin 40-80 mg, rosuvastatin 20-40 mg) or is statin intolerant

AND

4.2 Patient is receiving ezetimibe or has a documented intolerance to ezetimibe

AND

5 - Patient is 18 years of age or older

AND

6 - Prescribed by or in consultation with a cardiologist

Product Name: Praluent, Repatha	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/26/2022	2023 New Implementation

Prior Authorization Administrative Guideline

Prior Authorization Guideline

Guideline ID	GL-116524
Guideline Name	Prior Authorization Administrative Guideline
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Drugs with a prior authorization requirement for which a guideline is unavailable, OR new FDA-approved indications which are not addressed in the existing drug-specific prior authorization guideline	
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria **1** - One of the following:	

1.1 Both of the following:

1.1.1 Prescribed medication is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.1.2 Both of the following labeling requirements have been confirmed:

1.1.2.1 All components of the FDA approved indication are met (e.g., concomitant use, previous therapy requirements, age limitations, testing requirements, etc.)

AND

1.1.2.2 Prescribed medication will be used at a dose which is within FDA recommendations

OR

1.2 Meets the off-label administrative guideline criteria

Notes	This guideline should not be used to address step therapy.

2 . Revision History

Date	Notes
11/1/2022	Per TSK004583729 copy over OptumRx Standard guidelines for Sam aritan 2023 Implementation

Procrit (epoetin alpha) - SCP

Prior Authorization Guideline

Guideline ID	GL-117913
Guideline Name	Procrit (epoetin alpha) - SCP
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Procrit	
Diagnosis	Anemia due to Chronic Kidney Disease (CKD)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of anemia due to Chronic Kidney Disease (CKD)

AND

2 - One of the following collected within 30 days:

- Anemia with hematocrit less than 30%
- hemoglobin less than 10g/dL

AND

3 - One of the following:

- Patient is on dialysis
- Patient is not on dialysis but the rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal

Product Name: Procrit	
Diagnosis	Anemia in HIV Patients
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Diagnosis of HIV
- Patient is receiving zidovudine therapy

AND

2 - One of the following collected within 30 days:

- Anemia with hematocrit less than 36%
- hemoglobin less than 12g/dL

AND

3 - Patient's serum erythropoietin less than or equal to 500mU/mL

Product Name: Procrit	
Diagnosis	Anemia due to Chemotherapy
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anemia due to chemotherapy

AND

2 - Both of the following collected two weeks of request:

- Anemia with hematocrit less than 30%
- hemoglobin less than 10 g/dL

AND

3 - All other causes of anemia have been ruled out

AND

4 - Cancer is a non-myeloid malignancy

AND

5 - One of the following*:

- Patient is concurrently on chemotherapy
- Patient will receive concomitant chemotherapy for a minimum of 2 months

Notes	*Drug will not be approved if patient is not receiving cancer chemothe rapy

Product Name: Procrit	
Diagnosis	Preoperative for reduction of allogeneic blood transfusion
Approval Length	1 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient scheduled for an elective, non-cardiac, non-vascular surgery

AND

2 - Perioperative hemoglobin is greater than 10 to less than or equal to 13 g/dL

AND

3 - Patient is at high risk of blood loss

AND

4 - Patient is unwilling or unable to donate autologous blood pre-operatively

Product Name: Procrit	
Diagnosis	Anemia in Myelodysplastic Syndrome (MDS)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Anemia in Myelodysplastic Syndrome (MDS)

AND

2 - One of the following:

- Serum erythropoietin less than or equal to 500mU/mL
- Diagnosis of transfusion dependent MDS

Product Name: Procrit	
Diagnosis	All Indications

Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming patient needs continued therapy by one of the following:

- Improvement in the hematocrit and hemoglobin levels
- Significant decrease in transfusion requirements

2 . Revision History

Date	Notes
12/6/2022	New Implementation

Prolia (denosumab)

Prior Authorization Guideline

Guideline ID	GL-110165
Guideline Name	Prolia (denosumab)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	8/17/2010
P&T Revision Date:	07/15/2020 ; 08/13/2020 ; 08/19/2021 ; 8/18/2022

1 . Indications

Drug Name: Prolia (denosumab)
Treatment of postmenopausal women with osteoporosis at high risk for fracture Indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral, and hip fractures. **Treatment to increase bone mass in men with osteoporosis at high risk for fracture** Indicated for treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.

Treatment of bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer [A] Indicated as a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. In these patients Prolia also reduced the incidence of vertebral fractures. NOTE: The use of Prolia for the treatment of bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer should not be confused with the use of Xgeva (another injectable formulation of denosumab) for the prevention of skeletal-related events (SREs) in patients with bone metastases from solid tumors (including breast cancer and prostate cancer).

Treatment of bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer [B] Indicated as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. NOTE: The use of Prolia for the treatment of bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer should not be confused with the use of Xgeva (another injectable formulation of denosumab) for the prevention of skeletal-related events (SREs) in patients with bone metastases from solid tumors (including breast cancer and prostate cancer).

Treatment of Glucocorticoid-Induced Osteoporosis Indicated for the treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months. High risk of fracture is defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

2 . Criteria

Product Name: Prolia	
Diagnosis	Bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer
Approval Length	12 months [D]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of nonmetastatic prostate cancer

AND

2 - Patient is undergoing androgen deprivation therapy with one of the following: [11,A]

2.1 Luteinizing hormone-releasing hormone (LHRH)/gonadotropin releasing hormone (GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), and Zoladex (goserelin)]

OR

2.2 Bilateral orchiectomy (i.e., surgical castration)

AND

3 - One of the following:

3.1 Age greater than or equal to 70 years [11,C]

OR

3.2 Both of the following:

3.2.1 Age less than 70 years [11]

AND

3.2.2 One of the following:

3.2.2.1 Bone mineral density (BMD) scan T-score less than -1.0 (1.0 standard deviation or greater below the mean for young adults) [11]

OR

3.2.2.2 History of one of the following resulting from minimal trauma: [9,11]

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

AND

4 - Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., zoledronic acid) [19]

Product Name: Prolia	
Diagnosis	Bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer
Approval Length	12 months [D]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is undergoing androgen deprivation therapy with one of the following: [11,A]

1.1 Luteinizing hormone-releasing hormone (LHRH)/gonadotropin releasing hormone (GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), and Zoladex (goserelin)]

OR

1.2 Bilateral orchiectomy (i.e., surgical castration)

AND

2 - No evidence of metastases

AND

3 - Patient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.)

Product Name: Prolia	
Diagnosis	Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer
Approval Length	12 months [D]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Patient is receiving adjuvant aromatase inhibitor therapy (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole]) [12,B]

AND

3 - One of the following:

3.1 Bone mineral density (BMD) scan T-score less than -1.0 (1.0 standard deviation or greater below the mean for young adults) [12,E]

OR

3.2 History of one of the following resulting from minimal trauma: [9]

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

AND

4 - Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., alendronate) [20]

Product Name: Prolia	
Diagnosis	Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer
Approval Length	12 months [D]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving adjuvant aromatase inhibitor therapy (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole]) [12]

AND

2 - Patient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.)

Product Name: Prolia	
Diagnosis	Postmenopausal women with osteoporosis or osteopenia at a high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of postmenopausal osteoporosis or osteopenia [2,5]

AND

2 - One of the following: [5,17]

2.1 Bone mineral density (BMD) scan indicative of osteoporosis: T-score less than or equal to -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

OR

2.2 Both of the following:

2.2.1 BMD scan indicative of osteopenia: T-score between -1.0 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1.0) in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

OR

2.3 History of one of the following resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

AND

3 - Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., alendronate)

Product Name: Prolia	
Diagnosis	Postmenopausal women with osteoporosis or osteopenia at a high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects

Product Name: Prolia	
Diagnosis	Increase bone mass in men at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is a male with osteoporosis or osteopenia

AND

2 - One of the following: [16,17]

2.1 Bone mineral density (BMD) scan indicative of osteoporosis: T-score less than or equal to -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

OR

2.2 Both of the following:

2.2.1 BMD scan indicative of osteopenia: T-score between -1.0 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1.0) in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

OR

2.3 History of one of the following resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

AND

3 - Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., alendronate)

Product Name: Prolia	
Diagnosis	Increase bone mass in men at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects

Product Name: Prolia

Diagnosis	Glucocorticoid-induced osteoporosis at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of glucocorticoid-induced osteoporosis

AND

2 - Patient is initiating or continuing on greater than or equal to 7.5 mg/day of prednisone (or its equivalent) and is expected to remain on glucocorticoid therapy for at least 6 months

AND

3 - One of the following: [F]

3.1 BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site)

OR

3.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

OR

3.3 History of one of the following fractures resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

AND

4 - Trial and failure, contraindication, or intolerance to one bisphosphonate (e.g., alendronate) [G]

Product Name: Prolia	
Diagnosis	Glucocorticoid-induced osteoporosis at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects

3 . Definitions

Definition	Description
Bone mineral density (BMD) [3]	A risk factor for fractures. By DXA, BMD is expressed as the amount of mineralized tissue in the area scanned (g/cm(to the power of 2)); with some technologies, BMD is expressed as the amount per volume of bone (g/cm(to the power of 3)). Hip BMD by DXA is

	considered the best predictor of hip fracture; it appears to predict other types of fractures as well as measurements made at other skeletal sites. Spine BMD may be preferable to assess changes early in menopause and after bilateral ovariectomy.
Dual x-ray absorptiometry (DXA) [3]	A diagnostic test used to assess bone density in the spine, hip, or wrist using radiation exposure about one tenth that of a standard chest x-ray. Central DXA (spine, hip) is the preferred measurement for definitive diagnosis and for monitoring the effects of therapy.
Fracture [3]	Breakage of a bone, either complete or incomplete. Most studies of osteoporosis focus on hip, vertebra and/or distal forearm fractures. Vertebral fractures include morphometric as well as clinical fractures.
Osteopenia [3]	The designation for bone density between 1.0 and 2.5 standard deviations below the mean for young normal adults (T-score between -1 and -2.5).
Osteoporosis [3]	A chronic, progressive disease characterized by low bone mass, microarchitectural deterioration and decreased bone strength, bone fragility and a consequent increase in fracture risk; bone density 2.5 or more standard deviations below the young normal mean (T-score at or below -2.5).
Peripheral DXA [3]	A DXA test used to assess bone density in the forearm, finger and heel.
Quantitative computed tomography (QCT) [3]	A diagnostic test used to assess bone density; reflects three-dimensional bone mineral density. Usually used to assess the lumbar spine, but has been adapted for other skeletal sites. It is also possible to measure trabecular and cortical bone density in the periphery by peripheral QCT (pQCT).
Quantitative ultrasound densitometry (QUS) [3]	A diagnostic test used to assess bone density at the calcaneus or patella. Ultrasound measurements correlate only modestly with other assessments of bone density in the same patient, yet some prospective studies indicate that ultrasound may predict fractures as well as other measures of bone density.
Remodeling [3]	The ongoing dual processes of bone formation and bone resorption after cessation of growth.

Resorption [3]	The loss of substance (in this case, bone) through physiological or pathological means.
Risk factors [3]	For osteoporotic fractures, includes low BMD, parental history of hip fracture, low body weight, previous fracture, smoking, excess alcohol intake, glucocorticoid use, secondary osteoporosis (e.g., rheumatoid arthritis) and history of falls. These readily accessible and commonplace factors are associated with the risk of hip fracture and, in most cases, with that of vertebral and other types of fracture as well.
Severe or "established" osteoporosis [3]	Osteoporosis characterized by bone density that is 2.5 standard deviations or more below the young normal mean (T-score at or below -2.5), accompanied by the occurrence of at least one fragility-related fracture.
T-score [3]	In describing bone mineral density, the number of standard deviations above or below the mean for young normal adults of the same sex.
Z-score [3]	In describing bone mineral density, the number of standard deviations above or below the mean for persons of the same age and sex.

4 . Endnotes

A. Androgen deprivation therapy (ADT) is commonly used in the treatment of prostate cancer. ADT can be accomplished using luteinizing hormone-releasing hormone (LHRH) agonists (medical castration), also known as gonadotropin releasing hormone (GnRH) agonists, or bilateral orchiectomy (surgical castration), which are equally effective. [13] Examples of LHRH agonists include Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), and Zoladex (goserelin).
B. Aromatase inhibitors (AIs) include selective, nonsteroidal AIs (Arimidex [anastrozole] and Femara [letrozole]) and steroidal AIs (Aromasin [exemestane]).
C. Meta-analyses have shown that advancing age increases fracture risk beyond that predicted by age related loss of BMD. Although typical changes in BMD would predict a 4-fold increase in fracture risk from ages 50 to 90 years, fracture risk actually increases 30-fold. Estimated fracture rates using FRAX calculations reflect a strong influence of older age on risk for clinical fracture. When clinical factors were used without BMD in one cross-sectional study, FRAX estimated that 76.6% of men in their 70s and virtually

all men 80 years old or older exceeded the NOF recommended risk threshold for drug therapy. [14]

D. Most men run a 2-year course of androgen deprivation therapy while most women receive treatment with aromatase inhibitors for about 5 years. A one year treatment authorization is reasonable. [15]
E. Owing to the rate of bone loss associated with breast cancer treatments (i.e., aromatase inhibitors), and uncertainties about the interaction between aromatase inhibitor use and BMD for fracture risk, the threshold for intervention has been set at a higher level than that generally recommended for postmenopausal osteoporosis. [8]
F. According to the American College of Rheumatology (ACR) guidelines for the prevention and treatment of glucocorticoid-induced osteoperosis, patients considered at high risk of fractures are as follows: (a) prior osteoporotic fracture, (b) a hip or spine BMD T-score less than or equal to -2.5, or (c) FRAX 10-year risk of hip or major osteoporotic fracture at 3 percent or more and 20 percent or more, respectively. [18]
G. According to ACR, oral bisphosphonates are considered first-line for patients with glucocorticod-induced osteoperosis at high risk for fractures. For patients in whom oral bisphosphonates are not appropriate, IV bisphosphonates should be considered. [18]

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6 . Revision History

Date	Notes

8/4/2022	2022 Annual Review - No changes to criteria, updated background information

Pulmonary Arterial Hypertension Agents - PA, NF

Prior Authorization Guideline

Guideline ID	GL-126185
Guideline Name	Pulmonary Arterial Hypertension Agents - PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	8/15/2005
P&T Revision Date:	07/17/2019 ; 11/14/2019 ; 12/18/2019 ; 02/13/2020 ; 02/18/2021 ; 06/16/2021 ; 10/20/2021 ; 11/18/2021 ; 02/17/2022 ; 07/20/2022 ; 10/19/2022 ; 02/16/2023 ; 03/15/2023 ; 04/19/2023 ; 7/19/2023

1 . Indications

Drug Name: Adcirca (tadalafil) Tablets, Alyq (tadalafil) Tablets, Tadliq (tadalafil) Oral Suspension
Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) to improve exercise ability. Studies establishing effectiveness included predominately patients with New York Heart Association (NYHA) Functional Class II–III symptoms and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (23%).
Drug Name: Adempas (riociguat) Tablets

Pulmonary Arterial Hypertension (PAH) Indicated for treatment of adults with PAH (WHO Group I) to improve exercise capacity, WHO Functional Class, and to delay clinical worsening. Efficacy was shown in patients on riociguat monotherapy or in combination with endothelin receptor antagonists or prostanoids. Studies establishing effectiveness included predominantly patients with WHO Functional Class II to III and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (25%).

Chronic-Thromboembolic Pulmonary Hypertension (CTEPH) Indicated for treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH), (WHO Group 4) after surgical treatment, or inoperable CTEPH, to improve exercise capacity and WHO Functional Class.

Drug Name: Flolan (epoprostenol sodium) Injection

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to improve exercise capacity. Studies establishing effectiveness included predominantly (97%) patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH (49%) or PAH associated with connective tissue diseases (51%).

Drug Name: Letairis (ambrisentan) Tablets

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to 1) improve exercise ability and delay clinical worsening and 2) in combination with tadalafil to reduce the risks of disease progression and hospitalization for worsening PAH, and to improve exercise ability. Studies establishing effectiveness included predominantly patients with WHO Functional Class II-III symptoms and etiologies of idiopathic or heritable PAH (60%) or PAH associated with connective tissue diseases (34%).

Drug Name: Liqrev (sildenafil) suspension

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) in adults to improve exercise ability and delay clinical worsening.

Drug Name: Opsumit (macitentan) Tablets

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to reduce the risks of disease progression and hospitalization for PAH. Effectiveness was established in a long-term study in PAH patients with predominantly WHO Functional Class II-III symptoms treated for an average of 2 years. Patients had idiopathic and heritable PAH (57%), PAH caused by connective tissue disorders (31%), and PAH caused by congenital heart disease with repaired shunts (8%).

Drug Name: Orenitram (treprostinil) Tablets
Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to delay disease progression and to improve exercise capacity. The studies that established effectiveness included predominately patients with WHO functional class II-III symptoms and etiologies of idiopathic or heritable PAH (66%) or PAH associated with connective tissue disease (26%).
Drug Name: Remodulin (treprostinil sodium) Injection
Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to diminish symptoms associated with exercise. Studies establishing effectiveness included patients with NYHA Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (58%), PAH associated with congenital systemic-to-pulmonary shunts (23%), or PAH associated with connective tissue diseases (19%). Indicated to diminish the rate of clinical deterioration in patients with PAH requiring transition from epoprostenol. Consider the risks and benefits of each drug prior to transition.
Drug Name: Revatio (sildenafil) Injection, Tablets, Oral Suspension
Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I): 1) In adults to improve exercise ability and delay clinical worsening. 2) in pediatric patients 1 to 17 years old to improve exercise ability and, in pediatric patients too young to perform standardized exercise testing, pulmonary hemodynamics thought to underly improvements in exercise.
Drug Name: Tracleer (bosentan) Tablets, Tablets for Suspension
Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I): 1) In adults to improve exercise ability and to decrease clinical worsening. Studies establishing effectiveness included predominantly patients with WHO Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (60%), PAH associated with connective tissue diseases (21%), and PAH associated with congenital heart disease with left-to right shunts (18%). 2) In pediatric patients aged 3 years and older with idiopathic or congenital PAH to improve pulmonary vascular resistance (PVR), which is expected to result in an improvement in exercise ability.
Drug Name: Tyvaso (treprostinil) Inhalation Solution, Tyvaso (treprostinil) DPI Inhalation Powder
Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to improve exercise ability. Studies establishing effectiveness included predominately patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with connective tissue diseases (33%). The effects diminish over the

minimum recommended dosing interval of 4 hours; treatment timing can be adjusted for planned activities. While there are long-term data on use of treprostinil by other routes of administration, nearly all controlled clinical experience with inhaled treprostinil has been on a background of bosentan (an endothelin receptor antagonist) or sildenafil (a phosphodiesterase type 5 inhibitor). The controlled clinical experience was limited to 12 weeks in duration.

Pulmonary Hypertension Associated with Interstitial Lung Disease (ILD) Indicated for the treatment of pulmonary hypertension associated with ILD (PH-ILD; WHO Group 3) to improve exercise ability. The study establishing effectiveness predominately included patients with etiologies of idiopathic interstitial pneumonia (IIP) (45%) inclusive of idiopathic pulmonary fibrosis (IPF), combined pulmonary fibrosis and emphysema (CPFE) (25%), and WHO Group 3 connective tissue disease (22%).

Drug Name: Veletri (epoprostenol) Injection

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I) to improve exercise capacity. Studies establishing effectiveness included predominantly patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases.

Drug Name: Ventavis (iloprost) Inhalation Solution

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to improve a composite endpoint consisting of exercise tolerance, symptoms (NYHA Class), and lack of deterioration. Studies establishing effectiveness included predominately patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH (65%) or PAH associated with connective tissue diseases (23%).

Drug Name: Uptravi (selexipag) Tablets and Injection

Pulmonary Arterial Hypertension Indicated for the treatment of PAH (WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH. Effectiveness was established in a long-term study in PAH patients with WHO Functional Class II-III symptoms. Patients had idiopathic and heritable PAH (58%), PAH associated with connective tissue disease (29%), PAH associated with congenital heart disease with repaired shunts (10%).

2 . Criteria

Product Name: Generic Alyq tablet, Generic tadalafil tablet, Adempas tablet, Brand Flolan injection, Generic epoprostenol injection, Generic ambrisentan tablet, Opsumit tablet, Orenitram tablet, Generic treprostinil injection, Generic sildenafil tablet, Generic bosentan tablet, Tracleer tablet for suspension, Tyvaso inhalation solution, Tyvaso Refill inhalation solution, Tyvaso Starter inhalation solution, Tyvaso DPI, Veletri injection, or Ventavis inhalation solution	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

Product Name: Brand Adcirca tablet, Tadliq oral suspension	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Trial and failure or intolerance to generic tadalfil

Product Name: Brand Letairis tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Trial and failure or intolerance to generic ambrisentan

Product Name: Brand Remodulin injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Trial and failure or intolerance to generic treprostinil

Product Name: Brand Revatio tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Trial and failure or intolerance to generic sildenafil tablet

Product Name: Brand Tracleer tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist

- Cardiologist

AND

5 - Trial and failure or intolerance to generic bosentan tablet

Product Name: Brand Revatio injection or Generic sildenafil injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Patient is unable to take oral medications [2]

Product Name: Liqrev, Brand Revatio oral suspension or Generic sildenafil oral suspension	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - One of the following:

5.1 History of intolerance to generic Revatio tablets

OR

5.2 Patient is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to one of the following:

- Age
- Oral-motor difficulties
- Dysphagia

AND

6 - For Liqrev, trial and failure or intolerance to generic sildenafil suspension

Product Name: Adempas tablet	
Diagnosis	Chronic Thromboembolic Pulmonary Hypertension (CTEPH)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of inoperable or persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH)

AND

1.1.2 CTEPH is symptomatic

OR

1.2 Patient is currently on any therapy for the diagnosis of CTEPH

AND

2 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

Product Name: Tyvaso inhalation solution, Tyvaso Refill inhalation solution, or Tyvaso Start inhalation solution, Tyvaso DPI	
Diagnosis	Pulmonary Hypertension associated with Interstitial Lung Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary hypertension associated with interstitial lung disease

AND

2 - Diagnosis of pulmonary hypertension associated with interstitial lung disease was confirmed by diagnostic test(s) (e.g., right heart catheterization, doppler echocardiogram, computerized tomography imaging)

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

Product Name: Brand Adcirca tablet, Generic tadalafil tablet, Generic Alyq tablet, Tadliq oral suspension, Adempas tablet, Brand Flolan injection, Generic epoprostenol injection, Brand Letairis tablet, Liqrev, Generic ambrisentan tablet, Opsumit tablet, Orenitram tablet, Brand Remodulin injection, Generic treprostinil injection, Brand Revatio injection, Generic sildenafil injection, Brand Revatio tablet, Generic sildenafil tablet, Brand Revatio oral suspension, Generic sildenafil oral suspension, Brand Tracleer tablet, Generic bosentan tablet, Tracleer tablet for suspension, Tyvaso inhalation solution, Tyvaso Refill inhalation solution, Tyvaso Starter inhalation solution, Tyvaso DPI, Veletri injection, or Ventavis inhalation solution

Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Uptravi tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Trial and failure, contraindication, or intolerance to one of the following:

- PDE-5 inhibitor [i.e., Adcirca (tadalafil), Revatio (sildenafil)]
- Adempas (riociguat)

AND

4.1.2 Trial and failure, contraindication, or intolerance to an endothelin receptor antagonist [e.g., Letairis (ambrisentan), Opsumit (macitentan), Tracleer (bosentan)]

OR

4.2 For continuation of prior therapy

AND

5 - Not taken in combination with a prostanoid/prostacyclin analogue [e.g., Flolan (epoprostenol), Ventavis (iloprost), Tyvaso/Remodulin/Orenitram (treprostinil)]

AND

6 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

Product Name: Uptravi injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Trial and failure, contraindication, or intolerance to one of the following:

- PDE-5 inhibitor [i.e., Adcirca (tadalafil), Revatio (sildenafil)]
- Adempas (riociguat)

AND

4.1.2 Trial and failure, contraindication, or intolerance to an endothelin receptor antagonist [e.g., Letairis (ambrisentan), Opsumit (macitentan), Tracleer (bosentan)]

OR

4.2 For continuation of prior therapy

AND

5 - Not taken in combination with a prostanoid/prostacyclin analogue [e.g., Flolan (epoprostenol), Ventavis (iloprost), Tyvaso/Remodulin/Orenitram (treprostinil)]

AND

6 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

7 - Patient is unable to take oral medications [13]

Product Name: Uptravi tablet/injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Not taken in combination with a prostanoid/prostacyclin analogue [e.g., Flolan (epoprostenol), Ventavis (iloprost), Tyvaso/Remodulin/Orenitram (treprostinil)]

Product Name: Brand Adcirca tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to generic tadalfil

Product Name: Brand Letairis tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to generic ambrisentan

Product Name: Brand Remodulin injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to generic treprostinil

Product Name: Brand Tracleer tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Submission of medical records (e.g., chart notes) confirming pulmonary arterial hypertension is symptomatic

AND

3 - Submission of medical records (e.g., chart notes) confirming one of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to generic bosentan tablet

3 . Endnotes

A. Require right heart catheterization in order to confirm pulmonary arterial hypertension diagnosis: Per clinical consult with cardiologist, PAH specialist, and P&T committee recommendation, February 20, 2014.

4 . References

1. Flolan Prescribing Information. GlaxoSmithKline. Research Triangle Park, NC. August 2021.
2. Revatio Prescribing Information. Pfizer Inc. New York, NY. January 2023.
3. Ventavis Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. March 2022.
4. Tyvaso Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. May 2022.

5. Remodulin Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. July 2021.
6. Adcirca Prescribing Information. Eli Lilly and Company. Indianapolis, IN. September 2020.
7. Letairis Prescribing Information. Gilead Sciences, Inc. Foster City, CA. August 2019.
8. Tracleer Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. July 2022.
9. Veletri Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. July 2022.
10. Opsumit Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. July 2022.
11. Adempas Prescribing Information. Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ. September 2021.
12. Orenitram Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. May 2021.
13. Uptravi Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. July 2022.
14. Alyq Prescribing Information. Teva Pharmaceuticals USA, Inc. North Wales, PA. September 2021.
15. Tyvaso DPI Prescribing Information. United Therapeutics Corporation. Research Triangle Park, NC. May 2022.
16. Tadliq Prescribing Information. CMP Pharma, Inc. Farmville, NC. June 2022.
17. Liqrev Prescribing Information. CMP Pharma, Inc. Farmville, NC. April 2023.

Pulmozyme (dornase alfa inhalation solution)

Prior Authorization Guideline

Guideline ID	GL-124326
Guideline Name	Pulmozyme (dornase alfa inhalation solution)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	5/27/2015
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Pulmozyme (dornase alpha) Inhalation Solution
Cystic Fibrosis Indicated, in conjunction with standard therapies, for the management of pediatric and adult patients with cystic fibrosis (CF) to improve pulmonary function. In CF patients with an FVC ≥ 40% of predicted, daily administration of PULMOZYME has also been shown to reduce the risk of respiratory tract infections requiring parenteral antibiotics.

2 . Criteria

Product Name: Pulmozyme	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF) [2,3]

Product Name: Pulmozyme	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Documentation of positive clinical response (i.e., improvement in lung function [forced expiratory volume in one second {FEV1}], decreased number of pulmonary exacerbations) to therapy

3 . References

1. Pulmozyme Prescribing Information. Genentech, Inc. South San Francisco, CA. July 2021.
2. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. Am J Respir Crit Care Med. 2013;187(7):680-9.

3. Flume PA, O'Sullivan BP, Robinson KA et al. Cystic fibrosis pulmonary guidelines. Am J Respir Crit Care Med. 2007;176:957-969

4 . Revision History

Date	Notes
4/6/2023	Annual review: No criteria changes.

Pulmozyme (dornase alfa)

Prior Authorization Guideline

Guideline ID	GL-116547
Guideline Name	Pulmozyme (dornase alfa)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Pulmozyme	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of cystic fibrosis	

Product Name: Pulmozyme	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations)

2 . Revision History

Date	Notes
9/24/2022	2023 New Implementation

Pyrukynd (mitapivat)

Prior Authorization Guideline

Guideline ID	GL-116551
Guideline Name	Pyrukynd (mitapivat)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Pyrukynd	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of polycystic kidney disease	

AND

2 - Submission of medications records (e.g., chart notes) confirming both of the following:

2.1 At least two mutations within the PKLR gene, including a missense mutation

AND

2.2 Current hemoglobin is ≤ 10mg/dL

AND

3 - Patient is not homozygous for the R479H mutation

AND

4 - Patient does not have two non-missense variants in the PKLR gene, without the presence of another missense variant

AND

5 - Patient has had at least 6 RBC transfusions within the previous year for hemolytic anemia due to PKD

AND

6 - Concomitant use of daily folic acid

AND

7 - The member does not have moderate or severe hepatic dysfunction

AND

8 - Patient is 18 years of age or older

AND

9 - Prescribed by or in consultations with a hematologist.

Product Name: Pyrukynd	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming an increase in Hb at least 1.5 mg/dL over baseline and/or a reduction in frequency of transfusions

2 . Revision History

Date	Notes
9/27/2022	New Implementation

Quantity Limit General

Prior Authorization Guideline

Guideline ID	GL-116525
Guideline Name	Quantity Limit General
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Less than or equal to the maximum dose as specified in the product prescribing information (in the absence of a drug-specific guideline)*	
Approval Length	12 Months (except for titration of loading-dose purposes)
Guideline Type	Administrative
Approval Criteria **1** - One of the following:	

1.1 Quantity limit override requests must involve an FDA-approved indication

OR

1.2 Quantity limit override requests involving off-label indications must meet off-label guideline approval criteria

AND

2 - One of the following:

2.1 For titration or loading-dose purposes (one time authorization)

OR

2.2 Requested strength/dose is commercially unavailable**

OR

2.3 Patient is on a dose alternating schedule

OR

2.4 For topical applications, patient requires a larger quantity to cover a larger surface area

Notes	Not to exceed maximum dose as specified in the product prescribing information or compendia for off-label uses. No override requests will be permitted for acetaminophen, alone or in combination with other agents, which will exceed a total of 4 grams of acetaminophen per day. *This guideline only applies in the absence of a drug-specific quantity limit override guideline. **Commercially available strength/dose requires a formulary drug.

Product Name: Greater than the maximum dose as specified in the product prescribing information (in the absence of a drug-specific guideline)*	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 Quantity limit override requests must involve an FDA-approved indication

OR

1.2 Quantity limit override requests involving off-label indications must meet off-label guideline requirements

AND

2 - One of the following:

2.1 The maximum doses specified under the quantity restriction have been tried for an adequate period of time and been deemed ineffective in the treatment of the member's disease or medical condition

OR

2.2 If lower doses have not been tried, there is clinical support (i.e., clinical literature, patient attributes, or characteristics of the drug) that the number of doses available under the quantity restriction will be ineffective in the treatment of the member's disease or medical condition

AND

3 - One of the following:

3.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

3.2 Higher dose or quantity is supported by one of following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

OR

3.3 Higher dose or quantity is supported by clinical research in two articles from major peer reviewed medical journals that present data supporting the proposed higher than maximum doses for the diagnosis provided as generally safe and effective

Notes	*This guideline only applies in the absence of a drug-specific quantity limit override guideline. No override requests will be permitted for ace taminophen, alone or in combination with other agents, which will exc eed a total of 4 grams of acetaminophen per day.

2 . Revision History

Date	Notes
11/1/2022	Per TSK004583729 copy over OptumRx Standard guidelines for Sam aritan 2023 Implementation

Qutenza (capsaicin)

Prior Authorization Guideline

Guideline ID	GL-113650
Guideline Name	Qutenza (capsaicin)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	12/1/2022
P&T Approval Date:	2/25/2016
P&T Revision Date:	08/13/2020 ; 10/21/2020 ; 11/12/2020 ; 11/18/2021 ; 10/19/2022

1 . Indications

Drug Name: Qutenza (capsaicin)
Neuropathic pain associated with postherpetic neuralgia Indicated for the treatment of neuropathic pain associated with postherpetic neuralgia (PHN). **Neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet** Indicated for the treatment of neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet.

2 . Criteria

Product Name: Qutenza	
Diagnosis	Neuropathic pain associated with postherpetic neuralgia (PHN)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neuropathic pain associated with postherpetic neuralgia (PHN)

AND

2 - Trial and failure, contraindication, or intolerance to generic lidocaine 5% patch [A]

AND

3 - Trial and failure, contraindication, or intolerance to one of the following [A]:

- gabapentin
- pregabalin
- tricyclic antidepressant (e.g., amitriptyline, nortriptyline, desipramine)

Product Name: Qutenza	
Diagnosis	Neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet

AND

2 - Trial and failure, contraindication, or intolerance to generic lidocaine 5% patch

AND

3 - Trial and failure, contraindication, or intolerance to one of the following:

- gabapentin
- pregabalin
- tricyclic antidepressant (e.g., amitriptyline, nortriptyline, desipramine)
- duloxetine

Product Name: Qutenza	
Diagnosis	All indications
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - It has been at least 3 months since the last application/administration [B]

AND

2 - Patient experienced pain relief with a prior course of therapy

AND

3 - Patient is experiencing a return of neuropathic pain

3 . Endnotes

A. The following agents are recommended: gabapentin, pregabalin, tricyclic antidepressants (TCAs), lidocaine patch, and controlled-release oxycodone or morphine sulfate. These agents are considered to have medium to high efficacy in managing PHN, good strength of evidence and a low level of side effects. [2]
B. Treatment with capsaicin may be repeated every three months as warranted by the return of pain (but not more frequently than every three months). [1]
C. Cavalli, E., Mammana, S., et al. The neuropathic pain: An overview of the current treatment and future therapeutic approaches. Int J Immunopathol Pharmacol. 2019 Jan-Dec; 33: 2058738419838383., Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6431761/. Accessed October 1, 2021.
D. Snyder, M., Gibbs, L. Treating Painful Diabetic Peripheral Neuropathy: An Update. Am Fam Physician. 2016 Aug 1;94(3):227-234.. Available at https://www.aafp.org/afp/2016/0801/p227.html. Accessed October 1, 2021.
E. Treatment of Painful Diabetic Neuropathy. American Academy of Neurology. Available at file:///C:/Users/kdekhtaw/Downloads/Treatment%20of%20Painful%20Diabetic%20Neuropathy.pdf. Accessed October 1, 2021.
F. Cohen, K., Shinkazh, N., et al. Pharmacological Treatment Of Diabetic Peripheral Neuropathy. 2015 Jun; 40(6): 372, 375-388. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4450668/. Accessed October 21, 2021.

4 . References

1. Qutenza Prescribing Information. Acorda Therapeutics, INC. Ardsley, NY. August 2022.

2. Dubinsky RM, Kabbani H, El-Chammi Z, et al. Practice parameter: treatment of postherpetic neuralgia: an evidence-based report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2004; 63(6):959-965.
3. Cavalli, E., Mammana, S., et al. The neuropathic pain: An overview of the current treatment and future therapeutic approaches. Int J Immunopathol Pharmacol. 2019 Jan-Dec; 33: 2058738419838383., Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6431761/. Accessed October 1, 2021.
4. Snyder, M., Gibbs, L. Treating Painful Diabetic Peripheral Neuropathy: An Update. Am Fam Physician. 2016 Aug 1;94(3):227-234.. Available at https://www.aafp.org/afp/2016/0801/p227.html. Accessed October 1, 2021.
5. Treatment of Painful Diabetic Neuropathy. American Academy of Neurology. Available at file:///C:/Users/kdekhtaw/Downloads/Treatment%20of%20Painful%20Diabetic%20Neuropathy.pdf. Accessed October 1, 2021.
6. Cohen, K., Shinkazh, N. et al. Pharmacological Treatment Of Diabetic Peripheral Neuropathy. P T. 2015 Jun; 40(6): 372, 375-388. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4450668/. Accessed October 21, 2021.

5 . Revision History

Date	Notes
9/11/2022	2022 Annual Review

Radicava (edaravone)

Prior Authorization Guideline

Guideline ID	GL-110180
Guideline Name	Radicava (edaravone)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	7/26/2017
P&T Revision Date:	08/13/2020 ; 08/19/2021 ; 06/15/2022 ; 07/20/2022 ; 8/18/2022

1 . Indications

Drug Name: Radicava (edaravone) injection, Radicava ORS (edaravone) oral suspension
Amyotrophic Lateral Sclerosis (ALS) Indicated for the treatment of Amyotrophic Lateral Sclerosis (ALS).

2 . Criteria

Product Name: Radicava IV, Radicava ORS

Diagnosis	Amyotrophic Lateral Sclerosis (ALS)
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of “definite” or “probable” amyotrophic lateral sclerosis (ALS) per the revised EL Escorial and Airlie House diagnostic criteria

AND

2 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis of ALS

AND

3 - Patient has scores greater than or equal to 2 in all items of the ALS Functional Rating Scale-Revised (ALSFRS-R) criteria at the start of treatment

AND

4 - Patient has a percent (%) forced vital capacity (%FVC) greater than or equal to 80% at the start of treatment

Product Name: Radicava IV, Radicava ORS	
Diagnosis	Amyotrophic Lateral Sclerosis (ALS)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., slowing in the decline of functional abilities)

AND

2 - Patient is not dependent on invasive ventilation or tracheostomy

3 . Endnotes

A. Authorization period is based on the pivotal study duration of 24 weeks. [1-3]

4 . References

1. Abe K, Itoyama Y, Sobue G, et al. Confirmatory double-blind, parallel-group, placebo-controlled study of efficacy and safety of edaravone (MCI-186) in amyotrophic lateral sclerosis patients. Amyotroph Lateral Scler Frontotemporal Degener. 2014; 15(7-8):610-7.
2. Radicava Prescribing Information. Mitsubishi Tanabe Pharma. March 2021.
3. The Writing Group. Safety and efficacy of edaravone in well defined patients with amyotrophic lateral sclerosis: a randomized, double-blind, placebo-controlled trial. Lancet Neurol 2017; 16(7):505-512.
4. Radicava ORS Prescribing Information. Mitsubishi Tanabe Pharma. Jersey City, NJ. May 2022.

5 . Revision History

Date	Notes

8/4/2022	2022 Annual Review - no criteria changes

Ranolazine

Prior Authorization Guideline

Guideline ID	GL-116506
Guideline Name	Ranolazine
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Ranolazine	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic angina	

AND **2** - Disease is not controlled with other antianginal therapy (e.g., beta blockers, calcium channel blockers, nitrates)

Product Name: Ranolazine	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	

2 . Revision History

Date	Notes
10/26/2022	New Implementation

Rebif (interferon beta-1a)

Prior Authorization Guideline

Guideline ID	GL-121370
Guideline Name	Rebif (interferon beta-1a)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	3/1/2023

1 . Criteria

Product Name: Rebif	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of relapsing forms of multiple sclerosis	

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Trial and failure, contraindication, or intolerance to all of the following (New Starts Only):

- dimethyl fumarate
- fingolimod
- glatopa/glatiramer acetate
- Avonex

Product Name: Rebif	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - For continuation of prior therapy

2 . Revision History

Date	Notes
2/22/2023	New Guideline

Reblozyl (luspatercept-aamt)

Prior Authorization Guideline

Guideline ID	GL-118201
Guideline Name	Reblozyl (luspatercept-aamt)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	3/1/2023
P&T Approval Date:	3/1/2021
P&T Revision Date:	06/17/2020 ; 01/20/2021 ; 01/19/2022 ; 1/18/2023

1 . Indications

Drug Name: Reblozyl (luspatercept-aamt)
Beta Thalassemia Indicated for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions. Limitations of Use: Reblozyl is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia. **Myelodysplastic Syndromes with Ring Sideroblasts or Myelodysplastic/ Myeloproliferative Neoplasm with Ring Sideroblasts and Thrombocytosis Associated Anemia** Indicated for the treatment of anemia failing an erythropoiesis stimulating agent and requiring 2 or more red blood cell units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis

(MDS/MPN-RS-T). Limitations of Use: Reblozyl is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.

2 . Criteria

Product Name: Reblozyl	
Diagnosis	Beta Thalassemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of beta thalassemia major [3]

AND

1.1.2 Patient requires regular red blood cell (RBC) transfusions

OR

1.2 Diagnosis of transfusion-dependent beta thalassemia [3]

AND

2 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

Product Name: Reblozyl	
Diagnosis	Beta Thalassemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy (e.g., reduction in RBC transfusion burden) [1,2]

Product Name: Reblozyl	
Diagnosis	Myelodysplastic Syndromes, Myelodysplastic/Myeloproliferative Neoplasm (MDS-RS, MDS/MPN-RS-T)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

1.1 Very low-to intermediate-risk myelodysplastic syndrome with ring sideroblasts (MDS-RS)

OR

1.2 Myelodysplastic or myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)

AND

2 - Patient has failed an erythropoiesis stimulating agent [e.g., Epogen (epoetin alfa), Aranesp (darbepoetin)]

AND

3 - Patient requires transfusions of 2 or more red blood cell (RBC) units over 8 weeks

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

Product Name: Reblozyl	
Diagnosis	Myelodysplastic Syndromes, Myelodysplastic/Myeloproliferative Neoplasm (MDS-RS, MDS/MPN-RS-T)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy (e.g., RBC transfusion independence, improvement in hemoglobin levels) [1,4]

3 . References

1. Reblozyl Prescribing Information. Celgene Corporation. Summit, NJ. September 2022.
2. Piga A, Perrotta S, Gamberini M, et al. Luspatercept improves hemoglobin levels and blood transfusion requirements in a study of patients with β-thalassemia. Blood 2019; 133 (12): 1279–1289.
3. Per clinical consult with oncologist, December 19, 2019.
4. Fenaux P, Platzbecker U, Ghulam J, et al. Luspatercept in patients with lower-risk myelodysplastic syndromes. N Engl J Med 2020; 382:140-151.

4 . Revision History

Date	Notes
1/4/2023	2023 UM Annual Review. No changes to criteria. Updated references

Repository Corticotropin Gel Products - PA, NF

Prior Authorization Guideline

Guideline ID	GL-110157
Guideline Name	Repository Corticotropin Gel Products - PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	5/19/2009
P&T Revision Date:	08/15/2019 ; 08/15/2019 ; 08/13/2020 ; 08/19/2021 ; 02/17/2022 ; 8/18/2022

1 . Indications

Drug Name: Acthar Gel (repository corticotropin injection)
Infantile spasms [2, 3] Indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age. **Exacerbations of Multiple Sclerosis [4, 5]** Indicated for the treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease. **All Other Disease States [A]** *Please Note: The request for Acthar for the treatment of a condition other than Infantile Spasms (IS) or Exacerbations of Multiple Sclerosis (MS) is not

authorized. There is no consensus in current peer-reviewed medical literature regarding the efficacy, safety, or long-term consequences of using repository corticotropin over conventional corticosteroids in these steroid-responsive conditions.

[Non-Approvable Use] Rheumatic Disorders* [6, 7, A] As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis, Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), Ankylosing spondylitis.

[Non-Approvable Use] Collagen Diseases* [8-10, A] During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis).

[Non-Approvable Use] Dermatologic Diseases* [A] Severe erythema multiforme, Stevens-Johnson syndrome.

[Non-Approvable Use] Allergic States* [A] Serum sickness.

[Non-Approvable Use] Ophthalmic Diseases* [14, A] Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis; optic neuritis; chorioretinitis; anterior segment inflammation.

[Non-Approvable Use] Respiratory Diseases* [11, A] Symptomatic sarcoidosis

[Non-Approvable Use] Edematous State* [12, 13, 15, A] To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

Drug Name: Purified Cortrophin Gel (repository corticotropin injection)

Exacerbations of Multiple Sclerosis [4, 5] Indicated for acute exacerbations of multiple sclerosis.

All Other Disease States [A] *Please Note: The request for Purified Cortrophin Gel for the treatment of a condition other than Infantile Spasms (IS) or Exacerbations of Multiple Sclerosis (MS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the efficacy, safety, or long-term consequences of using repository corticotropin over conventional corticosteroids in these steroid-responsive conditions.

[Non-Approvable Use] Rheumatic Disorders* [6, 7, A] Indicated as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis; Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy); Ankylosing spondylitis; Acute gouty arthritis.

[Non-Approvable Use] Collagen Diseases* [8-10, A] Indicated during an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis).

[Non-Approvable Use] Dermatologic Diseases* [A] Indicated for severe erythema multiforme (Stevens-Johnson syndrome), severe psoriasis.

[Non-Approvable Use] Allergic States* [A] Indicated for atopic dermatitis, serum sickness.

[Non-Approvable Use] Ophthalmic Diseases* [14, A] Indicated for severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: allergic conjunctivitis, keratitis, iritis and iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation.

[Non-Approvable Use] Respiratory Diseases* [11, A] Indicated for symptomatic sarcoidosis.

[Non-Approvable Use] Edematous States* [12, 13, 15, A] Indicated to induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

Off Label Uses: Infantile spasms [2, 3] Indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age.

2 . Criteria

Product Name: Acthar Gel, Purified Cortrophin Gel [off-label]	
Diagnosis	Infantile Spasms (West Syndrome)
Approval Length	4 Week(s)
Guideline Type	Prior Authorization, Non Formulary

Approval Criteria

1 - Diagnosis of infantile spasms (West Syndrome)

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Patient is less than 2 years of age

Product Name: Acthar Gel, Purified Cortrophin Gel	
Diagnosis	Multiple Sclerosis
Approval Length	3 Week(s)
Guideline Type	Prior Authorization, Non Formulary

Approval Criteria

1 - Diagnosis of acute exacerbation of multiple sclerosis

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - One of the following:

3.1 Both of the following:

- Patient is new to therapy with corticotropin

- Trial and failure, contraindication, or intolerance to treatment with two high dose corticosteroid treatments (e.g., prednisone, IV methylprednisolone)

OR

3.2 All of the following:

- Patient's multiple sclerosis exacerbations have been treated in the past with corticotropin
- Patient has benefitted from treatment with corticotropin for acute exacerbations of multiple sclerosis
- Medication is being used to treat a new exacerbation of multiple sclerosis

Product Name: Acthar Gel, Purified Cortrophin Gel	
Diagnosis	All Other Indications [A]
Approval Length	N/A - Requests for non-approvable diagnoses should not be approved
Guideline Type	Prior Authorization, Non Formulary

Approval Criteria

1 - The request for Acthar Gel and Purified Cortrophin Gel for the treatment of a condition other than Infantile Spasms (IS) or Exacerbations of Multiple Sclerosis (MS) is not authorized and will not be approved. There is no consensus in current peer-reviewed medical literature regarding the efficacy, safety, or long-term consequences of using repository corticotropin over conventional corticosteroids in these steroid-responsive conditions:

- Rheumatic Disorders* [6, 7, A] As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis, Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), Ankylosing spondylitis, Acute gouty arthritis.
- Collagen Diseases* [8-10, A] During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis).
- Dermatologic Diseases* [A] Severe erythema multiforme, Stevens-Johnson syndrome, Severe psoriasis.

• Allergic States* [A] Serum sickness, Atopic dermatitis. • Ophthalmic Diseases* [14, A] Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis; optic neuritis; chorioretinitis; anterior segment inflammation; Allergic conjunctivitis. • Respiratory Diseases* [11, A] Symptomatic sarcoidosis. • Edematous State* [12, 13, 15, A] To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus. • Any other disease state not mentioned [A]*	
Notes	*Other disease states lack published clinical literature to support the use of Acthar or Purified Cortrophin Gel [A]

3 . Endnotes

A. Grandfathered indications, although briefly mentioned in the labeling, do not have clinical studies in the prescribing information or medical literature supporting their use of Acthar or Purified Cortrophin Gel.

4 . References

1. Acthar prescribing information. Mallinckrodt ARD LLC. Bedminster, NJ. October 2021.
2. Baram TZ, Mitchell WG, Tournay A, et al. High-dose corticotropin (ACTH) versus prednisone for infantile spasms: a prospective, randomized, blinded study. Pediatrics. 1996 Mar: 97(3):375-379.
3. Hrachovy RA, Frost JD, Glaze DG. High-dose, long-duration versus low-dose, short-duration corticotropin therapy for infantile spasms. J Pediatr. 1994 May; 124(5): 803-806.
4. Thompson, AJ. Relative efficacy of IV methylprednisolone vs ACTH in acute relapse of MS. Neurology. 1989 July;39(7):969.
5. Citterio A, La Mantia L, Ciucci G, et al. Corticosteroids or ACTH for acute exacerbations in multiple sclerosis. Cochrane Database of Systematic Reviews 2000, Issue 4.
6. Gillis T, Crane M, Hinkle C, et al. Repository corticotropin injection as adjunctive therapy in patients with rheumatoid arthritis who have failed previous therapies with at least three different modes of action. Open Access Rheumatol. 2017;9:131-138.
7. Brown, A. Repository corticotropin injection in patients with refractory psoriatic arthritis: a case series. Open Access Rheumatol. 2016;8:97-102.

8. Furie R, Mitrane M, Zhao E, et al. Efficacy and tolerability of repository corticotropin injection in patients with persistently active SLE: results of a phase 4, randomised, controlled pilot study. Lupus Sci Med. 2016;3(1):e000180.
9. Patel A, Seely G, Aggarwal R. Repository corticotropin injection for treatment of idiopathic inflammatory myopathies. Case Rep Rheumatol. 2016;2016:9068061.
10. Aggarwal R, Marder G, Koontz DC, et al. Efficacy and safety of adrenocorticotropic hormone gel in refractory dermatomyositis and polymyositis. Ann Rheum Dis. 2018 May;77(5):720-727.
11. Baughman RP, Sweiss N, Keijsers R, et al. Repository corticotropin for chronic pulmonary sarcoidosis. Lung. 2017;195(3):313-322.
12. Bomback AS, Tumlin JA, Baranski J, et al. Treatment of nephrotic syndrome with adrenocorticotropic hormone (ACTH) gel. Drug Des Devel Ther. 2011;5:147-153.
13. Bomback AS, Canetta PA, Beck Jr LH, et al. Treatment of resistant glomerular diseases with adrenocorticotropic hormone gel: A prospective trial. Am J Nephrol 2012;36:58-67.
14. Sharon Y, Chu DS. Adrenocorticotropic hormone gel for patients with non-infectious uveitis. Am J Ophthalmol Case Rep. 2019;15:100502.
15. Madan A, Mojovic-Das S, Stankovic A, et al. Acthar gel in the treatment of nephrotic syndrome: a multicenter retrospective case series. BMC Nephrol. 2016;17:37.
16. Purified Cortrophin Gel prescribing information. ANI Pharmaceuticals, Inc. Baudette, MN. June 2022.

5 . Revision History

Date	Notes
8/4/2022	Annual Review: No criteria changes. Updated references, indications, and background.

Rebyota

Prior Authorization Guideline

Guideline ID	GL-116487
Guideline Name	Fecal Microbiota Agents - PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2024

1 . Indications

Drug Name: Rebyota (fecal microbiota, live-jslm) suspension
Recurrent Clostridioides difficile infection (CDI) Indicated for the prevention of recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibiotic treatment for recurrent CDI. Limitations of use: Rebyota is not indicated for treatment of CDI.

2 . Criteria

Product Name: Rebyota	
Approval Length	14 Day(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following:

- Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days
- A positive stool test for C.difficile toxin or toxigenic C.difficile

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has a history of one or more recurrent episodes of CDI

AND

4 - Both of the following:

4.1 Patient has completed at least 10 consecutive days of one of the following antibiotic therapies between 24 to 72 hours prior to initiating Rebyota:

- oral vancomycin
- Dificid (fidaxomicin)

AND

4.2 Previous episode of CDI is under control (e.g., less than 3 unformed/loose [i.e., Bristol Stool Scale type 6-7] stools/day for 2 consecutive days)

AND

5 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Infectious disease specialist

Product Name: Rebyota	
Approval Length	14 Day(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following:

- Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days
- A positive stool test for C.difficile toxin or toxigenic C.difficile

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has a history of one or more recurrent episodes of CDI

AND

4 - Both of the following:

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming patient has completed at least 10 consecutive days of one of the following antibiotic therapies between 24 to 72 hours prior to initiating Rebyota:

- oral vancomycin
- Dificid (fidaxomicin)

AND

4.2 Previous episode of CDI is under control (e.g., less than 3 unformed/loose [i.e., Bristol Stool Scale type 6-7] stools/day for 2 consecutive days)

AND

5 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Infectious disease specialist

2 . References

1. Rebyota Prescribing Information. Ferring Pharmaceuticals, Inc. Parsippany, NJ. November 2022.

4 . Revision History

Date	Notes
12/8/2023	Addition of EHB formulary. No changes to criteria.

Restasis (cyclosporine ophthalmic emulsion)

Prior Authorization Guideline

Guideline ID	GL-116487
Guideline Name	Restasis (cyclosporine ophthalmic emulsion)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Brand Restasis, Generic cyclosporine	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of lack of tear production due to ocular inflammation associated with keratoconjunctivitis sicca

AND

2 - One of the following:

2.1 Patient is not currently using a topical ophthalmic anti- inflammatory drug or punctal plug

OR

2.2 Both of the following:

2.2.1 The patient's current use of topical ophthalmic anti-inflammatory drug (e.g., ketorolac, diclofenac, flurbiprofen) or punctal plug will be discontinued before starting the requested agent

AND

2.2.2 The patient has previously tried or is currently using aqueous enhancements (e.g. artificial tears, gels, ointments)

OR

2.3 Patient has a documented intolerance, contraindication, or hypersensitivity to aqueous enhancements.

AND

3 - One of the following:

- Patient is not currently using Xiidra
- The patient's current use of Xiidra will be discontinued before starting Restasis.

Product Name: Brand Restasis, Generic cyclosporine	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
9/28/2022	2023 New Implementation

Retinal Vascular Disease Agents - PA, NF

Prior Authorization Guideline

Guideline ID	GL-123375
Guideline Name	Retinal Vascular Disease Agents - PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2025
P&T Approval Date:	
P&T Revision Date:	04/21/2021 ; 01/19/2022 ; 04/20/2022 ; 07/20/2022 ; 08/18/2022 ; 11/17/2022 ; 2/16/2023 ; 4/19/2023 ; 10/18/2023 ; 12/13/2023 ; 4/17/2024 ; 5/16/2024 ; 12/18/2024

1 . Indications

Drug Name: Beovu (brolucizumab)
Neovascular (Wet) Age-Related Macular Degeneration Indicated for the treatment of neovascular (wet) age-related macular degeneration (nAMD). **Diabetic Macular Edema (DME)** Indicated for the treatment of diabetic macular edema (DME).
Drug Name: Eylea (aflibercept)

Neovascular (Wet) Age-Related Macular Degeneration Indicated for the treatment of neovascular (wet) age-related macular degeneration (nAMD).

Macular Edema Following Retinal Vein Occlusion Indicated for the treatment of patients with macular edema following retinal vein occlusion (RVO).

Diabetic Macular Edema Indicated for the treatment of patients with diabetic macular edema (DME).

Diabetic Retinopathy Indicated for the treatment of diabetic retinopathy (DR).

Retinopathy of Prematurity (ROP) Indicated for the treatment of retinopathy of prematurity (ROP).

Drug Name: Eylea HD (aflibercept)

Neovascular (Wet) Age-Related Macular Degeneration Indicated for the treatment of neovascular (wet) age-related macular degeneration (nAMD).

Diabetic Macular Edema Indicated for the treatment of patients with diabetic macular edema (DME).

Diabetic Retinopathy Indicated for the treatment of diabetic retinopathy (DR).

Drug Name: Lucentis 0.5mg (ranibizumab), Byooviz (ranibizumab-nuna), Cimerli 0.5mg (ranibizumab-eqrn)

Neovascular (Wet) Age-Related Macular Degeneration Indicated for the treatment of patients with neovascular (wet) age-related macular degeneration (nAMD).

Macular Edema Following Retinal Vein Occlusion Indicated for the treatment of patients with macular edema following retinal vein occlusion (RVO).

Myopic Choroidal Neovascularization Indicated for the treatment of patients with myopic choroidal neovascularization (mCNV).

Drug Name: Lucentis 0.3 mg (ranibizumab), Cimerli 0.3mg (ranibizumab-eqrn)

Diabetic Macular Edema Indicated for the treatment of patients with diabetic macular edema (DME).

Diabetic Retinopathy Indicated for the treatment of diabetic retinopathy (DR).

Drug Name: Susvimo (ranibizumab)

Neovascular (Wet) Age-Related Macular Degeneration Indicated for the treatment of patients with neovascular (wet) age-related macular degeneration (nAMD) who have previously responded to at least two intravitreal injections of a vascular endothelial growth factor (VEGF) inhibitor.
Drug Name: Vabysmo (faricimab-svoa)
Diabetic Macular Edema Indicated for the treatment of patients with diabetic macular edema (DME). **Neovascular (Wet) Age-Related Macular Degeneration** Indicated for the treatment of patients with neovascular (wet) age-related macular degeneration (nAMD). **Macular Edema Following Retinal Vein Occlusion** Indicated for the treatment of patients with macular edema following retinal vein occlusion.
Drug Name: Pavblu (aflibercept-ayyh)
Neovascular (Wet) Age-Related Macular Degeneration Indicated for the treatment of neovascular (wet) age-related macular degeneration (nAMD). **Macular Edema Following Retinal Vein Occlusion** Indicated for the treatment of patients with macular edema following retinal vein occlusion (RVO). **Diabetic Macular Edema** Indicated for the treatment of patients with diabetic macular edema (DME). **Diabetic Retinopathy** Indicated for the treatment of diabetic retinopathy (DR).

2 . Criteria

Product Name: Beovu, Vabysmo

Diagnosis	Diabetic Macular Edema (DME), Neovascular (wet) age-related macular degeneration (nAMD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Neovascular (wet) age-related macular degeneration (nAMD) [A]
- Diabetic macular edema (DME)

AND

2 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name: Vabysmo	
Diagnosis	Macular Edema following Retinal Vein Occlusion
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of macular edema following retinal vein occlusion

AND

2 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name: Lucentis 0.3mg	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Diabetic macular edema (DME)
- Diabetic retinopathy (DR)

AND

2 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name: Byooviz, Lucentis 0.5mg	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Neovascular (wet) age-related macular degeneration (nAMD) [A]
- Macular edema following retinal vein occlusion (RVO)
- Myopic choroidal neovascularization (mCNV)

AND

2 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name: Cimerli 0.3mg	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Diabetic macular edema (DME)
- Diabetic retinopathy (DR)

AND

2 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name: Cimerli 0.5mg

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Neovascular (wet) age-related macular degeneration (nAMD) [A]
- Macular edema following retinal vein occlusion (RVO)
- Myopic choroidal neovascularization (mCNV)

AND

2 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Notes	*Note: Trial and failure of compounded bevacizumab can be accepted as meeting the trial and failure of compounded Avastin requirement

Product Name: Eylea, Pavblu	
Diagnosis	Neovascular (Wet) Age-Related Macular Degeneration, Macular Edema Following Retinal Vein Occlusion, Diabetic Macular Edema, Diabetic Retinopathy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Neovascular (wet) age-related macular degeneration (nAMD) [A]
- Macular edema following retinal vein occlusion (RVO)
- Diabetic macular edema (DME)
- Diabetic retinopathy (DR)

AND

2 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name: Eylea, Pavblu	
Diagnosis	Neovascular (Wet) Age-Related Macular Degeneration, Macular Edema Following Retinal Vein Occlusion, Diabetic Macular Edema, Diabetic Retinopathy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., Improvement in Best Corrected Visual Acuity (BCVA) compared to baseline, stable vision)

Product Name: Eylea Injectable Vial	
Diagnosis	Retinopathy of Prematurity (ROP) [2, C]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of retinopathy of prematurity (ROP)

AND

2 - ONE of the following: [2]

- Patient gestational age at birth less than or equal to 32 weeks [D]
- Patient birth weight less than or equal to 1500 grams

AND

3 - Patient weight greater than 800 grams on day of treatment [2]

AND

4 - Retinopathy of prematurity (ROP) is present in at least one eye with one of the following classifications: [2, E-H]

- ROP zone 1, stage 1 plus, 2 plus, 3, or 3 plus
- ROP zone 2, stage 2 plus or 3 plus
- AP - ROP (aggressive posterior ROP)

AND

5 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases [I, 13 -14]

Product Name: Eylea Injectable Vial	
Diagnosis	Retinopathy of Prematurity (ROP) [2, C]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by the absence of

active ROP and unfavorable structural outcomes (e.g., retinal detachment, macular dragging, macular fold, retrolental opacity) [2]

AND

2 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases [I, 13 -14]

Product Name: Eylea HD	
Diagnosis	Neovascular (Wet) Age-Related Macular Degeneration, Diabetic Macular Edema, Diabetic Retinopathy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Neovascular (wet) age-related macular degeneration (nAMD) [A]
- Diabetic macular edema (DME)
- Diabetic retinopathy (DR)

AND

2- Trial and failure, or intolerance to Eylea

AND

3- Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name: Eylea HD	
Diagnosis	All Other Indications
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., Improvement in Best Corrected Visual Acuity (BCVA) compared to baseline, stable vision)

Product Name: Susvimo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neovascular (wet) age-related macular degeneration (nAMD) [A]

AND

2 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name: Beovu, Byooviz, Cimerli, Lucentis, Susvimo, Vabysmo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., Improvement in Best Corrected Visual Acuity (BCVA) compared to baseline, stable vision)

3 . Definitions

Definition	Description
Retinopathy of Prematurity (ROP)	Retinopathy of prematurity (ROP) is a developmental vascular proliferative disorder that occurs in the retina of preterm infants with incomplete retinal vascularization. ROP is an important cause of severe visual impairment in childhood. [11]

4 . Endnotes

A. Neovascular Age-Related Macular Degeneration (nAMD) may also be referred to as wet or exudative AMD. [1]
B. Congress established the 503(B) facilities to provide compounded pharmaceuticals for office use without a prescription. 503(B) Outsourcing Facilities are compounding pharmacies that must meet higher federal safety, sterility, and quality control standards. [4,5]
C. Each sterile vial should only be used for the treatment of a single eye. Do not use the EYLEA pre-filled syringe for the treatment of ROP. [2]
D. Gestational age: The length of time between a baby's conception and birth. [10]
E. How serious the ROP is depends on what part of the eye is affected (the zone); how far the disease has progressed (the stage); and whether the blood vessels themselves are markedly abnormal (plus disease). Stages 1 and 2 are considered mild; Stages 3-5 are increasingly serious. [10]
F. Zone 1: This represents the least amount of retinal vascular development and includes retinal vascularization limited to a circular area centered around the optic nerve. Zone I ROP is a strong predictor for severe ROP. Zone 2: Vascularization limited to the circular area outside zone I with the optic nerve as the center. Zone 3: Vascularization within the remaining temporal, crescent-shaped area. Once vascularization extends to the nasal ora serrata and into zone III, there is little risk of a poor visual outcome from ROP. [11]
G. Plus disease. Defined as two quadrants of dilated and tortuous vessels and is a strong predictor of severe ROP. [11]
H. Stage 1. A demarcation line between vascularized and avascular retina. Stage 2. A ridge with volume in the region of the demarcation line. Stage 3. Neovascularization growing into the vitreous at the ridge. Stage 3 is a strong predictor of severe ROP and a poor outcome. Stage 4. A partial retinal detachment. Treatment of progressive stage 4 ROP can preserve and improve visual outcomes by preventing stage 5 ROP. Stage 4 is further classified by whether the macula is involved (4A without macular involvement and 4B with macular involvement) and by whether it is predominantly exudative or tractional. Exudative ROP that occurs after treatment with laser or cryotherapy may resolve spontaneously. Stage 5. Total retinal detachment. [11]
I. Examinations for ROP should be performed by an ophthalmologist who is experienced in the examination of preterm infants for ROP using a binocular indirect ophthalmoscope.

Pediatric ophthalmology and retina fellows are less adept than experienced attending ophthalmologists at identifying clinically significant ROP when examining digital images. [13, 14]

J. Eylea HD contains a higher molar dose of aflibercept designed to allow for longer dosing intervals between treatments. [16]

5 . References

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16. Eylea Healthcare Professionals website. Available at: https://eyleahcp.us/s/. Accessed September 26, 2023.
17. Pavblu Prescribing information. Amgen, Inc. Thousand Oaks, CA. August 2024.

6 . Revision History

Date	Notes
12/7/2024	Update guideline

Revcovi (elapegademase-lvlr)

Prior Authorization Guideline

Guideline ID	GL-120496
Guideline Name	Revcovi (elapegademase-lvlr)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	1/16/2019
P&T Revision Date:	01/15/2020 ; 02/17/2022 ; 2/16/2023

1 . Indications

Drug Name: Revcovi (elapegademase-lvlr)
Adenosine deaminase severe combined immune deficiency (ADA-SCID) Indicated for the treatment of adenosine deaminase severe combined immune deficiency (ADA-SCID) in pediatric and adult patients.

2 . Criteria

Product Name: Revcovi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of adenosine deaminase deficiency (ADA) with severe combined immunodeficiency (SCID)

Product Name: Revcovi	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . References

1. Revcovi Prescribing Information. Leadiant Biosciences, Inc. Gaithersburg, MD. December 2020.
2. Immune Deficiency Foundation Patient & Family Handbook for Primary Immunodeficiency Diseases. Fifth Edition. 2013.

4 . Revision History

Date	Notes

1/25/2023	Update program

Rexulti (brexipiprazole)

Prior Authorization Guideline

Guideline ID	GL-117536
Guideline Name	Rexulti (brexipiprazole)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Rexulti	
Diagnosis	Major depressive disorder (MDD)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of major depressive disorder (MDD)

AND

2 - Prior treatment failure (at least 3 weeks) of or contraindication to 3 prior antidepressants

AND

3 - Trial and failure, contraindication, or intolerance to one antipsychotic FDA approved as adjunct treatment for MDD

AND

4 - Rexulti will be used concurrently with an antidepressant

AND

5 - Patient is 18 years of age or older

Product Name: Rexulti	
Diagnosis	Schizophrenia
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of schizophrenia

AND

2 - Trial and failure to Vraylar

AND

3 - Patient is 13 years of age or older

Product Name: Rexulti	
Diagnosis	All indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive response to therapy

Reyvow (lasmiditan)

Prior Authorization Guideline

Guideline ID	GL-126336
Guideline Name	Reyvow (lasmiditan)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023

1 . Criteria

Product Name: Reyvow	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - The medication intended for use for acute use for the treatment migraine headaches	

AND

2 - Prescribed by or in consultation with a neurologist or headache specialist

AND

3 - Member is on preventative therapy for migraine headaches

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following: [24]

- Trial and failure or intolerance to three triptans (e.g., eletriptan, rizatriptan, sumatriptan) and NSAID (ibuprofen, naproxen, diclofenac) combined treatment
- Trial and failure or intolerance to NSAID treatment alone if triptans contraindicated
- Contraindication to all triptans and NSAIDS

AND

5 - Member is 18 years of age or older

Product Name: Reyvow	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy

2 . Revision History

Date	Notes
6/9/2023	New Program

Rezurock (belumosudil)

Prior Authorization Guideline

Guideline ID	GL-116567
Guideline Name	Rezurock (belumosudil)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Rezurock	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic graft-versus-host disease (cGVHD)	

AND

2 - Patient is 12 years of age or older

AND

3 - Trial and failure of at least TWO prior lines of systemic therapy for cGVHD (e.g., systemic steroids, calcineurin inhibitors)

AND

4 - Patient is not currently taking Imbruvica (ibrutinib)

AND

5 - Prescribed by or in consultation with ONE of the following:

- Oncologist
- Transplant specialist

Product Name: Rezurock	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/26/2022	New Implementation

Ribavirin

Prior Authorization Guideline

Guideline ID	GL-116530
Guideline Name	Ribavirin
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Generic ribavirin	
Diagnosis	Respiratory Syncytial Virus (RSV)
Approval Length	3 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of respiratory syncytial virus (RSV)

AND

2 - Prescribed by or in consultation with infectious disease specialist

2 . Revision History

Date	Notes
10/7/2022	2023 Implementation

Rinvoq (upadacitinib)

Prior Authorization Guideline

Guideline ID	GL-116591
Guideline Name	Rinvoq (upadacitinib)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Indications

Drug Name: Rinvoq (upadacitinib)
Rheumatoid Arthritis (RA) Indicated for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Rinvoq in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended. **Psoriatic Arthritis (PsA)** Indicated for the treatment of adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Rinvoq in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended. **Ankylosing Spondylitis (AS)** Indicated for the treatment of adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers.

Limitations of Use: Use of Rinvoq in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended.

Atopic Dermatitis (AD) Indicated for the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable. Limitations of Use: Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

Ulcerative Colitis (UC) Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Rinvoq is not recommended for use in combination with other JAK inhibitors, biological therapies for ulcerative colitis, or with potent immunosuppressants such as azathioprine and cyclosporine.

2 . Criteria

Product Name: Rinvoq	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia, Enbrel, Adalimumab, Simponi)

AND

5 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [4]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease

- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia, Enbrel, Adalimumab, Simponi)

AND

5 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia, Enbrel, Adalimumab, Simponi)

AND

5 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following [1, 5]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)

- Total active (swollen and tender) joint count

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Atopic Dermatitis (AD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe atopic dermatitis

AND

2 - Patient is 12 years of age or older

AND

3 - One of the following:

- Involvement of at least 10% body surface area (BSA)
- SCORing Atopic Dermatitis (SCORAD) index value of at least 25 [A]

AND

4 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

AND

5 - Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least ONE of the following:

- Medium or higher potency topical corticosteroid
- Pimecrolimus cream
- Tacrolimus ointment
- Eucrisa (crisaborole) ointment

AND

6 - One of the following:

6.1 Trial and failure of a minimum 12-week supply of at least one systemic drug product for the treatment of atopic dermatitis (examples include, but are not limited to, Adbry [tralokinumab-ldrm], Dupixent [dupilumab], etc.)

OR

6.2 Patient has a contraindication, intolerance, or treatment is inadvisable with both of the following FDA-approved atopic dermatitis therapies:

- Adbry (tralokinumab-ldrm)
- Dupixent (dupilumab)

AND

7 - Not used in combination with other JAK inhibitors, biologic immunomodulators (e.g., Dupixent, Adbry), or other immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Atopic Dermatitis (AD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in body surface area involvement from baseline
- Reduction in SCORing Atopic Dermatitis (SCORAD) index value from baseline [A]

AND

2 - Not used in combination with other JAK inhibitors, biologic immunomodulators (e.g., Dupixent, Adbry), or other immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq

Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [6, 7]:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, ESR, CRP)
- Dependent on, or refractory to, corticosteroids

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [6, 7]:

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine

- Corticosteroids (e.g., prednisone)

AND

5 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Adalimumab, Simponi)

AND

6 - Not used in combination with other JAK inhibitors, biological therapies for UC, or with potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 6, 7]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

AND **2** - Not used in combination with other JAK inhibitors, biological therapies for UC, or with potent immunosuppressants (e.g., azathioprine, cyclosporine)*	
Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

3 . Background

Clinical Practice Guidelines

Table 1. Relative potencies of topical corticosteroids [8]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05

	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1

Hydrocortisone acetate	Cream, ointment	0.5-1

4 . Endnotes

A. The Scoring Atopic Dermatitis (SCORAD) index is a clinical tool for assessing the severity of atopic dermatitis lesions based on affected body area and intensity of plaque characteristics. [9, 10] The extent and severity of AD over the body area (A) and the severity of 6 specific symptoms (erythema, edema/papulation, excoriations, lichenification, oozing/crusts, and dryness) (B) are assessed and scored by the Investigator. Subjective assessment of itch and sleeplessness is scored by the patient (C). The SCORAD score is a combined score (A/5 + 7B/2 + C) with a maximum of 103. Higher scores indicate greater severity/worsened state. A score of 25 to 50 indicates moderate disease severity and greater than 50 indicates severe disease. [11]

5 . References

1. Rinvoq Prescribing Information. AbbVie Biotechnology Ltd. North Chicago, IL. April 2022.
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11. Oranje AP. Practical issues on interpretation of scoring atopic dermatitis: SCORAD index, objective SCORAD, patient-oriented SCORAD and three-item severity score. Curr Probl Dermatol. 2011; 41:149-55.

6 . Revision History

Date	Notes
10/28/2022	Bulk copy OptumRx SP to Samaritan SP for 1/1/2023 Implementation

Rituxan Hycela (rituximab and hyaluronidase human)

Prior Authorization Guideline

Guideline ID	GL-123436
Guideline Name	Rituxan Hycela (rituximab and hyaluronidase human)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	7/26/2017
P&T Revision Date:	03/18/2020 ; 04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Rituxan Hycela (rituximab and hyaluronidase human)
Follicular Lymphoma Indicated for the treatment of adult patients with: 1) Relapsed or refractory, follicular lymphoma as a single agent 2) Previously untreated follicular lymphoma in combination with first line chemotherapy and, in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as single-agent maintenance therapy 3) Non-progressing (including stable disease), follicular lymphoma as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy. Limitations of Use: Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion. Rituxan Hycela is not indicated for the treatment of non-malignant conditions. **Diffuse Large B-cell Lymphoma** Indicated for the treatment of adult patients with previously

untreated diffuse large B-cell lymphoma in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens. Limitations of Use: Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion. Rituxan Hycela is not indicated for the treatment of non-malignant conditions.

Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of adult patients with previously untreated and previously treated CLL in combination with fludarabine and cyclophosphamide (FC). Limitations of Use: Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion. Rituxan Hycela is not indicated for the treatment of non-malignant conditions.

2 . Criteria

Product Name: Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Follicular Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of follicular lymphoma

AND

2 - One of the following:

2.1 Disease is relapsed or refractory

OR

2.2 Patient exhibited complete or partial response to prior treatment with rituximab in combination with chemotherapy

OR

2.3 Disease is non-progressing or stable following prior treatment with first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy

OR

2.4 Both of the following

2.4.1 Disease is previously untreated

AND

2.4.2 Medication is used in combination with first-line chemotherapy

AND

3 - One of the following:

3.1 Trial and failure, or intolerance to Ruxience

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing treatment regimen

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

Product Name: Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Follicular Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - One of the following:

2.1 Trial and failure, or intolerance to Ruxience

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Diffuse Large B-cell Lymphoma
Approval Length	12 months [A]

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of diffuse large B-cell lymphoma

AND

2 - Disease is previously untreated

AND

3 - Medication is being used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy

AND

4 - One of the following:

4.1 Trial and failure, or intolerance to Ruxience

OR

4.2 Continuation of therapy for patients currently in the midst of an ongoing treatment regimen

AND

5 - Prescribed by or in consultation with one of the following:

- Hematologist

- Oncologist

Product Name: Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Chronic Lymphocytic Leukemia
Approval Length	12 months [B]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia

AND

2 - Medication is being used in combination with fludarabine and cyclophosphamide (FC) therapy

AND

3 - One of the following:

3.1 Trial and failure, or intolerance to Ruxience

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing treatment regimen

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

3 . Endnotes

A. Treatment for DLBCL consists of up to 8 cycles of 21 days each, a total duration of 6 months [1,3]. There is little evidence that use of rituximab as continuation therapy following R-CHOP induction provides additional benefit above induction alone. [2] This is in contrast with follicular lymphoma, where evidence does support maintenance [4] therapy and NCCN recommends consolidation with rituximab monotherapy [3]. However, to account for potential delays in therapy without interrupting treatment, a 12 month authorization is provided.
B. Treatment for CLL consists of up to 6 cycles of 28 days each, a total duration of 6 months [1]. To account for potential delays in therapy without interrupting treatment, a 12 month authorization is provided.
C. An FDA-approved biosimilar is an appropriate substitute for rituximab. [3]
D. The FDA defines biosimilar as a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. [4]

4 . References

1. Rixtuan Hycela Prescribing Information. Genentech, Inc. South San Francisco, CA. June 2021.
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5. Salles G, Seymour JF, Lopez-Guillermo A, et al. Rituximab maintenance for 2 years in patients with high tumour burden follicular lymphoma responding to rituximab plus chemotherapy (PRIMA): a phase 3, randomized controlled trial. Lancet. 2011;377(9759):42-51.

5 . Revision History

Date	Notes
4/4/2023	Annual review - updated references.

Rituximab - PA, NF

Prior Authorization Guideline

Guideline ID	GL-127348
Guideline Name	Rituximab - PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	9/18/2019
P&T Revision Date:	09/18/2019 ; 11/14/2019 ; 10/16/2019 ; 01/15/2020 ; 01/15/2020 ; 02/13/2020 ; 03/18/2020 ; 09/16/2020 ; 02/18/2021 ; 07/21/2021 ; 10/20/2021 ; 12/15/2021 ; 01/19/2022 ; 02/17/2022 ; 07/20/2022 ; 10/19/2022 ; 02/16/2023 ; 7/19/2023

1 . Indications

Drug Name: Rituxan (rituximab)
Non-Hodgkin's Lymphoma (NHL) Indicated for the treatment of patients with: a. Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma as a single agent. b. Previously untreated follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with first-line chemotherapy and, in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, as a single-agent maintenance therapy. c. Non-progressing (including stable disease) low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma, as a single agent, after first-line CVP chemotherapy. d. Previously untreated diffuse large B-cell, CD20-positive non-Hodgkin's lymphoma in combination with

CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens.

Pediatric Non-Hodgkin's Lymphoma (NHL) Indicated for previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy in pediatric patients aged 6 months and older.

Rheumatoid Arthritis (RA) In combination with methotrexate, is indicated for the treatment of adult patients with moderately- to severely-active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies. Limitation of Use: Rituxan is not recommended for use in patients with severe, active infections.

Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with previously untreated and previously treated CD20-positive CLL in combination fludarabine and cyclophosphamide (FC). Limitations of Use: Rituxan is not recommended for use in patients with severe, active infections.

Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) Indicated for the treatment of adult patients with Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult and pediatric patients 2 years of age and older in combination with glucocorticoids. Limitations of Use: Rituxan is not recommended for use in patients with severe, active infections.

Pemphigus Vulgaris Indicated for the treatment of moderate to severe Pemphigus Vulgaris (PV) in adult patients.

Off Label Uses: Immune Thrombocytopenic Purpura (ITP) Has been used for the treatment of immune or idiopathic thrombocytopenic purpura. [1, 2] Overall response rates of 35% to 52% in patients with refractory idiopathic thrombocytopenic purpura. [3, 4]

Waldenstrom's Macroglobulinemia Has been used for the treatment of relapsed/refractory Waldenstrom's macroglobulinemia. Rituximab monotherapy (1 to 8 cycles) has shown efficacy in limited studies. [5-8]

Drug Name: Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

Non-Hodgkin's Lymphoma (NHL) Indicated for the treatment of patients with: a. Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma as a single agent. b. Previously untreated follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with first-line chemotherapy and, in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, as a single-agent maintenance therapy. c. Non-progressing (including stable disease) low-grade, CD20-positive, B-cell non-

Hodgkin's lymphoma, as a single agent, after first-line CVP chemotherapy. d. Previously untreated diffuse large B-cell, CD20-positive non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens.

Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC).

Rheumatoid Arthritis (RA) In combination with methotrexate, is indicated for the treatment of adult patients with moderately- to severely-active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.

Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) Indicated for the treatment of adults with Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in combination with glucocorticoids.

Off Label Uses: Pediatric Non-Hodgkin's Lymphoma (NHL) Indicated for previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy in pediatric patients aged 6 months and older. [25, C, D]

Drug Name: Riabni (rituximab-arrx)

Non-Hodgkin's Lymphoma (NHL) Indicated for the treatment of patients with: a. Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma as a single agent. b. Previously untreated follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with first-line chemotherapy and, in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, as a single-agent maintenance therapy. c. Non-progressing (including stable disease) low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma, as a single agent, after first-line CVP chemotherapy. d. Previously untreated diffuse large B-cell, CD20-positive non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens.

Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC).

Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) Indicated for the treatment of adults with Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in combination with glucocorticoids.

Rheumatoid Arthritis (RA) Indicated in combination with methotrexate for the treatment of adult patients with moderately- to severely- active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.

Off Label Uses: Pediatric Non-Hodgkin's Lymphoma (NHL) Indicated for previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy in pediatric patients aged 6 months and older. [25, C, D]

2 . Criteria

Product Name: Rituxan, Truxima, Riabni	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	1 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately- to severely-active rheumatoid arthritis

AND

2 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [26, 27]:

- methotrexate
- leflunomide
- sulfasalazine

AND

3 - Used in combination with methotrexate [A]

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab)
- Enbrel (etanercept)
- One formulary adalimumab product
- Simponi (golimumab)
- Rinvoq (upadacitinib)
- Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)

AND

4.1.2 Trial and failure, contraindication, or intolerance to BOTH of the following:

- Actemra (tocilizumab)
- Orencia (abatacept)

OR

4.2 Continuation of prior rituximab therapy, defined as no more than a 45-day gap in therapy

AND

5 - Trial and failure or intolerance to Ruxience

AND

6 - Prescribed by or in consultation with a rheumatologist

Notes	*Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Ruxience	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	1 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately- to severely-active rheumatoid arthritis

AND

2 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [26, 27]:

- methotrexate
- leflunomide
- sulfasalazine

AND

3 - Used in combination with methotrexate [A]

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab)
- Enbrel (etanercept)
- One formulary adalimumab product
- Simponi (golimumab)
- Rinvoq (upadacitinib)
- Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)

OR

4.2 Continuation of prior rituximab therapy, defined as no more than a 45-day gap in therapy

AND

5 - Prescribed by or in consultation with a rheumatologist

Notes	*Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Rituxan, Ruxience, Truxima, Riabni	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	1 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [10, 26, 27]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - At least 16 weeks have elapsed since last course of therapy [B]

Product Name: Riabni, Truxima	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	1 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderately- to severely-active rheumatoid arthritis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [26, 27]:

- methotrexate
- leflunomide
- sulfasalazine

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming that medication is used in combination with methotrexate [A]

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab)
- Enbrel (etanercept)
- One formulary adalimumab product
- Simponi (golimumab)
- Rinvoq (upadacitinib)
- Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)

AND

4.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to BOTH of the following:

- Actemra (tocilizumab)
- Orencia (abatacept)

OR

4.2 Both of the following:

4.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior rituximab therapy, defined as no more than a 45-day gap in therapy

AND

4.2.2 Documentation of positive clinical response to therapy as evidenced by at least one of the following [10, 26, 27]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to Ruxience

AND

6 - Prescribed by or in consultation with a rheumatologist

Notes	*Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Ruxience	
Diagnosis	Non-Hodgkin’s Lymphoma
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following: [10]

- Diagnosis of diffuse large B-cell, CD20-positive, non-Hodgkin’s lymphoma
- Used as first-line treatment in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens

OR

1.2 Both of the following:

- Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma
- Used as first-line treatment in combination with chemotherapy

OR

1.3 All of the following:

- Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma
- Patient achieved a complete or partial response to a rituximab product in combination with chemotherapy
- Followed by rituximab used as monotherapy for maintenance therapy

OR

1.4 Both of the following: [1]

1.4.1 Diagnosis of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma

AND

1.4.2 One of the following:

- Patient has stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy
- Patient achieved a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy

OR

1.5 Diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma.

OR

1.6 All of the following (off-label) [25, C, D]

1.6.1 Diagnosis of one of the following previously untreated, advanced stage indications:

- CD-20-positive diffuse large B-cell lymphoma (DLBCL)
- Burkitt lymphoma (BL)
- Burkitt-like lymphoma (BLL)
- Mature B-cell acute leukemia (B-AL)

AND

1.6.2 Patient is 6 months of age or older

AND

1.6.3 Used in combination with chemotherapy

AND

2 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Riabni, Rituxan, Truxima	
Diagnosis	Non-Hodgkin’s Lymphoma
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following: [10]

- Diagnosis of diffuse large B-cell, CD20-positive, non-Hodgkin’s lymphoma
- Used as first-line treatment in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens

OR

1.2 Both of the following:

- Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma
- Used as first-line treatment in combination with chemotherapy

OR

1.3 All of the following:

- Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma
- Patient achieved a complete or partial response to a rituximab product in combination with chemotherapy
- Followed by rituximab used as monotherapy for maintenance therapy

OR

1.4 Both of the following: [1]

1.4.1 Diagnosis of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma

AND

1.4.2 One of the following:

- Patient has stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy
- Patient achieved a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy

OR

1.5 Diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin’s lymphoma.

OR

1.6 All of the following (off-label for Riabni, Truxima) [25, C, D]:

1.6.1 Diagnosis of one of the following previously untreated, advanced stage indications:

- CD-20-positive diffuse large B-cell lymphoma (DLBCL)
- Burkitt lymphoma (BL)
- Burkitt-like lymphoma (BLL)
- Mature B-cell acute leukemia (B-AL)

AND

1.6.2 Patient is 6 months of age or older

AND

1.6.3 Used in combination with chemotherapy

AND

2 - One of the following:

2.1 Trial and failure, or intolerance to Ruxience

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

AND

3 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Riabni, Truxima	
Diagnosis	Non-Hodgkin's Lymphoma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 Both of the following: [10]

- Diagnosis of diffuse large B-cell, CD20-positive, non-Hodgkin’s lymphoma
- Used as first-line treatment in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens

OR

1.2 Both of the following:

- Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma
- Used as first-line treatment in combination with chemotherapy

OR

1.3 All of the following:

- Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma
- Patient achieved a complete or partial response to a rituximab product in combination with chemotherapy
- Followed by rituximab used as monotherapy for maintenance therapy

OR

1.4 Both of the following: [1]

1.4.1 Diagnosis of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma

AND

1.4.2 One of the following:

- Patient has stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy
- Patient achieved a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy

OR

1.5 Diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma.

OR

1.6 All of the following (off-label) [25, C, D]:

1.6.1 Diagnosis of one of the following previously untreated, advanced stage indications:

- CD-20-positive diffuse large B-cell lymphoma (DLBCL)
- Burkitt lymphoma (BL)
- Burkitt-like lymphoma (BLL)
- Mature B-cell acute leukemia (B-AL)

AND

1.6.2 Patient is 6 months of age or older

AND

1.6.3 Used in combination with chemotherapy

AND

2 - One of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Ruxience

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen, defined as no more than a 45-day gap in therapy

AND

3 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Ruxience	
Diagnosis	Chronic Lymphocytic Leukemia
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia [2, 12, 15-19]

AND

2 - Used in combination with fludarabine and cyclophosphamide

AND

3 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Riabni, Rituxan, Truxima	
Diagnosis	Chronic Lymphocytic Leukemia
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia [2, 12, 15-19]

AND

2 - Used in combination with fludarabine and cyclophosphamide

AND

3 - One of the following:

3.1 Trial and failure, or intolerance to Ruxience

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

AND

4 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Riabni, Truxima

Diagnosis	Chronic Lymphocytic Leukemia
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia [2, 12, 15-19]

AND

2 - Used in combination with fludarabine and cyclophosphamide

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Ruxience

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen, defined as no more than a 45-day gap in therapy

AND

4 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Rituxan

Diagnosis	Immune or Idiopathic Thrombocytopenic Purpura [1, 2] (Off-Label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of immune or idiopathic thrombocytopenic purpura (off-label) [3, 4, 11]

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Trial and failure, contraindication, or intolerance to at least ONE of the following: [12]

- Glucocorticoids (e.g., prednisone, methylprednisolone)
- Immunoglobulins (e.g., IVIg)
- Splenectomy

AND

4 - Documented platelet count of less than 50 x 10^9 / L [11]

Product Name: Rituxan	
Diagnosis	Pemphigus Vulgaris
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe Pemphigus Vulgaris

AND

2 - Prescribed by or in consultation with a dermatologist

Product Name: Rituxan	
Diagnosis	Pemphigus Vulgaris
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Rituxan therapy

Product Name: Rituxan	
Diagnosis	Waldenstrom's macroglobulinemia
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsed/refractory Waldenstrom's macroglobulinemia (off-label) [1, 2, 5-8]

Product Name: Ruxience	
Diagnosis	Wegener's Granulomatosis and Microscopic Polyangiitis
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis)
- Microscopic Polyangiitis

AND

2 - Used in combination with glucocorticoids (e.g., prednisone)

AND

3 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Pulmonologist
- Rheumatologist

Product Name: Riabni, Rituxan, Truxima	
Diagnosis	Wegener's Granulomatosis and Microscopic Polyangiitis
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis)
- Microscopic Polyangiitis

AND

2 - Used in combination with glucocorticoids (e.g., prednisone)

AND

3 - One of the following:

3.1 Trial and failure, or intolerance to Ruxience

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

AND

4 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Pulmonologist
- Rheumatologist

Product Name: Riabni, Truxima	
Diagnosis	Wegener's Granulomatosis and Microscopic Polyangiitis

Approval Length	3 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following diagnoses:

- Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis)
- Microscopic Polyangiitis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming medication is used in combination with glucocorticoids (e.g., prednisone)

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Ruxience

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen, defined as no more than a 45-day gap in therapy

AND

4 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Pulmonologist
- Rheumatologist

3 . Endnotes

A. Aggressive, continuous and early treatment with DMARDs may slow the destructive processes in RA by preventing or delaying cartilage and bone destruction. [11] Often used in combination, the most commonly prescribed DMARDs include hydroxychloroquine, sulfasalazine, leflunomide and methotrexate, with methotrexate being the gold standard.
B. An open-label extension analysis of RA patients previously treated with Rituxan was conducted. Patients were eligible for the second course if they demonstrated a greater than or equal to 20% reduction in both swollen joint count and the tender joint count at any visit 16 weeks after initial treatment or later and had active disease (swollen joint count greater than or equal to 8 and tender joint count greater than or equal to 8). Repeat courses of treatment were administered at the investigator's discretion, with a minimum interval between treatment courses of 16 weeks. [15]
C. The FDA defines biosimilar as a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. [22]
D. An FDA-approved biosimilar is an appropriate substitute for rituximab. [23, 25]

4 . References

1. DRUGDEX Information System [Internet database]. Greenwood Village, Colorado: Thomson Micromedex. Accessed January 27, 2022.
2. AHFS Drug Information (Adult and Pediatric) [Internet database]. Hudson, Ohio: Lexicomp. Accessed on January 27, 2022.
3. Stasi R, Pagano A, Stipa E, et al. Rituximab chimeric anti-CD20 monoclonal antibody treatment for adults with chronic idiopathic thrombocytopenic purpura. Blood. 2001;98:952-7.
4. Saleh MN, Moore M, Feinberg B, et al. A pilot study of anti-CD20 MoAB rituximab in patients with refractory immune thrombocytopenic purpura (ITP). Blood. 2001;96:521a.
5. Dimopoulos MA, Kiamouris C, Karkantaris C, et al. Prospective evaluation of rituximab for the treatment of waldenstrom's macroglobulinemia. Blood. 2000;96:169a.
6. Treon SP, Agus DB, Link B, et al. Rituximab is an active agent in waldenstrom's macroglobulinemia (WM).Proc Am Soc Clin Oncol. 2000;19:6a.

7. Weide R, Heymanns J, & Koppler H. The polyneuropathy associated with Waldenstrom's macroglobulinaemia can be treated effectively with chemotherapy and the anti-CD20 monoclonal antibody rituximab. Br J Haematol. 2000;109:838-841.
8. Byrd JC, White CA, Link B, et al. Rituximab therapy in Waldenstrom's macroglobulinemia: preliminary evidence of clinical activity. Ann Oncol. 1999;10:1525-7.
9. American College of Rheumatology 2008 Recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. Arthritis Rheum. 2008;59(6):762-784.
10. Rituxan Prescribing Information. Genentech, Inc. South San Francisco, CA. December 2021.
11. Gudbrandsdottir S, Birgens HS, Frederiksen H, et al. Rituximab and dexamethasone vs dexamethasone monotherapy in newly diagnosed patients with primary immune thrombocytopenia. Blood. 2013;121(11):1976-81.
12. George JN, Woolf SH, Raskob GE, et al. Idiopathic thrombocytopenic purpura: a practice guideline developed by explicit methods for the American Society of Hematology. Blood. 1996;88:3-40.
13. Stone JH, Merkel PA, Spiera R, et al. Rituximab versus cyclophosphamide for ANCA-associated vasculitis. N Engl J Med. 2010;363:221-32.
14. Per clinical consult with rheumatologist. March 10, 2014.
15. Byrd JC, Murphy T, Howard RS, et al. Rituximab using a thrice weekly dosing schedule in B-cell chronic lymphocytic leukemia and small lymphocytic lymphoma demonstrates clinical activity and acceptable toxicity. J Clin Oncol. 2001;19:2153-2164.
16. Byrd JC, Peterson BL, Morrison VA, et al. Randomized phase II study of fludarabine with concurrent versus sequential treatment with rituximab in symptomatic, untreated patients with B-cell chronic lymphocytic leukemia: results from Cancer and Leukemia Group B 9712 (CALGB 9712). Blood. 2003;101:6-14.
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5 . Revision History

Date	Notes
6/30/2023	Addition of Cyltezo, Hyrimoz, and brand Adalimumab-adaz as preferred step options for RA

Rybelsus (semaglutide)

Prior Authorization Guideline

Guideline ID	GL-116516
Guideline Name	Rybelsus (semaglutide)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Rybelsus	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication	

AND

2 - Drug is not solely being used for weight loss

AND

3 - Trial and failure, contraindication, or intolerance to one of the following generics:

- Metformin
- Metformin ER
- Glipizide-metformin
- Glyburide-metformin
- Pioglitazone-metformin

2 . References

1. American Diabetes Association. Standards of medical care in diabetes. Diabetes Care. 2022; 45 (suppl 1): S125-143.
2. Rybelsus Prescribing Information. Novo Nordisk A/S. Bagsvaerd, Denmark. September 2021.

3 . Revision History

Date	Notes
10/31/2022	2023 New Implementation

Ryplazim (plasminogen, human-tvmh)

Prior Authorization Guideline

Guideline ID	GL-116462
Guideline Name	Ryplazim (plasminogen, human-tvmh)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	11/18/2021
P&T Revision Date:	11/17/2022

1 . Indications

Drug Name: Ryplazim (plasminogen, human-tvmh)
Hypoplasminogenemia Indicated for the treatment of patients with plasminogen deficiency type 1 (hypoplasminogenemia).

2 . Criteria

Product Name: Ryplazim

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of plasminogen deficiency type 1 (hypoplasminogenemia) as confirmed by both of the following [2, A, B]:

1.1 Deficiency of plasminogen activity evidenced by a level of less than or equal to 50%, as confirmed by a chromogenic assay [3-5, B]

AND

1.2 Abnormal plasminogen antigen plasma level of less than 9 mg/dL, as confirmed by an enzyme-linked immunosorbent assay [3-5, B]

AND

2 - Presence of clinical symptoms and signs of the disease (e.g., ligneous conjunctivitis, ligneous gingivitis, occlusive hydrocephalus) [1, 5, A]

AND

3 - Prescribed by or in consultation with a hematologist

Product Name: Ryplazim	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., plasminogen activity trough level increased by at least 10 percentage points from baseline, improvement or resolution of lesions) [5, C]

3 . Endnotes

A. The diagnosis of pseudo-membranous disease secondary to plasminogen deficiency requires both clinical and laboratory findings. Clinical symptoms from ligneous lesions and abnormally decreased plasminogen activity establishes the diagnosis [1].
B. Laboratory evaluation for plasminogen deficiency should include both plasminogen antigen and activity level. The study procedures in the Shapiro et al clinical trial included measuring plasminogen activity using a commercially available chromogenic assay and measuring plasminogen antigen using a commercially available enzyme-linked immunosorbent assay. Decreased plasminogen activity and concordant decrease in protein level is associated with plasminogen deficiency type 1, whereas patients with plasminogen deficiency type II have reduced plasminogen activity but normal or only slightly reduced plasminogen antigen level and have never been reported to develop pseudo-membranous lesions at other mucosal sites. Plasminogen values in patients with hypoplasminogenemia ranged from < 1 to 9 mg/dL for plasminogen antigen plasma level and < 1%-51% for functional plasminogen activity. These values provide a rough threshold between symptomatic and asymptomatic hypoplasminogenemia [3-5].
C. The primary end point success of the clinical study was defined as at least 80% of evaluable patients achieving target trough plasminogen activity levels, which was an increase of individual plasminogen activity trough level by at least an absolute 10% above baseline for at least 3 measurements in 12 weeks. The secondary end point success was defined as 50% of patients with clinically visible or other measurable lesions achieving ≥ 50% reduction in lesion number and/or size or improved organ function [5].

4 . References

1. Mehta R and Shapiro AD. Plasminogen deficiency. Haemophilia. 2008; 14:1261-1268. doi: 10.1111/j.1365-2516.2008.01825.x

2. Ryplazim Prescribing Information. Prometic Biotherapeutics, Inc. Fort Lee, New Jersey. November 2021.
3. Schuster V, Hügle B, Tefs K. Plasminogen deficiency. J Thromb Haemost. 2007;5(12):2315-2322. doi:10.1111/j.1538-7836.2007.02776.x
4. Schuster V, Seregard S. Ligneous conjunctivitis. Surv Ophthalmol. 2003;48(4):369-388. doi:10.1016/s0039-6257(03)00056-0
5. Shapiro AD, Nakar C, Parker JM, et al. Plasminogen replacement therapy for the treatment of children and adults with congenital plasminogen deficiency. Blood. 2018;131(12):1301-1310. doi:10.1182/blood-2017-09-806729

5 . Revision History

Date	Notes
11/18/2022	Annual review - updated references.

Saphnelo (anifrolumab-fnia)

Prior Authorization Guideline

Guideline ID	GL-113478
Guideline Name	Saphnelo (anifrolumab-fnia)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	11/1/2022
P&T Approval Date:	10/20/2021
P&T Revision Date:	10/19/2022

1 . Indications

Drug Name: Saphnelo (anifrolumab-fnia)
Systemic Lupus Erythematosus (SLE) Indicated for the treatment of adult patients with moderate to severe SLE, who are receiving standard therapy. Limitations of Use: The efficacy of Saphnelo has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Use of Saphnelo is not recommended in these situations.

2 . Criteria

Product Name: Saphnelo	
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe systemic lupus erythematosus (SLE)

AND

2 - Trial and failure, contraindication, or intolerance to two standard of care treatments for active SLE (e.g., antimalarials [e.g., Plaquenil (hydroxychloroquine)], corticosteroids [e.g., prednisone], or immunosuppressants [e.g., methotrexate, Imuran (azathioprine)]) [4]

AND

3 - Currently receiving standard of care treatment for SLE (e.g., antimalarials [e.g., Plaquenil (hydroxychloroquine)], corticosteroids [e.g., prednisone], or immunosuppressants [e.g., methotrexate, Imuran (azathioprine)]) [1-3]

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name: Saphnelo	
Approval Length	6 Months [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., decrease or stabilization of symptoms, improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications)

3 . Endnotes

A. SLE is a disease that fluctuates. The undulating course of typical lupus patients requires frequent reassessment. A 6-month authorization period is reasonable. [2]

4 . References

1. Saphnelo Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. July 2021.
2. Per clinical consult with rheumatologist, October 4, 2017.
3. American College of Rheumatology Ad Hoc Committee on Systemic Lupus Erythematosus Guidelines. Guidelines for referral and management of systemic lupus erythematosus. Arthritis Rheum. 1999 Sep;42(9):1785-96.
4. Fanouriakis A, Kostopoulou M, Alunno A, et al. Ann Rheum Dis 2019;78:736–745.

5 . Revision History

Date	Notes
10/5/2022	Annual review: Updated criteria and background.

Scemblix (asciminib)

Prior Authorization Guideline

Guideline ID	GL-116568
Guideline Name	Scemblix (asciminib)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Scemblix	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic myelogenous/myeloid leukemia (CML)	

AND

2 - Disease is Philadelphia chromosome-positive (Ph+)

AND

3 - Patient is 18 years of age or older

AND

4 - One of the following:

4.1 Patient has been previously treated with at least two alternative tyrosine kinase inhibitors (TKI) (e.g., ponatinib, nilotinib, dasatinib)

OR

4.2 Both of the following:

- Disease is T315I mutation positive
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1

AND

5 - Prescribed by or in consultation with ONE of the following:

- Hematologist
- Oncologist

Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/28/2022	New Implementation

Scenesse (afamelanotide)

Prior Authorization Guideline

Guideline ID	GL-124311
Guideline Name	Scenesse (afamelanotide)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	4/15/2020
P&T Revision Date:	04/21/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Scenesse (afamelanotide)
Erythropoietic protoporphyria - Phototoxic dermatitis Indicated to increase pain free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria (EPP).

2 . Criteria

Product Name: Scenesse	
Approval Length	6 Month(s) [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of erythropoietic protoporphyria (EPP) confirmed by laboratory or genetic testing [B]

AND

2 - Patient has history of phototoxic reactions

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Hepatologist

Product Name: Scenesse	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy (e.g., increased duration of exposure to direct sunlight without pain, decreased number of phototoxic reactions)

3 . Endnotes

A. Patients enrolled in clinical trial (Study CUV039, NCT 01605136) were assessed after 180 days and consultant agreed that 6 month approval duration is appropriate to determine if patient is responding to therapy. [1, 2]
B. Per recommendation from consultant to avoid off-label use, diagnosis of erythropoietic protoporphyria (EPP) should be confirmed by laboratory (porphyrin levels in serum and stool) or genetic testing. [2]

4 . References

1. Scenesse Prescribing Information. Clinuvel, Inc. West Menlo Park, CA. January 2023.
2. Per clinical consult with dermatologist, December 19, 2019.

5 . Revision History

Date	Notes
4/7/2023	Annual Review, no criteria changes.

Serotonin Modulators Step Therapy

Prior Authorization Guideline

Guideline ID	GL-116486
Guideline Name	Serotonin Modulators Step Therapy
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Trintellix, Viibryd, Generic Vilazodone	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Trial and failure, or intolerance to two generic selective serotonin reuptake inhibitors (SSRIs) (e.g., sertraline, fluoxetine, citalopram) and/or Serotonin–norepinephrine (SNRIs) (e.g., duloxetine, venlafaxine)

2 . Revision History

Date	Notes
10/27/2022	2023 New Implementation

SGLT2 Inhibitors

Prior Authorization Guideline

Guideline ID	GL-116511
Guideline Name	SGLT2 Inhibitors
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Glyxambi, Synjardy, Synjardy XR, Trijardy XR	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication	

AND

2 - Trial and failure of a minimum 30-day supply, contraindication, or intolerance to one of the following generics:

- metformin
- metformin ER
- glipizide-metformin
- glyburide-metformin
- pioglitazone-metformin

Product Name: Farxiga	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of heart failure (NYHA class II-IV) with reduced ejection fraction

AND

1.1.2 Trial and failure of a minimum 30-day supply, contraindication, or intolerance to one of the following: [14, 15]

- captopril
- enalapril
- lisinopril
- quinapril
- ramipril

- fosinopril
- trandolapril
- perindopril
- candesartan
- valsartan
- losartan
- bisoprolol
- carvedilol IR/ER
- metoprolol succinate CR/XL
- spironolactone
- eplerenone
- Entresto (sacubitril-valsartan)

OR

1.2 Both of the following:

1.2.1 Diagnosis of type 2 diabetes mellitus

AND

1.2.2 Trial and failure of a minimum 30-day supply, contraindication, or intolerance to one of the following generics:

- metformin
- metformin ER
- glipizide-metformin
- glyburide-metformin
- pioglitazone-metformin

OR

1.3 Diagnosis of chronic kidney disease

Product Name: Jardiance	
Approval Length	12 month(s)

Guideline Type	Step Therapy

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of type 2 diabetes mellitus

AND

1.1.2 Trial and failure of a minimum 30-day supply, contraindication, or intolerance to one of the following generics:

- metformin
- metformin ER
- glipizide-metformin
- glyburide-metformin
- pioglitazone-metformin

OR

1.2 One of the following:

1.2.1 Both of the following:

1.2.1.1 Diagnosis of heart failure (NYHA class II-IV) with reduced ejection fraction

AND

1.2.1.2 Trial and failure of a minimum 30-day supply, contraindication, or intolerance to one of the following: [14, 15]

- captopril

- enalapril
- lisinopril
- quinapril
- ramipril
- fosinopril
- trandolapril
- perindopril
- candesartan
- valsartan
- losartan
- bisoprolol
- carvedilol IR/ER
- metoprolol succinate CR/XL
- sprinolactone
- eplerenone
- Entresto (sacubitril-valsartan)

OR

1.2.2 One of the following:

- Diagnosis of heart failure with preserved ejection fraction [16]
- Diagnosis of heart failure with mildly reduced ejection fraction

Product Name: Xigduo XR	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of heart failure (NYHA class II-IV) with reduced ejection fraction

AND

1.1.2 Trial and failure of a minimum 30-day supply, contraindication, or intolerance to one of the following: [14, 15]

- captopril
- enalapril
- lisinopril
- quinapril
- ramipril
- fosinopril
- trandolapril
- perindopril
- candesartan
- valsartan
- losartan
- bisoprolol
- carvedilol IR/ER
- metoprolol succinate CR/XL
- spironolactone
- eplerenone
- Entresto (sacubitril-valsartan)

OR

1.2 Both of the following:

1.2.1 Diagnosis of type 2 diabetes mellitus

AND

1.2.2 Trial and failure of a minimum 30-day supply, contraindication, or intolerance to one of the following generics:

- metformin
- metformin ER

- glipizide-metformin
- glyburide-metformin
- pioglitazone-metformin

OR

1.3 Diagnosis of chronic kidney disease

2 . Revision History

Date	Notes
10/25/2022	New Implementation

Signifor, Signifor LAR (pasireotide) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-115519
Guideline Name	Signifor, Signifor LAR (pasireotide) - PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	2/19/2013
P&T Revision Date:	11/14/2019 ; 11/12/2020 ; 11/18/2021 ; 01/19/2022 ; 11/17/2022

1 . Indications

Drug Name: Signifor LAR (pasireotide)
Acromegaly Indicated for the treatment of patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option. **Cushing's disease** Indicated for the treatment of patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.
Drug Name: Signifor (pasireotide)
Cushing's disease Indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

2 . Criteria

Product Name: Signifor LAR	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - One of the following:

- Inadequate response to surgery
- Patient is not a candidate for surgery

Product Name: Signifor LAR	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., patient's growth hormone level or insulin-like growth factor 1 level for age and gender has normalized/improved)

Product Name: Signifor, Signifor LAR	
Diagnosis	Cushing's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endogenous Cushing's disease

AND

2 - One of the following:

2.1 Pituitary surgery has not been curative for the patient

OR

2.2 Patient is not a candidate for pituitary surgery

AND

3 - Prescribed by or in consultation with an endocrinologist

Product Name: Signifor, Signifor LAR	
Diagnosis	Cushing's disease

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease)

Product Name: Signifor	
Diagnosis	Cushing's disease
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of endogenous Cushing's disease

AND

2 - One of the following:

2.1 Pituitary surgery has not been curative for the patient

OR

2.2 Patient is not a candidate for pituitary surgery

AND **3** - Prescribed by or in consultation with an endocrinologist

3 . Background

Benefit/Coverage/Program Information
Quantity Limit These products are subject to an Samaritan Large Group standard quantity limit. The quantity limit may vary from the standard limit based upon plan-specific benefit design. Please refer to your benefit materials.

4 . References

1. Signifor LAR Prescribing Information. Recordati Rare Diseases Inc. Lebanon, NJ. July 2020.
2. Signifor Prescribing Information. Recordati Rare Diseases Inc. Lebanon, NJ . March 2020.

5 . Revision History

Date	Notes
11/22/2022	Annual review: update initial authorization duration for acromegaly fr om 6 months to 12 months

Sildenafil citrate

Prior Authorization Guideline

Guideline ID	GL-116563
Guideline Name	Sildenafil citrate
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Sildenafil citrate	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of pulmonary arterial hypertension (PAH)	

AND

2 - Will not be used for erectile dysfunction

AND

3 - Prescribed by or in consultation with one of the following:

- Cardiologist
- Pulmonologist

Product Name: Sildenafil citrate	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/7/2022	New Implementation

Simponi (golimumab)

Prior Authorization Guideline

Guideline ID	GL-117619
Guideline Name	Simponi (golimumab)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Indications

Drug Name: Simponi (golimumab) - for subcutaneous use
Rheumatoid Arthritis (RA) In combination with methotrexate, indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis. **Psoriatic Arthritis (PsA)** Alone or in combination with methotrexate, indicated for the treatment of adult patients with active psoriatic arthritis. **Ankylosing Spondylitis (AS)** Indicated for the treatment of adult patients with active ankylosing spondylitis. **Ulcerative Colitis (UC)** Indicated in adult patients with moderately to severely active ulcerative colitis who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine or 6-mercaptopurine for: (1) inducing and maintaining clinical response, (2) improving endoscopic

appearance of the mucosa during induction, (3) inducing clinical remission, and (4) achieving and sustaining clinical remission in induction responders.

2 . Criteria

Product Name: Simponi	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active RA

AND

2 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [3, 4]:

- methotrexate
- leflunomide
- sulfasalazine

AND

3 - Used in combination with methotrexate

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name: Simponi	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Simponi	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active PsA

AND

2 - One of the following [6]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Product Name: Simponi	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 2, 6]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name: Simponi

Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [7]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Simponi	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following [1, 2, 7]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)

- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name: Simponi	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [8, 9]:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, ESR, CRP)
- Dependent on, or refractory to, corticosteroids

AND

3 - One of the following:

3.1 Patient is corticosteroid dependent (i.e., an inability to successfully taper corticosteroids without a return of the symptoms of UC)

OR

3.2 Trial and failure, contraindication, or intolerance to one of the following conventional therapies [1, 8, 9]

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name: Simponi	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 8, 9]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

3 . References

1. Simponi Prescribing Information. Janssen Biotech Inc. Horsham, PA. September 2019.
2. Simponi Aria Prescribing Information. Janssen Biotech, Inc. Horsham, PA. February 2021.
3. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.
4. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
5. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Rheumatol. 2019;71(6):846-863.
6. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
7. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613.
8. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.
9. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterol. 2020;158:1450-1461.

4 . Revision History

Date	Notes
12/2/2022	Update Guideline

Simponi Aria

Prior Authorization Guideline

Guideline ID	GL-126096
Guideline Name	Simponi Aria
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Simponi Aria	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

2 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses:

- methotrexate
- leflunomide
- sulfasalazine

AND

3 - Used in combination with methotrexate

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name: Simponi Aria	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA)

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses:

- leflunomide
- methotrexate

Product Name: Simponi Aria	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis (PsA)

AND

2 - One of the following:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease

- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Product Name: Simponi Aria	
Diagnosis	Ankylosing Spondylitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Simponi Aria

Diagnosis	All Indications Listed Above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
6/8/2023	New program

Skyrizi (risankizumab-rzaa)

Prior Authorization Guideline

Guideline ID	GL-116592
Guideline Name	Skyrizi (risankizumab-rzaa)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Indications

Drug Name: Skyrizi SC (risankizumab-rzaa)
Plaque Psoriasis (PsO) Indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. **Psoriatic Arthritis (PsA)** Indicated for the treatment of active psoriatic arthritis in adults. **Crohn's Disease (CD)** Indicated for the treatment of moderately to severely active Crohn's disease in adults.
Drug Name: Skyrizi IV (risankizumab-rzaa)
Crohn's Disease (CD) Indicated for the treatment of moderately to severely active Crohn's disease in adults.

2 . Criteria

Product Name: Skyrizi SC 75 mg, 150 mg	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin

- coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name: Skyrizi SC 75 mg, 150 mg	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1-3]:

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name: Skyrizi SC 75 mg, 150 mg	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis (PsA)

AND

2 - One of the following [4]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Product Name: Skyrizi SC 75 mg, 150 mg	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name: Skyrizi IV	
Diagnosis	Crohn's Disease (CD)
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease (CD)

AND

2 - One of the following [5, 6]:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CDAI) greater than 220

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies [5, 6]:

- 6-mercaptopurine
- Azathioprine
- Methotrexate
- Corticosteroid (e.g., prednisone)

AND

4 - Will be administered as an intravenous induction dose

AND

5 - Prescribed by or in consultation with a gastroenterologist

Product Name: Skyrizi SC 360 mg	
Diagnosis	Crohn's Disease (CD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease (CD)

AND

2 - Will be used as a maintenance dose following the intravenous induction doses

AND

3 - Prescribed by or in consultation with a gastroenterologist

Product Name: Skyrizi SC 360 mg	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 5, 6]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

3 . References

1. Skyrizi Prescribing Information. AbbVie, Inc. North Chicago, IL. June 2022.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
3. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
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6. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508.

4 . Revision History

Date	Notes
10/28/2022	Bulk copy OptumRx SP to Samaritan SP for 1/1/2023 Implementation

Sofosbuvir/Velpatasvir – SCP

Prior Authorization Guideline

Guideline ID	GL-116584
Guideline Name	Sofosbuvir/Velpatasvir – SCP
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 1, 2, 3, 4, 5, or 6
Approval Length	12 Week(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient does NOT have decompensated liver disease (Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6 - Patients with Decompensated Liver Disease - Epclusa plus ribavirin
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Both of the following:

- Patient has decompensated liver disease (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6 - Patients with Decompensated Liver Disease - Ribavirin Intolerance/Ineligible OR Prior Sofosbuvir or NS5A-based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient has decompensated liver disease (Child-Pugh Class B or C)

AND

4 - One of the following:

4.1 Patient is ribavirin intolerant or ineligible

OR

4.2 Both of the following:

4.2.1 Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based treatment

AND

4.2.2 Used in combination with ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

2 . Revision History

Date	Notes
10/28/2022	2023 New Implementation

Soliris (eculizumab)

Prior Authorization Guideline

Guideline ID	GL-118741
Guideline Name	Soliris (eculizumab)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	11/19/2014
P&T Revision Date:	09/18/2019 ; 12/18/2019 ; 02/13/2020 ; 01/20/2021 ; 02/18/2021 ; 02/17/2022 ; 09/21/2022 ; 2/16/2023

1 . Indications

Drug Name: Soliris (eculizumab)
Paroxysmal Nocturnal Hemoglobinuria (PNH) Indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis. **Atypical Hemolytic Uremic Syndrome (aHUS)** Indicated for the treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy. Limitations of Use: Soliris is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS). **Generalized Myasthenia Gravis (gMG)** Indicated for the treatment of adult patients with generalized Myasthenia Gravis (gMG) who are anti-acetylcholine receptor (AchR) antibody

positive.

Neuromyelitis Optica Spectrum Disorder (NMOSD) Indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

2 . Criteria

Product Name: Soliris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

AND

2 - Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab)

AND

3 - One of the following:

3.1 Prescribed medication is used for induction therapy and will not exceed 600 mg weekly for the first 4 weeks

OR

3.2 Prescribed medication is used for maintenance therapy and will not exceed 900 mg weekly at week 5, then 900 mg every 2 weeks thereafter

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Soliris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy

AND

2 - Prescribed medication is used for maintenance therapy and will not exceed 900 mg every 2 weeks

Product Name: Soliris	
Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of atypical hemolytic uremic syndrome (aHUS)

AND

2 - Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab)

AND

3 - One of the following:

3.1 For patients 18 years of age and older:

3.1.1 Prescribed medication is used for induction therapy and will not exceed 900 mg weekly for the first 4 weeks

OR

3.1.2 Prescribed medication is used for maintenance therapy and will not exceed 1200 mg weekly at week 5, then 1200 mg every 2 weeks thereafter

OR

3.2 For patients less than 18 years of age, dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for aHUS (refer to Table 1 in Background Section for dosing schedule)

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Nephrologist

Product Name: Soliris	
Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response (e.g., increase in mean platelet counts, hematologic normalization) to therapy

AND

2 - One of the following:

2.1 For patients 18 years of age and older, prescribed medication is used for maintenance therapy and will not exceed 1200 mg every 2 weeks

OR

2.2 For patients less than 18 years of age, dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for aHUS (refer to Table 1 in Background Section for MAINTENANCE dosing schedule)

Product Name: Soliris	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis (gMG)

AND

2 - Patient is anti-acetylcholine receptor (AChR) antibody positive

AND

3 - One of the following: [2, 3]

3.1 Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

OR

3.2 Both of the following:

3.2.1 Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

AND

3.2.2 Trial and failure, contraindication, or intolerance to one of the following:

- Chronic plasmapheresis or plasma exchange (PE)
- Intravenous immunoglobulin (IVIG)

AND

4 - Trial and failure, contraindication, or intolerance to one of the following:

- Ultomiris (ravulizumab)
- Vyvgart (efgartigimod)

AND

5 - One of the following:

5.1 Prescribed medication is used for induction therapy and will not exceed 900 mg weekly for the first 4 weeks

OR

5.2 Prescribed medication is used for maintenance therapy and will not exceed 1200 mg at week 5, then 1200 mg every 2 weeks thereafter

AND

6 - Prescribed by or in consultation with a neurologist

Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Prescribed medication is used for maintenance therapy and will not exceed 1200 mg every 2 weeks

Product Name: Soliris	
Diagnosis	Neuromyelitis Optica Spectrum Disorder (NMOSD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neuromyelitis optica spectrum disorder (NMOSD)

AND

2 - Patient is anti-aquaporin-4 (AQP4) antibody positive

AND

3 - One of the following:

3.1 Prescribed medication is used for induction therapy and will not exceed 900 mg weekly for the first 4 weeks

OR

3.2 Prescribed medication is used for maintenance therapy and will not exceed 1200 mg at week 5, then 1200 mg every 2 weeks thereafter

AND

4 - Prescribed by or in consultation with one of the following:

- Neurologist
- Ophthalmologist

Product Name: Soliris	
Diagnosis	Neuromyelitis Optica Spectrum Disorder (NMOSD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Prescribed medication is used for maintenance therapy and will not exceed 1200 mg every 2 weeks

3 . Background

Benefit/Coverage/Program Information

Table 1. Dosing Recommendations for Atypical Hemolytic Uremic Syndrome (aHUS) in Patients Less Than 18 Years of Age

Patient Body Weight	Induction Therapy	Maintenance Therapy
40 kg and over	900 mg weekly for 4 dose	1200 mg at week 5; Then 1200 mg every 2 weeks
30 kg to less than 40 kg	600 mg weekly for 2 doses	900 mg at week 3; Then 900 mg every 2 weeks
20 kg to less than 30 kg	600 mg weekly for 2 doses	600 mg at week 3; Then 600 mg every 2 weeks
10 kg to less than 20 kg	600 mg weekly for 1 dose	300 mg at week 2; Then 300 mg every 2 weeks
5 kg to less than 10 kg	300 mg weekly for 1 dose	300 mg at week 2; Then 300 mg every 3 weeks

4 . References

1. Soliris Prescribing Information. Alexion Pharmaceuticals, Inc. Boston, MA. November 2020.
2. Howard JF Jr, Utsugisawa K, Benatar M, et al. Safety and efficacy of eculizumab in anti-acetylcholine receptor antibody-positive refractory generalised myasthenia gravis (REGAIN): a phase 3, randomised, double-blind, placebo-controlled, multicentre study. Lancet Neurol. 2017;16(12):976-986.
3. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis. Neurology. 2016;87(4):419-25.

5 . Revision History

Date	Notes
1/25/2023	2023 UM Annual Review. No changes.

Somatuline Depot (lanreotide) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-114114
Guideline Name	Somatuline Depot (lanreotide) - PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	12/1/2022
P&T Approval Date:	11/13/2007
P&T Revision Date:	11/14/2019 ; 10/21/2020 ; 10/20/2021 ; 03/16/2022 ; 07/20/2022 ; 10/19/2022

1 . Indications

Drug Name: Somatuline Depot (lanreotide)
Acromegaly Indicated for the long-term treatment of acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. The goal of treatment in acromegaly is to reduce growth hormone (GH) and insulin growth factor-1 (IGF-1) levels to normal. **Gastroenteropancreatic Neuroendocrine Tumors (GEP-NET)** Indicated for the treatment of adult patients with unresectable, well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival.

Carcinoid Syndrome Indicated for the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.
Drug Name: Lanreotide Injection
Acromegaly Indicated for the long-term treatment of acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. The goal of treatment in acromegaly is to reduce growth hormone (GH) and insulin growth factor-1 (IGF-1) levels to normal. **Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)** Indicated for the treatment of adult patients with unresectable, well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival. **Off Label Uses: Carcinoid Syndrome [3]** Indicated for the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.

2 . Criteria

Product Name: Somatuline Depot, Brand Lanreotide	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - One of the following:

2.1 Inadequate response to one of the following:

- Surgery
- Radiotherapy

OR

2.2 Not a candidate for one of the following:

- Surgery
- Radiotherapy

AND

3 - Trial and failure or intolerance to Somatuline Depot (Applies to Brand Lanreotide only)

AND

4 - Prescribed by or in consultation with an endocrinologist

Product Name: Somatuline Depot, Brand Lanreotide	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy, such as a reduction or normalization of IGF-1/GH level for same age and sex

Product Name: Brand Lanreotide	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - One of the following:

2.1 Inadequate response to one of the following:

- Surgery
- Radiotherapy

OR

2.2 Not a candidate for one of the following:

- Surgery
- Radiotherapy

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to Somatuline Depot

AND

4 - Prescribed by or in consultation with an endocrinologist

Product Name: Somatuline Depot 120mg/0.5mL, Brand Lanreotide 120mg/0.5ml	
Diagnosis	Advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NET)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastroenteropancreatic neuroendocrine tumor (GEP-NET)

AND

2 - Disease is one of the following:

- Unresectable, locally advanced
- Metastatic

AND

3 - Trial and failure or intolerance to Somatuline Depot (Applies to Brand Lanreotide only)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Somatuline Depot 120mg/0.5mL, Brand Lanreotide 120mg/0.5ml	
Diagnosis	Advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NET)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Lanreotide 120mg/0.5ml	
Diagnosis	Advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NET)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of gastroenteropancreatic neuroendocrine tumor (GEP-NET)

AND

2 - Disease is one of the following:

- Unresectable, locally advanced
- Metastatic

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to Somatuline Depot

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Somatuline Depot 120mg/0.5mL, Brand Lanreotide 120mg/0.5ml [off-label]	
Diagnosis	Carcinoid Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of carcinoid syndrome

AND

2 - Used to reduce the frequency of short-acting somatostatin analog rescue therapy

AND

3 - Trial and failure or intolerance to Somatuline Depot (Applies to Brand Lanreotide only)

AND

4 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Oncologist

Product Name: Somatuline Depot 120mg/0.5mL, Brand Lanreotide 120mg/0.5ml [off-label]	
Diagnosis	Carcinoid Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Brand Lanreotide 120mg/0.5ml [off-label]	
Diagnosis	Carcinoid Syndrome
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of carcinoid syndrome

AND

2 - Used to reduce the frequency of short-acting somatostatin analog rescue therapy

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to Somatuline Depot

AND

4 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Oncologist

3 . References

1. Somatuline Depot Prescribing Information. Ipsen Biopharmaceuticals, Inc. Cambridge, MA. June 2019.
2. Lanreotide Injection Prescribing Information. Exelan Pharmaceuticals, Inc. Boca Raton, FL. February 2022.
3. Lanreotide Acetate. In: IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com/. Accessed September 19, 2022.

4 . Revision History

Date	Notes
10/20/2022	Annual review: no criteria changes.

Spinraza (nusinersen)

Prior Authorization Guideline

Guideline ID	GL-126112
Guideline Name	Spinraza (nusinersen)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	
P&T Revision Date:	12/16/2020 ; 06/16/2021 ; 06/15/2022 ; 6/1/2023

1 . Indications

Drug Name: Spinraza (nusinersen)
Spinal Muscular Atrophy Indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.

2 . Criteria

Product Name: Spinraza

Diagnosis	Spinal Muscular Atrophy
Approval Length	3 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of spinal muscular atrophy (SMA) Type I, II, or III [1-4, B]

AND

2 - Both of the following: [1-7]

2.1 The mutation or deletion of genes in chromosome 5q resulting in one of the following: [C]

2.1.1 Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13)

OR

2.1.2 Compound heterozygous mutation (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2])

AND

2.2 Patient has at least 2 copies of SMN2 [D]

AND

3 - Patient is not dependent on invasive ventilation or tracheostomy [2-4, E]

AND

4 - Patient is not dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep [2-4, E]

AND

5 - At least one of the following exams (based on patient age and motor ability) has been conducted to establish baseline motor ability*: [2-10]

- Hammersmith Infant Neurological Exam (HINE) (infant to early childhood)
- Hammersmith Functional Motor Scale Expanded (HFMSE)
- Upper Limb Module (ULM) Test (Non ambulatory)
- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)

AND

6 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA

AND

7 - Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures [1]

AND

8 - Patient is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Evrysdi) [2-4, F]

AND

9 - One of the following: [2-4, 11, F]

9.1 Patient has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma)

OR

9.2 Both of the following:

- Patient has previously received gene therapy for the treatment of SMA (e.g., Zolgensma)
- Documentation of an inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months)

AND

10 - One of the following:

10.1 Trial and failure or intolerance to Evrysdi

OR

10.2 Patient is younger than 2 months

Notes	*Baseline assessments for patients less than 2 months of age requesting nusinersen proactively are not necessary in order to not delay access to initial therapy in recently diagnosed infants. Initial assessments shortly post-therapy can serve as baseline with respect to efficacy re authorization assessment.

Product Name: Spinraza

Diagnosis	Spinal Muscular Atrophy
Approval Length	12 Months [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy from pretreatment baseline status as demonstrated by the most recent results from one of the following exams:

1.1 One of the following HINE-2 milestones: [2]

- Improvement or maintenance of previous improvement of at least a 2 point (or maximal score) increase in ability to kick
- Improvement or maintenance of previous improvement of at least a 1 point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp
- Patient exhibited improvement, or maintenance of a previous improvement in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement)
- Patient has achieved and maintained any new motor milestones from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

1.2 One of the following HFMSE milestones: [3, 9-10]

- Improvement or maintenance of a previous improvement of at least a 3 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

1.3 One of the following ULM test milestones: [3, 12-13]

- Improvement or maintenance of a previous improvement of at least a 2 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

1.4 One of the following CHOP INTEND milestones: [2, 4]

- Improvement or maintenance of a previous improvement of at least a 4 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

AND

2 - Patient continues to not be dependent on invasive ventilation or tracheostomy [2-4, E]

AND

3 - Patient continues to not be dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep [2-4, E]

AND

4 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA

AND

5 - Spinraza is to be administered intrathecally by, or under the direction of, healthcare professionals experienced in performing lumbar punctures [1]

AND

6 - Patient is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Evrysdi) [2-4, F]

AND

7 - One of the following: [2-4, 11, F]

7.1 Patient has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma)

OR

7.2 Both of the following:

- Patient has previously received gene therapy for the treatment of SMA (e.g., Zolgensma)
- Documentation of an inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months)

3 . Endnotes

A. Spinraza is for intrathecal use only. Treatment is initiated with 4 loading doses; the first 3 loading doses should be administered at 14-day intervals, and the 4th loading dose should be administered 30 days after the 3rd loading dose. A maintenance dose should

be administered once every 4 months thereafter. If a loading dose is delayed or missed, Spinraza should be administered as soon as possible, with at least 14 days between doses. If a maintenance dose is delayed or missed, Spinraza should be administered as soon as possible with continued dosing every 4 months. [1]

B. There were 3 key pivotal trials demonstrating safety and efficacy of Spinraza (ENDEAR, CHERISH, NURTURE). ENDEAR enrolled patients with infantile-onset SMA (defined by the study as individuals diagnosed with 5q SMA and symptom onset at younger than 6 months of age), also known as SMA Type 1. CHERISH enrolled patients with later-onset SMA (defined by the study as individuals diagnosed with 5q SMA and symptom onset after 6 months of age), generally considered as SMA Type 2 or 3. NURTURE only enrolled patients with a diagnosis of 5q SMA who were ≤6 weeks old at first dose of Spinraza. This would be considered SMA Type 1. [2-4]
C. This is the definition that the clinical trials ENDEAR, CHERISH, and NURTURE used. Also consistent with clinical guidelines. [2-7]
D. ENDEAR required patients to have 2 copies of SMN2, CHERISH included patients with 2 to 4 copies of SMN2, and NURTURE only enrolled patients with 2 or 3 copies of SMN2. [2-4]
E. Invasive ventilation or tracheostomy was an exclusion criteria in the ENDEAR, CHERISH, and NURTURE trials. [2-4]
F. A recent European ad-hoc consensus statement on SMA stated that there currently is no published evidence that the combination of two disease modifying therapies (e.g., Spinraza and Evrysdi) is superior to any single treatment alone. Both ENDEAR, CHERISH, and NURTURE excluded patients that were had previous treatment with either gene therapy or prior antisense oligonucleotide (ASO) treatment (e.g., Zolgensma). RESPOND is a phase 4 clinical study that will assess the efficacy and safety of Spinraza in patients with suboptimal clinical response to Zolgensma. It is planned to begin enrollment in 2021. [2-4, 11, 14]

4 . References

1. Spinraza Prescribing Information. Biogen, Inc. Cambridge, MA. June 2020.
2. Finkel RS, Mercuri E, Darras, BT, et al. Nusinersen versus Sham Control in Infantile-Onset Spinal Muscular Atrophy. N Engl J Med. 2017; 377:1723-1732.
3. Mercuri E, Darras BT, Chiriboga CA, et al. Nusinersen versus sham control in later-onset spinal muscular atrophy. N Engl J Med. 2018;378:625-635.
4. De Vivo DC, Bertini E, Swoboda KJ, et al. Nusinersen initiated in infants during the pre-symptomatic stage of spinal muscular atrophy: Interim efficacy and safety results from the Phase 2 NURTURE study. Neuromuscul Disord. 2019;29(11):P842-856.
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5 . Revision History

Date	Notes
6/19/2023	Annual review

Spravato (esketamine) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-124281
Guideline Name	Spravato (esketamine) - PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	5/16/2019
P&T Revision Date:	05/14/2020 ; 10/21/2020 ; 05/20/2021 ; 05/19/2022 ; 07/20/2022 ; 5/18/2023

1 . Indications

Drug Name: Spravato (esketamine)
Depression Indicated, in conjunction with an oral antidepressant, for the treatment of: - Treatment-resistant depression (TRD) in adults - Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior. Limitations of Use: The effectiveness of Spravato in preventing suicide or in reducing suicidal ideation or behavior has not been demonstrated. Use of Spravato does not preclude the need for hospitalization if clinically warranted, even if patients experience improvement after an initial dose of Spravato. Spravato is not approved as an anesthetic agent. The safety and effectiveness of Spravato as an anesthetic agent have not been established.

2 . Criteria

Product Name: Spravato	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of major depressive disorder

AND

1.1.2 Patient has not experienced a clinical meaningful improvement after treatment with at least two antidepressants from different classes for an adequate duration (at least 4 weeks each) in the current depressive episode [1-5, A, B]

OR

1.2 Both of the following:

1.2.1 Diagnosis of major depressive disorder

AND

1.2.2 Patient has both of the following:

- Depressive symptoms
- Acute suicidal ideation or behavior

AND

2 - Used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline)

AND

3 - Prescribed by or in consultation with a psychiatrist

Product Name: Spravato	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline)

Product Name: Spravato	
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 Submission of medical records (e.g. chart notes) documenting Both of the following:

1.1.1 Diagnosis of major depressive disorder

AND

1.1.2 Patient has not experienced a clinical meaningful improvement after treatment with at least two antidepressants from different classes for an adequate duration (at least 4 weeks each) in the current depressive episode [1-5, A, B]

OR

1.2 Submission of medical records (e.g. chart notes) documenting Both of the following:

1.2.1 Diagnosis of major depressive disorder

AND

1.2.2 Patient has both of the following:

- Depressive symptoms
- Acute suicidal ideation or behavior

AND

2 - Submission of medical records (e.g. chart notes) or paid claims documenting use in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline)

AND

3 - Prescribed by or in consultation with a psychiatrist

3 . Endnotes

A. According to the American Psychiatric Association, generally, 4–8 weeks of treatment are needed before concluding that a patient is partially responsive or unresponsive to a specific intervention. [2]
B. Per clinical consults with psychiatrists: A trial of antidepressants should include different classes (mechanisms of action) when defining treatment resistance. [4-5]

4 . References

1. Spravato Prescribing Information. Janssen Pharmaceuticals, Inc. Titusville, NJ. July 2020.
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4. Per clinical consult with psychiatrist, April 25, 2019.
5. Per clinical consult with psychiatrist, April 18, 2019.

5 . Revision History

Date	Notes
4/10/2023	Annual review - criteria update for clinical clarity

State Mandate Reference Document

Prior Authorization Guideline

Guideline ID	GL-116526
Guideline Name	State Mandate Reference Document
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Guideline Type	Administrative

Approval Criteria

1 - For Arizona, (effective 12/31/2022), when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will

not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity. Note: Samples may not count as sufficient experience with the prescribed medication to be considered stable on the medication.

OR

2 - The following mandates apply to Arkansas:

2.1 Effective 7/22/2015, all clinical criteria are deemed met when the medication is being used for pain control in someone who is terminally ill (defined as no expectation of recovery and death as a result of the illness or disease is reasonably expected within six [6] months).

OR

2.2 Effective 1/1/2022, when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity.

OR

3 - The following mandates apply to California:

3.1 Effective 1/1/2017, step therapy requirements are deemed met if the provider submits medical records confirming the patient has been on the medication, it is appropriately prescribed, and that the medication is considered safe and effective in treating the patient's condition.

OR

3.2 Effective 7/1/1999 (applies to small group only), all clinical criteria are deemed met when the patient has previously been approved for coverage of the medication and the patient has had no reasonable break in therapy (i.e., last dose was within the last 60 days per claims history). The medication should be approved for the quantity the patient was previously taking as long as it is considered safe and effective for treating the medical condition.

OR

3.3 Effective 1/1/2022, step therapy requirements are deemed met if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is not in the best interest of the patient, based on medical necessity.

OR

4 - The following mandates apply to Colorado:

4.1 Effective 1/1/2019, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced

metastatic cancer and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

4.2 Effective 1/1/2023, when the provider confirms that a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as a documented step one prescription drug, and the prescription drug is ineffective or was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration.

OR

5 - The following mandates apply to Connecticut:

5.1 Effective 1/1/2012, step therapy may not be required for pain medications when a non AB rated alternative is required as first line.

OR

5.2 Effective 1/1/2015, only a 30 day trial of first step drugs will be required.

OR

5.3 Effective 1/1/2015, step therapy requirements are deemed met if submitted justification

and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity.

OR

5.4 Effective 1/1/2018, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

6 - The following mandates apply to Delaware:

6.1 Effective 9/1/2017, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

6.2 Effective 1/1/2020, when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity.

OR

7 - The following mandates apply to Georgia:

7.1 Effective 7/1/2015, all clinical criteria are deemed met when a patient is diagnosed as terminally ill and the medication requested is FDA-approved or meets off-label criteria for use directly related to the terminal illness. Terminal illness is defined as any disease, illness, or health condition that a physician has diagnosed and expected to result in death in 24 months or less.

OR

7.2 Effective 7/1/2019, when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective.

OR

8 - The following mandates apply to Illinois:

8.1 Effective 1/1/2018, step therapy requirements are deemed met if the provider submits medical records confirming the patient is currently stabilized on the requested medication for the medical condition under consideration.

OR

8.2 Effective 1/1/2019, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

9 - For Indiana, (effective 7/1/2016), when the provider submits medical records confirming a patient has previously received either a documented step one prescription drug or another prescription drug that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria.

OR

10 - For Iowa, (effective 1/1/2018), when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration. Note: Samples and drugs obtained through coupon cards may

not count as sufficient experience with the prescribed medication to be considered stable on the medication.

OR

11 - The following mandates apply to Kentucky:

11.1 Effective 7/12/2012, only a 30 day trial of first step drugs will be required.

OR

11.2 Effective 1/1/2023, when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity.

OR

12 - The following mandates apply to Louisiana:

12.1 Effective 8/1/2019, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer and treatment is consistent with the U.S. Food and Drug Administration-approved indication, or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer, or the prescribed drug or drug regimen is supported by peer-reviewed, evidenced-based medical literature.

OR

12.2 Effective 1/1/2021, step therapy and non-formulary requirements are deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is not in the best interest of the patient or expected to be ineffective based on medical necessity.

OR

13 - The following mandates apply to Maine:

13.1 Effective 1/1/2020, when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, the required step one prescription drug is not in the best interest of the patient based on medical necessity, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective.

OR

13.2 Effective 1/1/2022, all clinical criteria are deemed met when the medication is being prescribed to assess or treat the patient's serious mental illness, defined in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association, as a mental disorder that results in serious functional impairment that substantially interferes with or limits one or more major life activities.

OR

14 - The following mandates apply to Maryland:

14.1 Effective 7/1/2015, step therapy requirements are deemed met if the provider submits medical records confirming the patient has been on the medication in the past 180 days and that the medication is effective in treating the patient's condition.

OR

14.2 Effective 7/1/2015, step therapy requirements may not require trial of a drug that has not been approved by the U.S. Food and Drug Administration for the medical condition being treated.

OR

14.3 Effective 10/1/2017, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

15 - For Minnesota, (effective 1/1/2020), any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer, or an associated condition, and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

16 - For Nebraska, (effective 1/1/2022), step therapy requirements are deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is not in the best interest of the patient or expected to be ineffective based on medical necessity.

OR

17 - For Nevada, (effective 1/1/2022), any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage three or four cancer, or an associated condition, AND; the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity.

OR

18 - The following mandates apply to New Mexico:

18.1 Effective 1/1/2019, when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be

tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria.

OR

18.2 Effective 7/1/2019, step therapy requirements are deemed met if the prescription drug requested is generic AND the required step one prescription drug is a therapeutically equivalent generic.

OR

19 - For New York, (effective 1/1/2017), when the provider submits medical records confirming a patient has previously received either a documented step one prescription drug or another prescription drug that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration. Note: Samples and drugs obtained through coupon cards may not count as sufficient experience with the prescribed medication to be considered stable on the medication.

OR

20 - For North Dakota, (effective 8/5/2019), any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

21 - For Ohio, (effective 3/24/2021), any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer, or an associated condition, and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer, or consistent with best practices for the treatment of stage four advanced metastatic cancer, as supported by peer-reviewed medical literature.

OR

22 - For Oklahoma, (effective 11/1/2019), step therapy and non-formulary requirements are deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is not in the best interest of the patient based or expected to be ineffective based on medical necessity.

OR

23 - For Oregon, (effective 1/1/2022), when the provider confirms that a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as a documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for a period of at least 90 days for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity. Note: Samples and drugs obtained through coupon cards may not

count as sufficient experience with the prescribed medication to be considered stable on the medication.

OR

24 - For Pennsylvania, (effective 10/12/2020), any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer, or a severe adverse health condition experienced as a result of stage four metastatic cancer, and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

25 - For South Dakota, (effective 1/1/2021), step therapy and non-formulary requirements are deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is not in the best interest of the patient based or expected to be ineffective based on medical necessity.

OR

26 - For Tennessee, (effective 1/1/2023), step therapy requirements are deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity. Note: Samples and drugs obtained through coupon cards may not count as sufficient experience with the prescribed medication to be considered stable on the medication.

OR

26 - The following mandates apply to Texas:

26.1 Effective 1/1/2018, when the provider confirms that a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as a documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration.

OR

26.2 Effective 1/1/2020, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer, or an associated condition, and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

27 - For Virginia, (effective 1/1/2020), step therapy requirements are deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective.

OR

28 - For Washington, (effective 1/1/2021), when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical

records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity.

OR

29 - For West Virginia, (effective 1/1/2017), when the provider submits medical records confirming that a patient has previously received either a documented step one prescription drug or another prescription drug that has the same mechanism of action as a the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration.

OR

31 - For Wisconsin, (effective 11/1/2019), when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met

due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective.

2 . Background

Benefit/Coverage/Program Information
Background: This document serves as a reference for changes requested to pharmacy utilization management programs based on state mandates. This includes but is not limited to step therapy, prior authorization regulations, supply limits, first line trial duration limitations, and pain therapy/end of life regulations. **Additional Clinical Rules:** • Applicable clinical programs will apply.

3 . Revision History

Date	Notes
11/1/2022	Per TSK004583729 copy over OptumRx Standard guidelines for Sam aritan 2023 Implementation

Ustekinumab

Prior Authorization Guideline

Guideline ID	GL-116593
Guideline Name	Ustekinumab
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Indications

Drug Name: Selarsdi SC, Steqeyma SC, Yesintek SC
Plaque Psoriasis (PsO) Indicated for the treatment of patients 6 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. **Psoriatic Arthritis (PsA)** Indicated for the treatment of patients 6 years or older with active psoriatic arthritis. **Crohn's Disease (CD)** Indicated for the treatment of adult patients with moderately to severely active Crohn's disease. **Ulcerative Colitis (UC)** Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.
Drug Name: Selarsdi IV, Steqeyma IV, Yesintek IV

Crohn's Disease (CD) Indicated for the treatment of adult patients with moderately to severely active Crohn's disease. **Ulcerative Colitis (UC)** Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.

2 . Criteria

Product Name: Selarsdi SC, Steqeyma SC, Yesintek SC 45 mg/0.5 mL	
Diagnosis	Plaque Psoriasis
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Patient is 6 years of age or older

AND

4 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

5 - Prescribed by or in consultation with a dermatologist

Notes	*Approval Duration: 6 months. **QL Override (For new starts only): For psoriasis, please enter 2 PAs as follows: First PA: Approve one syringe or vial per 28 days for the two months with a fill count of 2; Second PA: Approve one syringe or vial per 56 days (no overrides needed) for the remaining 4 months. (Ustekinumab is hard-coded with a quantity of one prefilled syringe/vial per 56 days; 0.5 mL per 45 mg vial or syringe and 1 mL per 90 mg syringe)

Product Name: Selarsdi SC, Steqeyma SC, Yesintek SC 90 mg/1 mL	
Diagnosis	Plaque Psoriasis
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Patient's weight is greater than 100 kg (220 lbs)

AND

4 - Patient is 6 years of age or older

AND

5 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

6 - Prescribed by or in consultation with a dermatologist

Notes	*Approval Duration: 6 months. **QL Override (For new starts only): For psoriasis, please enter 2 PAs as follows: First PA: Approve one syringe or vial per 28 days for the two months with a fill count of 2; Second PA: Approve one syringe or vial per 56 days (no overrides needed) for the remaining 4 months. (Ustekinumab is hard-coded with a quantity of one prefilled syringe/vial per 56 days; 0.5 mL per 45 mg vial or syringe and 1 mL per 90 mg syringe)

Product Name: Selarsdi SC, Steqeyma SC, Yesintek SC	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1-3]:

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name: Selarsdi SC, Steqeyma SC, Yesintek SC 45 mg/0.5 mL	
Diagnosis	Psoriatic arthritis
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [4]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Patient is 6 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Notes	*Approval Duration: 6 months. **QL Override (For new starts only): For psoriatic arthritis, please enter 2 PAs as follows: First PA: Approve one syringe or vial per 28 days for the two months with a fill count of 2; Second PA: Approve one syringe or vial per 56 days (no overrides needed) for the remaining 4 months. (Ustekinumab is hard-coded with a quantity of one prefilled syringe/vial per 56 days; 0.5 mL per 45 mg vial or syringe and 1 mL per 90 mg syringe)

Product Name: Selarsdi SC, Steqeyma SC, Yesintek SC 90 mg/1 mL	
Diagnosis	Psoriatic arthritis
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [4]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Diagnosis of co-existent moderate to severe psoriasis [1, 4]

AND

4 - Patient's weight is greater than 100 kg (220 lbs)

AND

5 - Patient is 6 years of age or older

AND

6 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Notes	*Approval Duration: 6 months. **QL Override (For new starts only): For psoriatic arthritis, please enter 2 PAs as follows: First PA: Approve one syringe or vial per 28 days for the two months with a fill count of 2; Second PA: Approve one syringe or vial per 56 days (no overrides needed) for the remaining 4 months. (Ustekinumab is hard-coded with a quantity of one prefilled syringe/vial per 56 days; 0.5 mL per 45 mg vial or syringe and 1 mL per 90 mg syringe)

Product Name: Selarsdi SC, Steqeyma SC, Yesintek SC	
Diagnosis	Psoriatic arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name: Selarsdi IV, Steqeyma IV, Yesintek IV	
Diagnosis	Crohn's Disease
Approval Length	1 Time(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - One of the following [5, 6]:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CDAI) greater than 220

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [5, 6]:

- 6-mercaptopurine
- azathioprine
- corticosteroids (e.g., prednisone)
- methotrexate

AND

4 - Ustekinumab is to be administered as an intravenous induction dose

AND

5 - Ustekinumab induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's disease:

- 260 mg for patients weighing 55 kg or less
- 390 mg for patients weighing more than 55 kg to 85 kg
- 520 mg for patients weighing more than 85 kg

AND

6 - Prescribed by or in consultation with a gastroenterologist

Product Name: Selarsdi SC, Steqeyma SC, Yesintek SC	
Diagnosis	Crohn's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - One of the following [5, 6]:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CDAI) greater than 220

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [5, 6]:

- 6-mercaptopurine
- azathioprine
- corticosteroids (e.g., prednisone)
- methotrexate

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name: Selarsdi IV, Steqeyma IV, Yesintek IV	
Diagnosis	Ulcerative Colitis
Approval Length	1 Time(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [7, 8]:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, ESR, CRP)
- Dependent on, or refractory to, corticosteroids

AND

3 - Trial and failure, contraindication, or intolerance to treatment with at least ONE of the following [7, 8]:

- Corticosteroid (e.g., prednisone)
- 6-mercaptopurine
- Azathioprine
- Aminosalicylates (e.g., mesalamine, olsalazine, sulfasalazine)

AND

4 - Ustekinumab is to be administered as an intravenous induction dose

AND

5 - Ustekinumab induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for ulcerative colitis:

- 260 mg for patients weighing 55 kg or less
- 390 mg for patients weighing more than 55 kg to 85 kg
- 520 mg for patients weighing more than 85 kg

AND

6 - Prescribed by or in consultation with a gastroenterologist

Product Name: Selarsdi SC, Steqeyma SC, Yesintek SC	
Diagnosis	Ulcerative Colitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [7, 8]:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, ESR, CRP)
- Dependent on, or refractory to, corticosteroids

AND

3 - Trial and failure, contraindication, or intolerance to treatment with at least ONE of the following [7, 8]:

- Corticosteroid (e.g., prednisone)
- 6-mercaptopurine
- Azathioprine
- Aminosalicylates (e.g., mesalamine, olsalazine, sulfasalazine)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name: Selarsdi SC, Steqeyma SC, Yesintek SC	
Diagnosis	Crohn's Disease and Ulcerative Colitis
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 5-8]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

3. Revision History

Date	Notes
10/28/2022	Bulk copy OptumRx SP to Samaritan SP for 1/1/2023 Implementation
07/01/2025	Updated to remove Stelara from preferred and add Selarsdi, Steqeyma, and Yesintek as preferred.

Sunlenca (lenacapavir)

Prior Authorization Guideline

Guideline ID	GL-124260
Guideline Name	Sunlenca (lenacapavir)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	5/1/2023

1 . Criteria

Product Name: Sunlenca	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Both of the following:	

1.1 Diagnosis of multidrug-resistant (MDR) HIV-1 infection

AND

1.2 Resistance to at least two drugs in each of at least three of the following classes: NRTIs, NNRTIs, PTs, and INSTIs

AND

2 - Prescribed by or in consultation with a HIV Specialist

AND

3 - Used in combination with an optimized baseline regimen (OBR)

AND

4 - Current antiretroviral (ARV) regimen has been stable for at least 2 months

AND

5 - HIV-1 RNA is greater than or equal to 400 copies per mL

AND

6 - Member is 18 years of age or older

Product Name: Sunlenca

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Will be used in combination with an optimized background regimen (OBR)

AND

2 - Provider states that patient continues to receive clinical benefit from the treatment

2 . Revision History

Date	Notes
4/11/2023	New Program

Syfovre (pegcetacoplan)

Prior Authorization Guideline

Guideline ID	GL-103382
Guideline Name	Syfovre (pegcetacoplan)
Formulary	• IHN-CCO

Guideline Note:

Effective Date:	6/1/2024
P&T Approval Date:	
P&T Revision Date:	4/17/2024

1 . Indications

Drug Name: Synagis (palivizumab)
Geographic Atrophy (GA) Indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

2 . Criteria

Product Name: Syfovre	
Approval Length	12 month (s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) as confirmed by one of the following:

- Fundus photography (e.g. fundus autofluorescence [FAF])
- Optical coherence tomography (OCT)
- Fluorescein angiography

AND

2 - GA is not secondary to any other conditions (e.g., Stargardt disease, cone rod dystrophy, toxic maculopathies)

AND

3 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name: Syfovre	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria
1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in growth rate of GA lesion)

3. References

1. Syfovre Prescribing Information. Apellis Pharmaceuticals, Inc. Waltham, MA. November 2023.

4 . Revision History

Date	Notes
3/13/2024	2024 Annual review. No changes to clinical content. Updated references.

Symdeko (tezacaftor/ivacaftor)

Prior Authorization Guideline

Guideline ID	GL-116533
Guideline Name	Symdeko (tezacaftor/ivacaftor)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Symdeko	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming both of the following:

- Diagnosis of cystic fibrosis
- Patient is homozygous for the F508del mutation

AND

2 - Patient is 6 years of age or older

AND

3 - Prescribed by or in consultation with a pulmonologist

Product Name: Symdeko	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
9/12/2022	2023 New Implementation

Symlin (pramlintide acetate)

Prior Authorization Guideline

Guideline ID	GL-116504
Guideline Name	Symlin (pramlintide acetate)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Symlin	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of type 2 diabetes	

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has an HbA1c less than or equal to 9%.

AND

4 - Patient is currently on mealtime insulin

AND

5 - Patient is monitoring blood glucose levels regularly and reliably (3 or more times per day)

AND

6 - Patient is capable of monitoring blood glucose levels pre- and post- meals and at bedtime

AND

7 - Patient has failed to achieve adequate control of blood glucose levels despite individualized management of their insulin therapy

AND

8 - Patient is receiving ongoing care under the guidance of a health care provider skilled in use of insulin and supported by the services of a diabetes educator

Product Name: Symlin	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/26/2022	New Implementation

Synagis (palivizumab)

Prior Authorization Guideline

Guideline ID	GL-103382
Guideline Name	Synagis (palivizumab)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	4/1/2022
P&T Approval Date:	3/17/2000
P&T Revision Date:	10/21/2020 ; 10/20/2021 ; 3/16/2022

1 . Indications

Drug Name: Synagis (palivizumab)
Prophylaxis of respiratory syncytial virus (RSV) Indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients: with a history of premature birth (less than or equal to 35 weeks gestational age) and who are 6 months of age or younger at the beginning of respiratory syncytial virus (RSV) season; with bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and who are 24 months of age or younger at the beginning of respiratory syncytial virus (RSV) season; with hemodynamically significant congenital heart disease (CHD) and who are 24 months of age or younger at the beginning of respiratory syncytial virus (RSV) season. Limitations of use: The safety and efficacy of Synagis have not been established for treatment of RSV disease.

2 . Criteria

Product Name: Synagis	
Diagnosis	Premature Infants (without other indications)
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Born prematurely at or before 29 weeks, 0 days gestation [2, B]

AND

2 - Age < 12 months at the start of the respiratory syncytial virus (RSV) season [A].

AND

3 - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region.

Notes	Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A] Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refer to the CDC surveillance reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) to confirm the start of RSV season based on region.

Product Name: Synagis	
Diagnosis	Chronic Lung Disease of Prematurity
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Chronic lung disease (CLD) of prematurity [2]

AND

2 - Born before 32 weeks, 0 days gestation [2]

AND

3 - Received greater than 21% oxygen supplementation for at least the first 28 days after birth

AND

4 - One of the following:

4.1 Age < 12 months at the start of the respiratory syncytial virus (RSV) season.

OR

4.2 Both of the following:

- Age at least 12 to < 24 months at the start of the RSV season
- Received medical support (i.e., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) within 6 months before the start of the second RSV season

AND

5 - Prescribed by or in consultation with one of the following:

- Pediatric pulmonologist
- Neonatologist
- Pediatric intensivist
- Infectious disease specialist

AND

6 - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region.

Notes	Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A] Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refer to the CDC surveillance reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) to confirm the start of RSV season based on region.

Product Name: Synagis	
Diagnosis	Hemodynamically Significant Congenital Heart Disease
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Age < 12 months at the start of the respiratory syncytial virus (RSV) season, with one of the following: [C] (persons of all ages).

1.1.1 All of the following:

- Acyanotic heart failure
- Receiving medication to control congestive heart failure
- Patient will require a cardiac surgical procedure

OR

1.1.2 Moderate to severe pulmonary hypertension

OR

1.1.3 Cyanotic heart defect

OR

1.2 Both of the following*: [D]

- Age < 24 months
- Patient will or has undergone a cardiac transplantation during the respiratory syncytial virus (RSV)season

AND

2 - Prescribed by or in consultation with a pediatric cardiologist

AND

3 - Used for the prevention of serious lower respiratory tract disease caused by respiratory

syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region	
Notes	Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. *ONE additional postoperative dose allowed for patients undergoing cardiac transplantation, cardiac bypass or extracorporeal membrane oxygenation. [A, D] Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refer to the CDC surveillance reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) to confirm the start of RSV season based on region.

Product Name: Synagis	
Diagnosis	Pulmonary Abnormality or Neuromuscular Disorder
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Pulmonary abnormalities (e.g., pulmonary malformations, tracheoesophageal fistula, conditions requiring tracheostomy) or neuromuscular disease (e.g., cerebral palsy) [2]

AND

2 - Age < 12 months at the start of the respiratory syncytial virus (RSV) season.

AND

3 - Impaired ability to clear secretions from the upper airway due to an ineffective cough

AND

4 - Prescribed by or in consultation with one of the following:

- Pediatric pulmonologist
- Neurologist

AND

5 - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region

Notes	Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A] Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refer to the CDC surveillance reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) to confirm the start of RSV season based on region.

Product Name: Synagis	
Diagnosis	Immunocompromised Children
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Received or will receive a solid organ transplant, hematopoietic stem cell transplant, or chemotherapy during the respiratory syncytial virus (RSV) season.

AND

2 - Age < 24 months

AND

3 - Lymphocyte count is below the normal range for patient's age

AND

4 - Prescribed by or in consultation with one of the following:

- Pediatric pulmonologist
- Infectious disease specialist
- Pediatric intensivist

AND

5 - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region

Notes	Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A] Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refer to the CDC surveillance reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) to confirm the start of RSV season based on region.

Diagnosis	Children with Cystic Fibrosis
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis [2]

AND

2 - One of the following:

2.1 Both of the following:

- Age < 12 months
- Clinical evidence of chronic lung disease (CLD) and/or nutritional compromise (i.e., failure to thrive)

OR

2.2 Both of the following:

- Age at least 12 to < 24 months
- Severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life, abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length < 10th percentile on pediatric growth chart [E]

Notes	Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A] Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refer to the CDC surveillance reports (http://www.cdc.gov/surveillance/nre

	vss/rsv/index.html) to confirm the start of RSV season based on regio n.

3 . Endnotes

A. Five monthly doses of palivizumab will provide more than 6 months of prophylactic serum palivizumab concentrations. Administration of more than five monthly doses is not recommended. If RSV season onset is in November, the first dose should be administered in November, and the fifth and final dose should be administered in March. If RSV season onset is in November and the first dose is given in January, the third and final dose should be administered in March. In most of North America, peak RSV activity typically occurs between November and March, usually beginning in November or December, peaking in January or February, and ending by the end of March or sometime in April. Communities in the southern United States, particularly some communities in the state of Florida, tend to experience the earliest onset of RSV. Data from the Centers for Disease Control and Prevention (CDC) have identified variations in the onset and offset of the RSV “season” in the state of Florida that could affect the timing of palivizumab administration. [2] For analysis of National Respiratory and Enteric Virus Surveillance System (NREVSS) reports in the CDC Morbidity and Mortality Weekly Report (MMWR), season onset is defined as the first of 2 consecutive weeks during which the mean percentage of specimens testing positive for RSV antigen is at least 10% and RSV season offset is defined as the last of 2 consecutive weeks during which the mean percentage of positive specimens is at least 10%. [3] NREVSS surveillance data can be viewed here (http://www.cdc.gov/surveillance/nrevss/rsv/)
B. Palivizumab prophylaxis is not recommended for otherwise healthy infants born at or after 29 weeks, 0 days' gestation. [2]
C. The following conditions are NOT considered hemodynamically significant congenital heart disease: secundum atrial septal defect, small ventricular septal defect, pulmonary stenosis, uncomplicated aortic stenosis, mild coaractation of the aorta, and patent ductus arteriosus; lesions adequately corrected by surgery, unless continuing required medication for congestive heart failure; mild cardiomyopathy and not receiving medical therapy for the condition; children in the second year of life. [2]
D. Pediatric growth charts can be viewed here (http://www.cdc.gov/growthcharts/who_charts.htm)
E. Children undergoing these procedures should receive an additional dose of palivizumab as soon as possible after the procedure. Thereafter, doses should be administered monthly as scheduled. [2]
F. Monthly prophylaxis should be discontinued in any infant or child who experiences a breakthrough RSV hospitalization. [2]
G. Palivizumab prophylaxis is not recommended for prevention of health care-associated RSV disease. [2]

H. The burden of RSV disease and costs associated with transport from remote locations may result in a broader use of palivizumab for RSV prevention in Alaska Native populations and possibly in selected other American Indian populations. [2]

4 . References

1. Synagis Prescribing Information. Swedish Orphan Biovitrum AB (publ). Stockholm, Sweden September 2021.
2. Commitee on Infectious Diseases and Bronchiolitis Guidelines Committee. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalizations for respiratory syncytial virus infection. Pediatrics. 2014 Aug;134(2):415-20. doi: 10.1542/peds.2014-1665.
3. Panozzo CA, Stockman LJ, et al. Use of respiratory syncytial virus surveillance data to optimize the timing of immunoprophylaxis. Pediatrics. 2010 Jul;126(1):e116-23.

5 . Revision History

Date	Notes
3/3/2022	Updated notes to add guidance on RSV season variance

Synagis (palivizumab) - SCP

Prior Authorization Guideline

Guideline ID	GL-116542
Guideline Name	Synagis (palivizumab) - SCP
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Synagis	
Diagnosis	Palivizumab prophylaxis
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Infants less than 12 months of age with congenital airway abnormality or neuromuscular disorder that decreases the ability to manage airway secretions
- Infants less than 12 months of age with cystic fibrosis with clinical evidence of CLD and/or nutritional compromise
- Children less than 24 months with cystic fibrosis with severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length less than the 10th percentile
- Infants and children less than 24 months who are profoundly immunocompromised
- Infants and children less than 24 months undergoing cardiac transplantation during RSV season

Product Name: Synagis	
Diagnosis	Respiratory syncytial virus
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Infants born at less than or equal to 28 weeks 6 days gestational age and less than 12 months at the start of Respiratory syncytial virus (RSV) season (November)
- Infants less than 12 months of age with chronic lung disease (CLD) of prematurity
- Infants less than or equal to 12 months of age with hemodynamically significant congenital heart disease (CHD)
- Infants and children less than 24 months of age with CLD of prematurity necessitating medical therapy (e.g., supplemental oxygen, bronchodilator, diuretic, or chronic steroid therapy) within 6 months prior to the beginning of RSV season.

2 . Revision History

Date	Notes

10/25/2022	New Implementation

Tacrolimus ointment

Prior Authorization Guideline

Guideline ID	GL-116512
Guideline Name	Tacrolimus ointment
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Tacrolimus ointment	
Diagnosis	Atopic dermatitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of moderate to severe atopic dermatitis

AND

2 - One of the following:

- Involvement of at least 10% body surface area (BSA)
- Affected area involves the hand, foot, or mucous membrane
- Patient has functional impairment

AND

3 - One of the following:

3.1 Trial and failure to one of the following:

- Topical steroids (e.g., clobetasol propionate 0.05%, fluocinonide 0.05% gel/ointment/solution, fluticasone 0.05% ointment)
- UVB phototherapy

OR

3.2 Please provide reason for why listed alternatives would not be medically appropriate

Product Name: Tacrolimus ointment	
Diagnosis	Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe psoriasis

AND

2 - One of the following:

- Involvement of at least 10% body surface area (BSA)
- Affected area involves the hand, foot, or mucous membrane
- Patient has functional impairment

AND

3 - Trial and failure, or contraindication to one of the following:

- High potency topical corticosteroid (e.g., clobetasol propionate 0.05%, fluocinonide 0.05% gel/ointment/solution, fluticasone 0.05% ointment)
- UVB phototherapy

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name: Tacrolimus ointment	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/26/2022	New Implementation

Tadalafil (Adcirca, Alyq)

Prior Authorization Guideline

Guideline ID	GL-116537
Guideline Name	Tadalafil (Adcirca, Alyq)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Generic Alyq tablet, Generic tadalafil tablet	
Diagnosis	Pulmonary Arterial Hypertension (PAH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of pulmonary arterial hypertension (PAH)

AND

2 - Medication is NOT being used to treat erectile dysfunction

AND

3 - Prescribed by or in consultation with one of the following:

- Cardiologist
- Pulmonologist

Product Name: Generic Alyq tablet, Generic tadalafil tablet	
Diagnosis	Pulmonary Arterial Hypertension (PAH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/24/2022	2023 New Implementation

Taltz (ixekizumab)

Prior Authorization Guideline

Guideline ID	GL-116596
Guideline Name	Taltz (ixekizumab)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Taltz	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - One of the following:

5.1 Trial and failure, contraindication, or intolerance to ONE of the following:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)

- One formulary adalimumab product
- Skyrizi (risankizumab)
- One formulary ustekinumab product
- Tremfya (guselkumab)

OR

5.2 For continuation of prior Taltz therapy, defined as no more than a 45-day gap in therapy

Product Name: Taltz	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1-3]:

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name: Taltz	
Diagnosis	Psoriatic Arthritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [4]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to ONE of the following:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- One formulary adalimumab product
- Simponi (golimumab)
- One formulary ustekinumab product
- Tremfya (guselkumab)
- Skyrizi (risankizumab-rzaa)
- Rinvoq (upadacitinib)
- Xeljanz/XR (tofacitinib/ER)

OR

4.2 For continuation of prior Taltz therapy, defined as no more than a 45-day gap in therapy

Product Name: Taltz	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name: Taltz	
Diagnosis	Ankylosing Spondylitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- One formulary adalimumab product
- Simponi (golimumab)
- Rinvoq (upadacitinib)
- Xeljanz/XR (tofacitinib/ER)

OR

4.2 For continuation of prior Taltz therapy, defined as no more than a 45-day gap in therapy

Notes	* Includes attestation that a total of two TNF inhibitors have already b een tried in the past, and the patient should not be made to try a third TNF inhibitor.

Product Name: Taltz

Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following [1, 5]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name: Taltz	
Diagnosis	Non-radiographic Axial Spondyloarthritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active non-radiographic axial spondyloarthritis

AND

2 - Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of

inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) [1, 3]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

5 - One of the following:

5.1 Trial and failure, contraindication, or intolerance to Cimzia (certolizumab pegol)

OR

5.2 For continuation of prior Taltz therapy, defined as no more than a 45-day gap in therapy

Product Name: Taltz	
Diagnosis	Non-radiographic Axial Spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following [1, 5]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

2 . References

1. Taltz prescribing information. Eli Lilly and Company. Indianapolis, IN. May 2022.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
3. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
5. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613.

3 . Revision History

Date	Notes
10/28/2022	New Implementation

Talvey (talquetamab-tgvs)

Prior Authorization Guideline

Guideline ID	GL-124083
Guideline Name	Talvey (talquetamab-tgvs)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	11/1/2023
P&T Approval Date:	10/18/2023
P&T Revision Date:	

1 . Indications

Drug Name: Talvey (talquetamab-tgvs)
Multiple Myeloma Indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication

may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2 . Criteria

Product Name: Talvey	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1- Diagnosis of multiple myeloma

AND

2- Disease is one of the following:

- Relapsed
- Refractory

AND

3- Patient has received at least four prior lines of therapy which include all of the following:

- An immunomodulatory agent (e.g., lenalidomide, thalidomide)
- A proteasome inhibitor (e.g., bortezomib, carfilzomib)
- A CD38-directed monoclonal antibody (e.g. daratumumab)

Product Name: Talvey	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Talvey Prescribing Information. Janssen Biotech, Inc. Horsham, PA. August 2023.

4 . Revision History

Date	Notes
9/28/2023	New program

Tasigna (nilotinib)

Prior Authorization Guideline

Guideline ID	GL-116529
Guideline Name	Tasigna (nilotinib)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Tasigna	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - One of the following:	

1.1 Newly diagnosed of Ph+ chronic myelogenous leukemia (CML) in chronic phase

OR

1.2 Chronic phase and accelerated phase Ph+ CML with one of the following:

- Resistant or intolerant to prior therapy, including imatinib
- The member has a Sokal risk score >1.2 (High risk)

AND

2 - Member is 1 year of age or older

AND

3 - Prescribed by or in consultation with an oncologist or hematologist

Product Name: Tasigna	
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of provider follow-up indicating safety and efficacy with medication adherence over previous approval duration

2 . Revision History

Date	Notes
8/30/2022	2023 New Implementation

Tazarotene

Prior Authorization Guideline

Guideline ID	GL-116513
Guideline Name	Tazarotene
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Tazarotene	
Diagnosis	Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of moderate to severe psoriasis

AND

2 - One of the following:

- Involvement of at least 10% body surface area (BSA)
- Affected area involves the hand, foot, or mucous membrane
- Patient has functional impairment

AND

3 - One of the following:

3.1 Trial and failure of high potency topical corticosteroids (e.g., clobetasol propionate 0.05%, fluocinonide 0.05% gel/ointment/solution, fluticasone 0.05% ointment)

OR

3.2 Please provide reason for why the listed alternative would not be medically appropriate

Product Name: Tazarotene	
Diagnosis	Other FDA approved indications (i.e., severe acne)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Trial and failure or contraindication to TWO formulary alternatives used to treat the approved indication

Product Name: Tazarotene	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	

2 . Revision History

Date	Notes
10/26/2022	New Implementation

Tecvayli (teclistamab-cqyv)

Prior Authorization Guideline

Guideline ID	GL-124083
Guideline Name	Tecvayli (teclistamab-cqyv)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	12/14/2022
P&T Revision Date:	7/19/2023

1 . Indications

Drug Name: Tecvayli (teclistamab-cqyv)
Multiple Myeloma Indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.

2 . Criteria

Product Name: Tecvayli	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1- Diagnosis of multiple myeloma

AND

2- Disease is one of the following:

- Relapsed
- Refractory

AND

3- Patient has received at least four prior lines of therapy which include all of the following:

- An immunomodulatory agent (e.g., lenalidomide, thalidomide)
- A proteasome inhibitor (e.g., bortezomib, carfilzomib)
- A CD38-directed monoclonal antibody (e.g. daratumumab)

Product Name: Tecvayli	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Tecvayli Prescribing Information. Janssen Biotech, Inc. Horsham, PA. October 2022.

4 . Revision History

Date	Notes
7/5/2023	Removed specialist requirement

Tepezza (teprotumumab-trbw)

Prior Authorization Guideline

Guideline ID	GL-125572
Guideline Name	Tepezza (teprotumumab-trbw)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	3/18/2020
P&T Revision Date:	03/17/2021 ; 03/16/2022 ; 03/15/2023 ; 6/21/2023

1 . Indications

Drug Name: Tepezza (teprotumumab-trbw)
Thyroid Eye Disease (TED) Indicated for the treatment of thyroid eye disease regardless of Thyroid Eye Disease (TED) activity or duration.

2 . Criteria

Product Name: Tepezza

Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of thyroid eye disease (TED)

AND

2 - Prescribed by or in consultation with one of the following: [3]

- Endocrinologist
- Ophthalmologist

AND

3 - Treatment with Tepezza has not exceeded a total of 8 infusions [1]

3 . References

1. Tepezza prescribing information. Horizon Therapeutics USA, Inc. Deerfield, IL. April 2023.
2. Tepezza for Healthcare Professionals. Available at: https://www.tepezzahcp.com/about-thyroid-eye-disease/. Accessed May 2, 2023.
3. Burch, H., Perros, P., e al. Management of Thyroid Eye Disease: A Consensus Statement by the American Thyroid Association and the European Thyroid Association. 2022 Nov 12. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9727317/. Accessed May 2, 2023.
4. ClinicalTrials.gov. A Study Evaluating Tepezza Treatment in Patients with Chronic (Inactive) Thyroid Eye Disease. Available at: https://www.clinicaltrials.gov/ct2/show/NCT04583735?term=NCT04583735&draw=2&rank=1. Accessed May 2, 2023.
5. UptoDate.Treatment of Thyroid Eye Disease. Available at: https://www.uptodate.com/contents/treatment-of-thyroid-eye-

disease?search=thyroid%20eye%20disease&source=search_result&selectedTitle=2~56&usage_type=default&display_rank=2#H472030470. Accessed May 2, 2023.

4 . Revision History

Date	Notes
5/10/2023	update guideline

Testosterone

Prior Authorization Guideline

Guideline ID	GL-124160
Guideline Name	Testosterone
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	
P&T Revision Date:	11/14/2019 ; 02/13/2020 ; 02/13/2020 ; 04/15/2020 ; 04/21/2021 ; 03/16/2022 ; 05/19/2022 ; 09/21/2022 ; 08/18/2022 ; 09/21/2022 ; 11/17/2022 ; 01/18/2023 ; 02/16/2023 ; 03/15/2023 ; 4/19/2023

1 . Indications

Drug Name: Androderm (testosterone [T] patch), Androgel (T gel and pump), Fortesta (T gel), Natesto (T nasal gel), Testim (T gel), and Vogelxo (T gel and pump)
Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy or toxic damage from alcohol or heavy metals. These men usually have low testosterone serum levels and gonadotropins (FSH, LH) above the normal range. Important limitations of use: Safety and efficacy in men with "age-related hypogonadism (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy in males less

than 18 years old have not been established. Topical testosterone products may have different doses, strengths, or application instructions that may result in different systemic exposure.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Important limitations of use: Safety and efficacy in men with "age-related hypogonadism (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy in males less than 18 years old have not been established. Topical testosterone products may have different doses, strengths, or application instructions that may result in different systemic exposure.

Drug Name: Methitest (methyltestosterone) tablet

Delayed puberty in males Indicated for stimulation of puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be obtained every six months to assess the effect of treatment on the epiphyseal centers.

Metastatic mammary cancer in females Indicated for secondary use in women with advancing inoperable metastatic (skeletal) mammary cancer who are 1 to 5 years postmenopausal. Primary goals of therapy in these women include ablation of the ovaries. Other methods of counteracting estrogen activity are adrenalectomy, hypophysectomy, and/or antiestrogen therapy. This treatment has also been used in premenopausal women with breast cancer who have benefited from oophorectomy and are considered to have a hormone-responsive tumor. Judgment concerning androgen therapy should be made by an oncologist with expertise in this field.

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome, or orchidectomy.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired) is idiopathic gonadotropin or LHRH deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation. If the

above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty.

Drug Name: Depo-Testosterone (testosterone cypionate) injection

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchiectomy. Safety and efficacy of Depo-Testosterone (testosterone cypionate) in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired) - Gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. Safety and efficacy of Depo-Testosterone (testosterone cypionate) in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

Drug Name: Testopel (testosterone) pellet

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchiectomy. If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sex characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty. Safety and efficacy of Testopel in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism" have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired)-idiopathic gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty. If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sex characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone

deficiency after puberty. Safety and efficacy of Testopel in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism" have not been established.

Delayed puberty in males Indicated for stimulation of puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be obtained every six months to assess the effect of treatment on the epiphyseal centers.

Drug Name: Aveed (testosterone undecanoate) injection

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Aveed should only be used in patients who require testosterone replacement therapy and in whom the benefits of the product outweigh the serious risks of pulmonary oil microembolism and anaphylaxis. Limitations of use: Safety and efficacy of Aveed in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy of Aveed in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Aveed should only be used in patients who require testosterone replacement therapy and in whom the benefits of the product outweigh the serious risks of pulmonary oil microembolism and anaphylaxis. Limitations of use: Safety and efficacy of Aveed in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy of Aveed in males less than 18 years old have not been established.

Drug Name: Testone CIK (testosterone cypionate) injection

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - testicular failure due to

cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome; or orchidectomy. Limitations of Use: Safety and efficacy of testosterone cypionate in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired) - idiopathic gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. Limitations of Use: Safety and efficacy of testosterone cypionate in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.

Drug Name: Xyosted (testosterone enanthate) injection

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter’s syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (FSH, LH) above the normal range. Safety and efficacy of Xyosted in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired) - Gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Safety and efficacy of Xyosted in males less than 18 years old have not been established.

Drug Name: Jatenzo (testosterone undecanoate) capsule

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Limitations of Use: Safety and efficacy of Jatenzo in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Hypogonadotropic hypogonadism (congenital or acquired) is

gonadotropin or luteinizing hormone releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Limitations of Use: Safety and efficacy of Jatenzo in males less than 18 years old have not been established.

Drug Name: Tlando (testosterone undecanoate) capsule

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Limitations of Use: Safety and efficacy of Tlando in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Hypogonadotropic hypogonadism (congenital or acquired) is gonadotropin or luteinizing hormone releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Limitations of Use: Safety and efficacy of Tlando in males less than 18 years old have not been established.

Drug Name: Kyzatrex (testosterone undecanoate) capsule

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Limitations of Use: Safety and efficacy of Kyzatrex in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Hypogonadotropic hypogonadism (congenital or acquired) is gonadotropin or luteinizing hormone releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Limitations of Use: Safety and efficacy of Kyzatrex in males less than 18 years old have not been established.

Drug Name: Androderm, Androgel, Aveed, Depo-Testosterone, Fortesta, Methitest, Natesto, Testone CIK, Testim, Testopel, Vogelxo, Xyosted
Off Label Uses: Transgender male (female-to-male) - Gender Dysphoria/Gender Incongruence [11-12, 17, 28-29] Testosterone in 3 different formulations, including transdermal gel, significantly increased testosterone levels from the physiological range for women to the normal male range by week 30 of treatment in an observational study in transgender male (female-to-male) individuals. Hormonal sex reassignment therapy was associated with significantly fewer symptoms related to social distress, anxiety, and depression compared with those not receiving hormonal therapy in 1 cross-sectional study. Gender transition treatment can be initiated in adults and adolescents with confirmed persistent gender dysphoria/gender incongruence who have the capacity to make fully informed decisions and consent, usually by age 16 years, and have well-controlled, if any, mental health concerns. The goals of therapy are to suppress endogenous sex hormones of the designated gender and to replace these with endogenous sex hormones of the affirmed gender. Either parenteral or transdermal testosterone may be used to achieve and maintain testosterone levels in the normal male range. Avoid sustained supraphysiologic levels to reduce risk of adverse reactions. Compelling reasons may exist to initiate therapy at younger than 16 years; although, studies in this population are minimal. Initial therapy to undergo suppression of pubertal development at Tanner stages G2/B2 is suggested. Neither puberty suppression nor gender-affirming hormone therapies are recommended in pre-pubertal children.

2 . Criteria

Product Name: Androderm, Brand Androgel gel and pump (1%), Brand Androgel gel and pump (1.62%), Generic testosterone gel and pump 20.25 mg/1.25 g, 40.5 mg/2.5 g (1.62%), Natesto, Generic testosterone gel 25 mg/2.5 g (1%), Generic testosterone gel 50 mg/5 g (1%), Generic testosterone gel pump (1%), Generic testosterone topical solution 30 mg/act, Generic testosterone gel 10 mg/act (2%), Aveed, Generic testosterone enanthate, Brand Depo-Testosterone, Brand Fortesta, Brand Testim, Brand Testosterone Cypionate, Testone CIK, Testopel, Testosterone implant pellets, Brand Testosterone Propionate, Xyosted, Brand Vogelxo	
Diagnosis	Male hypogonadism
Approval Length	6 months for patients new to testosterone therapy; or 12 months for patients continuing testosterone therapy but without a current authorization on file with Samaritan Large Group [B]
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hypogonadism (e.g., testicular hypofunction, male hypogonadism)

AND

2 - Male patient at birth [C]

AND

3 - Patient is 18 years of age or older

AND

4 - One of the following:

4.1 Two pre-treatment serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab** [7, 9]

OR

4.2 Both of the following:

4.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

4.2.2 One pre-treatment calculated free or bioavailable testosterone level less than 5 ng/dL (< 0.17 nmol/L) or less than the reference range for the lab**

OR

4.3 Patient has a history of one of the following:

- Bilateral orchiectomy
- Panhypopituitarism
- A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

OR

4.4 Both of the following:

4.4.1 Patient is continuing testosterone therapy

AND

4.4.2 One of the following:

4.4.2.1 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal limits of the reporting lab

OR

4.4.2.2 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted

AND

5 - Trial and failure or intolerance to both of the following (applies to Aveed, Testopel, Testosterone implant pellets, Testone CIK, Brand Depo-Testosterone, Brand Testosterone Cypionate and Brand Testosterone Propionate only):

- Generic testosterone cypionate
- Generic testosterone enanthate

AND

6 - Trial and failure or intolerance to generic testosterone gel (applies to Brand Androgel, Brand Fortesta, Brand Testim, Brand Vogelxo, and Brand Natesto only)

Notes	**This may require treatment to be temporarily held.

Product Name: Generic testosterone cypionate	
Diagnosis	Male hypogonadism
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hypogonadism (e.g., testicular hypofunction, male hypogonadism)

AND

2 - Male patient at birth [C]

AND

3 - Patient is 18 years of age or older

AND

4 - One of the following:

4.1 Two pre-treatment serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab** [7, 8]

OR

4.2 Both of the following:

4.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

4.2.2 One pre-treatment calculated free or bioavailable testosterone level less than 5 ng/dL (< 0.17 nmol/L) or less than the reference range for the lab**

OR

4.3 Patient has a history of one of the following:

- Bilateral orchiectomy
- Panhypopituitarism
- A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

OR

4.4 Both of the following:

4.4.1 Patient is continuing testosterone therapy

AND

4.4.2 One of the following:

4.4.2.1 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal limits of the reporting lab

OR

4.4.2.2 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted

Notes	**This may require treatment to be temporarily held.

Product Name: Methitest, Generic methyltestosterone, Jatenzo, Kyzatrex, Tlando	
Diagnosis	Male hypogonadism
Approval Length	6 months for patients new to testosterone therapy; or 12 months for patients continuing testosterone therapy but without a current authorization on file with Samaritan Large Group [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of hypogonadism (e.g., testicular hypofunction, male hypogonadism)

AND

2 - Male patient at birth [C]

AND

3 - Patient is 18 years of age or older

AND

4 - One of the following:

4.1 Two pre-treatment serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab*** [7, 8]

OR

4.2 Both of the following:

4.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

4.2.2 One pre-treatment calculated free or bioavailable testosterone level less than 5 ng/dL (< 0.17 nmol/L) or less than the reference range for the lab***

OR

4.3 Patient has a history of one of the following:

- Bilateral orchiectomy
- Panhypopituitarism
- A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

OR

4.4 Both of the following:

4.4.1 Patient is continuing testosterone therapy

AND

4.4.2 One of the following:

4.4.2.1 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal limits of the reporting lab

OR

4.4.2.2 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted

AND

5 - Trial and failure or intolerance to both of the following:

- Androderm (testosterone patch)
- Generic testosterone gel

Notes	***This may require treatment to be temporarily held.

Product Name: Androderm, Brand Androgel gel and pump (1%), Generic testosterone gel 25 mg/2.5 g (1%), Brand Androgel gel and pump (1.62%), Generic testosterone gel and pump 20.25 mg/1.25 g, 40.5 mg/2.5 g (1.62%), Generic testosterone topical solution 30 mg/act, Brand Fortesta, Generic testosterone gel 10 mg/act (2)%, Jatenzo, Kyzatrex, Methitest, Natesto, Brand Testim, Generic methyltestosterone, Brand Vogelxo gel and pump (1%), Generic testosterone gel 50 mg/5 g (1%), Generic testosterone pump (1%), Aveed, Generic testosterone enanthate, Brand Depo-Testosterone, Brand Testosterone Cypionate, Testone CIK, Testopel, Testosterone implant pellets, Brand Testosterone Propionate, Tlando, Xyosted	
Diagnosis	Gender Dysphoria/Gender Incongruence (off-label) [11-12, 17, 26 D]
Approval Length	6 months for patients new to testosterone therapy; or 12 months for patients continuing testosterone therapy but without a current authorization on file with Samaritan Large Group [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gender dysphoria/gender incongruence [11-12, 17, 26]

AND

2 - Using hormones to change characteristics to align with gender expression [11, 17, 28-29]

AND

3 - Trial and failure or intolerance to both of the following (applies to Aveed, Testopel, Testosterone implant pellets, Testone CIK, Brand Depo-Testosterone, Brand Testosterone Cypionate, Brand Testosterone Propionate):

- Generic testosterone cypionate
- Generic testosterone enanthate

AND

4 - Trial and failure or intolerance to generic testosterone (applies to Brand Androgel, Brand Fortesta, Brand Testim, Brand Vogelxo, Brand Natesto only)

Product Name: Generic testosterone cypionate	
Diagnosis	Gender Dysphoria/Gender Incongruence (off-label) [11-12, 17, 26 D]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gender dysphoria/gender incongruence [11-12, 17, 26]

AND

2 - Using hormones to change characteristics to align with gender expression [11, 17, 28-29]

Product Name: Androderm, Brand Androgel gel and pump (1%), Generic testosterone gel 25 mg/2.5 g (1%), Brand Androgel gel and pump (1.62%), Generic testosterone gel and pump 20.25 mg/1.25 g, 40.5 mg/2.5 g (1.62%), Generic testosterone topical solution 30 mg/act, Brand Fortesta, Generic testosterone gel 10 mg/act (2)%, Jatenzo, Kyzatrex, Methitest, Natesto, Brand Testim, Generic methyltestosterone, Brand Vogelxo gel and pump (1%), Generic testosterone gel 50 mg/5 g (1%), Generic testosterone pump (1%), Aveed, Generic testosterone enanthate, Brand Depo-Testosterone, Brand Testosterone Cypionate, Generic testosterone cypionate, Testone CIK, Testopel, Testosterone implant pellets, Brand Testosterone Propionate, Tlando, Xyosted	
Diagnosis	Male hypogonadism, Gender dysphoria/Gender incongruence
Approval Length	12 Month [B]
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Follow-up total serum testosterone level drawn within the past 6 months for patients new to testosterone therapy, or 12 months for patients continuing testosterone therapy, is within or below the normal limits of the reporting lab

OR

1.2 Follow-up total serum testosterone level drawn within the past 6 months for patients new to testosterone therapy, or 12 months for patients continuing testosterone therapy, is outside of upper limits of normal for the reporting lab and the dose is adjusted

OR

1.3 Both of the following:

1.3.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

1.3.2 One of the following:

1.3.2.1 Follow-up calculated free or bioavailable testosterone level drawn within the past 6 months for patients new to testosterone therapy, or 12 months for patients continuing testosterone therapy, is within or below the normal limits of the reporting lab

OR

1.3.2.2 Follow-up calculated free or bioavailable testosterone level drawn within the past 6 months for patients new to testosterone therapy, or 12 months for patients continuing testosterone therapy, is outside of upper limits of normal for the reporting lab and the dose is adjusted

Product Name: Methitest, Generic testosterone enanthate, Testopel, Testosterone implant pellets, Generic methyltestosterone, Brand Testosterone Cypionate [off-label]	
Diagnosis	Delayed puberty [E]
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of delayed puberty [A]

AND

2 - Male patient at birth [C]

AND

3 - Trial and failure or intolerance to both of the following (applies to Testopel and Testosterone implant pellets only):

- Generic testosterone cypionate [F]
- Generic testosterone enanthate

Product Name: Generic testosterone cypionate [off-label]	
Diagnosis	Delayed puberty [E]
Approval Length	12 month(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of delayed puberty [A]

AND

2 - Male patient at birth [C]

Product Name: Methitest, Generic methyltestosterone, Generic testosterone enanthate	
Diagnosis	Inoperable breast cancer in women
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Breast cancer is inoperable

AND

3 - Used for palliative treatment

AND

4 - Female patient at birth [C]

3 . Endnotes

A. Delayed puberty is defined as the lack of the initial signs of sexual maturation by an age that is more than 2-2.5 standard deviations above the mean for the population (traditionally, the age of 14 years in boys and 13 years in girls). In most cases, delayed puberty is not due to an underlying pathology, but instead represents an extreme end of the normal spectrum of pubertal timing, a developmental pattern referred to as constitutional delay of growth and puberty (CDGP). CDGP is the most common cause of delayed puberty in both sexes, but it can be diagnosed only after underlying conditions have been ruled out. Management of CDGP may involve expectant observation or therapy with low-dose sex steroids. [9]
B. Initial authorization of 6 months, and reauthorization of 12 months is based on the Endocrine Society's Clinical Practice Guideline's recommendation to monitor testosterone level 3 to 6 months after initiation of testosterone therapy, and then annually to assess whether symptoms have responded to treatment and whether the patient is suffering from any adverse effects. [8]
C. The gender criteria in place for male hypogonadism, delayed puberty, and inoperable breast cancer are to ensure safe and effective medication utilization due to FDA-approved labeling supporting the gender restriction [refer to individual Package Inserts]. Age and/or gender criteria will remain in the guideline, consistent with the following direction approved by Samaritan Large Group Legal & Regulatory: “Age and gender edits in place due to FDA safety guidance, labeling or supported by medical literature to satisfy medical necessity criteria would not be inconsistent with the [Section 1557 HCR non-discrimination] regulation."
D. According to DRUGDEX, for the treatment of transgender male (female-to-male) patients with gender dysphoria, various forms and dosages of testosterone have been used. [12] Clinical studies have also demonstrated the efficacy of several different androgen preparations to induce masculinization in female-to-male transgender persons. Regimens to change secondary sex characteristics follow the general principle of hormone replacement treatment of male hypogonadism. Either parenteral or transdermal preparations can be used to achieve testosterone values in the normal male range. [11]
E. An X-ray of the hand and wrist to determine bone age should be taken every 6 months to assess the effect of treatment on epiphyseal center [19-20].
F. Per consult with specialist, the pharmacokinetics of T. cypionate and T. enanthate are quite similar and physiologically produce similar results. The two agents are very close in efficacy and behavioral effects. Although T. cypionate isn't FDA-approved for delayed puberty, it is used in practice due to its similarity to T. enanthate. [25]

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5 . Revision History

Date	Notes
4/5/2023	Updated the step through both Generic testosterone cypionate and G eneric testosterone enanthate as drug shortage has been resolved

Testosterone Topical Step Therapy

Prior Authorization Guideline

Guideline ID	GL-116938
Guideline Name	Testosterone Topical Step Therapy
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Generic testosterone gel	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Step Therapy

Approval Criteria

1 - Diagnosis of one of the following:

- Gender dysphoria
- Aids wasting syndrome
- Post-menopausal breast cancer
- Hypogonadism

AND

2 - Trial and failure or contraindication to injectable testosterone

Product Name: Generic testosterone gel	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Step Therapy

Approval Criteria

1 - For continuation of prior therapy

2 . Revision History

Date	Notes
11/15/2022	Update guideline

Tezspire (tezepelumab-ekko) - PA

Prior Authorization Guideline

Guideline ID	GL-127168
Guideline Name	Tezspire (tezepelumab-ekko) - PA
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	3/16/2022
P&T Revision Date:	07/20/2022 ; 03/15/2023 ; 7/19/2023

1 . Indications

Drug Name: Tezspire (tezepelumab-ekko) injection, for subcutaneous use
Severe Asthma Indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma. Limitations of Use: Tezspire is not indicated for the relief of acute bronchospasm or status asthmaticus.

2 . Criteria

Product Name: Tezspire	
Approval Length	6 Month(s) [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe asthma

AND

2 - Patient is 12 years of age or older

AND

3 - One of the following: [2,3]

- Patient has had two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months
- Prior asthma-related hospitalization within the past 12 months

AND

4 - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

4.1 Both of the following: [2,3]

- High-dose inhaled corticosteroid (ICS) (i.e., greater than 500 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium)

OR

4.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol], Breo Ellipta [fluticasone/vilanterol]) [B]

AND

5 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name: Tezspire	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by one of the following:

- A reduction in asthma exacerbations
- Improvement in forced expiratory volume in 1 second (FEV1) from baseline

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene

receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications [4]

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

3 . Endnotes

A. The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention update recommends that patients with asthma should be reviewed regularly to monitor their symptom control, risk factors and occurrence of exacerbations, as well as to document the response to any treatment changes. Ideally, after initiation of treatment, patients should be re-evaluated in 3 to 6 months. [4]
B. The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention guideline recommend patients with severe asthma should be treated with maximal optimized high dose ICS-LABA therapy. [4]

4 . References

1. Tezspire (tezepelumab-ekko) Prescribing Information. Amgen Inc, Thousand Oaks, CA. February 2023
2. Menzies-Gow A, Corren J, Bourdin A, et al. Tezepelumab in Adults and Adolescents with Severe, Uncontrolled Asthma. N Engl J Med. 2021;384(19):1800-1809.
3. Corren J, Parnes JR, Wang L, et al. Tezepelumab in Adults with Uncontrolled Asthma. N Engl J Med. 2017;377(10):936-946.
4. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention (2021 update). 2021 www.ginasthma.org. Accessed February 2021.

5 . Revision History

Date	Notes
7/10/2023	Removal of trial requirements of other asthma biologics and removal of NF criteria

Thalomid (thalidomide)

Prior Authorization Guideline

Guideline ID	GL-124374
Guideline Name	Thalomid (thalidomide)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	5/22/2007
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 05/19/2022 ; 5/18/2023

1 . Indications

Drug Name: Thalomid (thalidomide)
Erythema Nodosum Leprosum (ENL) Indicated for the acute treatment of the cutaneous manifestations of moderate to severe ENL. Not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis. Also indicated as a maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence. **Newly Diagnosed Multiple Myeloma** Indicated in combination with dexamethasone for the treatment of patients with newly diagnosed multiple myeloma.

2 . Criteria

Product Name: Thalomid	
Diagnosis	Erythema Nodosum Leprosum (ENL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe erythema nodosum leprosum (ENL) with cutaneous manifestations

AND

2 - Thalomid is not used as monotherapy if moderate to severe neuritis is present

Product Name: Thalomid	
Diagnosis	Erythema Nodosum Leprosum (ENL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Thalomid	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - Used in combination with dexamethasone, unless the patient has an intolerance to steroids

AND

3 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Thalomid	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Thalomid Prescribing Information. Celgene Corporation. Summit, NJ. December 2022.

4 . Revision History

Date	Notes
5/3/2023	Annual review - updated references.

Tibsovo (ivosidenib)

Prior Authorization Guideline

Guideline ID	GL-116562
Guideline Name	Tibsovo (ivosidenib)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Tibsovo	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of Acute Myeloid Leukemia (AML)

AND

2 - Submission of medical records (e.g., char notes) confirming patient is IDH1 mutation positive as detected by a U.S. Food and Drug Administration (FDA) cleared test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Patient is 18 years of age or older

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Tibsovo	
Diagnosis	Cholangiocarcinoma
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Cholangiocarcinoma

AND

2 - Submission of medical records (e.g., char notes) confirming patient is IDH1 mutation

positive as detected by a U.S. Food and Drug Administration (FDA) cleared test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Trial and failure, intolerance or contraindication to at least one chemotherapy regimen (e.g., FOLFOX)

AND

4 - Patient is 18 years of age or older

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Tibsovo	
Diagnosis	All indications
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes

10/6/2022	New Implementation

Tier Lowering Exceptions Process

Prior Authorization Guideline

Guideline ID	GL-116527
Guideline Name	Tier Lowering Exceptions Process
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Tier Lowering Exceptions Process	
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria **1** - A prescribed drug will be considered for coverage under the prescribed drug's lower tier when one of the following are met:	

1.1 All lower-tiered medication alternatives would be less effective or have been demonstrated to be ineffective for treating the patient's condition when used at optimized dose and frequency

OR

1.2 All lower-tiered medication alternatives would have adverse effects (intolerance or contraindication) in the treatment of the patient's condition.

2 . Revision History

Date	Notes
11/1/2022	Per TSK004583729 copy over OptumRx Standard guidelines for Sam aritan 2023 Implementation

Toremifene

Prior Authorization Guideline

Guideline ID	GL-116501
Guideline Name	Toremifene
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Generic toremifene	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of metastatic breast cancer	

AND

2 - Patient is both of the following:

- Female
- Postmenopausal

AND

3 - Patient does not have congenital/acquired QT prolongation (long QT syndrome)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Generic toremifene	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

2 . Revision History

Date	Notes
9/24/2022	2023 New Implementation

Toujeo (insulin glargine) Step Therapy

Prior Authorization Guideline

Guideline ID	GL-116484
Guideline Name	Toujeo (insulin glargine) Step Therapy
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Toujeo	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria **1** - Trial and failure or intolerance to any non-concentrated basal insulin product (i.e., Basaglar, Levemir, NPH, etc) within the past 365 days	

OR **2** - Member has documented administration barriers OR requires multiple doses of non-concentrated basal insulin

2 . Revision History

Date	Notes
10/27/2022	2023 New Implementation

Trelegy (fluticasone-umeclidinium-vilanterol) Step Therapy

Prior Authorization Guideline

Guideline ID	GL-116485
Guideline Name	Trelegy (fluticasone-umeclidinium-vilanterol) Step Therapy
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Trelegy	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Patient must have a documented 4-week trial and failure of or had an inadequate response to one of the following within the past 120 days:

- A combined Long-acting Beta Agonist/Inhaled Corticosteroid (LABA/ICS) (e.g., Advair, Symbicort, Dulera)
- A combined Long-acting Muscarinic Antagonist/ Long-acting Beta Agonist (LAMA/LABA) (e.g., Anoro)
- An Inhaled Corticosteroids (ICS) (e.g., Asmanex, Pulmicort) combined with a Long-acting Beta Agonist (e.g. Serevent)

2 . Revision History

Date	Notes
10/27/2022	2023 New Implementation

Tremfya (guselkumab)

Prior Authorization Guideline

Guideline ID	GL-116594
Guideline Name	Tremfya (guselkumab)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Indications

Drug Name: Tremfya (guselkumab)
Plaque Psoriasis (PsO) Indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. **Psoriatic Arthritis (PsA)** Indicated for the treatment of adult patients with active psoriatic arthritis.

2 . Criteria

Product Name: Tremfya

Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate-to-severe plaque psoriasis

AND

2 - One of the following [2]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name: Tremfya	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1-3]:

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name: Tremfya	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis (PsA)

AND

2 - One of the following [4]:

- Actively inflamed joints
- Dactylitis

- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Product Name: Tremfya	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

3 . References

1. Tremfya prescribing information. Janssen Biotech, Inc. Horsham, PA. July 2020.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.

3. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.

4 . Revision History

Date	Notes
10/28/2022	Bulk copy OptumRx SP to Samaritan SP for 1/1/2023 Implementation

Tresiba (Insulin Degludec)

Prior Authorization Guideline

Guideline ID	GL-116518
Guideline Name	Tresiba (Insulin Degludec)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Tresiba, Brand Insulin Degludec	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Type 1 or Type 2 Diabetes	

AND

2 - Trial and failure, contraindication or intolerance to Basaglar

AND

3 - Patient has significant barriers to standardized administration requiring flexibility in dose timing

AND

4 - If request is for U-200 strength, both of the following (APPLIES TO U-200/200 U/ML ONLY):

- Patient requires greater than 160 units of insulin per dose
- Patient has difficulty with multiple daily injections

Product Name: Tresiba, Brand Insulin Degludec	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/31/2022	2023 New Implementation

Trikafta (elexacaftor/tezacaftor/ivacaftor)

Prior Authorization Guideline

Guideline ID	GL-125639
Guideline Name	Trikafta (elexacaftor/tezacaftor/ivacaftor)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	11/14/2019
P&T Revision Date:	11/14/2019 ; 11/12/2020 ; 02/18/2021 ; 08/19/2021 ; 11/18/2021 ; 11/17/2022 ; 6/21/2023

1 . Indications

Drug Name: Trikafta (elexacaftor/tezacaftor/ivacaftor)
Cystic Fibrosis Indicated for the treatment of cystic fibrosis (CF) in patients aged 2 years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive based on in vitro data. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one F508del mutation or a mutation that is responsive based on in vitro data.

2 . Criteria

Product Name: Trikafta	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - One of the following:

- For granule packets, patient is at least 2 to less than 6 years of age
- For tablets, patient is 6 years of age or older

AND

3 - Patient has at least one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected by a FDA-cleared cystic fibrosis mutation test or a test performed at a Clinical Laboratory Improvement Amendments (CLIA)-approved facility:*

- F508del mutation
- A mutation in the CFTR gene that is responsive based on in vitro data

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist

• Specialist affiliated with a CF care center	
Notes	*Please consult Background section for table of CFTR gene mutations responsive to Trikafta.

Product Name: Trikafta	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy (e.g., improvement in lung function [percent predicted forced expiratory volume in one second {PPFEV1}] or decreased number of pulmonary exacerbations) [1,2]

3 . Background

Clinical Practice Guidelines

CFTR Mutations that are responsive to Trikafta

*Intent of table is to provide a quick reference; PA team members should still review at point of request for clinical appropriateness as off label support continuously evolves. [Last Reviewed: 10/31/22]

List of *CFTR* Gene Mutations that are Responsive to Trikafta					
3141del9	*E822K*	*G1069R*	*L967S*	*R117L*	*S912L*
546insCTA	*F191V*	*G1244E*	*L997F*	*R117P*	*S945L*

A46D	*F311del*	*G1249R*	*L1077P*	*R170H*	*S977F*
A120T	*F311L*	*G1349D*	*L1324P*	*R258G*	*S1159F*
A234D	*F508C*	*H139R*	*L1335P*	*R334L*	*S1159P*
A349V	*F508C;S1251N †*	*H199Y*	*L1480P*	*R334Q*	*S1251N*
A455E	*F508del **	*H939R*	*M152V*	*R347H*	*S1255P*
A554E	*F575Y*	*H1054D*	*M265R*	*R347L*	*T338I*
A1006E	*F1016S*	*H1085P*	*M952I*	*R347P*	*T1036N*
A1067T	*F1052V*	*H1085R*	*M952T*	*R352Q*	*T1053I*
D110E	*F1074L*	*H1375P*	*M1101K*	*R352W*	*V201M*
D110H	*F1099L*	*I148T*	*P5L*	*R553Q*	*V232D*
D192G	*G27R*	*I175V*	*P67L*	*R668C*	*V456A*
D443Y	*G85E*	*I336K*	*P205S*	*R751L*	*V456F*
D443Y;G576A;R668C †	*G126D*	*I502T*	*P574H*	*R792G*	*V562I*
D579G	*G178E*	*I601F*	*Q98R*	*R933G*	*V754M*
D614G	*G178R*	*I618T*	*Q237E*	*R1066H*	*V1153E*
D836Y	*G194R*	*I807M*	*Q237H*	*R1070Q*	*V1240G*
D924N	*G194V*	*I980K*	*Q359R*	*R1070W*	*V1293G*
D979V	*G314E*	*I1027T*	*Q1291R*	*R1162L*	*W361R*
D1152H	*G463V*	*I1139V*	*R31L*	*R1283M*	*W1098C*
D1270N	*G480C*	*I1269N*	*R74Q*	*R1283S*	*W1282R*

E56K	*G551D*	*I1366N*	*R74W*	*S13F*	*Y109N*
E60K	*G551S*	*K1060T*	*R74W;D1270N* †	*S341P*	*Y161D*
E92K	*G576A*	*L15P*	*R74W;V201M* †	*S364P*	*Y161S*
E116K	*G576A;R668C* †	*L165S*	*R74W;V201M;D1270N* †	*S492F*	*Y563N*
E193K	*G622D*	*L206W*	*R75Q*	*S549N*	*Y1014C*
E403D	*G628R*	*L320V*	*R117C*	*S549R*	*Y1032C*
E474K	*G970D*	*L346P*	*R117G*	*S589N*	
E588V	*G1061R*	*L453S*	*R117H*	*S737F*	

* *F508del* is a responsive *CFTR* mutation based on both clinical and *in vitro* data.

† Complex/compound mutations where a single allele of the *CFTR* gene has multiple mutations; these exist independent ofthe presence of mutations on the other allele.

4 . References

1. Trikafta Prescribing information. Vertex Pharmaceuticals Inc. Boston, MA. April 2023.
2. Keating D, Marigowda G, Burr L, et al. VX-445–tezacaftor–ivacaftor in patients with cystic fibrosis and one or two Phe508del alleles. N Engl J Med. 2018;379:1612-20.

5 . Revision History

Date	Notes
5/16/2023	Added in new granule formulation and added age criteria to guideline

Tysabri (natalizumab)

Prior Authorization Guideline

Guideline ID	GL-124857
Guideline Name	Tysabri (natalizumab)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	11/20/2000
P&T Revision Date:	05/14/2020 ; 01/20/2021 ; 05/20/2021 ; 05/19/2022 ; 10/19/2022 ; 5/18/2023

1 . Indications

Drug Name: Tysabri (natalizumab)
Multiple Sclerosis (MS) Indicated as monotherapy for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Tysabri increases the risk of progressive multifocal leukoencephalopathy (PML). When initiating and continuing treatment with Tysabri, physicians should consider whether the expected benefit of Tysabri is sufficient to offset this risk. **Crohn's Disease (CD)** Indicated for inducing and maintaining clinical response and remission in adult patients with moderately to severely active CD with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and

inhibitors of TNF-alpha. In CD, Tysabri should not be used in combination with immunosuppressants (e.g., 6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) or inhibitors of TNF-alpha.

2 . Criteria

Product Name: Tysabri	
Diagnosis	Multiple Sclerosis (MS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [B]

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to one of the following disease-modifying therapies for MS:

- Aubagio (teriflunomide)
- Lemtrada (alemtuzumab)
- Mavenclad (cladribine)
- Plegridy (peginterferon beta-1a)
- Any one of the interferon beta-1a injections (e.g., Avonex)
- Any one of the interferon beta-1b injections (e.g., Betaseron)
- Any one of the glatiramer acetate injections (e.g., Copaxone, Glatopa, generic glatiramer acetate)

- Any one of the oral fumarates (e.g., generic dimethyl fumarate)
- Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (e.g., Gilenya, Mayzent, Zeposia)
- Any one of the B-cell targeted therapies (e.g., Kesimpta)

OR

2.2 Patient is not a candidate for any of the drugs listed as prerequisites due to the severity of their multiple sclerosis [2]

OR

2.3 For continuation of prior therapy [2]

AND

3 - Not used in combination with another disease-modifying therapy for MS

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Tysabri	
Diagnosis	Multiple Sclerosis (MS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS

AND

3 - Prescribed by or in consultation with a neurologist

Product Name: Tysabri	
Diagnosis	Crohn’s Disease (CD)
Approval Length	3 Months [1]**
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - Crohn's disease has evidence of inflammation (e.g., elevated C-reactive protein [CRP], elevated erythrocyte sedimentation rate, presence of fecal leukocytes)

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies [3, 7]:

- corticosteroids (e.g., prednisone)
- 6-mercaptopurine
- azathioprine
- methotrexate

AND

4 - Trial and failure, contraindication, or intolerance to a tumor necrosis factor (TNF)-inhibitor (e.g., Cimzia [certolizumab pegol], Adalimumab, infliximab)

AND

5 - Not used in combination with an immunosuppressant (e.g., 6-MP, azathioprine, cyclosporine, or methotrexate) [A, C]

AND

6 - Not used in combination with a TNF-inhibitor (e.g., Enbrel [etanercept], Adalimumab, or infliximab) [A, C]

AND

7 - Prescribed by or in consultation with a gastroenterologist

Notes	**In CD, discontinue Tysabri in patients that have not experienced ther apeutic benefit by 12 weeks of induction therapy, and in patients that cannot discontinue chronic concomitant steroids within six months of starting therapy. [1]

Product Name: Tysabri

Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 3, 7]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

AND

2 - Not used in combination with an immunosuppressant (e.g., 6-MP, azathioprine, cyclosporine, or methotrexate) [A, C]

AND

3 - Not used in combination with a TNF-inhibitor (e.g., Enbrel [etanercept], Adalimumab, or infliximab) [A, C]

3 . Endnotes

A. To minimize the risk of progressive multifocal leukoencephalopathy, natalizumab must be administered as a monotherapy without concomitant immunosuppressive therapy. Aminosalicylates may be continued during treatment with Tysabri. [1, 3]
B. Of the four disease courses of MS, relapse-remitting MS (RRMS) is characterized primarily by relapse, while secondary-progressive MS (SPMS) has both relapsing and progressive characteristics. Most patients with RRMS eventually develop SPMS. As a

person transitions from RRMS to SPMS, the disease begins to worsen more steadily, with or without occasional relapses, slight remissions, or plateaus. As long as the patient continues to have relapses, the SPMS course is considered to be both progressive and relapsing. [4]

C. In the postmarketing setting, additional cases of PML have been reported in multiple sclerosis and Crohn's disease patients who were receiving no concomitant immunomodulatory therapy. Three factors that are known to increase the risk of PML in TYSABRI-treated patients have been identified: 1) Longer treatment duration, especially beyond 2 years. There is limited experience in patients who have received more than 4 years of TYSABRI treatment. 2) Prior treatment with an immunosuppressant (e.g., mitoxantrone, azathioprine, methotrexate, cyclophosphamide, mycophenolate mofetil). 3) The presence of anti-JCV antibodies. Patients who are anti-JCV antibody positive have a higher risk for developing PML. [1]

4 . References

1. Tysabri Prescribing Information. Biogen Inc. Cambridge, MA. April 2023.
2. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline: Disease-modifying therapies for adults with multiple sclerosis. Neurology 2018;90:777-788.
3. Lichtenstein GR, Loftus EV, Isaacs KL, et al. Management of Crohn's disease in adults. Am J Gastroenterol. 2018;113:481-517.
4. National Multiple Sclerosis Society. Types of MS. Available at: https://www.nationalmssociety.org/What-is-MS/Types-of-MS. Accessed April 11, 2022.
5. FDA Drug Safety Communication: New risk factor for progressive multifocal leukoencephalopathy (PML) associated with Tysabri (natalizumab). January 20, 2012. Available at: http://www.fda.gov/Drugs/DrugSafety/ucm288186.htm. Accessed April 11, 2022.
6. Nelson SML, Nguyen TM, McDonald J, MacDonald JK. Natalizumab for induction of remission in Crohn's disease. Cochrane Database of Systematic Reviews 2018, Issue 8. Art. No.: CD006097. DOI: 10.1002/14651858.CD006097.pub3.
7. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508.

5 . Revision History

Date	Notes

4/26/2023	2023 UM Annual Review. No criteria changes. Updated references

Ultomiris (ravulizumab-cwvz)

Prior Authorization Guideline

Guideline ID	GL-120947
Guideline Name	Ultomiris (ravulizumab-cwvz)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	2/14/2019
P&T Revision Date:	12/18/2019 ; 03/18/2020 ; 12/16/2020 ; 03/17/2021 ; 08/19/2021 ; 03/16/2022 ; 09/21/2022 ; 3/15/2023

1 . Indications

Drug Name: Ultomiris (ravulizumab-cwvz)
Paroxysmal Nocturnal Hemoglobinuria (PNH) Indicated for the treatment of patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH). **Atypical Hemolytic Uremic Syndrome (aHUS)** Indicated for the treatment of adults and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA). **Generalized Myasthenia Gravis (gMG)** Indicated for the treatment of adult patients with

generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive.

2 . Criteria

Product Name: Ultomiris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

AND

2 - Patient is one month of age and older

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Ultomiris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy

Product Name: Ultomiris	
Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of atypical hemolytic uremic syndrome (aHUS) [1]

AND

2 - Patient is one month of age and older

AND

3 - Prescribed by or in consultation with one of the following:

- Hematologist
- Nephrologist

Product Name: Ultomiris

Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy

Product Name: Ultomiris	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis (gMG)

AND

2 - Patient is anti-acetylcholine receptor (AChR) antibody positive

AND

3 - One of the following: [2]

3.1 Trial and failure, contraindication, or intolerance to two immunosuppressive therapies

(e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

OR

3.2 Both of the following:

3.2.1 Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

AND

3.2.2 Trial and failure, contraindication, or intolerance to one of the following:

- Chronic plasmapheresis or plasma exchange (PE)
- Intravenous immunoglobulin (IVIG)

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Ultomiris	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . References

1. Ultomiris Prescribing Information. Alexion Pharmaceuticals, Inc. Boston, MA. April 2022.
2. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis. Neurology. 2016;87(4):419-25.

4 . Revision History

Date	Notes
2/22/2023	2023 UM Annual Review. No changes

Uplizna (inebilizumab-cdon)

Prior Authorization Guideline

Guideline ID	GL-125365
Guideline Name	Uplizna (inebilizumab-cdon)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	8/13/2020
P&T Revision Date:	01/20/2021 ; 06/16/2021 ; 06/15/2022 ; 6/21/2023

1 . Indications

Drug Name: Uplizna (inebilizumab-cdon)
Neuromyelitis Optica Spectrum Disorder (NMOSD) Indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

2 . Criteria

Product Name: Uplizna	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neuromyelitis optica spectrum disorder (NMOSD)

AND

2 - Patient is anti-aquaporin-4 (AQP4) antibody positive

AND

3 - Prescribed by or in consultation with one of the following:

- Neurologist
- Ophthalmologist

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to rituximab

OR

4.2 For continuation of prior therapy

Product Name: Uplizna	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	

3 . References

1. Uplizna Prescribing Information. Horizon Therapeutics USA, Inc. Deerfield, IL. July 2021.

4 . Revision History

Date	Notes
6/7/2023	Annual review: No updates required.

Veopoz (pozelimab)

Prior Authorization Guideline

Guideline ID	GL-124083
Guideline Name	Veopoz (pozelimab)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	11/1/2023
P&T Approval Date:	10/18/2023
P&T Revision Date:	

1 . Indications

Drug Name: Veopoz (pozelimab)
CD55-deficient protein-losing enteropathy (PLE) Indicated for the treatment of adult and pediatric patients 1 year of age and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease.

2 . Criteria

Product Name: Veopoz	
Diagnosis	CD55-deficient protein-losing enteropathy (PLE)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1- Diagnosis of active CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease

AND

2- Patient has a confirmed genotype of biallelic CD55 loss-of-function mutation

AND

3- Patient is 1 year of age or older

AND

4- Patient has hypoalbuminemia (serum albumin concentration of ≤3.2 g/dL)

AND

5- Patient has at least one of the following signs or symptoms within the last six months:

- abdominal pain
- diarrhea
- peripheral edema
- facial edema

AND

6 - Prescribed by or in consultation with one of the following:

- Immunologist
- Geneticist
- Hematologist

Product Name: Veopoz	
Diagnosis	CD55-deficient protein-losing enteropathy (PLE)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g. decrease in albumin transfusions and hospitalizations, normalization of serum IgG concentrations, etc.)

3 . References

1. Veopoz Prescribing Information. Regeneron Pharmaceuticals, Inc. Tarrytown, NY. August 2023.

4 . Revision History

Date	Notes
9/29/2023	New Program for Veopoz

Verzenio (abemaciclib)

Prior Authorization Guideline

Guideline ID	GL-116575
Guideline Name	Verzenio (abemaciclib)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Verzenio	
Diagnosis	Early Breast Cancer
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of early breast cancer at high risk of recurrence

AND

2 - Disease is hormone receptor (HR)-positive

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

4 - Disease is node-positive

AND

5 - Patient is 18 years of age or older

AND

6 - Used in combination with one of the following endocrine therapies:

- Tamoxifen
- Aromatase inhibitor (e.g., anastrozole, letrozole, exemestane)

AND

7 - Prescribed by or in consultation with an oncologist

Product Name: Verzenio	
Diagnosis	Advanced or Metastatic Breast Cancer
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced or metastatic breast cancer

AND

2 - Disease is hormone receptor (HR)-positive

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

4 - One of the following:

4.1 Both of the following:

- Used in combination with an aromatase inhibitor (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole])
- Patient is male or a postmenopausal female

OR

4.2 Both of the following:

- Used in combination with Faslodex (fulvestrant)
- Disease has progressed following endocrine therapy

OR

4.3 All of the following:

- Used as monotherapy
- Disease has progressed following endocrine therapy
- Patient has already received at least one prior chemotherapy regimen

AND

5 - Patient is 18 years of age or older

AND

6 - Prescribed by or in consultation with an oncologist

Product Name: Verzenio	
Diagnosis	All indications listed above
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/21/2022	2023 New Implementation

Vijoice (alpelisib)

Prior Authorization Guideline

Guideline ID	GL-116580
Guideline Name	Vijoice (alpelisib)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Vijoice	
Approval Length	24 Week(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of phosphatidylinositol-3-kinase catalytic subunit alpha (PIK3CA)-Related Overgrowth Spectrum (PROS)

AND

2 - Patient has at least one severe clinical manifestation of PROS

AND

3 - Patient has a PIK3CA mutation that is confirmed by genetic testing

AND

4 - Patient is 2 years of age or older

AND

5 - Prescribed by or in consultation with a provider who specializes in treatment of genetic disorders

Product Name: Vijoice	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of a reduction in volume from baseline in at least one lesion

AND **2** - Improvement in at least one symptom of PROS from baseline

2 . Endnotes

A. Patients without any response assessment at Week 24 were considered non-responders. [1]

3 . References

1. Vijoice Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, New Jersey. April 2022.

4 . Revision History

Date	Notes
11/1/2022	2023 New Implementation

Viltepso (viltolarsen) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-113471
Guideline Name	Viltepso (viltolarsen) - PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	12/1/2022
P&T Approval Date:	10/21/2020
P&T Revision Date:	06/16/2021 ; 10/20/2021 ; 12/15/2021 ; 06/15/2022 ; 10/19/2022

1 . Indications

Drug Name: Viltepso (viltolarsen)
Duchenne muscular dystrophy (DMD) Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with Viltepso. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

2 . Criteria

Product Name: Viltepso	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of Duchenne muscular dystrophy (DMD)

AND

1.2 Documentation of a confirmed mutation of the dystrophin gene amenable to exon 53 skipping

AND

2 - Patient is 4 years of age or older

AND

3 - Prescribed by or in consultation with a neurologist who has experience treating children

AND

4 - Dose will not exceed 80 milligrams per kilogram of body weight infused once weekly

AND

5 - Documentation that the patient is ambulatory, as evaluated via the 6-minute walk test (6MWT) or North Star ambulatory assessment (NSAA) [2, 3]

Product Name: Viltepso	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is tolerating therapy

AND

2 - Dose will not exceed 80 milligrams per kilogram of body weight infused once weekly

AND

3 - Prescribed by or in consultation with a neurologist who has experience treating children

AND

4 - Documentation that the patient is maintaining ambulatory status, as evaluated via the 6-minute walk test (6MWT) or North Star ambulatory assessment (NSAA)

Product Name: Viltepso

Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting both of the following:

1.1 Diagnosis of Duchenne muscular dystrophy (DMD)

AND

1.2 Documentation of a confirmed mutation of the dystrophin gene amenable to exon 53 skipping

AND

2 - Patient is 4 years of age or older

AND

3 - Prescribed by or in consultation with a neurologist who has experience treating children

AND

4 - Dose will not exceed 80 milligrams per kilogram of body weight infused once weekly

AND

5 - Submission of medical records (e.g., chart notes, laboratory values) documenting the

patient is ambulatory, as evaluated via the 6-minute walk test (6MWT) or North Star ambulatory assessment (NSAA) [2, 3]

3 . References

1. Viltepso Prescribing Information. NS Pharma, Inc. Paramus, NJ. March 2021.
2. ClinicalTrials.gov. Safety and Dose Finding Study of NS-065/NCNP-01 in Boys With Duchenne Muscular Dystrophy (DMD). NCT02740972. Website. Available at: https://clinicaltrials.gov/ct2/show/NCT02740972?term=NCT02740972&draw=2&rank=1. Accessed September 7, 2022.
3. Per Clinical Consultation with a Pediatrician, April 25, 2019 and January 22, 2020.

4 . Revision History

Date	Notes
10/5/2022	Annual review: Background updates.

Vimizim (elosulfase alfa)

Prior Authorization Guideline

Guideline ID	GL-109146
Guideline Name	Vimizim (elosulfase alfa)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	10/1/2022
P&T Approval Date:	6/24/2015
P&T Revision Date:	07/15/2020 ; 07/21/2021 ; 8/18/2022

1 . Indications

Drug Name: Vimizim (elosulfase alfa)
Mucopolysaccharidosis type IVA Indicated for patients with Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome).

2 . Criteria

Product Name: Vimizim

Approval Length	60 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome) confirmed by both of the following: [1-3]

1.1 Documented clinical signs and symptoms of the disease (e.g., kyphoscoliosis, genu valgum, pectus carinatum, gait disturbance, growth deficiency, etc.)

AND

1.2 Documented reduced fibroblast or leukocyte GALNS enzyme activity or molecular genetic testing of GALNS

3 . References

1. Vimizim prescribing information. BioMarin Pharmaceutical Inc. Novato, CA. December 2019.
2. UptoDate. Mucopolysaccharidoses: Clinical features and diagnosis. Available at https://www.uptodate.com/contents/mucopolysaccharidoses-clinical-features-and-diagnosis?search=Mucopolysaccharidoses:%20clinical%20features%20and%20diagnosis.%20&source=search_result&selectedTitle=1~66&usage_type=default&display_rank=1. Accessed July 6, 2022.
3. Mucopolysaccharidosis IV. Available at https://rarediseases.org/rare-diseases/morquio-syndrome/#:~:text=Excessive%20amounts%20of%20keratan%20sulfate,to%20identify%20GALNS%20gene%20mutations. Accessed July 6, 2022.

4 . Revision History

Date	Notes
8/18/2022	2022 Annual Review.

Vyondys 53 (golodirsen) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-118142
Guideline Name	Vyondys 53 (golodirsen) - PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	5/16/2019
P&T Revision Date:	02/13/2020 ; 02/18/2021 ; 06/16/2021 ; 12/15/2021 ; 02/17/2022 ; 06/15/2022 ; 2/16/2023

1 . Indications

Drug Name: Vyondys 53 (golodirsen)
Duchenne muscular dystrophy (DMD) Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with VYONDYS 53. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.

2 . Criteria

Product Name: Vyondys 53	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Duchenne muscular dystrophy (DMD)

AND

2 - Documentation of a confirmed mutation of the dystrophin gene amenable to exon 53 skipping

AND

3 - Patient is 6 years of age or older [2, 3]

AND

4 - Prescribed by or in consultation with a neurologist who has experience treating children

AND

5 - Dose will not exceed 30 milligrams per kilogram of body weight infused once weekly

AND

6 - Patient is ambulatory, as evaluated via the 6-minute walk test (6MWT) or North Star ambulatory assessment (NSAA) [2, 3]

Product Name: Vyondys 53	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is tolerating therapy

AND

2 - Dose will not exceed 30 milligrams per kilogram of body weight infused once weekly

AND

3 - Prescribed by or in consultation with a neurologist who has experience treating children

AND

4 - Patient is maintaining ambulatory status, as evaluated via the 6-minute walk test (6MWT) or North Star ambulatory assessment (NSAA)

Product Name: Vyondys 53

Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting both of the following:

1.1 Diagnosis of Duchenne muscular dystrophy (DMD)

AND

1.2 Documentation of a confirmed mutation of the dystrophin gene amenable to exon 53 skipping

AND

2 - Patient is 6 years of age or older [2, 3]

AND

3 - Prescribed by or in consultation with a neurologist who has experience treating children

AND

4 - Dose will not exceed 30 milligrams per kilogram of body weight infused once weekly

AND

5 - Submission of medical records (e.g., chart notes, laboratory values) documenting the

patient is ambulatory, as evaluated via the 6-minute walk test (6MWT) or North Star ambulatory assessment (NSAA) [2, 3]

3 . References

1. Vyondys 53 Prescribing Information. Sarepta Therapeutics, Inc. Cambridge, MA. February 2021.
2. Muntoni F, Frank DE, Morgan J, et al. Golodirsen induces exon skipping leading to sarcolemmal dystrophin expression in patients with genetic mutations amenable to exon 53 skipping [abstract]. Neuromuscul Disord. 2018;28:S5. Abstract D01.
3. Per Clinical Consultation with a Pediatrician, April 25, 2019 and January 22, 2020.

4 . Revision History

Date	Notes
2/2/2023	Annual review: No updates required.

Vyvanse (lisdexamfetamine)

Prior Authorization Guideline

Guideline ID	GL-116514
Guideline Name	Vyvanse (lisdexamfetamine)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Vyvanse	
Diagnosis	Attention Deficit Hyperactivity Disorder (ADHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Trial and failure (defined as at least 6 weeks of treatment) to all of the following:

- generic Adderall XR
- generic Concerta
- generic Focalin XR

OR

2 - In cases of concern of stimulant abuse, one of the following:

2.1 Trial and failure of one long-acting formulary stimulant

OR

2.2 Clinical justification as to why formulary long-acting stimulants are contraindicated for the patient

Product Name: Vyvanse	
Diagnosis	Binge Eating Disorder (BED)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of binge eating disorder (BED) confirmed per DSM-5 criteria

AND

2 - Trial and failure of at least two therapeutic alternatives (e.g., SSRIs, topiramate, methylphenidate)

AND

3 - Patient is 18 years of age or older

Product Name: Vyvanse	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/21/2022	2023 New Implementation

Vyvgart (efgartigimod alfa-fcab)

Prior Authorization Guideline

Guideline ID	GL-118755
Guideline Name	Vyvgart (efgartigimod alfa-fcab)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	2/17/2022
P&T Revision Date:	09/21/2022 ; 2/16/2023

1 . Indications

Drug Name: Vyvgart (efgartigimod alfa)
Generalized Myasthenia Gravis (gMG) Indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

2 . Criteria

Product Name: Vyvgart

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis (gMG)

AND

2 - Patient is anti-acetylcholine receptor (AChR) antibody positive

AND

3 - One of the following:

3.1 Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

OR

3.2 Both of the following:

3.2.1 Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

AND

3.2.2 Trial and failure, contraindication, or intolerance to one of the following:

- Chronic plasmapheresis or plasma exchange (PE)
- Intravenous immunoglobulin (IVIG)

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Vyvgart	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . References

1. Vyvgart Prescribing Information. Argenx US, Inc. Boston, MA. April 2022.

4 . Revision History

Date	Notes
1/25/2023	2023 UM Annual Review. No changes to criteria. Updated references

Welireg (belzutifan)

Prior Authorization Guideline

Guideline ID	GL-116564
Guideline Name	Welireg (belzutifan)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Welireg	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Von Hippel-Lindau (VHL) disease with VHL alteration confirmation	

AND

2 - Patient requires therapy for one of the following:

- Renal cell carcinoma
- Pancreatic neuroendocrine tumors
- CNS hemangioblastoma

AND

3 - Patient is not eligible currently for surgery

AND

4 - Patient has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1

AND

5 - Patient is 18 years of age or older

AND

6 - Prescribed by or in consultation with an oncologist

Product Name: Welireg	
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/7/2022	2023 New Implementation

Xalkori (crizotinib)

Prior Authorization Guideline

Guideline ID	GL-116565
Guideline Name	Xalkori (crizotinib)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Xalkori	
Diagnosis	Non-small cell Lung Cancer (NSCLC)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is one of the following:

- Locally advanced
- Metastatic

AND

3 - Submission of medical records (e.g., chart notes) conforming an anaplastic lymphoma kinase (ALK)-positive or ROS1-positive tumor

AND

4 - Patient is 18 years of age or older

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Xalkori	
Diagnosis	anaplastic large cell lymphoma (ALCL)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anaplastic large cell lymphoma (ALCL)

AND

2 - Submission of medical records (e.g., chart notes) conforming an anaplastic lymphoma kinase (ALK) positive tumor

AND

3 - Patient is 1 years of age or older

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Xalkori	
Diagnosis	All indications
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes

10/7/2022	New Implementation

Xeljanz, Xeljanz XR (tofacitinib)

Prior Authorization Guideline

Guideline ID	GL-116595
Guideline Name	Xeljanz, Xeljanz XR (tofacitinib)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Indications

Drug Name: Xeljanz (tofacitinib) tablets, Xeljanz XR (tofacitinib) extended-release tablets
Rheumatoid Arthritis (RA) Indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Xeljanz/Xeljanz XR in combination with biologic disease-modifying antirheumatic drugs (DMARDs) or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended. **Psoriatic Arthritis (PsA)** Indicated for the treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Xeljanz/Xeljanz XR in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended. **Ankylosing Spondylitis (AS)** Indicated for the treatment of adult patients with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Xeljanz/Xeljanz XR in combination with biologic

DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Ulcerative Colitis (UC) Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis, who have an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Xeljanz/Xeljanz XR in combination with biological therapies for UC or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Drug Name: Xeljanz (tofacitinib) tablets and oral solution

Polyarticular Course Juvenile Idiopathic Arthritis Indicated for the treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Xeljanz in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

2 . Criteria

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Rheumatoid Arthritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia, Enbrel, Adalimumab, Simponi)

AND

5 - Not used in combination with biologic DMARDs or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Rheumatoid Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - Not used in combination with biologic DMARDs or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets and oral solution	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active polyarticular course juvenile idiopathic arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:

- leflunomide
- methotrexate

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Enbrel, Adalimumab)

AND

5 - Not used in combination with biologic DMARDs or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Xeljanz may be used with concomitant methotrexate, topical or inhal ed corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets and oral solution	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline

- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - Not used in combination with biologic DMARDs or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Xeljanz may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Psoriatic Arthritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis (PsA)

AND

2 - One of the following [5]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia, Enbrel, Adalimumab, Simponi)

AND

5 - Not used in combination with biologic DMARDs or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 5]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline

- Reduction in the body surface area (BSA) involvement from baseline

AND

2 - Not used in combination with biologic DMARDs or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [6]

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia, Enbrel, Adalimumab, Simponi)

AND

5 - Not used in combination with biologic DMARDs or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following [1, 6]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

AND

2 - Not used in combination with biologic DMARDs or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Ulcerative Colitis
Approval Length	4 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [7, 8]:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, ESR, CRP)
- Dependent on, or refractory to, corticosteroids

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [7, 8]:

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND

4 - Prescribed by or in consultation with a gastroenterologist

AND

5 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Adalimumab, Simponi)

AND

6 - Not used in combination with biological therapies for UC or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 7, 8]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

AND

2 - Not used in combination with biological therapies for UC or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

3 . Endnotes

A. Initial approval length of 4 months based on dosing recommendation provided in the labeling of Xeljanz 10 mg twice daily or Xeljanz XR 22 mg once daily for at least 8 weeks, followed by Xeljanz 5 mg once or twice daily, 10 mg twice daily, or Xeljanz XR 11 mg once daily depending on therapeutic response. Xeljanz should be discontinued after 16 weeks (4 months) of treatment with Xeljanz 10 mg twice daily or Xeljanz XR 22 mg once daily if adequate therapeutic response is not achieved.

4 . References

1. Xeljanz, Xeljanz XR Prescribing Information. Pfizer, Inc. New York, NY. January 2022.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.
3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.

4. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. Arthritis Rheumatol. 2019;71(6):846-863.
5. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
6. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis Rheumatol. 2019;71(10):1599-1613.
7. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. Am J Gastroenterol 2019;114:384–413.
8. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterol. 2020;158:1450-1461.

5 . Revision History

Date	Notes
10/28/2022	Bulk copy OptumRx SP to Samaritan SP for 1/1/2023 Implementation

Xenpozyme (olipudase alfa)

Prior Authorization Guideline

Guideline ID	GL-114909
Guideline Name	Xenpozyme (olipudase alfa)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	12/1/2022
P&T Approval Date:	11/17/2022
P&T Revision Date:	

1 . Indications

Drug Name: Xenpozyme (olipudase alfa)
Acid Sphingomyelinase Deficiency (ASMD) Indicated for treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients.

2 . Criteria

Product Name: Xenpozyme	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acid sphingomyelinase deficiency (ASMD)*

AND

2 - Disease confirmed by ONE of the following: [2]

2.1 Molecular genetic testing confirms biallelic pathogenic variants in the SMPD1 (sphingomyelin phophodiesterase-1) gene

OR

2.2 Residual acid sphingomyelinase activity that is less than 10% of controls (in peripheral blood lymphocytes or cultured skin fibroblasts)

AND

3 - Submission of medical records (e.g., chart notes) documenting patient has non-central nervous system manifestations of ASMD

AND

4 - Prescribed by or in consultation with ONE of the following:

- Metabolic disease specialist

• Geneticist	
Notes	*Acid Sphingomyelinase Deficiency is also known as Niemann-Pick Di sease types A, A/B, and B [1]

Product Name: Xenpozyme	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy (e.g., decrease in spleen size, decrease in liver size, increase in platelet count, improved lung function)

3 . References

1. Healthcare professional brochure. Available at www.xenpozyme.com/pdfs/v0.0.1/hcp/hcp-brochure.pdf. Accessed October 4, 2022.
2. Wasserstein, M., Schuchman, E., et al. Acid Sphingomyelinase Deficiency. Available at https://pubmed.ncbi.nlm.nih.gov/20301544/. Accessed October 4, 2022.
3. McGovern, M., Dionisi-Vici, C., et al. Consensus recommendation for a diagnostic guideline for acid sphingomyelinase deficiency. Available at https://pubmed.ncbi.nlm.nih.gov/28406489/. Accessed October 4, 2022.
4. Living with ASMD. Available at Proactive Symptom Management While Living with ASMD (asmdfacts.com). Accessed October 4, 2022.
5. Xenpozyme prescribing information. Cambridge, MA. Genzyme Corporation. August 2022.

4 . Revision History

Date	Notes

11/21/2022	New UM PA criteria

Xeomin (incobotulinumtoxinA)

Prior Authorization Guideline

Guideline ID	GL-111552
Guideline Name	Xeomin (incobotulinumtoxinA)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	11/1/2022
P&T Approval Date:	11/14/2011
P&T Revision Date:	09/16/2020 ; 10/21/2020 ; 02/18/2021 ; 04/21/2021 ; 09/15/2021 ; 9/21/2022

1 . Indications

Drug Name: Xeomin (incobotulinumtoxinA)
Blepharospasm Indicated for the treatment of blepharospasm in adults. **Cervical Dystonia** Indicated for the treatment of cervical dystonia in adults. **Chronic Sialorrhea** Indicated for the treatment of chronic sialorrhea in patients 2 years of age and older. **Adult Upper Limb Spasticity** Indicated for the treatment of upper limb spasticity in adults. **Pediatric Upper Limb Spasticity** Indicated for the treatment of upper limb spasticity in

pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy.

Glabellar Lines* Is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adults. *Note: Use of Xeomin for the improvement in the appearance of glabellar lines is excluded, as this is considered a cosmetic use.

2 . Criteria

Product Name: Xeomin	
Diagnosis	Cervical Dystonia (also known as spasmodic torticollis)
Approval Length	3 months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cervical dystonia (also known as spasmodic torticollis) [1]

Product Name: Xeomin	
Diagnosis	Cervical Dystonia (also known as spasmodic torticollis)
Approval Length	3 months [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Confirmed improvement in symptoms with initial treatment

AND

2 - At least 3 months have elapsed or will have elapsed since the last treatment [1]

Product Name: Xeomin	
Diagnosis	Blepharospasm
Approval Length	3 months [1, B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of blepharospasm

Product Name: Xeomin	
Diagnosis	Blepharospasm
Approval Length	3 months [1, 4, C]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Confirmed improvement in symptoms with initial treatment

AND

2 - At least 3 months have elapsed or will have elapsed since the last treatment [C]

Product Name: Xeomin	
Diagnosis	Upper Limb Spasticity
Approval Length	3 months [1, 3]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of upper limb spasticity [1]

AND

2 - Patient is 2 years of age or older

Product Name: Xeomin	
Diagnosis	Upper Limb Spasticity
Approval Length	3 months [1, 3, D]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Confirmed improvement in symptoms with initial treatment

AND

2 - At least 3 months have elapsed or will have elapsed since the last treatment [D]

Product Name: Xeomin	
Diagnosis	Chronic Sialorrhea
Approval Length	3 months [1, D]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic sialorrhea

AND

2 - Patient is 2 years of age or older

Product Name: Xeomin	
Diagnosis	Chronic Sialorrhea
Approval Length	3 months [1, D]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Confirmed improvement in symptoms with initial treatment

AND

2 - At least 4 months have elapsed or will have elapsed since the last treatment [E]

3 . Endnotes

A. In a randomized, double-blind, active-controlled, parallel group study, 463 patients with a documented stable therapeutic response to Botox as a result of the last two consecutive injection sessions directly prior to trial entry (70 to 300 Units) were included. Patients in the study received IM injections of 70 to 300 Units of Xeomin or Botox, based on the previous two consecutive doses of Botox prior to study entry. [2]
B. The total initial dose of Xeomin in both eyes should not exceed 50 Units (25 Units/eye). [1]
C. The median onset of treatment effect with incobotulinumtoxinA was 4 days (range, 0 to 30 days), time to waning of treatment effect was 6 weeks (range 1 to 15 weeks), and duration of treatment effect was 10.6 weeks (range, 6.1 to 19.1 weeks). [4]
D. The typical duration of effect of each treatment is up to 12-16 weeks; however, the duration of effect may vary in individual patients. [1]
E. The timing for repeat treatment of chronic sialorrhea should be determined based on the actual clinical need of the individual patient, and no sooner than every 16 weeks (4 months). [1]

4 . References

1. Xeomin prescribing information. Merz Pharmaceuticals, LLC. Raleigh, NC. August 2021.
2. Benecke R, Jost WH, Kanovsky P, Ruzicka E, Comes G, Grafe S. A new botulinum toxin type A free of complexing proteins for treatment of cervical dystonia. Neurology. 2005;64:1949-1951.
3. Kanovsky P, Slawek J, Denes Z, et al. Efficacy and safety of treatment with incobotulinum toxin A (botulinum neurotoxin type A free from complexing proteins; NT 201) in post-stroke upper limb spasticity. J Rehabil Med 2011; 43(6):486-492.
4. Jankovic J, Comella C, Hanschmann A, et al. Efficacy and safety of incobotulinumtoxinA (NT 201, Xeomin) in the treatment of blepharospasm-a randomized trial. Mov Disord 2011; 26(8):1521-1528.

5 . Revision History

Date	Notes
9/6/2022	Annual review - added age criterion to chronic sialorrhea and upper li mb spasticity indications to align with prescribing information. Updat ed references.

Xiaflex (collagenase clostridium histolyticum)

Prior Authorization Guideline

Guideline ID	GL-123250
Guideline Name	Xiaflex (collagenase clostridium histolyticum)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	2/25/2016
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Xiaflex (collagenase clostridium histolyticum)
Dupuytren's Contracture Indicated for the treatment of adult patients with Dupuytren's contracture with a palpable cord. **Peyronie's Disease** Indicated for the treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy.

2 . Criteria

Product Name: Xiaflex	
Diagnosis	Dupuytren's contracture
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Dupuytren's contracture with a palpable cord

AND

2 - Patient has a positive "table top test" (defined as the inability to simultaneously place the affected finger and palm flat against a table top) [A]

AND

3 - Patient has a documented contracture of at least 20 degrees flexion for a metacarpophalangeal joint or a proximal interphalangeal joint [B]

AND

4 - Patient has a flexion deformity that results in functional limitations

Product Name: Xiaflex	
Diagnosis	Peyronie's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Peyronie's disease

AND

2 - Patient has a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy [C]

AND

3 - The plaques do not involve the penile urethra

AND

4 - Patient has a curvature deformity that results in pain (e.g., pain upon erection or intercourse) [C]

Product Name: Xiaflex	
Diagnosis	Peyronie's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Peyronie's disease

AND

2 - Patient has a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy

AND

3 - The plaques do not involve the penile urethra

AND

4 - Patient has a curvature deformity that results in pain (e.g., pain upon erection or intercourse)

AND

5 - Patient has a new plaque that results in a curvature deformity

3 . Endnotes

A. Dupuytren's disease diagnosis can include a table top test to assess the severity of the disease. When a patient is unable to place his or her palm and the affected finger flat on the table, the test can help diagnosis Dupuytren's disease. [1]
B. Dupuytren's disease is associated with joint contracture. Xiaflex was studied in a patient population with joint contracture of at least 20 degrees. Evidence does not support any benefit in patients with joint contracture less than 20 degrees. Our program requires that the patient has a flexion deformity that results in functional limitations to protect against cosmetic use. [1]
C. Peyronie's disease is characterized by a curvature deformity. Xiaflex was studied in a patient population with a curvature deformity of at least 30 degrees. Evidence does not support any benefit in patients with a curvature deformity less than 30 degrees. To

prevent cosmetic use, patients must also have a curvature deformity that results in pain. [1]

4 . References

1. Xiaflex Prescribing Information. Endo Pharmaceuticals, Inc. Malvern, PA. July 2022.

5 . Revision History

Date	Notes
3/28/2023	2023 Annual Review. No criteria changes. Updated references

Xifaxan (rifaximin)

Prior Authorization Guideline

Guideline ID	GL-116491
Guideline Name	Xifaxan (rifaximin)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Xifaxan 550 mg tablets	
Diagnosis	Irritable Bowel Syndrome with Diarrhea (IBS-D)
Approval Length	14 Day(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of irritable bowel syndrome with diarrhea (IBS-D)

Product Name: Xifaxan 550 mg tablets	
Diagnosis	Irritable Bowel Syndrome with Diarrhea (IBS-D)
Approval Length	30 Day(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Xifaxan 550 mg tablets	
Diagnosis	Hepatic Encephalopathy (HE)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatic encephalopathy (HE)

AND

2 - One of the following:

2.1 Both of the following:

- Used as add-on therapy to lactulose

- Patient unable to achieve an optimal clinical response with lactulose monotherapy

OR

2.2 History of contraindication or intolerance to lactulose

Product Name: Xifaxan 550 mg tablets	
Diagnosis	Hepatic Encephalopathy (HE)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
10/24/2022	2023 New Implementation

Xiidra (lifitgrast)

Prior Authorization Guideline

Guideline ID	GL-116488
Guideline Name	Xiidra (lifitgrast)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Xiidra	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of lack of tear production due to ocular inflammation associated with keratoconjunctivitis sicca

AND

2 - One of the following:

2.1 Patient is not currently using a topical ophthalmic anti- inflammatory drug or punctal plug

OR

2.2 Both of the following:

2.2.1 The patient's current use of topical ophthalmic anti-inflammatory drug (e.g., ketorolac, diclofenac, flurbiprofen) or punctal plug will be discontinued before starting the requested agent

AND

2.2.2 The patient has previously tried or is currently using aqueous enhancements (e.g., artificial tears, gels, ointments)

OR

2.3 Patient has a documented intolerance, contraindication, or hypersensitivity to aqueous enhancements.

AND

3 - One of the following:

- Patient is not currently using Restasis
- The patient's current use of Restasis will be discontinued before starting Xiidra.

Product Name: Xiidra	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
9/28/2022	2023 New Implementation

Xipere (triamcinolone acetonide injectable suspension)

Prior Authorization Guideline

Guideline ID	GL-119348
Guideline Name	Xipere (triamcinolone acetonide injectable suspension)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	1/19/2022
P&T Revision Date:	2/16/2023

1 . Indications

Drug Name: Xipere
Uveitis Indicated for the treatment of macular edema associated with uveitis.

2 . Criteria

Product Name: Xipere	
Diagnosis	Uveitis

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of macular edema due to uveitis is confirmed by ONE of the following tests: [2, 3]

- Slit lamp exam
- Fundoscopic exam
- Fluorescein angiography
- Optical coherence tomography (OCT)

AND

2 - Patient is free of ocular and peri-ocular infections [1]

AND

3 - Patient does not have untreated intraocular pressure or uncontrolled glaucoma [1]

AND

4 - Trial and failure, contraindication or intolerance to at least ONE other corticosteroid (e.g., methylprednisolone, Ozurdex, prednisolone, prednisone, triamcinolone) [3]

AND

5 - Patient has not received any of the following sustained-release intravitreal corticosteroids: [4, 5]

- Dexamethasone (e.g., Ozurdex) within the past 6 months
- Fluocinolone acetonide within the past 30 months (e.g., Retisert) or 36 months (e.g., Iluvien, Yutiq)

AND

6 - Prescribed by or in consultation with an ophthalmologist

Product Name: Xipere	
Diagnosis	Uveitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., improvement in Best Corrected Visual Acuity, stable vision)

AND

2 - Prescribed by or in consultation with an ophthalmologist

3 . References

1. Xipere Prescribing Information. Clearside Biomedical, Inc. Alpharetta, GA. February 2022.
2. National Organization for Rare Disorders. Posterior Uveitis. Available at https://rarediseases.org/rare-diseases/posterior-uveitis/. Acessed December 19, 2021
3. Koronis, S., Stavrakas, P., et al. Update in Treatment of Uveitic Macular Edema. Available at https://www.dovepress.com/update-in-treatment-of-uveitic-macular-edema-peer-reviewed-fulltext-article-DDDT. Accessed December 19, 2021.

4. Haghjou, N., Soheilian, M., et al. Sustained Release Intracoular Drug Delivery Devices for Treatment of Uveitis. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3306122/. Accessed December 19, 2021.
5. Yutiq Prescribing Information. EyePoint Pharmaceuticals, Inc. Watertown, MA. October 2018.

4 . Revision History

Date	Notes
1/3/2023	2023 Annual Review.

Xolair (omalizumab)

Prior Authorization Guideline

Guideline ID	GL-117528
Guideline Name	Xolair (omalizumab)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023

1 . Criteria

Product Name: Xolair	
Diagnosis	Severe asthma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of moderate to severe persistent asthma

AND

2 - Submission of medical records (e.g., chart notes) confirming smoking status

AND

3 - Positive skin test or RAST to a perennial aeroallergen

AND

4 - Submission of medical records (e.g., chart notes) confirming baseline IgE serum level within FDA label

AND

5 - Submission of medical records (e.g., chart notes) confirming the steps taken to avoid within reason environmental allergens and other triggers

AND

6 - Submission of medical records (e.g., chart notes) confirming trial and failure of one of the following:

- High dose inhaled corticosteroid with a long-acting beta agonist (e.g., Advair)
- Long acting anti-muscarinic (e.g., Spiriva)
- Leukotriene Inhibitor (e.g., Singulair)

AND

7 - Submission of medical records (e.g., chart notes) confirming trial and failure, contraindication to an allergen immunotherapy (e.g. subq immunotherapy, sublingual immunotherapy, grastek)

AND

8 - Submission of medical records (e.g., chart notes or claims review) confirming compliance/adherence with prescribed asthma medications

AND

9 - Patient is 6 years of age or older

AND

10 - Prescribed by or in consultation with a pulmonologist or immunologist

Product Name: Xolair	
Diagnosis	Severe asthma
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Xolair	
Diagnosis	Nasal Polyps

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming recurrent nasal polyps after prior sinus surgery

AND

2 - Trial and failure of at least 2 intranasal corticosteroids (e.g. mometasone, Beconase AQ) and Sinuva nasal implant

AND

3 - Submission of medical records (e.g., chart notes) confirming adherence to a nasal corticosteroid with Xolair intended as adjunct therapy

AND

4 - Submission of medical records (e.g., chart notes) confirming risk of another sinus surgery, or a statement why sinus surgery is not medically appropriate

AND

5 - Patient is 18 years of age or older

AND

6 - Prescribed by or in consultation with an allergist or ear nose throat specialist

Product Name: Xolair	
Diagnosis	Nasal Polyps
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Xolair	
Diagnosis	Idiopathic chronic urticaria- refractory
Approval Length	4 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic spontaneous or idiopathic urticaria

AND

2 - Submission of medical records (e.g., chart notes) confirming trial and failure (including dose escalation) of both first and second- generation antihistamines for at least 6 weeks:

- 1st generation antihistamnes (e.g., doxepin, hydroxyzine)

- 2nd generation antihistamines (e.g., cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine)

AND

3 - Submission of medical records (e.g., chart notes) confirming trial and failure of an H2 antihistamine (e.g., famotidine, cimetidine)

AND

4 - Submission of medical records (e.g., chart notes) confirming trial and failure (at least 4 weeks) of, or contraindication to a leukotriene inhibitor (e.g., montelukast, zafirlukast)

AND

5 - Patient is 12 years of age or older

AND

6 - Prescribed by or in consultation with an immunologist or allergist

Product Name: Xolair	
Diagnosis	Idiopathic chronic urticaria- refractory
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Zoladex (goserelin)

Prior Authorization Guideline

Guideline ID	GL-126575
Guideline Name	Zoladex (goserelin)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/1/2023

1 . Criteria

Product Name: Zoladex (goserelin)	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient is diagnosed with prostate cancer

AND

2 - Drug is being used for one of the following:

2.1 In combination with first generation antiandrogen therapy for management of stage T2b-T4 with radiation therapy with one of the following:

- Bicalutamide, or
- Flutamide, or
- Nilutamide

OR

2.2 Adjuvant therapy for lymph node positive disease found during pelvic lymph node dissection (PLND)

OR

2.3 Initial androgen deprivation therapy for one of the following risk groups:

- Intermediate risk group; or
- High or very high risk group; or
- Regional risk group; or
- Metastatic disease

OR

2.4 Palliative treatment of advanced/metastatic prostate cancer

OR

2.5 Recurrent disease in patients who experienced treatment failure after previous therapy

OR

2.6 Progressive castration-naïve disease

AND

3 - Prescribed by or in consultation with an oncologist or urologist

Product Name: Zoladex (goserelin)	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is diagnosed with breast cancer

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient is premenopausal

AND

2.1.2 Patient has hormone receptor (HR)-positive disease in combination with one of the following:

- Adjuvant endocrine therapy; or
- Endocrine therapy for recurrent or metastatic disease

OR

2.2 Both of the following:

2.2.1 Patient is undergoing (neo)-adjuvant chemotherapy

AND

2.2.2 Patient has early-stage breast cancer

OR

2.3 All of the following:

2.3.1 Patient has advanced breast cancer

AND

2.3.2 One of the following:

- Patient is premenopausal; or
- Patient is perimenopausal; or
- Patient is male with suppression of testicular steroidogenesis

AND

2.3.3 Treatment is palliative

AND

3 - Prescribed in consultation with an oncologist

Product Name: Zoladex (goserelin)	
Diagnosis	Prostate Cancer, Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Revision History

Date	Notes
6/15/2023	New program

Zolgensma (onasemnogene abeparvovec-xioi) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-126111
Guideline Name	Zolgensma (onasemnogene abeparvovec-xioi) - PA, NF
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	
P&T Revision Date:	06/17/2020 ; 11/12/2020 ; 04/21/2021 ; 06/16/2021 ; 06/15/2022 ; 12/14/2022 ; 6/21/2023

1 . Indications

Drug Name: Zolgensma (onasemnogene abeparvovec-xioi)
Spinal Muscular Atrophy (SMA) Indicated for the treatment of pediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene. Limitation of Use: • The safety and effectiveness of repeat administration of ZOLGENSMA have not been evaluated. • The use of ZOLGENSMA in patients with advanced SMA (e.g., complete paralysis of limbs, permanent ventilator dependence) has not been evaluated.

2 . Criteria

Product Name: Zolgensma	
Approval Length	1 Time Authorization in Lifetime
Guideline Type	Prior Authorization

Approval Criteria

1 - The mutation or deletion of genes in chromosome 5q resulting in one of the following: [1-8, A]

1.1 Homozygous gene deletion or mutation of SMN1 gene (e.g., homozygous deletion of exon 7 at locus 5q13)

OR

1.2 Compound heterozygous mutation of SMN1 gene (e.g., deletion of Survival of Motor Neuron 1 [SMN1] exon 7 [allele 1] and mutation of SMN1 [allele 2])

AND

2 - One of the following:

2.1 Both of the following: [1-5]

2.1.1 Diagnosis of symptomatic spinal muscular atrophy (SMA) confirmed by a neurologist with expertise in the diagnosis and treatment of SMA [B]

AND

2.1.2 Patient is less than or equal to 2 years of age

OR

2.2 All of the following:

2.2.1 Diagnosis of SMA based on the results of SMA newborn screening

AND

2.2.2 Patient has 4 copies or less of Survival of Motor Neuron 2 (SMN 2)

AND

2.2.3 Patient is less than or equal to 6 months of age [2-5]

AND

3 - Patient is not dependent on invasive ventilation or tracheostomy [2-5, C]

AND

4 - Patient is not dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep [2-5, C]

AND

5 - Documentation of anti-AAV9 antibody titers being less than or equal to 1:50 [1]

AND

6 - Patient is not to receive concomitant chronic survivor motor neuron (SMN) modifying therapy for the treatment of SMA (e.g. Spinraza, Evrysdi) [2-5,D]

AND

7 - Prescribed by a neurologist with expertise in the diagnosis and treatment of SMA

AND

8 - Patient has never received Zolgensma treatment in their lifetime [1]

Product Name: Zolgensma	
Approval Length	1 Time Authorization in Lifetime
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting the mutation or deletion of genes in chromosome 5q resulting in one of the following: [1-8, A]

1.1 Homozygous gene deletion or mutation of SMN1 gene (e.g., homozygous deletion of exon 7 at locus 5q13)

OR

1.2 Compound heterozygous mutation of SMN1 gene (e.g., deletion of Survival of Motor Neuron 1 [SMN1] exon 7 [allele 1] and mutation of SMN1 [allele 2])

AND

2 - One of the following:

2.1 Both of the following: [1-5]

2.1.1 Diagnosis of symptomatic spinal muscular atrophy (SMA) confirmed by a neurologist with expertise in the diagnosis and treatment of SMA [B]

AND

2.1.2 Patient is less than or equal to 2 years of age

OR

2.2 All of the following:

2.2.1 Diagnosis of SMA based on the results of SMA newborn screening

AND

2.2.2 Patient has 4 copies or less of Survival of Motor Neuron 2 (SMN 2)

AND

2.2.3 Patient is less than or equal to 6 months of age [2-5]

AND

3 - Patient is not dependent on invasive ventilation or tracheostomy [2-5, C]

AND

4 - Patient is not dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep [2-5, C]

AND

5 - Submission of medical records (e.g., chart notes) documenting anti-AAV9 antibody titers being less than or equal to 1:50 [1]

AND

6 - Patient is not to receive concomitant chronic survivor motor neuron (SMN) modifying therapy for the treatment of SMA (e.g. Spinraza, Evrysdi) [2-5,D]

AND

7 - Prescribed by a neurologist with expertise in the diagnosis and treatment of SMA

AND

8 - Patient has never received Zolgensma treatment in their lifetime [1]

3 . Endnotes

A. This is the definition that the clinical trials used. Also consistent with clinical guidelines. [2-8]
B. There were 3 key clinical trials for Zolgensma (START, STR1VE, SPR1NT). START and STR1VE only enrolled patients with SMA Type 1 and SPR1NT enrolled pre-symptomatic SMA patients. [2-5]
C. Exclusion criteria found in clinical trials. [2-5]
D. A recent European ad-hoc consensus statement on SMA stated that there currently is no published evidence that the combination of two disease modifying therapies (e.g., Spinraza and Zolgensma) is superior to any single treatment alone. RESPOND is a phase

4 trial that will assess the efficacy and safety of Spinraza in patients with suboptimal clinical response to Zolgensma. It is planned to begin enrollment in 2021. [9-10]

4 . References

1. Zolgensma Prescribing Information. AveXis Inc. Bannockburn, IL. October 2021.
2. Mendell J.R., Al-Zaidy S, Shell R, etc. Single-Dose Gene Replacement Therapy for Spinal Muscular Atrophy. New Eng J of Med. 2017; 377:1713-22.
3. Al-Zaidy S, Pickard AS, Kotha K, et al. Health outcomes in spinal muscular atrophy type 1 following AVXS-101 gene replacement therapy. Pediatr Pulmonol. 2019;54(2):179-185.
4. Day JW, Chiriboga CA, Crawford TO, et al. AVXS-101 gene-replacement therapy for spinal muscular atrophy type 1: phase 3 study (STR1VE) update. Poster presented at: The 71st Annual American Academy of Neurology Meeting, Philadelphia PA, May 4-10, 2019.
5. Strauss KA, Swoboda KJ, Farrar MA, et al. AVXS-101 gene-replacement therapy in presymptomatic spinal muscular atrophy: SPR1NT study update. Poster presented at the 71st Annual American Academy of Neurology Meeting; May 4-10; 2019; Philadelphia, PA.
6. Markowitz JA, Sing P, Darras BT. Spinal muscular atrophy: a clinical and research update. Pediatr Neurol. 2012;46(1):1-12.
7. Wang CH, Finkel RS, Bertini ES, et al. Consensus statement for standard of care in spinal muscular atrophy. J Child Neurol. 2007;22(8):1027-1049.
8. Mercuri E, Finkel RS, Muntoni F, et al. Diagnosis and management of spinal muscular atrophy: Part 1: Recommendations for diagnosis, rehabilitation, orthopedic and nutritional care. J Neuromuscul Dis. 2018;28(2):103-115.
9. Kirschner J, Butoianu N, Goemans N, et al. European ad-hoc consensus statement on gene replacement therapy for spinal muscular atrophy. Eur J Paediatr Neurol. 2020. https://doi.org/10.1016/j.ejpn.2020.07.001.
10. Biogen. Biogen plans to initiate phase 4 study evaluating benefit of Spinraza® (nusinersen) in patients treated with Zolgensma® (onasemnogene abeparvovec). https://investors.biogen.com/news-releases/news-release-details/biogen-plans-initiate-phase-4-study-evaluating-benefit-spinrazar. July 21, 2020. Accessed October 6, 2020.

5 . Revision History

Date	Notes
6/19/2023	Annual Review

Zulresso (brexanolone)

Prior Authorization Guideline

Guideline ID	GL-124083
Guideline Name	Zulresso (brexanolone)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	5/16/2019
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 05/19/2022 ; 08/18/2022 ; 5/18/2023

1 . Indications

Drug Name: Zulresso (brexanolone)
Postpartum Depression (PPD) Indicated for the treatment of PPD in patients 15 years of age or older.

2 . Criteria

Product Name: Zulresso

Approval Length	30 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of postpartum depression (PPD)

AND

2 - Patient is 15 years of age or older

AND

3 - Onset of symptoms during the third trimester of pregnancy or within 4 weeks of delivery [1, 2]

AND

4 - Patient is 6 months postpartum or less [2]

AND

5 - Prescribed by or in consultation with a psychiatrist

3 . References

1. Zulresso Prescribing Information. Sage Therapeutics, Inc. Cambridge, MA. June 2022.
2. Psychopharmacologic Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee Meeting. FDA Briefing Document. November 2, 2018. Available at: https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Dr

ugs/PsychopharmacologicDrugsAdvisoryCommittee/UCM624643.pdf. Accessed March 31, 2023.

4 . Revision History

Date	Notes
5/4/2023	Annual review: Background updates.

Zykadia (ceritinib)

Prior Authorization Guideline

Guideline ID	GL-118637
Guideline Name	Zykadia (ceritinib)
Formulary	• Samaritan Large Group

Guideline Note:

Effective Date:	1/1/2023
P&T Approval Date:	
P&T Revision Date:	

1 . Criteria

Product Name: Zykadia	
Approval Length	3 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Medication is being used for FDA approved indication

OR

1.2 Diagnosis is supported as a use in the National Cancer network (NCCN) Drugs and Biologics Compendium with a category of Evidence and Consensus of 1, 2A, or 2B

AND

2 - Prescribed by or in consultation with an oncologist or hematologist

Product Name: Zykadia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

2 . Background

Benefit/Coverage/Program Information	
NCCN Categories of Evidence and Consensus:	
Category	**Level of Consensus**

1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

3 . Revision History

Date	Notes
12/20/2022	Update guideline