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 9/1/2025. For more recent information or other questions, please contact Pharmacy Services at **541-768-4550** or toll free **800-832-4580** (TTY 800-735-2900) or visit **samhealthplans.org**. Pharmacy Services is available Monday through Friday, from 8 a.m. to 5 p.m.

Prior Authorization Guideline

Guideline Name	Maximum Dosage and Frequency Policy

Guideline Note:

Effective Date:	9/1/2024

Note:

Dosing and frequency are based on U.S. Food and Drug Administration (FDA) approved drug dosage and frequency limits, manufacturer, and clinical recommendations.

1 . Criteria

Approval Length	6 month(s)
Guideline Type	Administrative

Approval Criteria

1 - The drug dosage, frequency and route of administration going above the maximum recommended dosage may be considered on an individual basis for an approved indication when supported by ONE or more of the following:

- Micromedex DRUGDEX System
- National Comprehensive Cancer Network (NCCN) Drug & Biologics Compendium
- American Hospital Formulary Service Drug Information (AHFS) Drug Information
- The quantity is supported by clinical research in two articles from major peer reviewed medical journals that present data supporting the proposed dose and frequency as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal

Prior Authorization Guideline

Guideline Name	Oncology Admin - Optum Specialty Fusion & Cancer Guidance Program (MBM)

Guideline Note:

Effective Date:	8/1/2022

Note:

This guideline should be used for clients who have elected to participate in the Optum Specialty Fusion program or Medical Benefit Management (MBM) Cancer Guidance Program to review in scope drugs when used for cancer indications.

1 . Criteria

Product Name:In Scope Drug	
Diagnosis	Cancer Indications
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria	

1 - The drug is being used as indicated by National Comprehensive Cancer Network (NCCN) guidelines with a Category of Evidence and Consensus of 1, 2A, or 2B

Prior Authorization Guideline

Guideline Name	Provider Administered Drugs - Site of Care Policy

Guideline Note:

Effective Date:	9/1/2024

1 . Criteria

Approval Length	6 Months*
Guideline Type	Administrative

Approval Criteria

1 - History of severe adverse event following infusion (i.e., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure) that require a more intense level of care and have not been successfully managed through pre-medications (e.g., diphenhydramine, acetaminophen, steroids, fluids, etc.)

OR

2 - Conditions that cause an increased risk for severe adverse event (i.e., unstable renal function, cardiopulmonary conditions, unstable vascular access)

OR

3 - Complex patient status that requires enhanced monitoring beyond the capabilities of the office or home infusion settings

OR

4 - To start new therapy or re-initiate products for a short duration (note: approval will be for 4 weeks)

OR

5 - Outpatient treatment in the office setting or home setting present a health risk due to a clinically significant physical or cognitive impairment

OR

6 - If the prescriber cannot infuse in the office location: homecare or infusion provider has deemed that the individual, caregiver, or home environment is not suitable for infusion therapy

Notes	*Authorization duration will be for up to 6 months at which time a reassessment of the individual's ability to receive therapy at a n alternative site of care must be considered.

Prior Authorization Guideline

Guideline Name	Specialty Drugs Admin - Optum Specialty Fusion & Specialty Guidance Program (MBM)

Guideline Note:

Effective Date:	4/1/2025

Note:

This guideline should be used for clients who have elected to participate in the Optum Specialty Fusion program or Medical Benefit Management (MBM) Cancer Guidance Program to review in scope drugs when used for cancer indications.

1 . Criteria

Product Name:In Scope Drug	
Diagnosis	Non-Cancer Indications
Approval Length	12 month(s)
Guideline Type	Administrative**
Approval Criteria	

1 - Medical Necessity: This health plan will provide coverage for medically necessary services when it is determined that the medical criteria and guidelines below are met:

1.1 General:

1.1.1 Service is medically appropriate for the symptoms and diagnosis, treatment of the condition, illness, disease or injury and is consistent with generally accepted professional medical standards of care (e.g., not experimental or unproven)

AND

1.1.2 Service is provided for the diagnosis or the direct care and treatment of the member's condition, illness, disease or injury

AND

1.1.3 Service is in accordance with generally accepted practice standards of good medical practice in the community

AND

1.1.4 Service is not primarily for the convenience of the patient, the patient's family or the patient's provider

AND

1.1.5 Service or supply must not be experimental, investigational, or cosmetic in purpose

Notes	**Only the member's medical condition is considered when deci ding medical necessity. The fact that a physician ordered, presc ribed, recommended, or approved a service or supply does not, i n itself, make the services medically necessary.

Prior Authorization Guideline

Guideline Name	Abrysvo (Respiratory syncytial virus vaccine)

Guideline Note:

Effective Date:	11/16/2023

1 . Criteria

Product Name:Abrysvo	
Approval Length	1 month(s)
Guideline Type	Prior Authorization
Approval Criteria **1** - Member is pregnant between 32 and 26 weeks gestational age	

Prior Authorization Guideline

Guideline Name	Actimmune (interferon Gamma-1b) - SAMLG

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

Prior Authorization Guideline

Guideline Name	Acute Infectious Disease

Guideline Note:

Effective Date:	9/21/2023

Note:

All drugs are part of Optum Specialty Fusion program.

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

Prior Authorization Guideline

Guideline Name	Adakveo (crizanlizumab-tmca)

Guideline Note:

Effective Date:	7/1/2025

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 hydroxyurea

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 - Patient demonstrates 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; June 2024.
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.

Prior Authorization Guideline

Guideline Name	Adasuve (loxapine)

Guideline Note:

Effective Date:	5/1/2025

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 a certified healthcare setting.

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.

Adstiladrin (nadofaragene firadenovec-vncg)

Prior Authorization Guideline

Guideline Name	Adstiladrin (nadofaragene firadenovec-vncg)

Guideline Note:

Effective Date:	6/1/2025

1 . Indications

Drug Name: Adstiladrin (nadofaragene firadenovec-vncg)
non-Muscle Invasive Bladder Cancer (NMIBC) Indicated the treatment of adult patients with high-risk Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

2 . Criteria

Product Name:Adstiladrin	
Approval Length	6 months [B-C, 1, 5]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of high-risk, non-Muscle Invasive Bladder Cancer (NMIBC)

AND

2 - Tumor is carcinoma in situ (CIS) with or without papillary tumors

AND

3 - Patient is not eligible for or has elected not to undergo cystectomy

AND

4 - Patient has received an adequate course of Bacillus Calmette Guérin (BCG) therapy defined as the administration of at least 5 of 6 doses of an initial induction course plus one of the following: [A, 2, 5]

- At least two of three doses of maintenance therapy
- At least two of six doses of a second induction course

AND

5 - Tumor is BCG unresponsive as defined by one of the following: [A, 2, 5]

- Persistent disease following adequate BCG therapy
- Disease recurrence after an initial tumor-free state following adequate BCG therapy
- T1 disease following a single induction course of BCG

AND

6 - The patient has had all resectable disease (Ta and T1 components) removed [1]

AND

7 - The patient does not have extra-vesical (i.e., urethra, ureter, or renal pelvis), muscle invasive (T2-T4), or metastatic urothelial carcinoma [1]

Product Name:Adstiladrin	
Approval Length	12 months [C-D, 1, 5]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy [1, 5]

3 . Endnotes

A. BCG is typically given weekly for 6 weeks at induction followed by maintenance of 3 weekly instillations at month 3, 6, 12, 18, 24, 30, and 36. Two 6-week BCG induction courses should be completed before the patient is considered non responsive to the therapy. Adequate BCG was defined as the administration of at least five of six doses of an initial induction course plus either at least two of three doses of maintenance therapy or at least two of six doses of a second induction course [2]
B. After the first administration of Adstiladrin, patients with no evidence of high-grade disease continue to receive further treatment with Adstiladrin every three months up to Month 12. Thereafter, patients continue to receive Adstiladrin every 3 months, at the discretion of the investigator, provided there is no evidence of high grade disease [5]
C. Patients received 75 mL (3 x 1011 vp/mL) Adstiladrin administered intravesically once every 3 months for up to 12 months. All patients with an absence of high-risk recurrence or progression were offered continued treatment every 3 months beyond 12 months [1]

4 . References

1. Adstiladrin prescribing information. Kuopio, Finland: Ferring Pharmaceuticals; December 2022.
2. Boorjian SA, Alemozaffar M, Konety BR, et al. Intravesical nadofaragene firadenovec gene therapy for BCG-unresponsive non-muscle-invasive bladder cancer: a single-arm, open-label, repeat-dose clinical trial. Lancet Oncol. 021;22(1):107-117. doi:10.1016/S1470-2045(20)30540-4[PubMed 33253641]
3. clinicaltrials.gov. Adstiladrin (=Instiladrin) in Patients With High Grade, Bacillus Calmette-Guerin (BCG) Unresponsive Non-Muscle Invasive Bladder Cancer (NMIBC). Available at: https://clinicaltrials.gov/search?term=nct02773849. Accessed August 9, 2023.
4. Chang SS, Boorjian SA, Chou R et al: Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline (2020). Available at: https://www.auanet.org/guidelines-and-quality/guidelines/bladder-cancer-non-muscle-invasive-guideline. Accessed August 9, 2023.
5. FDA Review Adstiladrin. Available at: https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/adstiladrin. Accessed August 8, 2023.

Prior Authorization Guideline

Guideline Name	Adzynma (ADAMTS13, recombinant-krhn)

Guideline Note:

Effective Date:	4/1/2025

1 . Indications

Drug Name: Adzynma (ADAMTS13, recombinant-krhn)
Congenital Thrombotic Thrombocytopenic Purpura (cTTP) Indicated for prophylactic or on demand enzyme replacement therapy (ERT) in adult and pediatric patients with congenital thrombotic thrombocytopenic purpura (cTTP).

2 . Criteria

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

Approval Criteria

1 - Diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP)

AND

2 - Molecular genetic testing confirms mutations in the ADAMTS13 gene

AND

3 - Trial and inadequate response, contraindication or intolerance to plasma-based infusions [B, 11]

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

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Trial and inadequate response, contraindication or intolerance to plasma-based infusions [B, 11]

3 . Definitions

Definition	Description
ISTH	International Society of Thrombosis and Haemostasis.

4 . Endnotes

A. Acute TTP events were defined in protocol by a drop in platelet count (≥50% of baseline or a platelet count <100,000/μL) and an elevation of lactate dehydrogenase (LDH) (>2× baseline or >2× upper limit normal (ULN)). Subacute events were defined by a thrombocytopenia event or a microangiopathic hemolytic anemia event; and organ-specific signs and symptoms including but not limited to renal dysfunction events, neurological symptoms events, fever, fatigue/lethargy, and/or abdominal pain. Thrombocytopenia events were defined as a drop in platelet count ≥25% of baseline or a platelet count <150,000/μL. Microangiopathic hemolytic anemia events were defined as an elevation of LDH >1.5×baseline or >1.5 ×ULN. [2]
B. A trial of plasma-based infusions would be acceptable for both prophylactic and acute use in cTTP. Adzynma may be an option for those patients who have risk of antibody production, allergic reactions, time-constraints (few hours with plasma-based infusions), refractory to plasma-based infusions, volume restrictions (e.g., renal failure) etc... [11]

5 . References

1. Adzynma Prescribing Information. Takeda Pharmaceuticals USA, Inc. Lexington, MA. June 2024.
2. Manufacturer drug website. Available at: https://www.adzynma.com/. Accessed February 6, 2024.
3. ClinicalTrials.gov. A Study of BAX 930 in Children, Teenagers, and Adults Born With Thrombotic Thrombocytopenic Purpura (TTP). Available at: https://classic.clinicaltrials.gov/ct2/show/NCT03393975?cond=nct03393975&draw=2&rank=1. Accessed January 6, 2024.
4. ClinicalTrials.gov. A Study of TAK-755 in Participants With Congenital Thrombotic Thrombocytopenic Purpura. Available at: https://classic.clinicaltrials.gov/ct2/show/NCT04683003?cond=nct04683003&draw=2&rank=1. Accessed January 6, 2024.
5. Sukumar, S., Lammle, B., Cataland, S. Thrombotic Thrombocytopenia Purpura: Pathophysiology, Diagnosis, and Management. Available at:

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7867179/. Accessed January 6, 2024.
6. Alwan, F., Vendramin, C., Liesner, R., et al. Characterization and treatment of congenital thrombotic thrombocytopenic purpura. Available at: https://www.sciencedirect.com/science/article/pii/S0006497120426357?via%3Dihub. Accessed January 6, 2024.
7. Asmis, L., Serra, A., Krafft, A., et al. Recombinant ADAMTS13 for Hereditary Thrombotic Thrombocytopenic Purpura. Available at: https://www.nejm.org/doi/full/10.1056/NEJMoa2211113. Accessed January 6, 2024.
8. UptoDate: Hereditary thrombotic thrombocytopenic purpura (hTTP). Available at: https://www.uptodate.com/contents/hereditary-thrombotic-thrombocytopenic-purpura-http?search=cttp&source=search_result&selectedTitle=1~37&usage_type=default&display_rank=1. Accessed January 6, 2024.
9. Zheng X., Vesely, S., Cataland, S., et al. ISTH guidelines for treatment of thrombotic thrombocytopenic purpura. Available at: https://onlinelibrary.wiley.com/doi/epdf/10.1111/jth.15010. Accessed January 6, 2024.
10. Zheng X., Vesely, S., Cataland, S., et al. ISTH guidelines for the diagnosis of thrombotic thrombocytopenic purpura. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8146131/. Accessed Jnauary 6, 2024.
11. Clinical Consult February 12, 2024.

Prior Authorization Guideline

Guideline Name	Aldurazyme (laronidase)

Guideline Note:

Effective Date:	8/1/2025

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 - Patient demonstrates positive clinical response to therapy

3 . References

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

Prior Authorization Guideline

Guideline Name	Alfa Interferons

Guideline Note:

Effective Date:	9/1/2024

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 1) Indicated for the treatment of Chronic Hepatitis C (CHC) in combination therapy with other hepatitis C virus drugs for adults with compensated liver disease. PEGASYS monotherapy is indicated only if patient has contraindication or significant intolerance to other HCV drugs. 2) indicated for the treatment of Chronic Hepatitis C (CHC) in combination with ribavirin for pediatric patients 5 years of age and older with compensated liver disease. 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: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 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: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 Both of the following:

- Diagnosis of metastatic renal cell carcinoma
- Used in combination with Avastin (bevacizumab)

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.

Prior Authorization Guideline

Guideline Name	Alhemo (concizumab-mtci)

Guideline Note:

Effective Date:	6/1/2025

1 . Indications

Drug Name: Alhemo (concizumab-mtci)
Prevention or to reduce the frequency of bleeding episodes Indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with: Hemophilia A (congenital factor VIII deficiency) with FVIII inhibitors and Hemophilia B (congenital factor IX deficiency) with FIX inhibitors.

2 . Criteria

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

Approval Criteria

1 - Diagnosis of one of the following:

- hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors
- hemophilia B (congenital factor IX deficiency) with factor IX inhibitors

AND

2 - Drug will be used for prophylaxis to prevent or reduce the frequency of bleeding episodes

AND

3 - Patient is 12 years of age or older

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

AND

5 - One of the following: (applies to Hemophilia A only)

5.1 For continuation of prior therapy

OR

5.2 Trial and inadequate response, intolerance, or contraindication to Hemlibra (emicizumab-kxwh)

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

Approval Criteria

1 - Drug continues to be used for prophylaxis to prevent or reduce the frequency of bleeding episodes

AND

2 - Patient demonstrates positive clinical response to therapy (e.g., reduced bleeding episodes)

3 . References

1. Alhemo Prescribing Information. Novo Nordisk Inc. Plainsboro, NJ. December 2024.

Prior Authorization Guideline

Guideline Name	Alpha-1 Proteinase Inhibitors

Guideline Note:

Effective Date:	8/1/2025

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. 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 - Patient demonstrates 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. Takeda Pharmaceuticals USA Inc. Cambridge, MA October 2024.
2. Zemaira Prescribing Information. CSL Behring LLC. Kankakee, IL. January 2024.
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 2023.
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.
7. Stoller JK. Treatment of of alpha-1 antitrypsin deficiency. UpToDate. Accessed March 12, 2019.
8. Vogelmeir C, Agusti A, et al. The global strategy for diagnosis, management and prevention of COPD (2024Report). Global Initiative for Chronic Obstructive Lung Disease. Accessed February 18, 2025.
9. Brantly ML, Lascano JE, Shahmohammadi A. Intravenous alpha-1 antitrypsin therapy for alpha-1 antitrypsin deficiency: the current state of the evidence. Chronic Obstr Pulm Dis. 2019;6(1):100-114.
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.

Prior Authorization Guideline

Guideline Name	Amondys 45 (casimersen) - PA, NF

Guideline Note:

Effective Date:	8/1/2025

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 - Disease is confirmed by the presence of a mutation of the dystrophin gene amenable to exon 45 skipping as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Patient is 7 years of age or older

AND

4 - Prescribed by or in consultation with a neurologist with expertise in the treatment of DMD

AND

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

AND

6 - Patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)

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 with expertise in the treatment of DMD

AND

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

AND

4 - Patient is maintaining ambulatory status without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)

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) confirming both of the following:

1.1 Diagnosis of Duchenne muscular dystrophy (DMD)

AND

1.2 Disease is confirmed by the presence of a mutation of the dystrophin gene amenable to exon 45 skipping as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

2 - Patient is 7 years of age or older

AND

3 - Prescribed by or in consultation with a neurologist with expertise in the treatment of DMD

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) confirming the patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)

3 . References

1. Amondys 45 Prescribing Information. Sarepta Therapeutics, Inc. Cambridge, MA. July 2024.

Anktiva (nogapendekin alfa inbakicept-pmln)

Prior Authorization Guideline

Guideline Name	Anktiva (nogapendekin alfa inbakicept-pmln)

Guideline Note:

Effective Date:	8/1/2025

1 . Indications

Drug Name: Anktiva (nogapendekin alfa inbakicept-pmln)
non-Muscle Invasive Bladder Cancer (NMIBC) Indicated with Bacillus Calmette-Guérin (BCG) for the treatment of adult patients with BCG unresponsive nonmuscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

2 . Criteria

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

Approval Criteria

1 - Diagnosis of non-Muscle Invasive Bladder Cancer (NMIBC)

AND

2 - Tumor is carcinoma in situ (CIS) with or without papillary tumors

AND

3 - Patient is not eligible for or has elected not to undergo cystectomy

AND

4 - Patient has received an adequate course of Bacillus Calmette Guérin (BCG) monotherapy defined as the administration of at least 5 of 6 doses of an initial induction course plus one of the following:

- At least two of three doses of maintenance therapy
- At least two of six doses of a second induction course

AND

5 - Tumor is unresponsive to BCG monotherapy as defined by one of the following:

- Persistent disease following adequate BCG therapy
- Disease recurrence after an initial tumor-free state following adequate BCG therapy
- T1 disease following a single induction course of BCG

AND

6 - Medication is used in combination with Bacillus Calmette-Guérin (BCG) therapy

AND

7 - The patient has had all resectable disease (Ta and T1 components) removed

AND

8 - The patient does not have extra-vesical (i.e., urethra, ureter, or renal pelvis), muscle invasive (T2-T4), or metastatic urothelial carcinoma

Product Name:Anktiva	
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. Anktiva prescribing information. AGC Biologics. Bothell, WA. April 2024.
2. Chamie, K., Chang, S., Kramolowsky, E., et al. IL-15 Superagonist NAI in BCG-Unresponsive Non-Muscle-Invasive Bladder Cancer. Available at: https://evidence.nejm.org/doi/full/10.1056/EVIDoa2200167. Accessed June 17, 2024.
3. ClinicalTrials.gov. QUILT-3.032: A Multicenter Clinical Trial of Intravesical Bacillus Calmette-Guerin (BCG) in Combination With ALT-803 (N-803) in Patients With BCG Unresponsive High Grade Non-Muscle Invasive Bladder Cancer. Available at: https://www.clinicaltrials.gov/study/NCT03022825?cond=nct03022825&rank=1. Accessed June 17, 2024.

Prior Authorization Guideline

Guideline Name	Antiemetics for Chemotherapy

Guideline Note:

Effective Date:	1/16/2025

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	
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	
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

Prior Authorization Guideline

Guideline Name	Apretude

Guideline Note:

Effective Date:	9/21/2023

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

Prior Authorization Guideline

Guideline Name	Arcalyst (rilonacept)

Guideline Note:

Effective Date:	10/1/2024

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 - Patient demonstrates 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.

Prior Authorization Guideline

Guideline Name	Atypical Antipsychotics

Guideline Note:

Effective Date:	8/1/2025

1 . Indications

Drug Name: Fanapt (iloperidone)
Schizophrenia Indicated for the treatment of adults with schizophrenia. When deciding among the alternative treatments available for this condition, the prescriber should consider the finding that Fanapt is associated with prolongation of the QTc interval. Prolongation of the QTc interval is associated in some other drugs with the ability to cause torsade de pointes-type arrhythmia, a potentially fatal polymorphic ventricular tachycardia which can result in sudden death. In many cases this would lead to the conclusion that other drugs should be tried first. Whether Fanapt will cause torsade de pointes or increase the rate of sudden death is not yet known. Patients must be titrated to an effective dose of Fanapt. Thus, control of symptoms may be delayed during the first 1 to 2 weeks of treatment compared to some other antipsychotic drugs that do not require a similar titration. Prescribers should be mindful of this delay when selecting an antipsychotic drug for the treatment of schizophrenia. **Bipolar I disorder** Indicated for the acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.
Drug Name: Secuado (asenapine)

Schizophrenia Indicated for the treatment of adults with schizophrenia
Drug Name: Caplyta
Schizophrenia Indicated for the treatment of schizophrenia in adults **Bipolar Depression** Indicated for the treatment of depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults, as monotherapy and as adjunctive therapy with lithium or valproate
Drug Name: Lybalvi
Schizophrenia Indicated for the treatment of schizophrenia in adults **Bipolar I disorder** Indicated for the acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate in adults with Bipolar I disorder. Indicated as maintenance monotherapy treatment in adults with Bipolar I disorder.
Drug Name: Saphris
Schizophrenia Indicated for the treatment of schizophrenia in adults **Bipolar I Disorder** Indicated for acute monotherapy of manic or mixed episodes, in adults and pediatric patients 10 to 17 years of age, indicated for adjunctive treatment to lithium or valproate in adults, and indicated for maintenance monotherapy treatment in adults
Drug Name: Invega Hafyera (paliperidone palmitate)
Schizophrenia Indicated for the treatment of schizophrenia in adults after they have been adequately treated with either a once-a-month paliperidone palmitate extended-release injectable suspension (e.g., INVEGA SUSTENNA) for at least four months, or an every-three-month paliperidone palmitate extended-release injectable suspension (e.g., INVEGA TRINZA) for at least one three-month cycle.
Drug Name: Opipza (aripiprazole)
Schizophrenia Indicated for the treatment of schizophrenia in patients ages 13 years and older. **Major Depressive Disorder (MDD)** Indicated for adjunctive treatment of major depressive disorder (MDD) in adults. **Autism** Indicated for irritability associated with autistic disorder in pediatric patients 6 years and older.

Tourette's Syndrome Indicated for treatment of Tourette's disorder in pediatric patients 6 years and older.

2 . Criteria

Product Name:Fanapt, Fanapt Pak, Secuado, Brand Saphris, Lybalvi	
Approval Length	When approved; no reauthorization required
Guideline Type	Step Therapy

Approval Criteria

1 - Both of the following:

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

AND

1.2 Trial and failure (of a minimum 30 day supply), contraindication, or intolerance to two of the following:

- aripiprazole
- olanzapine
- quetiapine IR/ER
- risperidone
- clozapine
- ziprasidone
- paliperidone
- asenapine

OR

2 - For continuation of prior therapy

Notes	For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Invega Hafyera	
Approval Length	When approved; no reauthorization required
Guideline Type	Step Therapy

Approval Criteria

1 - Both of the following:

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

AND

1.2 Trial of one of the following:

- Invega Sustenna for at least 4 months
- Invega Trinza for at least one 3-month cycle

OR

2 - For continuation of prior therapy

Notes	For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Caplyta	
Approval Length	When approved; no reauthorization required
Guideline Type	Step Therapy

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of Schizophrenia

AND

1.2 Trial and failure (of a minimum 30 day supply), contraindication, or intolerance to two of the following:

- aripiprazole
- olanzapine
- quetiapine IR/ER
- risperidone
- clozapine
- ziprasidone
- paliperidone
- asenapine

OR

2 - BOTH of the following:

- Patient has a diagnosis of Bipolar Depression
- Trial and failure (of a minimum 30 day supply), contraindication, or intolerance to quetiapine IR/ER

OR

3 - For continuation of prior therapy

Notes	For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Opipza	
Diagnosis	Schizophrenia
Approval Length	When approved; no reauthorization required
Guideline Type	Step Therapy

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of Schizophrenia

AND

1.2 Trial and failure (of a minimum 30 day supply), contraindication, or intolerance to two of the following:

- aripiprazole
- olanzapine
- quetiapine IR/ER
- risperidone
- clozapine
- ziprasidone
- paliperidone
- asenapine

OR

2 - For continuation of prior therapy

Notes	For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Opipza	
Diagnosis	Major Depressive Disorder (MDD)
Approval Length	When approved; no reauthorization required

Guideline Type	Step Therapy

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of Major Depressive Disorder (MDD)

AND

1.2 Trial and failure (of a minimum 30 day supply), contraindication, or intolerance to both of the following: :

- aripiprazole
- quetiapine IR/ER

OR

2 - For continuation of prior therapy

Notes	For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Opipza	
Diagnosis	Autism
Approval Length	When approved; no reauthorization required
Guideline Type	Step Therapy

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of irritability associated with autistic disorder

AND

1.2 Trial and failure (of a minimum 30 day supply), contraindication (e.g., age), or intolerance to both of the following: :

- aripiprazole
- risperidone

OR

2 - For continuation of prior therapy

Notes	For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Opipza	
Diagnosis	Tourette's Syndrome
Approval Length	When approved; no reauthorization required
Guideline Type	Step Therapy

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of Tourette's Syndrome

AND

1.2 Trial and failure (of a minimum 30 day supply), or intolerance to aripiprazole

OR

2 - For continuation of prior therapy	
Notes	For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

3 . References

1. Fanapt prescribing information. Vanda Pharmaceuticals, Inc. Washington, D.C. January 2016.
2. Secuado prescribing information. Hisamitsu Pharmaceutical Co., Inc. Japan Saga Tosu. October 2019.
3. Caplyta prescribing information. Intra-Cellular Therapies, Inc. New York, NY. December 2021.
4. Saphris prescribing information. Allergan USA, Inc. Irvine, CA. February 2017.
5. Invega Hafyera prescribing information. Janssen Pharmaceuticals, Inc. Titusville, NJ. September 2021.
6. Lybalvi prescribing information. Alkermes, Inc. Waltham, MA. May 2021.
7. Opipza prescribing information. Xiamen LP Pharmaceutical Co., Ltd. Fujian, China. July 2024.
8. Abilify prescribing information. Otsuka America Pharmaceutical, Inc. Rockville, MD. November 2022.
9. Saphris prescribing information. Schering Corporation. Kenilworth, NJ. July 2009.
10. Geodon prescribing information. Pfizer Inc. New York, NY. January 2022.
11. Risperdal prescribing information. Janssen Pharmaceuticals, Inc. Titusville, NJ. March 2022.
12. Seroquel XR prescribing information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. January 2022.
13. Seroquel prescribing information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. January 2022.
14. Zyprexa prescribing information. Lilly USA, LLC. Indianapolis, IN. October 2019
15. Clozaril prescribing information. HLS Therapeutics (USA), Inc. Rosemont, PA. September 2024.
16. Invega prescribing information. Janssen Pharmaceuticals, Inc. Titusville, NJ. December 2021.

Prior Authorization Guideline

Guideline Name	Bendamustine Agents

Guideline Note:

Effective Date:	11/1/2024

1 . Indications

Drug Name: Belrapzo
Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with chronic lymphocytic leukemia. Efficacy relative to first line therapies other than chlorambucil has not been established. **Non-Hodgkin Lymphoma (NHL)** Indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.
Drug Name: Bendamustine
Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with chronic lymphocytic leukemia. Efficacy relative to first line therapies other than chlorambucil has not been established. **Non-Hodgkin Lymphoma (NHL)** Indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

Drug Name: Bendeka
Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with chronic lymphocytic leukemia. Efficacy relative to first line therapies other than chlorambucil has not been established. **Non-Hodgkin Lymphoma (NHL)** Indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.
Drug Name: Treanda
Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with chronic lymphocytic leukemia. Efficacy relative to first line therapies other than chlorambucil has not been established. **Non-Hodgkin Lymphoma (NHL)** Indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.
Drug Name: Vivimusta
Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with chronic lymphocytic leukemia. Efficacy relative to first line therapies other than chlorambucil has not been established. **Non-Hodgkin Lymphoma (NHL)** Indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

2 . Criteria

Product Name:Bendeka, Belrapzo, Brand Bendamustine, Brand Treanda, Vivimusta	
Diagnosis	Chronic lymphocytic leukemia (CLL)
Approval Length	6 Month(s) [A, C]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia (CLL)

AND

2 - One of the following:

2.1 Trial and failure, or intolerance to generic bendamustine

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Notes	If patient meets criteria above, please approve at NDC level.

Product Name:Bendeka, Belrapzo, Brand Bendamustine, Brand Treanda, Vivimusta	
Diagnosis	Non-Hodgkin lymphoma (NHL)
Approval Length	6 Month(s) [B, D]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of indolent B-cell non-Hodgkin lymphoma (NHL)

AND

2 - Disease has progressed during or within 6 months of treatment with rituximab or a rituximab-containing regimen

AND

3 - One of the following:

3.1 Trial and failure, or intolerance to generic bendamustine

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Notes	If patient meets criteria above, please approve at NDC level.

Product Name:Generic bendamustine	
Diagnosis	Chronic lymphocytic leukemia (CLL)
Approval Length	6 Month(s) [C]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia (CLL)

Notes	If patient meets criteria above, please approve at NDC level.

Product Name:Generic bendamustine	
Diagnosis	Non-Hodgkin lymphoma (NHL)
Approval Length	6 Month(s) [D]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of indolent B-cell non-Hodgkin lymphoma (NHL)

AND **2** - Disease has progressed during or within 6 months of treatment with rituximab or a rituximab-containing regimen	
Notes	If patient meets criteria above, please approve at NDC level.

3 . Endnotes

A. For Bendeka: The recommended dose for chronic lymphocytic leukemia (CLL) is 100 mg/m2 administered intravenously over 10 minutes on Days 1 and 2 of a 28-day cycle, up to 6 cycles. [3]
B. For Bendeka: The recommended dose for non-Hodgkin lymphoma (NHL) is 120 mg/m2 administered intravenously over 10 minutes on Days 1 and 2 of a 21-day cycle, up to 8 cycles. [3]
C. For Belrapzo, Bendamustine, Treanda: The recommended dose for chronic lymphocytic leukemia (CLL) is 100 mg/m2 administered intravenously over 30 minutes on Days 1 and 2 of a 28-day cycle, up to 6 cycles. [1, 2, 4]
D. For Belrapzo, Bendamustine, Treanda: The recommended dose for non-Hodgkin lymphoma (NHL) is 120 mg/m2 administered intravenously over 60 minutes on Days 1 and 2 of a 21-day cycle, up to 8 cycles. [1, 2, 4]
E. For Vivimusta: The recommended dose for chronic lymphocytic leukemia (CLL) is 100 mg/m2 administered intravenously over 20 minutes on Days 1 and 2 of a 28-day cycle for up to 6 cycles. [5]
F. For Vivimusta: The recommended dose for non-Hodgkin lymphoma (NHL) is 20 mg/m2 administered intravenously over 20 minutes on Days 1 and 2 of a 21-day cycle for up to 8 cycles. [5]

4 . References

1. Belrapzo prescribing information. Eagle Pharmaceuticals, Inc. Woodcliff Lake, NJ. June 2022.
2. Bendamustine prescribing information. Eagle Pharmaceuticals, Inc. Woodcliff Lake, NJ. May 2019.
3. Bendeka prescribing information. Teva Pharmaceuticals USA, Inc. North Wales, PA. October 2021.

4. Treanda prescribing information. Teva Pharmaceuticals USA, Inc. North Wales, PA. June 2021.
5. Vivimusta prescribing information. Slayback Pharma LLC. Princeton, NJ. December 2022.

Prior Authorization Guideline

Guideline Name	Benlysta (belimumab)

Guideline Note:

Effective Date:	10/1/2024

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 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 SC prefilled syringe

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 - 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 autoinjector	
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 - Patient is 5 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 - Patient demonstrates 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. Benlysta Prescribing Information. GlaxoSmithKline LLC. Philadelphia, PA. June 2024.
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.

Prior Authorization Guideline

Guideline Name	Bevacizumab - PA, NF

Guideline Note:

Effective Date:	4/1/2025

1 . Indications

Drug Name: Avastin (bevacizumab)
Metastatic Colorectal Cancer (mCRC) Indicated for the first- or second-line treatment of patients with metastatic carcinoma of the colon or rectum in combination with intravenous 5-fluorouracil-based chemotherapy. Bevacizumab, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, is also indicated for second-line treatment of patients with metastatic colorectal cancer who have progressed on a first-line bevacizumab product-containing regimen. Limitation of use: Bevacizumab is not indicated for adjuvant treatment of colon cancer. **First-line Non-Squamous Non–Small Cell Lung Cancer (NSCLC)** Indicated for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer in combination with carboplatin and paclitaxel. **Recurrent Glioblastoma** Indicated for the treatment of recurrent glioblastoma in adults. **Metastatic Renal Cell Carcinoma (mRCC)** Indicated for the treatment of metastatic renal cell carcinoma in combination with interferon alfa.

Persistent, Recurrent, or Metastatic Cervical Cancer Indicated for the treatment of persistent, recurrent, or metastatic cervical cancer when used in combination with paclitaxel and cisplatin or paclitaxel and topotecan.

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Indicated, in combination with carboplatin and paclitaxel, followed by bevacizumab as a single agent, for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial resection. Indicated, in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens. Indicated, in combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by bevacizumab as a single agent, for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

Hepatocellular Carcinoma Indicated, in combination with atezolizumab, for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy.

Drug Name: Mvasi (bevacizumab-awwb), Zirabev (bevacizumab-bvzr), Alymsys (bevacizumab-maly), Vegzelma (bevacizumab-adcd)

Metastatic Colorectal Cancer (mCRC) Indicated for the first- or second-line treatment of patients with metastatic carcinoma of the colon or rectum in combination with intravenous 5-fluorouracil-based chemotherapy. Bevacizumab, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, is also indicated for second-line treatment of patients with metastatic colorectal cancer who have progressed on a first-line bevacizumab product-containing regimen. Limitation of use: Bevacizumab is not indicated for adjuvant treatment of colon cancer.

First-line Non-Squamous Non–Small Cell Lung Cancer (NSCLC) Indicated for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer in combination with carboplatin and paclitaxel.

Recurrent Glioblastoma Indicated for the treatment of recurrent glioblastoma in adults.

Metastatic Renal Cell Carcinoma (mRCC) Indicated for the treatment of metastatic renal cell carcinoma in combination with interferon alfa.

Persistent, Recurrent, or Metastatic Cervical Cancer Indicated for the treatment of persistent, recurrent, or metastatic cervical cancer when used in combination with

paclitaxel and cisplatin or paclitaxel and topotecan.

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Indicated, in combination with carboplatin and paclitaxel, followed by bevacizumab as a single agent, for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial resection. Indicated, in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens. Indicated, in combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by bevacizumab as a single agent, for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

Off Label Uses: Hepatocellular Carcinoma Indicated, in combination with atezolizumab, for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy. [4, A]

2 . Criteria

Product Name:Avastin, Mvasi, Zirabev, Alymsys, Vegzelma	
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 Requested 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

AND

2 - One of the following (applies to Avastin, Alymsys and Vegzelma only):

2.1 Trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Avastin, Mvasi, Zirabev, Alymsys, Vegzelma

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 (applies to Avastin, Alymsys and Vegzelma only):

2.1 Trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Alymsys, Vegzelma	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Requested 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

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 both of the following:

- Mvasi
- Zirabev

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

3 . Endnotes

A. 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. Avastin Prescribing Information. Genentech Inc. South San Francisco, CA. September 2022.
2. Mvasi Prescribing Information. Amgen Inc. Thousand Oaks, CA. February 2023.
3. Zirabev Prescribing Information. Pfizer Inc. New York, NY. February 2023.
4. U.S. Food and Drug Administration (FDA). Biosimilar and Interchangeable Products. Silver Spring, MD: FDA; October 23, 2017. Available at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm#biosimilar. Accessed December 4, 2023.
5. Alymsys Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. April 2022.
6. Vegzelma Prescribing Information. Celltrion USA, Inc. Jersey City, NJ. February 2023.

Prior Authorization Guideline

Guideline Name	Bortezomib

Guideline Note:

Effective Date:	2/1/2025

1 . Indications

Drug Name: Velcade (bortezomib)
Multiple Myeloma Indicated for the treatment of patients with multiple myeloma. **Mantle Cell Lymphoma** Indicated for the treatment of patients with mantle cell lymphoma.
Drug Name: Bortezomib (bortezomib)
Multiple Myeloma Indicated for the treatment of patients with multiple myeloma. **Mantle Cell Lymphoma** Indicated for the treatment of adult patients with mantle cell lymphoma.
Drug Name: Boruzu (bortezomib)
Multiple Myeloma Indicated for the treatment of adult patients with multiple myeloma.

Mantle Cell Lymphoma Indicated for the treatment of adult patients with mantle cell lymphoma.

2 . Criteria

Product Name:Brand Velcade, Generic bortezomib, Bortezomib	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma [1, 2, 5]

AND

2 - Trial and failure, contraindication or intolerance to generic bortezomib (Applies to Brand Velcade Only)

Product Name:Boruzu	
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 - One of the following:

2.1 Trial and failure, contraindication or intolerance to generic bortezomib

OR

2.2 For continuation of prior therapy

Product Name:Brand Velcade, Generic bortezomib, Bortezomib	
Diagnosis	Mantle Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mantle cell lymphoma [1, 3, 4, 5]

AND

2 - Trial and failure, contraindication or intolerance to generic bortezomib (Applies to Brand Velcade Only)

Product Name:Boruzu	
Diagnosis	Mantle Cell Lymphoma

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

Approval Criteria

1 - Diagnosis of mantle cell lymphoma

AND

2 - One of the following:

2.1 Trial and failure, contraindication or intolerance to generic bortezomib

OR

2.2 For continuation of prior therapy

Product Name:Brand Velcade, Generic bortezomib, Bortezomib, Boruzu	
Diagnosis	All Indications
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. Velcade Prescribing Information. Millennium Pharmaceuticals, Inc. Cambridge, MA. November 2021.
2. Richardson PG, Sonneveld P, Schuster MW, et al. Assessment of Proteasome Inhibition for Extending Remissions (APEX) Investigators. Bortezomib or high-dose dexamethasone for relapsed multiple myeloma. N Engl J Med. 2005 Jun 16;352(24):2487-98.
3. National Cancer Institute. Adult Non-Hodgkin Lymphoma Treatment (PDQ). Available at: http://www.cancer.gov/cancertopics/pdq/treatment/adult-non-hodgkins/healthprofessional. Accessed May 12, 2022.
4. Fisher RI, Bernstein SH, Kahl BS, et al. Multicenter phase II study of bortezomib in patients with relapsed or refractory mantle cell lymphoma. J Clin Oncol.2006;24(30):4867-74.
5. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org. Accessed May 12, 2022.
6. Bortezomib Prescribing Information. Fresenius Kabi USA, LLC. Lake Zurich, IL. December 2022.
7. Bortezomib Prescribing Information. Hospira, Inc.. Lake Forest, IL. December 2022.
8. Bortezomib Prescribing Information. Dr Reddy’s Laboratories, Inc. Princeton, NJ. December 2022.
9. Bortezomib Prescribing Information. Hikma Pharmaceuticals USA, Inc. Berkeley Heights, NJ. November 2021.
10. Bortezomib Prescribing Information. Fosun Pharma USA. Princeton, NJ. August 2022.
11. Boruzu Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. September 2024.
12. Boruzu Press Release. Available at:https://investors.amneal.com/news/press-releases/press-release-details/2024/Amneal-and-Shilpa-Announce-U.S.-FDA-Approval-of-BORUZU-the-First-Ready-to-Use-Version-of-Bortezomib-for-subcutaneous-administration/default.aspx. Accessed December 20, 2024.
13. FDA's 505(b)(2) Explained: A Guide to New Drug Applications. Available at: https://www.thefdagroup.com/blog/505b2. Accessed December 20, 2024.
14. Chandanais, R. 505 (b)(2) Regulatory Pathway for New Drug Approvals. Available at: https://www.pharmacytimes.com/view/505-b2-regulatory-pathway-for-new-drug-approvals-. Accessed December 20, 2024.
15. Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available at: https://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm. Accessed December 20, 2024.

Prior Authorization Guideline

Guideline Name	Brineura (cerliponase alfa)

Guideline Note:

Effective Date:	8/1/2025

1 . Indications

Drug Name: Brineura (cerliponase alfa)
Neuronal Ceroid Lipofuscinosis Type 2 Indicated to slow the loss of ambulation in pediatric patients with 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 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 does not have acute intraventricular access-related complications (e.g., leakage, device failure, or device-related infections)

AND

4 - Patient does not have ventriculoperitoneal shunts

AND

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

AND

6 - Administered in a healthcare setting by, or under the direction of, a physician knowledgeable in intraventricular administration and hypersensitivity reactions including anaphylaxis [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 - Administered in a healthcare setting by, or under the direction of, a physician knowledgeable in intraventricular administration and hypersensitivity reactions including anaphylaxis [A]

AND

4 - Patient demonstrates positive clinical response to 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. Anaphylaxis has occurred during the early course of enzyme replacement therapy and after extended duration of therapy. Administration of Brineura should be supervised by a healthcare provider

knowledgeable in the management of hypersensitivity reactions including anaphylaxis. Initiate Brineura in a healthcare setting with appropriate medical monitoring and support measures, including access to cardiopulmonary resuscitation equipment. [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 2024.
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.

Prior Authorization Guideline

Guideline Name	Cablivi (caplacizumab-yhdp)

Guideline Note:

Effective Date:	5/1/2025

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. April 2024
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.

Prior Authorization Guideline

Guideline Name	Cabotegravir Containing Agents - PA, NF

Guideline Note:

Effective Date:	7/1/2025

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 35 kg to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA <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.
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.

2 . Criteria

Product Name:Vocabria*	
Diagnosis	Treatment of HIV-1 Infection
Approval Length	When approved; no reauthorization required
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	For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve t hrough 12/31/2039 *If patient meets criteria above, please approve Vocabria 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 a nd Cabenuva at GPI list “CABOTEGRPA”.

Product Name:Vocabria**	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	When approved; no reauthorization required
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:

- 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	For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve t hrough 12/31/2039 **If patient meets criteria above, please approve Vocabria at GPI list “APRETUDEPA”

Product Name:Vocabria**	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	12 month(s)
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:

- 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 Vocabria 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. December 2023.
2. Vocabria Prescribing Information. ViiV Healthcare Company. Research Triangle Park, NC. December 2023.

Prior Authorization Guideline

Guideline Name	Cinqair (reslizumab)

Guideline Note:

Effective Date:	7/1/2025

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

5 - Age greater than or equal to 18 years

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 [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium])

OR

4.2 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

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 - 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 [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., 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

1. Cinqair Prescribing Information. Teva Respiratory, LLC. Frazer, PA. June 2020.
2. Castro M, Zangrilli J, Wechsler ME, et al. Reslizumab for inadequately controlled asthma with elevated blood eosinophil counts: results from two multicentre, parallel, doubleblind, randomised, placebo-controlled, phase 3 trials. Lancet Respir Med. 2015;3(5):355-366.
3. Bjermer L, Lemiere C, Maspero J, et al. A randomized phase 3 study of the efficacy and safety of reslizumab in subjects with asthma with elevated eosinophils. Eur Respir J. 2014;44(Suppl 58):P299. Paper presented at: European

Respiratory Society International Congress; September 6-10, 2014; Munich, Germany.
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.
5. 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.
6. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention (2024 update). 2024 https://ginasthma.org/reports/. Accessed April 1, 2025.
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 9 April, 2024.

Prior Authorization Guideline

Guideline Name	Colony-Stimulating Factors (CSFs) - PA, NF

Guideline Note:

Effective Date:	7/1/2025

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), Nypozi (filgrastim-txid)

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: Ryzneuta (efbemalenograstim alfa-vuxw)

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.

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]

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, Nypozi, 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, Nypozi, 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 - Both of the following:

3.1 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to both of the following formulary alternatives that have the same active ingredient:

- Nivestym
- Zarxio

AND

3.2 Submission of medical records confirming the formulary alternative(s) have not been effective AND valid clinical rationale provided explaining how Neupogen is expected to provide benefit when the formulary alternatives have not been shown to be effective despite having the same active ingredient

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, Nypozi, 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, Nypozi, 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 - Both of the following:

4.1 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to both of the following formulary alternatives that have the same active ingredient:

- Nivestym
- Zarxio

AND

4.2 Submission of medical records confirming the formulary alternative(s) have not been effective AND valid clinical rationale provided explaining how Neupogen is expected to provide benefit when the formulary alternatives have not been shown to be effective despite having the same active ingredient

Product Name:Fulphila, Fylnetra, Granix, Leukine (Off-Label), Neulasta/Neulasta Onpro*, Neupogen, Nivestym, Nypozi, Nyvepria, Releuko, Ryzneuta, 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, Nypozi, Releuko, and Granix only):

- Nivestym
- Zarxio

OR

3.2 Trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, Ryzneuta, 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 “FILGRAST PA”.

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 Both of the following:

3.1.1 One of the following:

3.1.1.1 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to both of the following formulary alternatives that has the same active ingredient (applies to Neupogen only):

- Nivestym
- Zarxio

OR

3.1.1.2 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to both of the following formulary alternatives that has the same active ingredient (applies to Fulphila, Fylnetra, Nyvepria, and Ziextenzo only):

- Neulasta/Neulasta Onpro
- Udenyca/Udenyca Onbody

AND

3.1.2 Submission of medical records confirming the formulary alternative(s) have not been effective AND valid clinical justification provided explaining how the Non-Formulary or Excluded Medication is expected to provide benefit when the formulary alternative(s) has not been shown to be effective despite having the same active ingredient

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 Granix only):

- Nivestym
- Zarxio

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, Nypozi, 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, l]

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, Nypozi, 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 "FILGRAST PA".

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 Both of the following:

5.1.1 One of the following:

5.1.1.1 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to both of the following formulary alternatives that has the same active ingredient (applies to Neupogen only):

- Nivestym
- Zarxio

OR

5.1.1.2 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to both of the following formulary alternatives that has the same active ingredient (applies to Fulphila, Fylnetra, Nyvepria, and Ziextenzo only):

- Neulasta/Neulasta Onpro
- Udenyca/Udenyca Onbody

AND

5.1.2 Submission of medical records confirming the formulary alternative(s) have not been effective AND valid clinical justification provided explaining how the Non-Formulary or Excluded Medication is expected to provide benefit when the formulary alternative(s) has not been shown to be effective despite having the same active ingredient

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 Granix only):

- Nivestym
- Zarxio

Product Name:Neupogen, Nivestym, Nypozi, 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, Nypozi, 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 - Both of the following:

3.1 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to both of the following formulary alternatives that have the same active ingredient:

- Nivestym
- Zarxio

AND

3.2 Submission of medical records confirming the formulary alternative(s) have not been effective AND valid clinical rationale provided explaining how Neupogen is expected to provide benefit when the formulary alternatives have not been shown to be effective despite having the same active ingredient

Product Name:Fulphila (Off-Label), Fylnetra (Off-label), Granix (Off-Label), Leukine, Neulasta, Neupogen, Nivestym (Off-Label), Nypozi, Nyvepria (Off-Label), Releuko (Off-

Label), Ryzneuta (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, Nypozi, Granix and Releuko only):

- Nivestym
- Zarxio

OR

3.2 Trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, Ryzneuta, 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 - Both of the following: (applies to Neupogen, Fulphila, Fylnetra, Nyvepria, and Ziextenzo only)

3.1 One of the following:

3.1.1 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to both of the following formulary alternatives that has the same active ingredient (applies to Neupogen only):

- Nivestym
- Zarxio

OR

3.1.2 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to both of the following formulary alternatives that has the same active ingredient (applies to Fulphila, Fylnetra, Nyvepria, and Ziextenzo only):

- Neulasta
- Udenyca

AND

3.2 Submission of medical records confirming the formulary alternative(s) have not been effective AND valid clinical justification provided explaining how the Non-Formulary or Excluded Medication is expected to provide benefit when the formulary alternative(s) has not been shown to be effective despite having the same active ingredient

Product Name:Leukine, Neupogen, Nivestym, Nypozi, 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, Nypozi, 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 - Both of the following:

4.1 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to both of the following formulary alternatives that have the same active ingredient:

- Nivestym
- Zarxio

AND

4.2 Submission of medical records confirming the formulary alternative(s) have not been effective AND valid clinical rationale provided explaining how Neupogen is expected to provide benefit when the formulary alternatives have not been shown to be effective despite having the same active ingredient

Product Name:Neupogen, Nivestym, Nypozi, 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, Nypozi, 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 - Both of the following:

3.1 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to both of the following formulary alternatives that have the same active ingredient:

- Nivestym
- Zarxio

AND

3.2 Submission of medical records confirming the formulary alternative(s) have not been effective AND valid clinical rationale provided explaining how Neupogen is expected to provide benefit when the formulary alternatives have not been shown to be effective despite having the same active ingredient

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]

5 . References

1. Neulasta Prescribing Information. Amgen Inc. Thousand Oaks, CA. February 2021.
2. Neupogen Prescribing Information. Amgen Inc. Thousand Oaks, CA. February 2021.
3. Leukine Prescribing Information. sanofi-aventis U.S. LLC. Bridgewater, NJ. May 2022.
4. Sulkowski M. Managing the hematologic complications of interferon/ribavirin. Clinical Care Options for Hepatitis Annual Update. Milford, MA: IMedoptions, 2003:101-102.

5. Soza A, Everhart JE, Gharny MG, et al. Neutropenia during combination therapy of interferon alfa and ribavirin for chronic hepatitis C. Hepatol. 2002;36:1273-1279.
6. Van Thiel DH, Faruki H. Combination treatment of advanced HCV associated liver disease with interferon and G-CSF. Hepatogastroenterol.1995;42:907-912.
7. Carreno V, Parra A, Navas S, Quiroga J. Granulocyte macrophage colony stimulating factors as adjuvant therapy for interferon alpha treatment of chronic hepatitis C. Cytokine. 1996;8:318-322.
8. Shiffman M, Hofmann, Luketic VA, Sanyal AJ. Use of granulocyte macrophage colony stimulating factor alone or in combination with interferon-alpha-2b for treatment of chronic hepatitis C. J Hepatol.1998;28:382-389.
9. Farmer D, Collantes R, Makay S, et al. Filgrastim for the neutropenia associated with combination therapy in chronic hepatitis C. Gastroenterol. 2005;128(4, Suppl2):a-725.
10. Stein DF, McKenzie SD. Peg-interferon alfa-2b and ribavirin in treatment naïve African American patients infected with HCV genotype 1. Hepatol.2003;38(4):642A.
11. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Accessed March 3, 2020.
12. Hermans P, Rozenbaum W, Jou A, et al. Filgrastim to treat neutropenia and support myelosuppressive medication dosing in HIV infections. G-CSF 92105 Study Group. AIDS 1996;10:1627-33.
13. Kuritzkes, DR, Parenti D, Ward DJ, et al. Filgrastim prevents severe neutropenia and reduces infective morbidity in patients with advanced HIV infection; results of a randomized, multicenter, controlled trial. AIDS 1998;12:65-74.
14. Levine AM, Karim R, Mack W, et al. Neutropenia in human immunodeficiency virus infection: data from the women's interagency HIV study. Arch Intern Med. 2006;166:405-410.
15. Centers for Disease Control and Prevention. Guidelines for Preventing Opportunistic Infections Among HIV-Infected Persons – 2002 Recommendations of the U.S. Public Health Service and the Infectious Disease Society of America. MMWR 2002;51(No. RR-8):1-52.
16. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Hematopoietic Growth Factors. v.2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Accessed March 29, 2023.
17. Smith TJ, Khatcheressian J, Lyman GH, et al. 2006 update of recommendations for the use of white blood cell growth factors: an evidence-based clinical practice guideline. J Clin Oncol. 2006;24:3187-205.
18. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Breast cancer. v.2.2022 Available at: http://www.nccn.org/professionals/physician_gls/PDF/breast.pdf. Accessed March 29, 2022.
19. Citron ML, Berry DA, Cirrincione C, et al. Randomized trial of dose-dense versus conventionally scheduled and sequential versus concurrent combination

chemotherapy as postoperative adjuvant treatment of node-positive primary breast cancer: first report of Intergroup Trial C9741/Cancer and Leukemia Group B trial. J Clin Oncol. 2003;21(8):1431-9.
20. Ziextenzo Prescribing Information. Sandoz Inc. Princeton, NJ. March 2021.
21. Pegasys Prescribing Information. Roche Pharmaceuticals. San Francisco, CA. March 2021.
22. PegIntron Prescribing Information. Schering Corporation. Kenilworth, NJ. August 2019.
23. American Gastroenterological Association. Medical Position Statement on the Management of Hepatitis C. Gastroenterol 2006;130:225-30.
24. Ghany MG, Strader DB, Thomas DL, Seeff LB; American Association for the Study of Liver Diseases. Diagnosis, management, and treatment of hepatitis C: an update. Hepatology. 2009;49(4):1335-74.
25. Hudis CA, Schmitz. Dose-dense chemotherapy in breast cancer and lymphoma. Seminar in Oncol. 2004;31(Suppl 8):19-23.
26. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Non-Hodgkin's Lymphoma. v.1.2016. Available at: http://www.nccn.org/professionals/physician_gls/PDF/nhl.pdf Accessed November 12, 2015.
27. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia v.1.2018. Available at: http://www.nccn.org/professionals/physician_gls/PDF/aml.pdf Accessed June 5, 2018.
28. Granix Prescribing Information. Cephalon, Inc. North Wales, PA. October 2019.
29. Zarxio Prescribing Information. Sandoz Inc. Princeton, NJ. July 2021.
30. Fulphila Prescribing Information. Mylan. Rockford, IL. March 2021.
31. Nivestym Prescribing Information. Pfizer, Inc. New York, NY. May 2021.
32. Udenyca Prescribing Information. Coherus BioSciences Inc. Redwood City, CA. December 2023.
33. U.S. Food and Drug Administration (FDA). Biosimilar and Interchangeable Products. Silver Spring, MD: FDA; October 23, 2017. Available at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm#biosimilar. Accessed March 3, 2020.
34. Smith TJ, Bohlke K, Lyman GH, et al. Recommendations for the use of WBC growth factors: American Society of Clinical Oncology clinical practice guideline update. J Clin Oncol. 2015;33(28):3199-3212.
35. Per clinical consult with hematologist/oncologist. December 20, 2018.
36. Dainiak N, Gent RN, Carr Z, et al. First global consensus for evidence-based management of the hematopoietic syndrome resulting from exposure to ionizing radiation. Disaster Med Public Health Prep. 2011;5(3):202.
37. Lexi-Comp Online [internet database]. Hudson, OH. Lexi-Comp, Inc. Updated periodically. Available by subscription at: http://online.lexi.com/. Accessed March 3, 2020.

38. Nyvepria Prescribing Information. Pfizer Laboratories Div Pfizer Inc. New York, NY. April 2021.
39. Releuko Prescribing Information. Kashiv BioSciences, LLC. Piscataway, NJ. February 2022.
40. Fylnetra Prescribing Information. Kashiv BioSciences, LLC. Piscataway, NJ. May 2022.
41. Rolvedon Prescribing Information.Spectrum Pharmaceuticals, Inc.Irvine, CA. September 2022.
42. Stimufend Prescribing Information.Fresenius Kabi USA, LLC. Lake Zurich, Illinois. September 2022.
43. Nypozi Prescribing Information. Tanvex BioPharma USA, Inc. San Diego, CA. June 2024.
44. Ryzneuta Prescribing Information. Acrotech Biopharma Inc. East Windsor, NJ. December 2024.

Prior Authorization Guideline

Guideline Name	Commercial MEDLIMIT CDUR Criteria

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 pre scriptions *Note: Ask provider, "Will there be a dose escalation in the patie nt's opioid utilization in the next 90 days?" If yes, approve MME l evel 90 daily MME 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.

3 . References

1. Agency Medical Directors Group. Interagency guideline on opioid dosing for chronic non-cancer pain: An educational aid to improve care and safety with opioid therapy. Available at: http://agencymeddirectors.wa.gov/Files/OpioidGdline.pdf. Accessed September 8, 2022.
2. Chou R, Fanciullo GJ, Fine PG, et al; American Pain Society-American Academy of Pain Medicine Opioids Guidelines Panel. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. J Pain 2009; 10:113-130.
3. Jamison, Robert. Substance abuse treatment for high risk chronic pain patients on opioid therapy. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 7/22/2011. Available from: http://clinicaltrials.gov/ct2/show/NCT00988962. NCT00988962. Accessed September 8, 2022.
4. Manchikan L, Abdi S, Atluri S, et al. American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 2 - Guidance. Pain Physician. 2012; 15:S67-S115.
5. Micromedex Healthcare Series. Available at http://www.thomsonhc.com/home/dispatch. Accessed September 8, 2022.
6. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1external icon.

Prior Authorization Guideline

Guideline Name	Compounded Drugs

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 Methamphetamine hydrochloride Methapyrilene	Urethane Valdexocib 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

1. Compounding and the FDA: Questions and Answers. Available at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm. Accessed July 6, 2022.
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.
4. DRUGDEX [Internet database]. Greenwood Village, CO: Thomson MICROMEDEX, updated periodically. Accessed October 31, 2018.
5. Flurbiprofen Tablet Prescribing Information. Mylan Pharmaceuticals. Morgantown, WV. May 2016.
6. Ocufen Prescribing Information. Allergan. Irvine, CA. July 2012.
7. Gralise prescribing information. Depmed. Neward, CA. December 2012.
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.
17. Spravato Prescribing Information. Janssen Pharmaceuticals. Titusville, NJ. May 2019.
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.

Prior Authorization Guideline

Guideline Name	Corticosteroid Intravitreal Implants

Guideline Note:

Effective Date:	9/21/2023

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

Prior Authorization Guideline

Guideline Name	Cosela (trilaciclib) - PA, NF

Guideline Note:

Effective Date:	4/1/2025

1 . Indications

Drug Name: Cosela (trilaciclib)
Chemotherapy-induced myelosuppression Indicated to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer (ES-SCLC).

2 . Criteria

Product Name:Cosela	
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of extensive-stage small cell lung cancer (ES-SCLC)

AND

2 - Patient is receiving one of the following anti-cancer chemotherapeutic regimens:

- Platinum/etoposide-containing regimen
- Topotecan-containing regimen

AND

3 - Infusion is completed within 4 hours prior to the start of chemotherapy

AND

4 - The interval between doses on sequential days will not be greater than 28 hours

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

Approval Criteria

1 - Diagnosis of extensive-stage small cell lung cancer (ES-SCLC)

AND

2 - Patient is receiving one of the following anti-cancer chemotherapeutic regimens:

- Platinum/etoposide-containing regimen

- Topotecan-containing regimen

AND

3 - Infusion is completed within 4 hours prior to the start of chemotherapy

AND

4 - The interval between doses on sequential days will not be greater than 28 hours

3 . References

1. Cosela Prescribing Information. G1 Therapeutics, Inc. Durham, NC. August 2023.

Prior Authorization Guideline

Guideline Name	Cotellic (cobimetinib)

Guideline Note:

Effective Date:	9/1/2024

1 . Indications

Drug Name: Cotellic (cobimetinib)
Melanoma Indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib. **Histiocytic Neoplasms** Indicated as a single agent for the treatment of adult patients with histiocytic neoplasms.

2 . Criteria

Product Name:Cotellic	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of unresectable or metastatic melanoma

AND

2 - One of the following: [A]

2.1 Patient has a BRAF V600E mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., cobas 4800 BRAF V600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

OR

2.2 Patient has a BRAF V600K mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., cobas 4800 BRAF V600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Used in combination with Zelboraf (vemurafenib)*

Notes	*This product may require prior authorization.

Product Name:Cotellic	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of histiocytic neoplasm

AND

2 - Used as monotherapy

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

Approval Criteria

1 - Patient has not experienced disease progression while on therapy

3 . Endnotes

A. The cobas 4800 BRAF V600 Mutation Test is an FDA approved option and was used in the pivotal trial. [2, 3] The cobas 4800 BRAF V600 Mutation Test is also listed as the FDA approved companion diagnostic device for Zelboraf (vemurafenib). [3]

4 . References

1. Cotellic Prescribing Information. Genentech USA, Inc. South San Francisco, CA. May 2023.

2. Larkin J, Ascierto PA, Dréno B, et al. Combined vemurafenib and cobimetinib in BRAF-mutated melanoma. N Engl J Med. 2014;371(20):1867-76.
3. U.S. Food and Drug Administration. List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Available at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm301431.htm. Accessed May 23, 2024.

Prior Authorization Guideline

Guideline Name	Coverage of Off-Label Non-FDA Approved Indications

Guideline Note:

Effective Date:	1/1/2025

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 such if the off-label criteria are not met. Please refer to drug specific PA guideline 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 Comprehensive 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 such if the off-label criteria are not met. Please refer to drug specific PA guideline 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 NCC consensus that the intervention is appropriate.
2A	Based upon lower-level evidence, there is uniform NC consensus that the intervention is appropriate.
2B	Based upon lower-level evidence, there is NCCN cons that the intervention is appropriate.
3	Based upon any level of evidence, there is major NCC 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 September 20, 2023.
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 September 20, 2023.
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 20, 2023.
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 September 20, 2023.
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 September 20, 2023.
6. Micromedex Healthcare Series. Recommendation, Evidence, and Efficacy Ratings. https://www.micromedexsolutions.com/micromedex2/librarian/CS/8F8397/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/136D2F/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.IntermediateToDocumentLink?docId=3198&contentSetId=50&title=Recommendation%2C+Evidence+and+Efficacy+Ratings&servicesTitle=Recommendation%2C+Evidence+and+Efficacy+Ratings. Accessed September 20, 2023.

Prior Authorization Guideline

Guideline Name	Crysvita (burosumab-twza)

Guideline Note:

Effective Date:	10/1/2024

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 - Patient demonstrates 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** - Patient demonstrates 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.

Prior Authorization Guideline

Guideline Name	Daraprim (pyrimethamine)

Guideline Note:

Effective Date:	8/1/2024

1 . Indications

Drug Name: Daraprim (pyrimethamine)
Treatment of toxoplasmosis Indicated for the treatment of toxoplasmosis when used conjointly with a sulfonamide, since synergism exists with this combination.

2 . Criteria

Product Name:Brand Daraprim, generic pyrimethamine	
Diagnosis	Toxoplasmosis
Approval Length	12 Months [A, B]
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 One of the following:

1.1.1 Patient is using pyrimethamine for one of the following: [2, 3]

- Active treatment of toxoplasmosis (e.g., toxoplasmic encephalitis, ocular toxoplasmosis)
- Secondary prophylaxis of toxoplasmosis
- Treatment of congenital toxoplasmosis

OR

1.1.2 All of the following: [2]

1.1.2.1 Patient is using pyrimethamine for primary prophylaxis of toxoplasmosis

AND

1.1.2.2 Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)

AND

1.1.2.3 One of the following:

1.1.2.3.1 Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate

OR

1.1.2.3.2 Evidence of life-threatening reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (e.g., toxic epidermal necrolysis [TEN], Stevens-Johnson syndrome)

AND

1.2 Prescribed by or in consultation with an infectious disease specialist

Product Name:Brand Daraprim, generic pyrimethamine	
Diagnosis	Malaria (off-label)
Guideline Type	Prior Authorization

Approval Criteria

1 - Requests for coverage of any pyrimethamine products for the treatment and/or prophylaxis of malaria are not authorized and will not be approved. The use of pyrimethamine for the treatment and/or prophylaxis of malaria is not recommended by the Centers for Disease Control and Prevention (CDC) [5]

3 . Endnotes

A. Prescriber should consider discontinuation of primary prophylaxis if CD4 is greater than 200 cells/mm3 for more than 3 months after institution of combination antiretroviral therapy. [2]
B. Prescriber should consider discontinuation of secondary prophylaxis if CD4 is greater than 200 cells/mm3 for more than 6 months after institution of combination antiretroviral therapy. [2]

4 . References

1. Daraprim Prescribing Information. Vyera Pharmaceuticals. New York, NY. August 2017.
2. Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections/treatment-hiv-associated. Accessed May 27, 2024.

3. Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children. https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/pediatric-oi/tables-pediatric-oi.pdf. Accessed May 27, 2024.
4. Parasites - Toxoplasmosis (Toxoplasma infection). https://www.cdc.gov/parasites/toxoplasmosis/health_professionals/index.html#tx. Accessed May 5, 2023.
5. Centers for Disease Control and Prevention. CDC Yellow Book 2024: Health Information for International Travel. New York: Oxford University Press; 2024. https://wwwnc.cdc.gov/travel/yellowbook/2024/infections-diseases/malaria. Accessed May 27, 2024.

Prior Authorization Guideline

Guideline Name	Darzalex (daratumumab), Darzalex Faspro (daratumumab and hyaluronidase-fihj) - PA, NF

Guideline Note:

Effective Date:	4/1/2025

1 . Indications

Drug Name: Darzalex (daratumumab)
Multiple Myeloma - Monotherapy Indicated as monotherapy for the treatment of adult patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent. **Multiple Myeloma - Combination therapy** Indicated in combination with lenalidomide and dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least one prior therapy. **Multiple Myeloma - Combination therapy** Indicated in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. **Multiple Myeloma - Combination therapy** Indicated in combination with carfilzomib and dexamethasone in adult patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy.

Multiple Myeloma - Combination therapy Indicated in combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.

Newly Diagnosed Multiple Myeloma Indicated in combination with bortezomib, melphalan, and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.

Newly Diagnosed Multiple Myeloma Indicated in combination with lenalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.

Newly Diagnosed Multiple Myeloma Indicated in combination with bortezomib, thalidomide, and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.

Drug Name: Darzalex Faspro (daratumumab and hyaluronidase-fihj)

Multiple Myeloma - Monotherapy Indicated as monotherapy for the treatment of adult patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.

Multiple Myeloma - Combination Indicated in combination with lenalidomide and dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least one prior therapy.

Multiple Myeloma - Combination Indicated in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.

Multiple Myeloma - Combination Indicated in combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor.

Multiple Myeloma - Combination Indicated in combination with carfilzomib and dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy.

Newly Diagnosed Multiple Myeloma Indicated in combination with lenalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple

myeloma who are ineligible for autologous stem cell transplant.

Newly Diagnosed Multiple Myeloma Indicated in combination with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.

Newly Diagnosed Multiple Myeloma Indicated in combination with bortezomib, thalidomide, and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.

Newly Diagnosed Multiple Myeloma Indicated in combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation in newly diagnosed patients who are eligible for autologous stem cell transplant.

Light Chain (AL) Amyloidosis Indicated in combination with bortezomib, cyclophosphamide, and dexamethasone for the treatment of adult patients with newly diagnosed light chain (AL) amyloidosis. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). Limitations of Use: DARZALEX FASPRO is not indicated and is not recommended for the treatment of patients with light chain (AL) amyloidosis who have NYHA Class IIIB or Class IV cardiac disease or Mayo Stage IIIB outside of controlled clinical trials.

2 . Criteria

Product Name:Darzalex	
Diagnosis	Relapsed/Refractory Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Used as monotherapy

AND

2.1.2 One of the following:

2.1.2.1 Patient has received at least three prior treatment regimens which included both of the following:

- Proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])
- Immunomodulatory agent (e.g., lenalidomide [Revlimid], thalidomide [Thalomid])

OR

2.1.2.2 Patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent

OR

2.2 Both of the following:

2.2.1 Used in combination with one of the following treatment regimens:

- lenalidomide and dexamethasone
- bortezomib and dexamethasone
- carfilzomib and dexamethasone

AND

2.2.2 Patient has received at least one prior therapy (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro], lenalidomide [Revlimid], thalidomide [Thalomid]) [2]

OR

2.3 Both of the following:

2.3.1 Used in combination with both of the following:

- pomalidomide
- dexamethasone

AND

2.3.2 Patient has received at least two prior therapies including lenalidomide and a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])

Product Name:Darzalex	
Diagnosis	Newly Diagnosed Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Newly diagnosed multiple myeloma

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient is ineligible for autologous stem cell transplant

AND

2.1.2 One of the following:

2.1.2.1 Used in combination with all of the following:

- bortezomib
- melphalan
- prednisone

OR

2.1.2.2 Used in combination with both of the following:

- lenalidomide
- dexamethasone

OR

2.2 Both of the following:

2.2.1 Patient is eligible for autologous stem cell transplant

AND

2.2.2 Used in combination with all of the following:

- bortezomib
- thalidomide

- dexamethasone

Product Name:Darzalex Faspro	
Diagnosis	Relapsed/Refractory Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Used as monotherapy

AND

2.1.2 One of the following:

2.1.2.1 Patient has received at least three prior treatment regimens which included both of the following:

- Proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])
- Immunomodulatory agent (e.g., lenalidomide [Revlimid], thalidomide [Thalomid])

OR

2.1.2.2 Patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent

OR

2.2 Both of the following:

2.2.1 Used in combination with one of the following treatment regimens:

- lenalidomide and dexamethasone
- bortezomib and dexamethasone
- carfilzomib and dexamethasone

AND

2.2.2 Patient has received at least one prior therapy (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro], lenalidomide [Revlimid], thalidomide [Thalomid]) [2]

OR

2.3 Both of the following:

2.3.1 Used in combination with both of the following:

- pomalidomide
- dexamethasone

AND

2.3.2 Patient has received at least one prior line of therapy including lenalidomide and a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])

Diagnosis	Relapsed/Refractory Multiple Myeloma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of multiple myeloma

AND

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

2.1 Both of the following:

2.1.1 Used as monotherapy

AND

2.1.2 One of the following:

2.1.2.1 Patient has received at least three prior treatment regimens which included both of the following:

- Proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])
- Immunomodulatory agent (e.g., lenalidomide [Revlimid], thalidomide [Thalomid])

OR

2.1.2.2 Patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent

OR

2.2 Both of the following:

2.2.1 Used in combination with one of the following treatment regimens:

- lenalidomide and dexamethasone
- bortezomib and dexamethasone
- carfilzomib and dexamethasone

AND

2.2.2 Patient has received at least one prior therapy (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro], lenalidomide [Revlimid], thalidomide [Thalomid]) [2]

OR

2.3 Both of the following:

2.3.1 Used in combination with both of the following:

- pomalidomide
- dexamethasone

AND

2.3.2 Patient has received at least one prior line of therapy including lenalidomide and a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])

Product Name:Darzalex Faspro	
Diagnosis	Newly Diagnosed Multiple Myeloma
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Newly diagnosed multiple myeloma

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient is ineligible for autologous stem cell transplant

AND

2.1.2 One of the following:

2.1.2.1 Used in combination with all of the following:

- bortezomib
- melphalan
- prednisone

OR

2.1.2.2 Used in combination with both of the following:

- lenalidomide
- dexamethasone

OR

2.2 Both of the following:

2.2.1 Patient is eligible for autologous stem cell transplant

AND

2.2.2 One of the following:

2.2.2.1 Used in combination with all of the following:

- bortezomib
- thalidomide
- dexamethasone

OR

2.2.2.2 Used in combination with all of the following: (2)

- bortezomib
- lenalidomide
- dexamethasone

Product Name:Darzalex Faspro	
Diagnosis	Newly Diagnosed Multiple Myeloma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming newly diagnosed multiple myeloma

AND

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

2.1 Both of the following:

2.1.1 Patient is ineligible for autologous stem cell transplant

AND

2.1.2 One of the following:

2.1.2.1 Used in combination with all of the following:

- bortezomib
- melphalan
- prednisone

OR

2.1.2.2 Used in combination with both of the following:

- lenalidomide
- dexamethasone

OR

2.2 Both of the following:

2.2.1 Patient is eligible for autologous stem cell transplant

AND

2.2.2 One of the following:

2.2.2.1 Used in combination with all of the following:

- bortezomib
- thalidomide
- dexamethasone

OR

2.2.2.2 Used in combination with all of the following: (2)

- bortezomib
- lenalidomide
- dexamethasone

Product Name:Darzalex Faspro	
Diagnosis	Light Chain Amyloidosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Newly diagnosed light chain (AL) amyloidosis

AND

2 - Used in combination with ALL of the following:

- Bortezomib
- Cyclophosphamide

- Dexamethasone

AND

3 - All of the following: [3]

- Patient does not have New York Heart Association (NYHA) Class IIIB disease
- Patient does not have New York Heart Association (NYHA) Class IV disease
- Patient does not have Mayo Stage IIIB disease

Product Name:Darzalex Faspro	
Diagnosis	Light Chain Amyloidosis
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming newly diagnosed light chain (AL) amyloidosis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming medication is being used in combination with ALL of the following:

- Bortezomib
- Cyclophosphamide
- Dexamethasone

AND

3 - All of the following: [3]

- Patient does not have New York Heart Association (NYHA) Class IIIB disease
- Patient does not have New York Heart Association (NYHA) Class IV disease
- Patient does not have Mayo Stage IIIB disease

Product Name:Darzalex, Darzalex Faspro	
Diagnosis	All Indications listed above
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. Darzalex Prescribing Information. Janssen Biotech, Inc. Horsham, PA. July 2024.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Multiple Myeloma v1.2025. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed January 9, 2025.
3. Darzalex Faspro Prescribing Information. Janssen Biotech, Inc. Horsham, PA. July 2024.

Prior Authorization Guideline

Guideline Name	DAW Override

Guideline Note:

Effective Date:	1/1/2025

Note:

The intent of this policy is to serve as guidance for clients who would like to implement a dispense as written (DAW) override program. The standard DAW (brand name) override criteria are for clients who opt for such a program to help manage prescription costs. The criteria is applied when a provider/patient requests for coverage of a brand medication when a generic is available.

1 . Criteria

Product Name:Brand drugs with two or more generic equivalents available	
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria	

1 - Patient has tried two generic equivalents of the requested drug from different manufacturers

AND

2 - One of the following:

2.1 Patient has had an allergic reaction or intolerance to an inactive ingredient

OR

2.2 Patient has experienced an inadequate response to the generic equivalent of the requested drug

AND

3 - One of the following:

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

OR

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

Product Name:Brand drugs with only one generic equivalent available	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - Patient has tried one generic equivalent of the requested drug from a different manufacturer

AND

2 - One of the following:

2.1 Patient has had an allergic reaction or intolerance to an inactive ingredient

OR

2.2 Patient has experienced an inadequate response to the generic equivalent of the requested drug

AND

3 - One of the following:

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

OR

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

2 . Endnotes

A. The standard DAW (brand name) override criteria are for clients who opt for such a program to help manage prescription costs. The criteria is applied when a provider/patient requests for coverage of a brand medication when a generic is available. There must be a clinical reason why the patient cannot take the generic version of the medication. Acceptable clinical reasons include having an inadequate response, an allergic reaction, or intolerance to two generic

manufacturers of the branded product (or one if only one generic equivalent is available). Intolerance of the generic version may occur due to excipients in the generic version of the product. In order to receive approval for the prescribed drug, the prescriber will document the clinical reason as to why the patient cannot use a generic version of the product.

Prior Authorization Guideline

Guideline Name	Daxxify (botulinum toxin type a injection)

Guideline Note:

Effective Date:	10/1/2024

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.

Prior Authorization Guideline

Guideline Name	Dysport (abobotulinumtoxinA)

Guideline Note:

Effective Date:	10/1/2024

1 . Indications

Drug Name: Dysport (abobotulinumtoxinA)
Cervical Dystonia Indicated for the treatment of cervical dystonia in adults. **Spasticity** Indicated for the treatment of spasticity in patients 2 years of age and older. **Cosmetic Uses [Non-approvable Use]** 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, as this is considered a cosmetic use.

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	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	All indications listed above
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 elapsed since the last treatment [A]

Product Name:Dysport	
Diagnosis	Cosmetic Uses
Guideline Type	Prior Authorization

Approval Criteria

1 - Requests for coverage of any Dysport 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. 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. January 2023.
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.

Prior Authorization Guideline

Guideline Name	Eculizumab Products

Guideline Note:

Effective Date:	6/1/2025

1 . Indications

Drug Name: Bkemv (eculizumab-aeeb)
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: Bkemv 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. **Off Label Uses: 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.
Drug Name: Epysqli (eculizumab-aagh)

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: Epysqli is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).

Off Label Uses: Generalized Myasthenia Gravis (gMG) Indicated for the treatment of generalized myasthenia gravis (gMG) in adult and pediatric patients six years of age and older 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.

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 generalized myasthenia gravis (gMG) in adult and pediatric patients six years of age and older 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:Bkemv, Epysqli, 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 - Prescribed by or in consultation with a hematologist/oncologist

Product Name:Bkemv, Epysqli, Soliris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy

AND

2 - Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab)

Product Name:Bkemv, Epysqli, 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 - Prescribed by or in consultation with one of the following:

- Hematologist
- Nephrologist

Product Name:Bkemv, Epysqli, Soliris	
Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response (e.g., increase in mean platelet counts, hematologic normalization) to therapy

AND

2 - Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab)

Product Name:Bkemv, Epysqli [off-label], 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 - Patient is 6 years of age or older

AND

4 - Trial and failure, contraindication (e.g., age), or intolerance to one of the following:

- Ultomiris (ravulizumab)
- Vyvgart (efgartigimod)

AND

5 - One of the following: [2, 3]

5.1 For patients between 6 and 17 years of age, trial and failure, contraindication, or intolerance to one of the following:

- Immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)
- Chronic plasmapheresis or plasma exchange (PE)
- Intravenous immunoglobulin (IVIG)

OR

5.2 For patients 18 years of age or older, one of the following:

5.2.1 Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

OR

5.2.2 Both of the following:

5.2.2.1 Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

AND

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

- Chronic plasmapheresis or plasma exchange (PE)
- Intravenous immunoglobulin (IVIG)

AND

6 - Prescribed by or in consultation with a neurologist

Product Name:Bkemv, Epysqli [off-label], Soliris	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Trial and failure, contraindication (e.g., age), or intolerance to one of the following:

- Ultomiris (ravulizumab)
- Vyvgart (efgartigimod)

Product Name:Bkemv, Epysqli [off-label], Soliris [off-label]	
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 - Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab)

AND

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

- Neurologist
- Ophthalmologist

Product Name:Bkemv, Epysqli [off-label], Soliris [off-label]	
Diagnosis	Neuromyelitis Optica Spectrum Disorder (NMOSD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab)

3 . References

1. Soliris Prescribing Information. Alexion Pharmaceuticals, Inc. Boston, MA. February 2025.
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.
4. Bkemv Prescribing Information. Amgen Inc. Thousand Oaks, CA. October 2024.
5. Epysqli Prescribing Information. Samsung Bioepis Co., Ltd. Incheon, Republic of Korea. July 2024.

Prior Authorization Guideline

Guideline Name	Elaprase (idursulfase)

Guideline Note:

Effective Date:	10/1/2024

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	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Hunter syndrome (Mucopolysaccharidosis II, MPS II)

Product Name:Elaprase (idursulfase)	
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. Elaprase Prescribing Information. Takeda Pharmaceuticals U.S.A., Inc. Lexington, MA. October 2021.

Prior Authorization Guideline

Guideline Name	Empaveli (pegcetacoplan)

Guideline Note:

Effective Date:	9/1/2024

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)

AND

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

- Hematologist
- Oncologist

Product Name:Empaveli	
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 hemoglobin level, hemoglobin stabilization, decrease in the number of red blood cell transfusions)

3 . References

1. Empaveli Prescribing Information. Apellis Pharmaceuticals, Inc. Waltham, MA. February 2024.
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.

Prior Authorization Guideline

Guideline Name	Encelto (revakinagene taroretcel-lwey)

Guideline Note:

Effective Date:	8/1/2025

1 . Indications

Drug Name: Encelto (revakinagene taroretcel-lwey)
Macular telangiectasia type 2 (MacTel) Indicated for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel).

2 . Criteria

Product Name:Encelto	
Approval Length	1 Time Authorization per Eye in Lifetime
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of macular telangiectasia type 2 (MacTel)

AND

2 - Ellipsoid Zone (EZ) loss as measured by optical coherence tomography (OCT) from .16mm^2 and 2.00mm^2."

AND

3 - Patient does not have neovascular macular telangiectasia (Mac Tel)

AND

4 - Patient's best corrected visual acuity (BCVA) is 20/80 or better

AND

5 - Provider attests patient has not received prior treatment with Encelto in the affected eye in their lifetime

AND

6 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

3 . References

1. Encelto Prescribing information. Neurotech Pharmaceuticals, Inc. Cumberland, RI. March 2025.
2. ClinicalTrials.gov. A Study to Determine the Safety and Efficacy of NT-501 in Macular Telangiectasia Type 2 - Protocol A. Available at:

https://www.clinicaltrials.gov/study/NCT03316300?cond=NCT03316300&rank=1#participation-criteria. Accessed June 13, 2025.
3. ClinicalTrials.gov. A Study to Determine the Safety and Efficacy of NT-501 in Macular Telangiectasia Type 2 - Protocol B. Available at: https://www.clinicaltrials.gov/study/NCT03319849?cond=NCT03319849&rank=1#participation-criteria. Accessed June 13, 2025.

Prior Authorization Guideline

Guideline Name	Enjaymo (sutimlimab-jome)

Guideline Note:

Effective Date:	6/1/2025

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 - Patient demonstrates 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. February 2024.
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.

Prior Authorization Guideline

Guideline Name	Entyvio (vedolizumab)

Guideline Note:

Effective Date:	5/1/2025

1 . Criteria

Product Name:Entyvio IV	
Diagnosis	Crohn's Disease (CD)
Approval Length	14 Weeks [1, A]
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

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)
- Skyrizi (risankizumab-rzaa)
- Any ustekinumab product

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 [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:

2.1 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	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)
- Any 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 th e TNF inhibitor 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 preferred 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 (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, 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.

Prior Authorization Guideline

Guideline Name	Erythropoietic Agents - PA, NF

Guideline Note:

Effective Date:	1/1/2025

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; (3) As a substitute for red blood cell (RBC) transfusions in patients who require immediate correction of anemia.

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 3 months to 17 years of age on dialysis or not on dialysis, 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 - Adequate iron stores confirmed by both of the following: [A, J]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

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

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 - Adequate iron stores confirmed by both of the following: [A, J]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

3 - One of the following:

3.1 All of the following:

3.1.1 Patient is 18 years of age or older

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 3 months and 17 years of age

AND

3.2.2 Patient's hemoglobin level has been stabilized by treatment with another erythropoietin stimulating agent (ESA) (e.g., Aranesp, Retacrit)

AND

3.2.3 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

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 1 g/dL from pre-treatment level

AND

4 - Adequate iron stores confirmed by both of the following: [A, J]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

Notes	^Authorization will be given if physician is aware of iron deficiency and is 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 - Submission of medical records (e.g., chart notes) confirming adequate iron stores by both of the following: [A, J]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

3 - Submission of medical records (e.g., chart notes) confirming 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

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 - Adequate iron stores confirmed by both of the following: [2-3, 33]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

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) [O]

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 1 g/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 - Submission of medical records (e.g., chart notes) confirming adequate iron stores by both of the following: [2-3, 33]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

2 - Submission of medical records (e.g., chart notes) confirming 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 - Submission of medical records (e.g., chart notes) confirming 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]

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 - Adequate iron stores confirmed by both of the following: [1-3, 8, 33, G]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

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

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 - Submission of medical records (e.g., chart notes) confirming 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 - Submission of medical records (e.g., chart notes) confirming adequate iron stores by both of the following: [1-3, 8, 33, G]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

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

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 - Adequate iron stores confirmed by both of the following: [2-3, 33]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

6 - History of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

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 - Submission of medical records (e.g., chart notes) confirming 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 - Submission of medical records (e.g., chart notes) confirming adequate iron stores by both of the following: [2-3, 33]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

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]

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 - Adequate iron stores confirmed by both of the following: [4, A, H]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

4 - History of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp
- Retacrit or Procrit

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 1.5 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]

- Diagnosis of transfusion-dependent MDS
- Serum erythropoietin level less than or equal to 500 mU/mL

AND

3 - Submission of medical records (e.g., chart notes) confirming adequate iron stores by both of the following: [4, A, H]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

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

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 - Adequate iron stores confirmed by both of the following: [2-3, 33]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

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
- peginterferon alfa

AND

5 - History of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

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 - Submission of medical records (e.g., chart notes) confirming adequate iron stores by both of the following: [2-3, 33]

- Patient's ferritin level is greater than 100 mcg/L
- Patient's transferrin saturation (TSAT) is greater than 20%

AND

3 - Submission of medical records (e.g., chart notes) confirming 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
- peginterferon alfa

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]

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 clinical 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 clinical 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. April 2024.
2. Epogen prescribing information. Amgen Inc. Thousand Oaks, CA. April 2024.
3. Procrit prescribing information. Amgen Inc. Thousand Oaks, CA. April 2024.
4. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Myelodysplastic Syndromes v.3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed October 8, 2024.
5. AHFS Drug Information website. Available at: http://online.lexi.com/lco/action/doc/retrieve/docid/complete_ashp/414035. Accessed October 8, 2024.
6. Micromedex Healthcare Series. Thomson Micromedex. Accessed October 31, 2022.

7. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Kidney inter., Suppl. 2012; 2: 279-335. https://kdigo.org/wp-content/uploads/2016/10/KDIGO-2012-Anemia-Guideline-English.pdf. Accessed October 8, 2024.
8. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Hematopoietic Growth Factors v.3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Accessed October 9, 2024.
9. Eschbach JW, Abdulhadi MH, Browne JE, et al. Recombinant human erythropoietin in anemic patients with end-stage renal disease. Ann Intern Med 1989;111:992-1000.
10. Rizzo JD, Lichtin AE, Woolf SH, et al. Use of epoetin in patients with cancer: evidence-based clinical practice guidelines of the American Society of Clinical Oncology and the American Society of Hematology. Blood 2002;100(7):2303-20.
11. Volberding P, Levine A, Dieterich D, et al. Anemia in HIV infection: clinical impact and evidence-based management strategies. Clin Infect Dis 2004;38:1454-63.
12. Yee HS, Currie SL, Darling JM, et al. Management and treatment of hepatitis c viral infection: recommendations from the Department of Veterans Affairs Hepatitis C Resource Center Program and the National Hepatitis C Program Office. Am J Gastroenterol 2006;101:2360-78.
13. AHRQ Evidence Report #29: Health Services/Technology Assessment Text. Use of erythropoietin for anemia in chronic renal failure. Available at: https://www.ncbi.nlm.nih.gov/books/NBK11934/. Accessed on November 3, 2020.
14. Remuzzi G, Ingelfinger JR. Correction of anemia-payoffs and problems. N Engl J Med. 2006;355:2144-6.
15. Drueke TB, Locatelli F, Clyne N,et al. Normalization of hemoglobin level in patients with chronic kidney disease and anemia. N Engl J Med. 2006 Nov 16;355(20):2071-84.
16. Singh AK, Szczech L, Tang KL, et al. Correction of anemia with epoetin alfa in chronic kidney disease. N Engl J Med 2006;355:2085-98.
17. Besarab A, Bolton WK, Browne JK, et al. The effects of normal as compared with low hematocrit values in patients with cardiac disease who are receiving hemodialysis and epoetin. N Engl J Med 1998;339:584-90.
18. Centers for Medicare and Medicaid Services. Decision memo for erythropoiesis stimulating agents (ESAs) for non-renal disease indications (CAG-00383N). July 30, 2007.
19. Rizzo J, Brouwers M, Hurley P, et al.American Society of Clinical Oncology/American Society of Hematology Clinical Practice Guideline Update on the Use of Epoetin and Darbepoetin in Adult Patients With Cancer Available at: http://jco.ascopubs.org/content/early/2010/10/25/JCO.2010.29.2201.full.pdf+html. Accessed February 21, 2011.

20. DRUGDEX System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Accessed October 9, 2024.
21. Centers for Medicare and Medicaid Services. Medicare Program: End-Stage Renal Disease Prospective Payment System: Final Rule and Proposed Rule. Federal Register. 2010;75(155):49030-49214.
22. National Kidney Foundation. KDOQI clinical practice guidelines for chronic kidney disease: evaluation, classification and stratification. Am J Kidney Dis;39(Suppl 1):S1-266.
23. Groopman JE, Itri LM. Chemotherapy-induced anemia in adults: Incidence and treatment. J Natl Cancer Inst.1999;91(19):1616-34Available at: http://jnci.oxfordjournals.org/content/91/19/1616.full.pdf+html. Accessed March 18, 2011.
24. Grossman HA, Goon B, Bowers P, Leitz G. Once-weekly epoetin alfa dosing is as effective as three times-weekly dosing in increasing hemoglobin levels and is associated with improved quality of life in anemic HIV-infected patients. J Acquir Immune Defic Syndr. 2003;34(4):368-78.
25. Revicki DA, Brown RE, Henry DA, et al. Recombinant human erythropoietin and health-related quality of life of AIDS patients with anemia. J Acquir Immune Defic Syndr. 1994;7:474-84.
26. Phair JP, Abels RI, McNeill MV, Sullivan DJ. Recombinant human erythropoietin treatment: investigational new drug protocol for the anemia of the acquired immunodeficiency syndrome. Arch Intern Med. 1993;153:2668-75.
27. Saag MS, Bowers P, Leitz GJ, Levine AM. Once-weekly epoetin alfa improves quality of life and increases hemoglobin in anemic HIV+ patients. AIDS Res Hum Retroviruses. 2004;20(10):1037-45.
28. HIV-associated cytopenias. UpToDate. Available at Uptodate.com. Accessed October 31, 2022.
29. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Kidney inter., Suppl. 2012; 2: 279-335. http://www.kdigo.org/clinical_practice_guidelines/pdf/KDIGO-Anemia%20GL.pdf. Accessed November 3, 2020.
30. The American Cancer Society website. Available at: https://www.cancer.org/cancer/glossary.html?letter=. Accessed November 3, 2020.
31. Mircera prescribing information. Vifor (International) Inc. St. Gallen, Switzerland. June 2024.
32. Centers for Medicare and Medicaid Services. Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Final Rule. Federal Register. 2014;79(215):66120-66265.
33. Retacrit prescribing information. Pfizer Inc. New York, NY. June 2024.
34. Per clinical consult with hematologist/oncologist, June 6, 2018.

35. EASL Clinical Practice Guidelines: Management of hepatitis C virus infection. J Hepatol. 2011;55(2):245-64.

Prior Authorization Guideline

Guideline Name	Evenity (romosozumab-aqqg injection)

Guideline Note:

Effective Date:	8/1/2025

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. Limitations of Use: 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.

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 treatment duration of 12 monthly doses. *Evenity will not be approved if the patient has already received 12 months of therapy; if the patient has not yet received 12 months of therapy, approval may be granted for the balance of the time remaining.

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 https://frax.shef.ac.uk/FRAX/ and incorporates multiple clinical factors that predict fracture risk, largely independent of BMD. [2]

4 . References

1. Evenity Prescribing Information. Amgen Inc. Thousand Oaks, CA. October 2024.
2. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the prevention and treatment of postmenopausal osteoporosis: 2020 update. Available at: https://pro.aace.com/disease-state-resources/bone-and-parathyroid/clinical-practice-guidelines/clinical-practice. Accessed April 29, 2024.
3. National Osteoporosis Foundation. Treatment and Adherence. Available at: https://www.nof.org/patients/treatment/medicationadherence/. Accessed May 6, 2025.
4. Eastell R, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: An endocrine society clinical practice guideline. J Clin Endocrin Metab. 2019; 104(5):1595-1622.

Prior Authorization Guideline

Guideline Name	Evkeeza (evinacumab-dgnb)

Guideline Note:

Effective Date:	7/1/2025

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	When approved; no reauthorization required
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by one of the following: [2]

1.1 Genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus

OR

1.2 Both of the following:

1.2.1 Untreated LDL-C greater than 400 mg/dL

AND

1.2.2 One of the following:

- Xanthoma before 10 years of age
- Evidence of heterozygous familial hypercholesterolemia in both parents

AND

2 - Patient is 5 years of age or older

AND

3 - One of the following:

- Patient is currently treated with maximally tolerated statin therapy

- Patient is statin intolerant as evidenced by an inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (e.g., creatine kinase)
- Patient has a contraindication to all statins

AND

4 - One of the following:

- Patient has been receiving ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy
- Patient has a history of intolerance or contraindication to ezetimibe
- Patient is less than 10 years of age

AND

5 - 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 is less than 10 years of age

AND

6 - Patient will continue other traditional lipid-lowering therapies (e.g., maximally tolerated statins, ezetimibe) in combination with Evkeeza

AND

7 - Dose will not exceed 15 mg/kg of bodyweight infused once every 4 weeks

AND **8** - Prescribed by or in consultation with one of the following: • Cardiologist • Endocrinologist • Hepatologist	
Notes	For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve t hrough 12/31/2039'

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. [3]
B. In patients treated with statins, it is recommended to measure creatine kinase levels in individuals with severe statin-associated muscle symptoms. [3]

4 . References

1. Evkeeza Prescribing Information. Regeneron Pharmaceuticals, Inc. Tarrytown, NY. March 2023.
2. Cuchel M, Raal FJ, Hegele RA, Al-Rasadi K, Arca M, Averna M, Bruckert E, Freiberger T, Gaudet D, Harada-Shiba M, Hudgins LC, Kayikcioglu M, Masana L, Parhofer KG, Roeters van Lennep JE, Santos RD, Stroes ESG, Watts GF, Wiegman A, Stock JK, Tokgözoğlu LS, Catapano AL, Ray KK. 2023 Update on European Atherosclerosis Society Consensus Statement on Homozygous Familial Hypercholesterolaemia: new treatments and clinical guidance. Eur Heart J. 2023 Jul 1;44(25):2277-2291. doi:10.1093/eurheartj/ehad197. PMID: 37130090; PMCID: PMC10314327.
3. 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.

Prior Authorization Guideline

Guideline Name	Excluded Drugs Administrative Policy

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 dysfunct they are excluded from coverage. No = Deny. The plan does not cover drugs that do not have clear information to prove it the problem. This should come from reliable medical sources. Samaritan uses these s to define which treatments have been proven to work. The drug you have requested do 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 reaso Kybella requested for <diagnosis> is not covered. No = Deny. The plan does not cover drugs that do not have clear information to prove it the problem. This should come from reliable medical sources. Samaritan uses these s to define which treatments have been proven to work. The drug you have requested do 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 informa prove they are effective. This should come from reliable medical sources. <drug> does 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 define which treatments have been proven to work. The drug you have requested does not meet these requirements.

Prior Authorization Guideline

Guideline Name	Exondys 51 (eteplirsen) - PA, NF

Guideline Note:

Effective Date:	8/1/2025

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 - Disease is confirmed by the presence of a mutation of the dystrophin gene amenable to exon 51 skipping as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Patient is 7 years of age or older [2-4]

AND

4 - Prescribed by or in consultation with a neurologist with expertise in the treatment of DMD

AND

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

AND

6 - Patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.) [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 with expertise in the treatment of DMD

AND

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

AND

4 - Patient is maintaining ambulatory status without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)

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) confirming both of the following:

1.1 Diagnosis of Duchenne muscular dystrophy (DMD)

AND

1.2 Disease is confirmed by the presence of a mutation of the dystrophin gene amenable to exon 51 skipping as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

2 - Patient is 7 years of age or older [2-4]

AND

3 - Prescribed by or in consultation with a neurologist with expertise in the treatment of DMD

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) confirming the patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.) [2-4]

3 . References

1. Exondys 51 Prescribing Information. Sarepta Therapeutics, Inc. Cambridge, MA. December 2024.
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.

Prior Authorization Guideline

Guideline Name	Fabry Disease Agents

Guideline Note:

Effective Date:	12/1/2024

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	12 month(s)
Therapy Stage	Initial Authorization
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 other drugs used for Fabry disease [A]

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

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

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 other drugs used for Fabry Disease [A]

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

Approval Criteria

1 - Patient demonstrates 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. July 2024.
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 September 16, 2024.

Prior Authorization Guideline

Guideline Name	Fasenra (benralizumab)

Guideline Note:

Effective Date:	7/1/2025

1 . Indications

Drug Name: Fasenra (benralizumab)
Severe 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: Fasenra is not indicated for treatment of other eosinophilic conditions. Fasenra is not indicated for the relief of acute bronchospasm or status asthmaticus. **Eosinophilic Granulomatosis with Polyangiitis:** Indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

2 . Criteria

Product Name:Fasenra	
Diagnosis	Severe Asthma

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 [5, B, F]

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, B]

OR

3.2 Prior asthma-related hospitalization within the past 12 months [C]

AND

4 - One of the following:

4.1 Both of the following:

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	
Diagnosis	Severe Asthma
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 [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., 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:Fasenra	
Diagnosis	Eosinophilic Granulomatosis with Polyangiitis
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)

AND

3 - Patient is currently receiving corticosteroid therapy (e.g., prednisolone, prednisone) unless there is a contraindication or intolerance to corticosteroid therapy

AND

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

- Pulmonologist
- Rheumatologist
- Allergist/Immunologist

Product Name:Fasenra	
Diagnosis	Eosinophilic Granulomatosis with Polyangiitis
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., increase in remission time)

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 [4]

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.

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 2. Low, medium and high daily doses of inhaled corticosteroids in children 6 – 11 years [4]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	100-200	> 200-400	> 400
Beclometasone dipropionate (pMDI, extrafine particle, HFA)	50-100	> 100-200	> 200
Budesonide (DPI, or pMDI, standard particle, HFA)	100-200	> 200-400	> 400
Budesonide (nebules)	250-500	>500-1000	>1000
Ciclesonide (pMDI, extrafine particle*, HFA)	80	>80-160	>160
Fluticasone furoate (DPI)	50		n.a.
Fluticasone propionate (DPI)	50-100	> 100-200	> 200
Fluticasone propionate (pMDI, standard particle, HFA)	50-100	> 100-200	> 200
Mometasone furoate (pMDI, standard particle, HFA)	100		200

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. 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 (2023 update). 2023 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.

Prior Authorization Guideline

Guideline Name	Fecal Microbiota Agents - PA, NF

Guideline Note:

Effective Date:	4/1/2025

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.
Drug Name: Vowst (fecal microbiota spores, live-brpk) capsule
Recurrent Clostridioides difficile infection (CDI) Indicated to prevent the recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI (rCDI). Limitations of use: Vowst is not indicated for treatment of CDI.
Drug Name: Zinplava (bezlotoxumab) injection
Recurrent Clostridioides difficile infection (CDI) Indicated to reduce recurrence of Clostridioides difficile infection (CDI) in adults and pediatric patients 1 year of age and older who are receiving antibacterial drug treatment for CDI and are at high risk for CDI recurrence. Limitations of use: Zinplava is not indicated for the treatment of CDI.

ZINPLAVA is not an antibacterial drug. ZINPLAVA should only be used in conjunction with antibacterial drug 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:Vowst	
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 two or more recurrent episodes of CDI within 12 months

AND

4 - All of the following:

4.1 Patient has completed at least 10 consecutive days of one of the following antibiotic therapies 2-4 days prior to initiating Vowst:

- oral vancomycin
- Dificid (fidaxomicin)

AND

4.2 Patient has completed the recommended course of magnesium citrate the day before and at least 8 hours prior to initiating Vowst [A]

AND

4.3 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

AND

6 - Trial and failure, contraindication or intolerance to Rebyota

Product Name:Vowst	
Approval Length	14 Day(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming 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 two or more recurrent episodes of CDI within 12 months

AND

4 - All of the following:

4.1 Patient has completed at least 10 consecutive days of one of the following antibiotic therapies 2-4 days prior to initiating Vowst:

- oral vancomycin
- Dificid (fidaxomicin)

AND

4.2 Patient has completed the recommended course of magnesium citrate the day before and at least 8 hours prior to initiating Vowst [A]

AND

4.3 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

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication or intolerance to Rebyota

Product Name:Zinplava	
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 in less than or equal to 24 hours
- A positive stool test for C.difficile toxin or toxigenic C.difficile

AND

2 - Used for the reduction of the recurrence of CDI

AND

3 - Used in combination with antibacterial drug treatment for CDI [e.g., oral Vancocin (vancomycin), Flagyl (metronidazole), or Dificid (fidaxomicin)]

AND

4 - Patient is 1 year of age or older

AND

5 - Patient has one or more of the following risk factors associated with CDI recurrence: [5-8, B]

- One or more prior episodes of CDI in the previous 6 months
- Immunocompromised
- Chronic dialysis
- Inflammatory bowel disease
- Continued use of non-CDI antimicrobials after diagnosis of CDI and/or after CDI treatment

AND

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

- Gastroenterologist
- Infectious disease specialist

3 . Endnotes

A. Patients are required to take magnesium citrate 24 hours prior to the first dose of Vowst per the prescribing information. There is currently no efficacy data regarding the use of Vowst without magnesium citrate and the thought is that it helps to clear the antibiotics prior to administration of Vowst. [2,3]
B. Risk factors for CDI recurrence: There is no specific guidance in regards to which patients should be considered high risk for CDI recurrence. There are a multitude of risk factors that increase patients' risk for recurrent CDI. Risk factors reported in one or more previously published studies and confirmed by consultant feedback include: one or more prior episodes of CDI in the previous 6 months, immunocompromised state, renal failure, inflammatory bowel disease, and continued use of non-CDI antimicrobials. Although patients greater than or equal to 65 years of age are at greater risk of recurrent CDI than younger patients, per consultant feedback, not all patients over 65 should be treated with Zinplava, only those with the highest risk. [5-11]

4 . References

1. Rebyota Prescribing Information. Ferring Pharmaceuticals, Inc. Parsippany, NJ. November 2022.
2. Vowst Prescribing Information. Aimmune Therapeutics, Inc. Brisbane, CA. June 2024.
3. Per clinical consult with gastroenterologist, May 3, 2023.
4. Zinplava Prescribing Information. Merck Sharp & Dohme LLC. Rahway, NJ. May 2023.
5. Cohen SH, Gerding DN, Johnson S, et al. Clinical practice guidelines for Clostridium difficile infection in adults: 2010 update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA). Infect Control Hosp Epidemiol. 2010;31(5):431-55.
6. Debast SB, Bauer MP, Kuijper EJ. European Society of Clinical Microbiology and Infectious Diseases: update of the treatment guidance document for Clostridium difficile infection. Clin Microbiol Infect. 2014;20 Suppl 2:1-26.

7. Zinplava Product Dossier. Merck and Co., Inc. May 2023.
8. Vincent Y, Manji A, Grgory-Miller K, et al. A review or management of Clostridium difficile infection: Primary and recurrence. Antibiotics. 2015;4(4):411-423.
9. Kelsen JR, Kim J, Latta D, et al. Recurrence rate of Clostridium difficile infection in hospitalized patients with inflammatory bowel disease. Inflamm Bowel Disease. 2011;17:50-55.
10. Kelly CP. Can we identify patients at high risk of recurrent Clostridium difficile infection? Clin Microbiol Infect. 2012;18 Suppl 6:21-27.
11. Per clinical consult with gastroenterologist, December 28, 2016.

Prior Authorization Guideline

Guideline Name	Filspari (sparsentan)

Guideline Note:

Effective Date:	9/1/2023

1 . Criteria

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

Approval Criteria

1 - Diagnosis of primary immunoglobulin A (IgA) nephropathy confirmed by biopsy

AND

2 - Member is 18 years or older

AND

3 - Prescribed by, or in consultation with a nephrologist

AND

4 - Member has no history of kidney transplant and not currently receiving dialysis

AND

5 - Urine protein-to-creatine ratio (UPCR) ≥ 1.5 and eGFR ≥ 30 mL/min^1.73 m2

AND

6 - Member has failed to achieve a reduction in proteinuria to under 1 gram/day while receiving maximally tolerated doses of an ACE inhibitor or ARB for at least 12 weeks

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

Approval Criteria

1 - One of the following:

- Improved or stable kidney function compared to baseline

- Reduction in proteinuria

Prior Authorization Guideline

Guideline Name	Gamifant (emapalumab-lzsg)

Guideline Note:

Effective Date:	5/1/2025

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 - Patient demonstrates 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 2023.
2. Per clinical consult with a pediatric hematologist/oncologist, January 18, 2019.
3. Wu Y, et al. Hemophagocytic lymphohistiocytosis: current treatment advances, emerging targeted therapy and underlying mechanisms. Journal of Hematology & Oncology. 2024; 17:106.

Prior Authorization Guideline

Guideline Name	Gaucher Disease Agents - PA, NF

Guideline Note:

Effective Date:	4/1/2025

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), Yargesa (miglustat), Generic 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). **Off Label Uses: Niemann-Pick disease type C (NPC)** Indicated for use in combination with Miplyffa (arimoclomol) for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adult and pediatric patients 2 years of age and older. [9-11]

2 . Criteria

Product Name:Cerezyme, Elelyso, or VPRIV	
Diagnosis	Type 1 Gaucher Disease
Approval Length	24 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	
Diagnosis	Type 1 Gaucher Disease
Approval Length	24 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:Brand Zavesca, Generic miglustat, or Yargesa	
Diagnosis	Type 1 Gaucher Disease
Approval Length	24 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mild to moderate Type 1 Gaucher disease

AND

2 - Patient is 18 years of age or older

Product Name:Brand Zavesca	
Diagnosis	Type 1 Gaucher Disease
Approval Length	24 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of mild to moderate Type 1 Gaucher disease

AND

2 - Patient is 18 years of age or older

Product Name:Brand Zavesca, Generic miglustat	
Diagnosis	Niemann-Pick disease type C (NPC) (off-label) [E]

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Niemann-Pick disease type C (NPC)

AND

2 - Requested drug will be used in combination with Miplyffa (arimoclomol)

AND

3 - Prescribed by or in consultation with a specialist knowledgeable in the treatment of Niemann-Pick disease type C

Product Name:Brand Zavesca, Generic miglustat	
Diagnosis	Niemann-Pick disease type C (NPC) (off-label) [E]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Requested drug will be used in combination with Miplyffa (arimoclomol)

Product Name:Brand Zavesca	
Diagnosis	Niemann-Pick disease type C (NPC) (off-label) [E]
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of Niemann-Pick disease type C (NPC)

AND

2 - Requested drug will be used in combination with Miplyffa (arimoclomol)

AND

3 - Prescribed by or in consultation with a specialist knowledgeable in the treatment of Niemann-Pick disease type C

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. Criteria is here to support the off-label use of miglustat for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in combination with Miplyffa as per Miplyffa FDA labelling. [12-14]

4 . References

1. Cerezyme Prescribing Information. Genzyme Corporation. Cambridge, MA. December 2024.
2. Elelyso Prescribing Information. Pfizer, Inc. New York, NY. July 2024.
3. VPRIV Prescribing Information. Takeda Pharmaceuticals U.S.A., Inc. Cambridge, MA. September 2024.
4. Cerdelga Prescribing Information. Genzyme Corporation. Cambridge, MA. January 2024.
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. Per clinical consult with geneticist, November 11, 2010.
11. Yargesa Prescribing Information. Edenbridge Pharmaceuticals LLC. Parsippany, NJ. October 2023.
12. Miplyffa Prescribing Information. Zevra Therapeutics, Inc. Celebration, FL. September 2024.
13. Mengel E, Patterson MC, Da Riol RM et al. Efficacy and safety of arimoclomol in Niemann-Pick disease type C: Results from a double-blind, randomised, placebo-controlled, multinational phase 2/3 trial of a novel treatment. J Inherit Metab Dis. 2021 Nov;44(6):1463-1480. doi: 10.1002/jimd.12428. Epub 2021 Sep 7.
14. FDA Review: Miplyffa. Food and Drug Administration Web Site. 2024. http://www.accessdata.fda.gov. Accessed November 4, 2024.

15. Miglustat Prescribing Information. ANI Pharmaceuticals, Inc. Baudette, MN. August 2022.

Prior Authorization Guideline

Guideline Name	Givlaari (givosiran)

Guideline Note:

Effective Date:	3/1/2025

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 - Patient demonstrates 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. April 2024.

Prior Authorization Guideline

Guideline Name	Gonadotropin-Releasing Hormone Agonists - SAMLG

Guideline Note:

Effective Date:	9/15/2024

1 . 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, Non-formulary
Approval Criteria **1** - Diagnosis of endometriosis	

AND

2 - One of the following: [8, 12]

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, Non-formulary

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, Non-formulary

Approval Criteria

1 - For use prior to surgery to reduce the size of fibroids to facilitate a surgical procedure (e.g., myomectomy, hysterectomy) [5]

Product Name:Lupron Depot (3.75 mg and 11.25 mg)	
Diagnosis	Uterine Leiomyomata (Fibroids) - Anemia [4,6]
Approval Length	3 month(s)
Guideline Type	Prior Authorization, Non-formulary

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: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, Non-formulary

Approval Criteria

1 - Diagnosis of advanced or metastatic prostate cancer

Product Name:Eligard, Brand Leuprolide Acetate (22.5 mg), Generic leuprolide acetate, Trelstar	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization, Non-formulary

Approval Criteria

1 - Diagnosis of advanced or metastatic prostate cancer

Product Name:Camcevi, Eligard, Brand Leuprolide Acetate (22.5 mg), Generic leuprolide acetate, Lupron Depot (7.5 mg, 22.5 mg, 30 mg and 45 mg), Trelstar	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization, Non-formulary

Approval Criteria

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

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, Non-formulary

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, Non-formulary

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., lack of progression or stabilization of secondary sexual characteristics, decrease in height velocity, a decrease in the ratio of bone age to chronological age, improvement in final height prediction, LH levels have been suppressed to pre-pubertal levels) [22]

AND

2 - Patient is currently younger than the appropriate time point for the onset of puberty (e.g., females younger than 11 years of age, males younger than 12 years of age) [22]

AND

3 - Prescribed by or in consultation with a pediatric endocrinologist

Product Name:Generic leuprolide acetate*	
Diagnosis	Treatment of Infertility (off-label) [5]

Guideline Type	Prior Authorization, Non-formulary

Approval Criteria

1 - Fertility Treatment is not covered by the plan. Request for treatment of infertility will be denied

Product Name:Lupron Depot, Lupron Depot-PED, Brand Leuprolide Acetate (22.5 mg), Generic leuprolide acetate, Eligard, Supprelin LA, Trelstar, Triptodur, Camcevi, Fensolvi	
Diagnosis	Gender Dysphoria/Gender Incongruence (off-label) [16, 17]
Approval Length	12 month(s)
Guideline Type	Prior Authorization, Non-formulary

Approval Criteria

1 - Using gonadotropin for suppression of puberty [16,17]

AND

2 - Diagnosis of gender dysphoria/gender incongruence

2 . Endnotes

A. Sixty days would be a reasonable length of authorization for the treatment of infertility. [13]

3 . References

1. Leuprolide acetate prescribing information. Sandoz Inc. Princeton, NJ. June 2020.

2. Lupron Depot (3.75 mg) prescribing information. AbbVie Inc. North Chicago, IL. January 2023.
3. Lupron Depot (3-Month 11.25 mg) prescribing information. AbbVie Inc. North Chicago, IL. March 2020.
4. Friedman AJ, Harrison-Atlas D, Barbieri RL, et al. A randomized, placebo-controlled, double-blind study evaluating the efficacy of leuprolide acetate depot in the treatment of uterine leiomyomata. Fertil Steril 1989;51:251-256.
5. DRUGDEX System [Internet database]. Greenwood Village, Colorado: Thomson Micromedex. Updated periodically. Accessed July 13, 2023.
6. Lethaby A, Vollenhoven B, Sowter M. Pre-operative GnRH analogue therapy before hysterectomy or myomectomy for uterine fibroids. Cochrane Database Syst Rev. 2001;(2):CD000547.
7. Supprelin LA prescribing information. Endo Pharmaceutical Inc. Malvern, PA. April 2022.
8. Ferrero, S., Barra, F. & Leone Roberti Maggiore, U. Current and Emerging Therapeutics for the Management of Endometriosis. Drugs 78, 995–1012 (2018).
9. Lupron Depot (7.5 mg, 22.5 mg, 30 mg, 45 mg) prescribing information. AbbVie Inc. North Chicago, IL. April 2022.
10. Eligard prescribing information. Tolmar Pharmaceuticals, Inc. Fort Collins, CO. April 2019.
11. Trelstar prescribing information. Verity Pharmaceuticals, Inc. Ewing, NJ. March 2023.
12. Practice bulletin no. 114: management of endometriosis. Obstet Gynecol. 2010 Jul; 116 (1): 223-36.
13. Per clinical consult with reproductive endocrinologist, April 10, 2013.
14. 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.
15. Lupron Depot-PED prescribing information. AbbVie Inc. North Chicago, IL. April 2023.
16. Hembree, Wylie C, Cohen-Kettenis P, Delemarre-van de Waal HA, et al. "Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline." The Journal of clinical endocrinology and metabolism 94.9 (2009):3132-3154.
17. 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.
18. Triptodur prescribing information. Azurity Pharmaceuticals, Inc. Woburn, MA. December 2022.
19. Fensolvi prescribing information. Tolmar Inc. Fort Collins, CO. February 2023.
20. Camcevi Prescriber Information. Accord BioPharma, Inc. Durham, NC. November 2022.

21. Leuprolide Acetate Depot prescribing information. Cipla USA, Inc. Warren, NJ. March 2023.
22. Harrington, J, Palmert, M. Treatment of precocious puberty. UpToDate. 2022. https://www.uptodate.com/contents/treatment-of-precocious-puberty?search=central%20precocious%20puberty&source=search_result&selectedTitle=2~30&usage_type=default&display_rank=2. Accessed August 2, 2023.

Prior Authorization Guideline

Guideline Name	Grastek (Timothy Grass)

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

Prior Authorization Guideline

Guideline Name	Growth Hormones

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 on set GH deficiency, utilize criteria for Transition Phase Adolescen t or Adult GH Deficiency. NOTE: Documentation of previous height, current height and go al 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 on set GH deficiency, utilize criteria for Transition Phase Adolescen t 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 expected 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 go al 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: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 go al expected 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 go al 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: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

1. Genotropin Prescribing Information. Pharmacia & Upjohn Co, a Division of Pfizer Inc. New York, NY. April 2019.
2. Humatrope Prescribing Information. Eli Lilly and Company. Indianapolis, IN. October 2019.
3. Norditropin Flexpro Prescribing Information. Novo Nordisk Inc. Plainsboro, NJ. March 2020.
4. Nutropin AQ NuSpin Prescribing Information. Genentech, Inc. South San Francisco, CA. December 2016.
5. Omnitrope Prescribing Information. Sandoz Inc. Princeton, NJ. June 2019.
6. Saizen Prescribing Information. EMD Serono, Inc. Rockland, MA. February 2020.
7. Serostim Prescribing Information. EMD Serono, Inc. Rockland, MA. June 2019.
8. Zomacton Prescribing Information. Ferring Pharmaceuticals Inc. Parsippany, NJ. July 2018.
9. Zorbtive Prescribing Information. EMD Serono, Inc. Rockland, MA. September 2019.
10. Gharib H, Cook DM, Saenger PH, et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for GH use in adults and children-2003 update. Endocr Pract. 2003;9(1):64-76.

11. Wilson TA, Rose SA, Cohen P, et al. Update on guidelines for the use of GH in children: The Lawson Wilkins pediatric endocrinology society drug and therapeutics committee. J Pediatrics 2003 (Oct): 415-21
12. GH Research society. Consensus guidelines for the diagnosis and treatment of GH deficiency in childhood and adolescence: Summary statement. J Clin Endocinol Metab. 2000; 85: 3990-93.
13. Badaru A, Wilson DM. Alternatives to growth hormone stimulation testing in children. Trends Endocrinol Metab 2004;15(6):252-8.
14. Gandrud LM, Wilson DM. Is growth hormone stimulation testing in children still appropriate? Growth Horm IGF Res 2004;14(3):185-94.
15. Corcoran C, Grinspoon S. Treatment for wasting in patients with the acquired immunodeficiency syndrome. N Engl J Med 1999; 340 (22):1740-50.
16. Byrne TA, Wilmore DW, Iyer K et al. Growth hormone, glutamine, and an optimal diet reduces parenteral nutrition in patients with short bowel syndrome. Ann Surg 2005;242:655-61.
17. Polsky B, Kotler D, Steinhart C. HIV-associated wasting in the HAART era: guidelines for assessment, diagnosis, and treatment. AIDS Patient Care STDS. 2001;15:411-23.
18. Polsky B, Kotler D, Steinhart C. Treatment guidelines for HIV-associated wasting. HIV Clin Trials. 2004;5:50-61.
19. Nemechek P, Polsky B, Gottlieb M. Treatment guidelines for HIV-associated wasting. Mayo Clin Proc. 2000;75:386-394.
20. Yuen KCJ, Biller BMK, Radovick S, et al. American Association of Clinical Endocrinologists and American College of Endocrinology guidelines for management of growth hormone deficiency in adults and patients transitioning from pediatric to adult care. Endocr Pract. 2019;25(No. 11):1191-1232. Available at: https://www.sciencedirect.com/science/article/pii/S1530891X20351454. Accessed July 12, 2021.
21. Cook DM, Yuen KC, Biller BM, Kemp SF, Vance ML. American Association of Clinical Endocrinologists medical guidelines for clinical practice for growth hormone use in growth hormone-deficient adults and transition patients -2009 update. Endocr Pract. 2009;15(suppl 2):1-29. Available at: https://www.researchgate.net/publication/38037397. Accessed July 12, 2021.
22. Mauras N, Attie KM, Reiter EO, Saenger P, Baptista J. High dose recombinant human growth hormone (GH) treatment of GH-deficient patients in puberty increases near-final height: a randomized, multicenter trial. Genentech, Inc., Cooperative Study Group. J Clin Endocrinol Metab. 2000;85(10):3653-60.
23. Grimberg A, DiVall SA, Polychronakos C, et al. Guidelines for growth hormone and insulin-like growth factor-treatment in children and adolescents: growth hormone deficiency, idiopathic short stature, and primary insulin-like growth factor-I deficiency. Horm Res Paediatr. 2016;86:361-397. Available at: https://www.karger.com/Article/Pdf/452150. Accessed June 21, 2019.
24. Wit JM, van Unen H. Growth of infants with neonatal growth hormone deficiency. Arch Dis Child. 1992; 67: 920-924.

25. Herber SM, Milner RD. Growth hormone deficiency presenting under age 2 years. Arch Dis Child. 1984 Jun; 59(6): 557–560.
26. Per clinical consult with pediatric endocrinologist, July 23, 2018.
27. Skytrofa Prescribing Information. Ascendis Pharma Endocrinology, Inc. Princeton, NJ. April 2022.

Prior Authorization Guideline

Guideline Name	Hemophilia B Gene Therapies - PA, NF

Guideline Note:

Effective Date:	4/1/2025

1 . Indications

Drug Name: Hemgenix (etranacogene dezaparvovec-drlb)
Hemophilia B Indicated for treatment of adults with Hemophilia B (congenital Factor IX deficiency) who currently use Factor IX prophylaxis therapy, have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes.
Drug Name: Beqvez (fidanacogene elaparvovec-dzkt)
Hemophilia B Indicated for the treatment of adults with moderate to severe hemophilia B (congenital factor IX deficiency) who currently use factor IX prophylaxis therapy, or have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes, and, do not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test. Select patients for therapy based on an FDA-approved companion diagnostic for Beqvez

2 . Criteria

Product Name:Hemgenix	
Approval Length	1 Time Authorization in Lifetime*
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Hemophilia B (congenital Factor IX deficiency)

AND

2 - One of the following:

2.1 Both of the following:

- Diagnosis of severe hemophilia B
- Documentation of endogenous Factor IX levels less than 1% of normal Factor IX (< 0.01 IU/mL)

OR

2.2 All of the following:

- Diagnosis of moderately severe hemophilia B
- Documentation of endogenous Factor IX levels greater than or equal to 1% to less than or equal to 2% (greater than or equal to 0.01 IU/mL to less than or equal to 0.02 IU/mL)
- Patient has current or historical life-threatening hemorrhage or repeated, serious spontaneous bleeding episodes

AND

3 - Patient is currently using Factor IX prophylaxis therapy (e.g., BeneFIX, Ixinity, Rixubis, etc.) and will discontinue treatment after stable on Hemgenix therapy

AND

4 - Patient has greater than 150 previous exposure days of treatment with a Factor IX agent

AND

5 - Patient is 18 years of age or older

AND

6 - Patient does not have any of the following:

- Positive human immunodeficiency virus (HIV) test at screening that is not controlled with anti-viral therapy
- Active infection with hepatitis B or C virus
- Currently on antiviral treatment for hepatitis B or C
- Positive Factor IX inhibitor titer test prior to therapy
- History of Factor IX inhibitor
- Anti-AAV antibody (e.g., AAV-5) titers exceeding 1:678

AND

7 - Provider attests that the following laboratory values have been checked prior to therapy and are less than two times the upper limit of normal:

- Alanine aminotransferase (ALT)
- Alkaline phosphatase (ALP)
- Aspartate aminotransferase (AST)
- Total bilirubin

AND

8 - Provider attests that hepatic ultrasound and elastography have been completed prior to therapy

AND

9 - Prescribed by a hematologist at a Hemophilia Treatment Center (HTC)

AND

10 - Patient has never received any previous Hemophilia B gene therapy treatment in their lifetime (e.g., Hemgenix, Beqvez)

Notes	*Per prescribing information, Hemgenix can be administered onl y once.

Product Name:Beqvez	
Approval Length	1 Time Authorization in Lifetime*
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Hemophilia B (congenital Factor IX deficiency)

AND

2 - One of the following:

2.1 Both of the following:

- Diagnosis of severe hemophilia B
- Documentation of endogenous Factor IX levels less than 1% of normal Factor IX (< 0.01 IU/mL)

OR

2.2 All of the following:

- Diagnosis of moderately severe hemophilia B
- Documentation of endogenous Factor IX levels greater than or equal to 1% to less than or equal to 2% (greater than or equal to 0.01 IU/mL to less than or equal to 0.02 IU/mL)
- Patient has current or historical life-threatening hemorrhage or repeated, serious spontaneous bleeding episodes

AND

3 - Patient is currently using Factor IX prophylaxis therapy (e.g., BeneFIX, Ixinity, Rixubis, etc.) and will discontinue treatment after stable on Beqvez therapy

AND

4 - Both of the following:

4.1 Patient has been on prophylactic Factor IX replacement therapy for at least 6 months

AND

4.2 Patient has greater than 50 previous exposure days of treatment with a Factor IX agent

AND

5 - Patient is 18 years of age or older

AND

6 - Patient does not have any of the following:

- Positive human immunodeficiency virus (HIV) test at screening that is not controlled with anti-viral therapy
- Active infection with hepatitis B or C virus
- Currently on antiviral treatment for hepatitis B or C
- Positive Factor IX inhibitor titer test prior to therapy
- History of Factor IX inhibitor
- Anti-AAVRh74var neutralizing antibodies (nAB)

AND

7 - Provider attests that the following laboratory values have been checked prior to therapy and are less than two times the upper limit of normal:

- Alanine aminotransferase (ALT)
- Alkaline phosphatase (ALP)
- Aspartate aminotransferase (AST)
- Total bilirubin

AND

8 - Provider attests that hepatic ultrasound and elastography have been completed prior to therapy

AND

9 - Prescribed by a hematologist at a Hemophilia Treatment Center (HTC)

AND

10 - Patient has never received any previous Hemophilia B gene therapy treatment in their lifetime (e.g., Hemgenix, Beqvez)	
Notes	*Per prescribing information, Beqvez is administered as a one-time single-dose intravenous infusion

Product Name:Hemgenix	
Approval Length	1 Time Authorization in Lifetime*
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Hemophilia B (congenital Factor IX deficiency)

AND

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

2.1 Both of the following:

- Diagnosis of severe hemophilia B
- Documentation of endogenous Factor IX levels less than 1% of normal Factor IX (< 0.01 IU/mL)

OR

2.2 All of the following:

- Diagnosis of moderately severe hemophilia B
- Documentation of endogenous Factor IX levels greater than or equal to 1% to less than or equal to 2% (greater than or equal to 0.01 IU/mL to less than or equal to 0.02 IU/mL)

- Patient has current or historical life-threatening hemorrhage or repeated, serious spontaneous bleeding episodes

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming that the patient is currently using Factor IX prophylaxis therapy (e.g., BeneFIX, Ixinity, Rixubis, etc.) and will discontinue treatment after stable on Hemgenix therapy

AND

4 - Patient has greater than 150 previous exposure days of treatment with a Factor IX agent

AND

5 - Patient is 18 years of age or older

AND

6 - Submission of medical records (e.g., chart notes) documenting that the patient does not have any of the following:

- Positive human immunodeficiency virus (HIV) test at screening that is not controlled with anti-viral therapy
- Active infection with hepatitis B or C virus
- Currently on antiviral treatment for hepatitis B or C
- Positive Factor IX inhibitor titer test prior to therapy
- History of Factor IX inhibitor
- Anti-AAV antibody (e.g., AAV-5) titers exceeding 1:678

AND

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

laboratory values have been checked prior to therapy and are less than two times the upper limit of normal: • Alanine aminotransferase (ALT) • Alkaline phosphatase (ALP) • Aspartate aminotransferase (AST) • Total bilirubin **AND** **8** - Submission of medical records (e.g., chart notes) documenting that hepatic ultrasound and elastography have been completed prior to therapy **AND** **9** - Prescribed by a hematologist at a Hemophilia Treatment Center (HTC) **AND** **10** - Patient has never received any previous Hemophilia B gene therapy treatment in their lifetime (e.g., Hemgenix, Beqvez)	
Notes	*Per prescribing information, Hemgenix can be administered onl y once.

3 . References

1. Hemgenix Prescribing Information. CSL Behring LLC. King of Prussia, PA. May 2023.
2. CSL Behring. Phase III, Open-label, Single-dose, Multi-center, Multinational Trial Investigating a Serotype 5 Adeno-associated Viral Vector Containing the Padua Variant of a Codon-optimized Human Factor IX Gene (AAV5-hFIXco-Padua, AMT-061) Administered to Adult Subjects With Severe or Moderately Severe Hemophilia B. clinicaltrials.gov. Published September 26, 2022. Accessed January 11, 2023. https://clinicaltrials.gov/ct2/show/study/NCT03569891
3. Beqvez Prescribing Information. Pfizer Inc. New York, NY. April 2024.

Prior Authorization Guideline

Guideline Name	Hereditary Angioedema Agents (HAE) Quantity Limit Override

Guideline Note:

Effective Date:	10/1/2024

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: 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: 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.
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: 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.

2 . Criteria

Product Name:Brand Firazyr, Generic icatibant, Sajazir, Ruconest, Kalbitor, Berinert	
Approval Length	3 month(s)
Guideline Type	Quantity Limit Override

Approval Criteria

1 - Prescriber attests patient has 3 or more acute HAE attacks per month (document number of attacks per month if available)

AND

2 - Prescriber attests patient has been evaluated for the use of prophylactic therapy

AND

3 - One of the following*:

3.1 For Kalbitor, requested quantity does not exceed the ceiling limit of 48 vials per 30 days. Note to provider: Ceiling limit is based on the quantity sufficient for the treatment of 8 acute attacks per month.

OR

3.2 For Brand Firazyr, generic icatibant, or Sajazir, requested quantity does not exceed the ceiling limit of 24 syringes [72 mL] per 30 days. Note to provider: Ceiling limit is based on the quantity sufficient for the treatment of 8 acute attacks per month. **OR** **3.3** For Ruconest, requested quantity does not exceed the ceiling limit of 32 vials per 30 days. Note to provider: Ceiling limit is based on the quantity sufficient for the treatment of 8 acute attacks per month. **OR** **3.4** For Berinert, requested quantity does not exceed the ceiling limit of 32 vials per 30 days. Note to provider: Ceiling limit is based on the quantity sufficient for the treatment of 8 acute attacks per month.	
Notes	Approve requests to MDD ceiling limits. Refer to background table for ceiling limits. *If all criteria above are met EXCEPT for the ceiling limit criterion, issue a partially favorable decision (i.e. approve to ceiling limit and deny quantities above ceiling limit for medical necessity). Denied quantities are reviewed on appeal.

3 . Background

Benefit/Coverage/Program Information
Ceiling Limits for HAE Agents Ceiling Limits for HAE Agents

Drug Name	Ceiling Limit (Amount sufficient to provide coverage for up to 8 acute attacks per month based on MDD)
Berinert	MDD = 1.1 (32 vials per 30 days)
Brand Firazyr Sajazir generic icatibant	MDD = 2.4 (24 syringes [72 mL] per 30 days)
Ruconest	MDD = 1.1 (32 vials per 30 days)
Kalbitor	MDD = 1.6 (48 vials per 30 days)

4 . References

1. Berinert Prescribing Information. CSL Behring, LLC. Kankakee, IL. September 2021.
2. Ruconest Prescribing Information. Pharming Healthcare Inc. Bridgewater, NJ. April 2020.
3. Firazyr Prescribing Information. Shire Orphan Therapies LLC. Lexington, MA. October 2021.
4. Kalbitor Prescribing Information. Dyax Corp. Lexington, MA. November 2021.
5. Sajazir Prescribing Information. Cipla Ltd., India. May 2022.

Prior Authorization Guideline

Guideline Name	Hereditary Angioedema Agents - PA, NF

Guideline Note:

Effective Date:	1/9/2025

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, Takhzyro

Diagnosis	Prophylaxis of HAE attacks
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) [A]

AND

2 - One of the following [A, E]:

2.1 Diagnosis has been confirmed by both of the following:

2.1.1 C4 level below the lower limit of normal

AND

2.1.2 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 Both of the following:

2.2.1.1 Normal C4 level

AND

2.2.1.2 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 factor XII, plasminogen, angiopoietin-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6 gene 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 - 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

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

- Immunologist
- Allergist

Product Name:Cinryze, Haegarda, Orladeyo, 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, Ruconest, or Kalbitor	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) [A]

AND

2 - One of the following [A, E]:

2.1 Diagnosis has been confirmed by both of the following:

2.1.1 C4 level below the lower limit of normal

AND

2.1.2 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 Both of the following:

2.2.1.1 Normal C4 level

AND

2.2.1.2 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 factor XII, plasminogen, angiopoietin-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6 gene 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 12 years of age or older (applies to Kalbitor only) [D]
- Patient is 13 years of age or older (applies to Ruconest only) [5]
- 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, Ruconest, or 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)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) [A]

AND

2 - One of the following [A, E]:

2.1 Diagnosis has been confirmed by both of the following:

2.1.1 C4 level below the lower limit of normal

AND

2.1.2 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 Both of the following:

2.2.1.1 Normal C4 level

AND

2.2.1.2 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 factor XII, plasminogen, angiopoietin-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6 gene 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 [5]:

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

2.1.1 C4 level below the lower limit of normal

AND

2.1.2 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 Both of the following:

2.2.1.1 Normal C4 level

AND

2.2.1.2 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 factor XII, plasminogen, angiopoietin-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6 gene 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 Both of the following:

6.2.1 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

AND

6.2.2 Patient demonstrates positive clinical response to therapy

AND

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

- Immunologist
- Allergist

Product Name:Brand Firazyr	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

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

2.1.1 C4 level below the lower limit of normal

AND

2.1.2 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 Both of the following:

2.2.1.1 Normal C4 level

AND

2.2.1.2 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 factor XII, plasminogen, angiopoietin-1, kininogen-1, myoferlin, or heparan sulfate-glucosamine 3-O-sulfotransferase 6 gene 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 - Patient is 18 years of age or older

AND

6 - Both of the following:

6.1 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) with generic icatibant

AND

6.2 Submission of medical records confirming generic icatibant has not been effective AND justification/rationale provided explaining how Brand Firazyr is expected to provide benefit when generic icatibant has not been shown to be effective despite having the same active ingredient

AND

7 - One of the following:

7.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication or intolerance to all of the following:

7.1.1 Berinert

AND

7.1.2 Kalbitor

AND

7.1.3 One of the following:

7.1.3.1 Ruconest

OR

7.1.3.2 Documentation that patient has history of laryngeal attacks

OR

7.2 Both of the following:

7.2.1 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

AND

7.2.2 Patient demonstrates positive clinical response to therapy

AND

8 - Prescribed by or in consultation with one of the following: [B]

- Immunologist
- Allergist

3 . Endnotes

A. HAE is a rare genetic disorder that can be broadly divided into two fundamental types: 1) HAE-C1INH (HAE Type 1 or Type 2), which presents with a deficiency of C1-INH; 2) HAE-n1-C1INH (previously referred to as HAE Type 3), a rare variant which presents with normal C1-INH levels. This condition is inherited in an autosomal dominant manner 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 Type 1 or Type 2 HAE requires laboratory testing to confirm low or abnormal levels of C1-inhibitor. HAE-n1-C1INH (previously referred to as HAE Type 3) presents a diagnostic challenge given the current lack of a validated biochemical test to confirm diagnosis. Per HAE guidelines, when a diagnosis of HAE-n1-CINH is suspected based on normal C1-INH levels, diagnosis should be confirmed by a known mutation associated with the disease or a positive family history of recurrent angioedema with a lack of efficacy to high-dose antihistamine therapy [10, 14].

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]

E. When HAE is suspected based on the clinical presentation, appropriate testing includes measurement of the serum C4 level, C1INH antigenic level, and C1INH functional level. Low C4 plus low C1INH antigenic or functional levels are consistent with a diagnosis of HAE-C1INH [14, 15].

4 . References

1. Cinryze Prescribing Information. Shire ViroPharma, Inc. Lexington, MA. February 2023.
2. Haegarda Prescribing Information. CSL Behring, LLC. Kankakee, IL. January 2022.
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.
4. Berinert Prescribing Information. CSL Behring, LLC. Kankakee, IL. September 2021.
5. Ruconest Prescribing Information. Pharming Healthcare Inc. Bridgewater, NJ. April 2020.
6. Firazyr Prescribing Information. Shire Orphan Therapies LLC. Lexington, MA. October 2021.
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, Zuraw 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.
14. Busse PJ, Christiansen S, Riedl M, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. J Allergy Clin Immunol. 2020. Available at: https://www.haea.org/assets/img/2020MAB_guidelines.pdf. Accessed June 26, 2024.
15. Maurer M, Magerl M, Betschel S, et al. The international WAO/EAACI guideline for the management of hereditary angioedema—The 2021 revision and update. European Journal of Allergy and Clinical Immunology. 10 January 2022. Available

at: https://onlinelibrary.wiley.com/doi/10.1111/all.15214. Accessed June 26, 2024.
16. Zuraw B, Bork K, et. al. Hereditary angioedema with normal C1 inhibitor - UpToDate web site. Available at: http:www.uptodate.com/. Accessed June 24, 2024.

Prior Authorization Guideline

Guideline Name	Hympavzi (marstacimab-hncq)

Guideline Note:

Effective Date:	5/1/2025

1 . Indications

Drug Name: Hympavzi (marstacimab-hncq)
Prevention or to reduce the frequency of bleeding episodes indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with: 1) hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors, or 2) hemophilia B (congenital factor IX deficiency) without factor IX inhibitors.

2 . Criteria

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

Approval Criteria

1 - Diagnosis of one of the following:

- hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors
- hemophilia B (congenital factor IX deficiency) without factor IX inhibitors

AND

2 - Drug will be used for prophylaxis to prevent or reduce the frequency of bleeding episodes

AND

3 - Patient is 12 years of age or older

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

AND

5 - One of the following: (applies to Hemophilia A only)

5.1 For continuation of prior therapy

OR

5.2 Trial and inadequate response, intolerance, or contraindication to Hemlibra (emicizumab-kxwh)

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

Approval Criteria

1 - Drug continues to be used for prophylaxis to prevent or reduce the frequency of bleeding episodes [A]

AND

2 - Patient demonstrates positive clinical response to therapy (e.g., reduced bleeding episodes)

3 . Endnotes

A. Do not use additional doses of HYMPAVZI to treat breakthrough bleeds. [1]

4 . References

1. Hympavzi Prescribing Information. Division of Pfizer Inc. New York, NY. October 2024.

Prior Authorization Guideline

Guideline Name	iDose TR (travoprost intracameral implant)

Guideline Note:

Effective Date:	4/1/2025

1 . Indications

Drug Name: iDose TR (travoprost intracameral implant)
Open-Angle Glaucoma Indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma (OAG). **Ocular Hypertension** Indicated for the reduction of intraocular pressure (IOP) in patients with ocular hypertension (OHT).

2 . Criteria

Product Name:iDose TR	
Approval Length	Maximum of 1 time for each eye [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of open angle glaucoma (OAG) or ocular hypertension (OHT)

AND

2 - Patient has not previously received iDose TR in the intended eye [A]

AND

3 - One of the following*: [B, D]

3.1 Trial and failure, contraindication or intolerance to three of the following prostaglandin analogs:

- generic bimatoprost 0.03% ophthalmic solution
- generic latanoprost 0.005% ophthalmic solution
- generic travoprost 0.004% ophthalmic solution
- generic tafluprost 0.0015% ophthalmic solution
- Lumigan (bimatoprost 0.01% ophthalmic solution)

OR

3.2 Both of the following: [C, D]

3.2.1 Trial and failure, contraindication or intolerance to two of the following prostaglandin analogs:

- generic bimatoprost 0.03% ophthalmic solution
- generic latanoprost 0.005% ophthalmic solution
- generic travoprost 0.004% ophthalmic solution
- generic tafluprost 0.0015% ophthalmic solution
- Lumigan (bimatoprost 0.01% ophthalmic solution)

AND **3.2.2** Trial and failure, contraindication, or intolerance to one ophthalmic product from the following pharmacological classes: • Beta-adrenergic antagonist (e.g., timolol ophthalmic solution, levobunolol, etc.) • Alpha-adrenergic agonist (e.g., brimonidine ophthalmic solution, etc.) • Carbonic anhydrase inhibitor (e.g., dorzolamide ophthalmic solution, etc.) • Parasympathomimetic agent (e.g., pilocarpine ophthalmic solution, etc.) • Rho-kinase inhibitor (e.g., Rhopressa [netarsudil] ophthalmic solution, etc.) **AND** **4** - Prescribed by an ophthalmologist

Notes	*Can be taken as monotherapy or as concomitant therapy [C, D]

3 . Endnotes

A. iDose TR should not be readministered to an eye that received a prior iDose TR. [1]
B. Prostaglandin analogs are the most frequently prescribed eye drops for lowering IOP in patients with glaucoma because they are most efficacious and well-tolerated, and they need to be instilled only once daily. Therefore, prostaglandin analogs are often selected as initial medical therapy unless other considerations, such as contraindications, side effects, intolerance, or patient refusal preclude their use. [5]
C. Sufficient treatment of glaucoma requires high level of adherence to therapy and multiple dosing requirements or side effects may impact a person's adherence to therapy. If a single medication is effective in lowering IOP but the target pressure is not reached, combination therapy or switching to an alternative therapy may be appropriate. If despite good adherence to therapy the medication fails to reduce IOP, an alternative agent should be used [5]
D. If pharmacologic therapy is chosen, topical prostaglandins are sugessted as first-line pharmacologic therapy rather than other topical medications. Prostaglandins have lower rates of systemic side effects and may have somewhat better efficacy than beta blockers. Combining drops from different classes (ie, beta blocker plus prostaglandin or beta blocker plus carbonic anhydrase inhibitor) can

cause a greater reduction in the IOP than monotherapy. Adding a second medication is reasonable if initial monotherapy is not effective. [4]

4 . References

1. iDose TR Prescribing Information. Glaukos Corp. San Clemente, CA. December 2023.
2. ClinicalTrials.gov. Randomized Study Comparing Two Models of a Travoprost Intraocular Implant to Timolol Maleate Ophthalmic Solution, 0.5%. Available at: https://www.clinicaltrials.gov/study/NCT03519386?cond=nct03519386&rank=1. Accessed January 24, 2024.
3. ClinicalTrials.gov. Clinical Study Comparing Two Models of a Travoprost Intraocular Implant. Available at: https://www.clinicaltrials.gov/study/NCT03868124?cond=nct03868124&rank=1. Accessed January 24, 2024.
4. UptoDate. Open-angle glaucoma: Treatment. Available at: https://www.uptodate.com/contents/open-angle-glaucoma-treatment?search=open%20angle%20glaucoma%20treatment&source=search_result&selectedTitle=1%7E150&usage_type=default&display_rank=1. Accessed December 30, 2024.
5. Primary Open-Angle Glaucoma PPP 2020. American Academy of Ophthalmology. Available at: https://www.aao.org/preferred-practice-pattern/primary-open-angle-glaucoma-ppp. Published November 2020. Accessed January 24, 2024.

Prior Authorization Guideline

Guideline Name	Ilaris (canakinumab injection)

Guideline Note:

Effective Date:	10/1/2024

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.

Gout Flares Indicated for the symptomatic treatment of adult patients with gout flares in whom nonsteroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate.

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], Humira [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 - Patient demonstrates 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], Humira [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], Humira [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 - Patient demonstrates 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], Humira [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], Humira [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 - Patient demonstrates 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], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

Product Name:Ilaris	
Diagnosis	Gout Flares
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gout flares

AND

2 - Trial and failure, contraindication, or intolerance to ALL of the following [1, 6]:

- Nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen)

- Colchicine
- Corticosteroids (e.g., prednisone)

AND

3 - Patient has not received Ilaris in the last 12 weeks [A]

AND

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

- Rheumatologist
- Nephrologist

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 . Endnotes

A. The recommended dose of Ilaris for adult patients with a gout flare is 150 mg administered subcutaneously. In patients who require re-treatment, there should be an interval of at least 12 weeks before a new dose of Ilaris may be administered [1].

5 . References

1. Ilaris Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. August 2023.
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.
3. Mimura T, Kondo Y, Ohta A et al. Evidence-based clinical practice guideline for adult Still's disease. Mod Rheumatol. 2018;28(5):736-757.
4. Lachmann HJ, Kone-Paut I, Kuemmerle-Deschner JB, et al. Use of canakinumab in the cryopyrin-associated periodic syndrome. N Engl J Med. 2009;360(23):2416-25.
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.
6. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology guideline for the management of gout. Arthritis Care Res. 2020;72(6):744-760.

Prior Authorization Guideline

Guideline Name	Ilumya (tildrakizumab-asmn) - PA, NF

Guideline Note:

Effective Date:	8/1/2025

Note:

For review process only: Refer to the Client Biosimilar Formulary Strategy List at the following link for carrier-specific formulary products: https://uhgazure.sharepoint.com/sites/ClinicalServices-UtilizationManagement/Internal%20Documents/Forms/AllItems.aspx?viewpath=%2Fsites%2FClinicalServices%2DUtilizationManagement%2FInternal%20Documents%2FForms%2FAllItems%2Easpx

1 . Indications

Drug Name: Ilumya (tildrakizumab-asmn)
Plaque Psoriasis (PsO) 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 - Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), 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)

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
- One formulary ustekinumab product
- Taltz (ixekizumab)
- Skyrizi (risankizumab)
- Tremfya (guselkumab)
- Otezla (apremilast)
- Sotyktu (deucravacitinib)

AND

5.1.2 Trial and failure, contraindication, or intolerance to Bimzelx (bimekizumab-bkzx)

OR

5.2 For continuation of prior 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 - Patient demonstrates positive clinical response to therapy as evidenced by ONE of the following [1-3]:

- Reduction in the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name:Ilumya	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a 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 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), 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)

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 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to THREE of the following:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- One formulary adalimumab product
- One formulary ustekinumab product
- Taltz (ixekizumab)
- Skyrizi (risankizumab)
- Tremfya (guselkumab)
- Otezla (apremilast)
- Sotyktu (deucravacitinib)

AND

5.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to Bimzelx (bimekizumab-bkzx)

OR

5.2 Both of the following:

5.2.1 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

AND

5.2.2 Patient demonstrates positive clinical response to therapy as evidenced by ONE of the following [1-3]:

- Reduction in 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. April 2024.
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.

Prior Authorization Guideline

Guideline Name	Imdelltra (tarlatamab-dlle)

Guideline Note:

Effective Date:	8/1/2024

1 . Indications

Drug Name: Imdelltra (tarlatamab-dlle)
Small cell lung cancer (SCLC) Indicated for the treatment of adult patients with extensive stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy. This indication is approved under accelerated approval based on overall response rate and duration 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:Imdelltra	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of extensive stage small cell lung cancer (ES-SCLC)

AND

2 - Disease has progressed on or after platinum-based chemotherapy (e.g., cisplatin, carboplatin)

AND

3 - Patient has an Eastern Cooperative Oncology Group (ECOG) Score of 0 or 1

Product Name:Imdelltra	
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. Imdelltra Prescribing Information. Amgen Inc. Thousand Oaks, CA. May 2024.

Prior Authorization Guideline

Guideline Name	Immune Globulins - PA, NF

Guideline Note:

Effective Date:	2/1/2024

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: Carimune NF (immune globulin [Human])

Idiopathic Thrombocytopenic Purpura (ITP) (1) Acute ITP: A controlled study was performed in children in which Carimune was compared with steroids for the treatment of acute (defined as less than 6 months duration) ITP. In this study sequential platelet levels of 30,000, 100,000, and 150,000/microliter were all achieved faster with Carimune than with steroids and without any of the side effects associated with steroids. However, it should be noted that many cases of acute ITP in childhood

resolve spontaneously within weeks to months. Carimune has been used with good results in the treatment of acute ITP in adult patients. In a study involving 10 adults with ITP of less than 16 weeks duration, Carimune therapy raised the platelet count to the normal range after a 5 day course. This effect lasted a mean of over 173 days, ranging from 30 to 372 days. (2) Chronic ITP: Children and adults with chronic (defined as greater than 6 months duration) ITP have also shown an increase (sometimes temporary) in platelet counts upon administration of Carimune. Therefore, in situations that require a rapid rise in platelet count, for example prior to surgery or to control excessive bleeding, use of Carimune should be considered. In children with chronic ITP, Carimune therapy resulted in a mean rise in platelet count of 312,000/microliter with a duration of increase ranging from 2 to 6 months. Carimune therapy may be considered as a means to defer or avoid splenectomy. In adults, Carimune therapy has been shown to be effective in maintaining the platelet count in an acceptable range with or without periodic booster therapy. The mean rise in platelet count was 93,000/microliter and the average duration of the increase was 20-24 days. However, it should be noted that not all patients will respond. Even in those patients who do respond, this treatment should not be considered to be curative.

Primary Immunodeficiency Disorders Indicated for the maintenance treatment of patients with primary immunodeficiencies (PID), e.g., common variable immunodeficiency, X-linked agammaglobulinemia, severe combined immunodeficiency. Carimune NF is preferable to intramuscular Immune Globulin (Human) preparations in treating patients who require an immediate and large increase in the intravascular immunoglobulin level, in patients with limited muscle mass, and in patients with bleeding tendencies for whom intramuscular injections are contraindicated. The infusions must be repeated at regular intervals.

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).
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: 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).

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 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

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 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

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 Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: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

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 Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: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

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 Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: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

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 Asceniv and Panzyga only):

- Gammagard

- Gammaplex
- Gamunex-C
- Privigen

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 - Patient demonstrates 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]

Product Name: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

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 Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: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

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 Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: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

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 Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

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

Product Name: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

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 Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

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

Product Name: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

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 - Prescribed by or in consultation with a neurologist

AND

5 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: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 - Prescribed by or in consultation with a neurologist

AND

5 - 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

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 Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

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

Product Name: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

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 Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

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

Product Name: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

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 Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

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

Product Name: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

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 Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C

- Privigen

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

Product Name: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

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 autoimmune neuropsychiatric Disorders associated with Streptococcal Infections, Pediatric Acute-onset Neuropsychiatric Syndrome (PANS)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Pediatric autoimmune neuropsychiatric Disorders associated with Streptococcal Infections, Pediatric Acute-onset Neuropsychiatric Syndrome (PANS)

AND

2 - Trial and failure, intolerance to two of the following:

- Short course antibiotic therapy
- NSAID therapy
- Corticosteroid
- SSRI therapy
- Behavior therapy

AND

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

- Pediatric neurologist

- Pediatric psychiatrist
- Pediatric mental health nurse practitioner
- Neurodevelopmental pediatrician
- Pediatric rheumatologist
- Pediatric allergist/immunologist

AND

4 - For Asceniv and Panzyga only: trial and failure, contraindication, or intolerance to two of the following

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name:Intravenous Immune Globulin (IVIG)	
Diagnosis	Pediatric autoimmune neuropsychiatric Disorders associated with Streptococcal Infections, Pediatric Acute-onset Neuropsychiatric Syndrome (PANS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Submission of medical records documenting of reevaluation at 3 months by the subspecialist

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]

4 . References

1. Gammagard Liquid Prescribing Information. Baxalta US Inc. Lexington, MA. March 2021.
2. Cuvitru Prescribing Information. Baxalta US Inc. Lexington, MA. September 2021.
3. Carimune NF Prescribing Information. CSL Behring LLC. Kankakee, IL. May 2018.
4. Varizig Prescribing Information. Saol Therapeutics Inc. Roswell, GA. September 2021.
5. Gammagard S/D Prescribing Information. Baxalta US Inc. Lexington, MA. March 2021.
6. Micromedex Healthcare Series [database on the internet]. Greenwood Village (CO): Thomson Reuters (Healthcare) Inc.; Updated periodically. Available by subscription at: http://www.thomsonhc.com/. Accessed March 1, 2023.
7. Newburger JW, Takahashi M, Beiser AS, et al. A single intravenous infusion of gamma globulin as compared with four infusions in the treatment of acute Kawasaki syndrome. N Engl J Med. 1991;324:1633-9.
8. Newburger JW, Takahashi M, Burns JC, et al. The treatment of Kawasaki syndrome with intravenous gamma globulin. N Engl J Med. 1986;315:341-7.
9. Terai M, Shulman ST. Prevalence of coronary artery abnormalities in Kawasaki disease is highly dependent on gamma globulin dose but independent of salicylate dose. J Pediatr 1997;131:888–93.

10. Cooperative Group for the Study of Immunoglobulin in Chronic Lymphocytic Leukemia: Intravenous immunoglobulin for the prevention of infection in chronic lymphocytic leukemia: a randomized, controlled trial. N Engl J Med. 1988;319:902-907.
11. Oscier D, Fegan C, Hillmen P, et al. Guidelines on the diagnosis and management of chronic lymphocytic leukaemia. Br J Haematol. 2004;125:294-317.
12. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology. Chronic lymphocytic leukemia/small lymphocytic lymphoma v2.2023. https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed March 1, 2023.
13. Gamm H, Huber C, Chapel H, et al. Intravenous immune globulin in chronic lymphocytic leukaemia. Clin Exp Immunol. 1994;97 Suppl 1:17-20.
14. Molica S, Musto P, Chiurazzi F, et al. Prophylaxis against infections with low-dose intravenous immunoglobulins (IVIG) in chronic lymphocytic leukemia. Results of a cross-over study. Haematologica. 1996;81:121-126.
15. Koller H, Kieseier BC, Jander S, et al. Chronic inflammatory demyelinating polyneuropathy. N Engl J Med. 2005;352(13):1343-56.
16. Saperstein DS, Katz JS, Amato AA, et al. Clinical spectrum of chronic acquired demyelinating polyneuropathies. Muscle Nerve. 2001;24:311-24.
17. Hughes R, Bensa S, Willison H, et al. Inflammatory Neuropathy Cause and Treatment (INCAT) Group. Randomized controlled trial of intravenous immunoglobulin versus oral prednisolone in chronic inflammatory demyelinating polyradiculoneuropathy. Ann Neurol. 2001;50:195-201.
18. Mendell JR, Barohn RJ, Freimer ML, et al. Working Group on Peripheral Neuropathy. Randomized controlled trial of IVIg in untreated chronic inflammatory demyelinating polyradiculoneuropathy. Neurology. 2001;56:445-9.
19. Dyck PJ, Litchy WJ, Kratz KM, et al. A plasma exchange versus immune globulin infusion trial in chronic inflammatory demyelinating polyradiculoneuropathy. Ann Neurol. 1994;36:838-45.
20. van Schaik IN, Winer JB, de Haan R, et al. Intravenous immunoglobulin for chronic inflammatory demyelinating polyradiculoneuropathy: a systematic review. Lancet Neurol. 2002;1:491-8.
21. Centers for Disease Control and Prevention; Infectious Disease Society of America; American Society of Blood and Marrow Transplantation. Guidelines for preventing opportunistic infections among hematopoietic stem cell transplant recipients. MMWR Recomm Rep. 2000;49(RR-10):1-125.
22. Sullivan KM, Kopecky KJ, Jocom J, et al. Immunomodulatory and antimicrobial efficacy of intravenous immunoglobulin in bone marrow transplantation. N Engl J Med. 1990;323:705-12.
23. Sullivan KM, Storek J, Kopecky K, et al. A controlled trial of long-term administration of intravenous immunoglobulin to prevent late infection and chronic graft-vs.-host disease after marrow transplantation: clinical outcome and effect on subsequent immune recovery. Biol Blood Marrow Transplant. 1996;2:44-53.

24. Sokos DR, Berger M, Lazarus HM. Intravenous immunoglobulin: appropriate indications and uses in hematopoietic stem cell transplantation. Biol Blood Marrow Transplant. 2002;8:117-30.
25. Dalakas MC, Illa I, Dambrosia JM, et al. A controlled trial of high-dose intravenous immune globulin infusions as treatment for dermatomyositis. N Engl J Med. 1993;329:1993-2000.
26. Danieli M, Malcangi G, Palmieri C, et al. Cyclosporin A and Intravenous Immunoglobulin Treatment in Polymyositis/Dermatomyositis. Ann Rheum Dis. 2002;61;37-41.
27. Cherin P, Herson S, Wechsler B, et al. Efficacy of intravenous gammaglobulin therapy in chronic refractory polymyositis and dermatomyositis: an open study with 20 adult patients. Am J Med. 1991;91:162-8.
28. Lang BA, Laxer RM, Murphy G, et al. Treatment of dermatomyositis with intravenous gammaglobulin. Am J Med. 1991;91:169–72.
29. Drake LA, Dinehart SM, Farmer ER, et al. Guidelines of care for dermatomyositis. American Academy of Dermatology. J Am Acad Dermatol. 1996;34:824-9.
30. van Schaik IN, van den Berg LH, de Haan R, et al. Intravenous immunoglobulin for multifocal motor neuropathy. Cochrane Database Syst Rev. 2005;(2):CD004429.
31. Federico P, Zochodne DW, Hahn AF, et al. Multifocal motor neuropathy improved by IVIg: randomized, double-blind, placebo-controlled study. Neurology. 2000;55:1256-62.
32. Van den Berg LH, Franssen H, Wokke JH. The long-term effect of intravenous immunoglobulin treatment in multifocal motor neuropathy. Brain. 1998;121:421-8.
33. Leger JM, Chassande B, Musset L, et al. Intravenous immunoglobulin therapy in multifocal motor neuropathy: a double-blind, placebo-controlled study. Brain. 2001;124:145-53.
34. Van den Berg LH, Kerkhoff H, Oey PL, et al. Treatment of multifocal motor neuropathy with high dose intravenous immunoglobulins: a double blind, placebo controlled study. J Neurol Neurosurg Psychiatry. 1995;59:248-52.
35. Mofenson LM, Moye J Jr, Bethel J, et al. Prophylactic intravenous immunoglobulin in HIV-infected children with CD4+ counts of 0.20 x 10(9)/L or more. Effect on viral, opportunistic, and bacterial infections. The National Institute of Child Health and Human Development Intravenous Immunoglobulin Clinical Trial Study Group. JAMA. 1992;268:483-8.
36. Mofenson LM, Moye J Jr, Korelitz J, et al. Crossover of placebo patients to intravenous immunoglobulin confirms efficacy for prophylaxis of bacterial infections and reduction of hospitalizations in human immunodeficiency virus-infected children. The National Institute of Child Health and Human Development Intravenous Immunoglobulin Clinical Trial Study Group. Pediatr Infect Dis J. 1994;13:477-84.
37. Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults

and Adolescents with HIV. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-oi/guidelines-adult-adolescent-oi.pdf. Accessed March 1, 2023.
38. Plasma Exchange/Sandoglobulin Guillain-Barre Syndrome Trial Group. Randomised trial of plasma exchange, intravenous immunoglobulin, and combined treatments in Guillain-Barre syndrome. Lancet. 1997;349:225-30.
39. van der Meche FG, Schmitz PI. A randomized trial comparing intravenous immune globulin and plasma exchange in Guillain-Barre syndrome. Dutch Guillain-Barre Study Group. N Engl J Med. 1992;326:1123-9
40. Hughes RA, Wijdicks EF, Barohn R, et al. Quality Standards Subcommittee of the American Academy of Neurology. Practice parameter: immunotherapy for Guillain-Barre syndrome: report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2003;61:736-40.
41. Bain PG, Motomura M, Newsom-Davis J, et al. Effects of intravenous immunoglobulin on muscle weakness and calcium-channel autoantibodies in the Lambert-Eaton myasthenic syndrome. Neurology. 1996;47:678-83.
42. Winston DJ, Antin JH, Wolff SN, et al. A multicenter, randomized, double-blind comparison of different doses of intravenous immunoglobulin for prevention of graft-versus-host disease and infection after allogeneic bone marrow transplantation. Bone Marrow Transplant. 2001;28:187-96.
43. Cordonnier C, Chevret S, Legrand M, et al. GREFIG Study Group. Should immunoglobulin therapy be used in allogeneic stem-cell transplantation? A randomized, double-blind, dose effect, placebo-controlled, multicenter trial. Ann Intern Med. 2003 1;139:8-18.
44. Immune Globulin. In: McEvoy GK, ed. AHFS 2004 Drug Information. Bethesda, MD: American Society of Health-System Pharmacists; 2004:3154-3164.
45. Gajdos P, Chevret S, Clair B, et al. Clinical trial of plasma exchange and high-dose intravenous immunoglobulin in myasthenia gravis. Myasthenia Gravis Clinical Study Group. Ann Neurol. 1997;41:789-96.
46. Wegner B, Ahmed I. Intravenous immunoglobulin monotherapy in long-term treatment of myasthenia gravis. Clin Neurol Neurosurg. 2002;105:3-8.
47. Jongen JL, van Doorn PA, van der Meche FG. High-dose intravenous immunoglobulin therapy for myasthenia gravis. J Neurol. 1998;245:26-31.
48. Gajdos P, Chevret S, Toyka K. Intravenous immunoglobulin for myasthenia gravis. Cochrane Database Syst Rev. 2006 Apr 19;(2):CD002277.
49. Sharshar T, Chevret S, Mazighi M, et al. Validity and reliability of two muscle strength scores commonly used as endpoints in assessing treatment of myasthenia gravis. J Neurol. 2000;247:286-90.
50. Fazekas F, Deisenhammer F, Strasser-Fuchs S, et al. Randomised placebo-controlled trial of monthly intravenous immunoglobulin therapy in relapsing-remitting multiple sclerosis. Austrian Immunoglobulin in Multiple Sclerosis Study Group. Lancet. 1997;349:589-93.
51. Achiron A, Gabbay U, Gilad R, et al. Intravenous immunoglobulin treatment in multiple sclerosis. Effect on relapses. Neurology. 1998;50:398-402.

52. Goodin DS, Frohman EM, Garmany GP Jr, et al. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology 2002;58:169-78.
53. Dalakas MC, Fujii M, Li M, et al. High-dose intravenous immune globulin for stiff-person syndrome. N Engl J Med. 2001;345:1870-6.
54. Newburger JW, Takahashi M, Gerber MA, et al. Diagnosis, treatment, and long-term management of Kawasaki disease: a statement for health professionals from the Committee on Rheumatic Fever, Endocarditis and Kawasaki Disease, Council on Cardiovascular Disease in the Young, American Heart Association. Circulation. 2004;110:2747-71.
55. Hughes RA, Bouche P, Cornblath DR, et al. European Federation of Neurological Societies/Peripheral Nerve Society guideline on management of chronic inflammatory demyelinating polyradiculoneuropathy: report of a joint task force of the EFNS and PNS. Eur J Neurol 2006 Apr;13(4):326-32.
56. Gammaplex 10% Prescribing Information. Bio Products Laboratory Ltd. Elstree, UK. November 2021.
57. Gamastan Prescribing Information. Grifols Therapeutics LLC. Research Triangle Park, NC. February 2018.
58. National Institute of Neurological Disorders and Stroke. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP). Available at: https://www.ninds.nih.gov/health-information/disorders/chronic-inflammatory-demyelinating-polyneuropathy-cidp. Accessed March 3, 2023.
59. Drachman DB. Myasthenia Gravis. N Engl J Med. 1994;1797-1810.
60. Cytogam Prescribing Information. CSL Behring LLC. King of Prussia, PA. May 2020.
61. Hizentra Prescribing Information. CSL Behring LLC. Kankakee, IL. April 2022.
62. Privigen Prescribing Information. CSL Behring LLC. Kankakee, IL. March 2022.
63. Octagam 10% Prescribing Information. Octapharma USA Inc. Paramus, NJ. April 2022.
64. Apostolski, ES, Doorn PV, Gilhus NE, et al. EFNS Task Force. EFNS guidelines for the use of intravenous immunoglobulin in treatment of neurological diseases. European Journal of Neurology 2008; 15:893-908.
65. Flebogamma 5% DIF Prescribing Information. Instituto Grifols, S.A. Barcelona, Spain. September 2019.
66. Flebogamma 10% DIF Prescribing Information. Instituto Grifols, S.A. Barcelona, Spain. September 2019.
67. Gammaplex 5% Prescribing Information. Bio Products Laboratory Ltd. Elstree, UK. November 2021.
68. Gamunex-C Prescribing Information. Grifols Therapeutics LLC. Research Triangle Park, NC. January 2020.
69. Gammaked Prescribing Information. Grifols Therapeutics LLC. Research Triangle Park, NC. January 2020.

70. Bivigam Prescribing Information. ADMA Biologics, Inc. Boca Raton, FL. December 2022.
71. Octagam 5% Prescribing Information. Octapharma USA Inc. Paramus, NJ. April 2022.
72. Orange JS, Hossny EM, Weiler CR, et al. Use of intravenous immunoglobulin in human disease: a review of evidence by members of the Primary Immunodeficiency Committee of the American Academy of Allergy, Asthma and Immunology. J Allergy Clin Immunol. 2006;117:S525-S553.
73. Bonilla FA, Bernstein L, Khan DA, et. al. Practice parameter for the diagnosis and management of primary immunodeficiency. Ann Allergy Asthma Immunol. 2005;94(suppl):S1-S63.
74. Patwa HS, Chaudhry V, Katzberg H, et al. Evidence-based guideline: intravenous immunoglobulin in the treatment of neuromuscular disorders: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology. 2012 Mar 27;78(13):1009-15.
75. AHFS Drug Information/Lexi-Comp Online [internet database]. Hudson, OH. Lexi-Comp, Inc. Updated periodically. Available by subscription at: http://online.lexi.com/. Accessed March 1, 2023.
76. Joint Task Force of the EFNS and the PNS. European Federation of Neurological Societies/Peripheral Nerve Society guideline on management of multifocal motor neuropathy. Report of a joint task force of the European Federation of Neurological Societies and the Peripheral Nerve Society--first revision. J Peripher Nerv Syst. 2010 Dec;15(4):295-301. doi: 10.1111/j.1529-8027.2010.00290.x.
77. Van den Bergh PY, Hadden RD, Bouche P, et al. European Federation of Neurological Societies/Peripheral Nerve Society guideline on management of chronic inflammatory demyelinating polyradiculoneuropathy: report of a joint task force of the European Federation of Neurological Societies [trunc]. Eur J Neurol 2010 Mar;17(3):356-63.
78. Oscier D, Fegan C, Hillmen P, et al. Guidelines on the diagnosis and management of chronic lymphocytic leukaemia. Br J Haematol. 2004;125:294-317.
79. Centers for Disease Control and Prevention. Guidelines for the Prevention and Treatment of Opportunistic Infections Among HIV-Exposed and HIV-Infected Children. MMWR 2009;58(No. RR-11):11-12.
80. Yap PL. Does intravenous immune globulin have a role in HIV-infected patients? Clin Exp Immunol. 1994 Jul;97 Suppl 1:59-67.
81. Maddison P. Treatment in Lambert-Eaton myasthenic syndrome. Ann N Y Acad Sci. 2012 Dec;1275:78-84. doi: 10.1111/j.1749-6632.2012.06769.x.
82. Sanders DB. Lambert-Eaton myasthenic syndrome: diagnosis and treatment. Ann N Y Acad Sci. 2003 Sep;998:500-8.
83. McKeon A, Robinson MT, McEvoy KM, et al. Stiff-man syndrome and variants: clinical course, treatments, and outcomes. Arch Neurol. 2012 Feb;69(2):230-8. doi: 10.1001/archneurol.2011.991.

84. Levy LM, Dalakas MC, Floeter MK. The stiff-person syndrome: an autoimmune disorder affecting neurotransmission of gamma-aminobutyric acid. Ann Intern Med. 1999 Oct 5;131(7):522-30.
85. Stasi R, Evangelista ML, Stipa E, et al. Idiopathic thrombocytopenic purpura: current concepts in pathophysiology and management. Thrombosis and Haemostasis 2008;99(1):4-13.
86. Per clinical consult with neurologist, July 23, 2013.
87. Per clinical consult with neurologist, August 15, 2013.
88. Joint Task Force of the EFNS and the PNS. European Federation of Neurological Societies/Peripheral Nerve Society guideline on management of multifocal motor neuropathy. Report of a joint task force of the European Federation of Neurological Societies and the Peripheral Nerve Society--first revision. J Peripher Nerv Syst. 2010 Dec;15(4):295-301. doi: 10.1111/j.1529-8027.2010.00290.x.
89. Panzyga Prescribing Information. Octapharma USA, Inc. Paramus, NJ. March 2021.
90. Cutaquig Prescribing Information. Octapharma USA, Inc. Paramus, NJ. November 2021.
91. Xembify Prescribing Information. Grifols Therapeutic LLC. Research Triangle Park, NC. August 2020.
92. Asceniv Prescribing Information. ADMA Biologics. Boca Raton, FL. April 2019.

Prior Authorization Guideline

Guideline Name	Infliximab – PA, NF

Guideline Note:

Effective Date:	8/1/2025

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]

Drug Name: Zymfentra (infliximab-dyyb) SC injection

Crohn's Disease (CD) Indicated in adults for maintenance treatment of moderately to severely active Crohn's disease following treatment with an infliximab product administered intravenously.

Ulcerative Colitis (UC) Indicated in adults for maintenance treatment of moderately to severely active ulcerative colitis following treatment with an infliximab product administered intravenously.

2 . Criteria

Product Name:Avsola, Inflectra	
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

Product Name:Avsola, Inflectra	
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:Avsola, Inflectra	
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

Product Name:Avsola, Inflectra	
Diagnosis	Psoriatic Arthritis (PsA)
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, 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	
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 - Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), 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)

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name:Avsola, Inflectra	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to infliximab therapy as evidenced by ONE of the following [1, 5]

- Reduction in the body surface area (BSA) involvement from baseline

- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name:Avsola, Inflectra	
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]

Product Name:Avsola, Inflectra	
Diagnosis	Ankylosing Spondylitis (AS)
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 improvement from baseline for at 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	
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

Product Name:Zymfentra	
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

AND

2 - Patient has achieved a clinical response following a minimum of 10 weeks of IV infliximab

AND

3 - One of the following:

3.1 Trial of BOTH of the following:

- Avsola
- Inflectra

OR

3.2 Provider attests that continued IV administration is not appropriate for the patient (e.g., problems with IV access)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name:Avsola, Inflectra, Zymfentra	
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 - Patient demonstrates 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:Zymfentra

Diagnosis	Crohn's Disease (CD)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - Patient has achieved a clinical response following a minimum of 10 weeks of IV infliximab

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial of BOTH of the following:

- Avsola
- Inflectra

OR

3.2 Submission of medical records (e.g., chart notes) confirming the provider attests that continued IV administration is not appropriate for the patient (e.g., problems with IV access)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name:Avsola, Inflectra	
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)

Product Name:Zymfentra	
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 - Patient has achieved a clinical response following a minimum of 10 weeks of IV infliximab

AND

3 - One of the following:

3.1 Trial of BOTH of the following:

- Avsola
- Inflectra

OR

3.2 Provider attests that continued IV administration is not appropriate for the patient (e.g., problems with IV access)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name:Avsola, Inflectra, Zymfentra	
Diagnosis	Ulcerative Colitis (UC)
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, 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:Zymfentra	
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 - Patient has achieved a clinical response following a minimum of 10 weeks of IV infliximab

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial of BOTH of the following:

- Avsola
- Inflectra

OR

3.2 Submission of medical records (e.g., chart notes) confirming the provider attests that continued IV administration is not appropriate for the patient (e.g., problems with IV access)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name:Avsola, Inflectra	
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)

Product Name:Avsola, Inflectra	
Diagnosis	Sarcoidosis [Off-label] [12-15]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to infliximab therapy

Product Name:Remicade, Infliximab, Renflexis	
Approval Length	12 month(s)
Guideline Type	Prior Authorization, Non Formulary

Approval Criteria

1 - Patient has one of the following diagnoses:

- Rheumatoid arthritis (RA)
- Psoriatic Arthritis (PsA)
- Plaque Psoriasis (PsO)
- Ankylosing Spondylitis (AS)
- Crohn's Disease (CD) or Fistulizing Crohn's Disease
- Ulcerative Colitis (UC)
- Sarcoidosis (off-label)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 6-month trial of BOTH of the following:

- Avsola
- Inflectra

AND

3 - Submission of medical records documenting why the covered products have not been effective

3 . References

1. Remicade Prescribing Information. Janssen Biotech, Inc. Horsham, PA. October 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. 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. 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.
6. 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.
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. 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.
9. 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.
10. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.
11. 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.
12. DRUGDEX System [Internet database]. Greenwood Village, Colo: Truven Health Analytics. Updated periodically. Accessed July 7, 2020.
13. Baughman RP, Drent M, Kavuru M, et al. Infliximab therapy in patients with chronic sarcoidosis and pulmonary involvement Am J Respir Crit Care Med. 2006 Oct 1;174(7):795-802.
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. Avsola Prescribing Information. Amgen Inc. Thousand Oaks, CA. September 2021.

17. Inflectra prescribing information. Hospira. Lake Forest, IL. March 2022.
18. Renflexis Prescribing Information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. December 2023.
19. Infliximab Prescribing Information. Janssen Biotech, Inc. Horsham, PA. October 2021.
20. Zymfentra Prescribing Information. Celltrion USA, Inc. Jersey City, NJ. February 2024.

Prior Authorization Guideline

Guideline Name	Invega Hafyera (paliperidone palmitate)

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

Prior Authorization Guideline

Guideline Name	Iron Products

Guideline Note:

Effective Date:	5/1/2025

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 Anemia 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). **Iron deficiency** Indicated for the treatment of iron deficiency in adult patients with heart failure and New York Heart Association class II/III to improve exercise capacity.

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, Brand Feraheme, generic ferumoxytol, 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

Product Name:Injectafer	
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 - One of the following:

2.1 Trial and failure of a minimum 30-day supply or intolerance to one of the following generics:

- ferrous sulfate
- ferrous gluconate
- ferrous fumarate

OR

2.2 Patient has New York Heart Association class II or III Heart Failure [A]

3 . Endnotes

A. 2022 ACC/AHA guidelines note that oral iron supplementation is not adequate to treat iron deficiency anemia in patients with heart failure so having patients try oral iron supplementation is not clinically appropriate. In patients with heart failure with reduced ejection fraction and iron deficiency with or without anemia, IV iron replacement is reasonable to improve functional status and quality of life. Oral iron supplementation did not demonstrate the same effective compared to IV formulations. [5]

4 . References

1. Accrufer Prescribing Information. Shield Therapeutics Inc. October 2023.

2. Feraheme Prescribing Information. AMAG Pharmaceuticals, Inc. Waltham, MA. June 2022.
3. Injectafer Prescribing Information. American Regent, Inc. Shirley, NY. January 2025.
4. Monoferric Prescribing Information. Pharmacosmos Therapeutics, Inc. Morristown, NJ. August 2022.
5. Heidenreich, P. A., Bozkurt, B., Aguilar, D., Allen, L. A., Byun, J. J., Colvin, M. M., Deswal, A., Drazner, M. H., Dunlay, S. M., Evers, L. R., Fang, J. C., Fedson, S. E., Fonarow, G. C., Hayek, S. S., Hernandez, A. F., Khazanie, P., Kittleson, M. M., Lee, C. S., Link, M. S., Milano, C. A., … Yancy, C. W. (2022). 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation, 145(18), e876–e894.

Prior Authorization Guideline

Guideline Name	Izervay (avacincaptad pegol)

Guideline Note:

Effective Date:	5/1/2025

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 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

Product Name:Izervay	
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 . Endnotes

A. In GATHER1 and GATHER2, the mean rate of GA growth (slope), measured by Fundus Autofluorescence (FAF), was evaluated at every 6 month time points from baseline. [1]

4 . References

1. Izervay Precribing Information. Iveric Bio, Inc. Parsippany, NJ. February 2025.
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.

Prior Authorization Guideline

Guideline Name	Jevtana (cabazitaxel)

Guideline Note:

Effective Date:	5/1/2025

1 . Indications

Drug Name: Jevtana (cabazitaxel)
Prostate Cancer Indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen.

2 . Criteria

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

Approval Criteria

1 - All of the following:

1.1 Diagnosis of metastatic castration-resistant prostate cancer

AND

1.2 Used in combination with prednisone

AND

1.3 Patient has been previously treated with a docetaxel-containing regimen

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

Approval Criteria

1 - Patient does not show evidence of progressive disease

3 . References

1. Jevtana Prescribing Information. Sanofi-Aventis U.S. LLC, Bridgewater, NJ. July 2023.

Prior Authorization Guideline

Guideline Name	Kanuma (sebelipase alfa)

Guideline Note:

Effective Date:	9/1/2024

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	12 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	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates 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. November 2021.
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.

Prior Authorization Guideline

Guideline Name	Kimyrsa

Guideline Note:

Effective Date:	9/21/2023

Note:

Drug is part of Optum Specialty Fusion program.

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

Prior Authorization Guideline

Guideline Name	Kineret (anakinra)

Guideline Note:

Effective Date:	6/1/2025

Note:

For review process only: Refer to the Client Biosimilar Formulary Strategy List at the following link for carrier-specific formulary products: https://uhgazure.sharepoint.com/sites/ClinicalServices-UtilizationManagement/Internal%20Documents/Forms/AllItems.aspx?viewpath=%2Fsites%2FClinicalServices%2DUtilizationManagement%2FInternal%20Documents%2FForms%2FAllItems%2Easpx

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
- Simponi (golimumab)
- Rinvoq (upadacitinib)
- 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 therapy, defined as no more than a 45-day gap in therapy

Notes	*Includes attestation that a total of two TNF inhibitors have alre ady been 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 - 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: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 - Patient demonstrates 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 - Patient demonstrates 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. September 2024.
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 February 6, 2023. http:www.uptodate.com. Accessed January 28, 2024.
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.

Prior Authorization Guideline

Guideline Name	Korlym (mifepristone)

Guideline Note:

Effective Date:	6/27/2025

1 . Indications

Drug Name: Korlym (mifepristone)
Hyperglycemia in Patients with Endogenous Cushing's Syndrome and Type 2 Diabetes Mellitus Indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. Limitations of use: Korlym should not be used in the treatment of patients with type 2 diabetes unless it is secondary to Cushing's syndrome.

2 . Criteria

Product Name:Brand Korlym, Generic mifepristone 300mg*	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endogenous Cushing's syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids) [A]

AND

2 - One of the following:

- Diagnosis of type 2 diabetes mellitus
- Diagnosis of glucose intolerance

AND

3 - Patient has hyperglycemia that is secondary to hypercortisolism

AND

4 - One of the following: [1,2]

- Patient has failed surgery
- Patient is not a candidate for surgery

AND

5 - Trial or intolerance to generic mifepristone 300 mg (applies to Brand Korlym only)

AND

6 - Prescribed by or in consultation with an endocrinologist

AND **7** - Patient is not pregnant [1]	
Notes	*If patient meets criteria above, please approve at GPI-14 level a nd with a MSC Y.

Product Name:Brand Korlym, Generic mifepristone 300mg*	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of one of the following: • Patient has improved glucose tolerance while on therapy • Patient has stable glucose tolerance while on therapy **AND** **2** - Trial or intolerance to generic mifepristone 300 mg (applies to Brand Korlym only)	
Notes	*If patient meets criteria above, please approve at GPI-14 level a nd with a MSC Y.

3 . Endnotes

A. Korlym should not be used in the treatment of patients with type 2 diabetes unless it is secondary to Cushing's syndrome. [1]

4 . References

1. Korlym prescribing information. Corcept Therapeutics Inc. Menlo Park, CA. November 2019.
2. Nieman LK, Biller BM, Findling JW, et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2015;100(8):2807-2831.
3. Mifepristone prescribing information. Actavis Pharma, Inc. May 2024.

Prior Authorization Guideline

Guideline Name	Korsuva (difelikefalin)

Guideline Note:

Effective Date:	7/1/2025

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 - Patient demonstrates 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. April 2024.
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.

Prior Authorization Guideline

Guideline Name	Koselugo (selumetinib)

Guideline Note:

Effective Date:	8/1/2024

1 . Indications

Drug Name: Koselugo (selumetinib)
Neurofibromatosis Type 1 Indicated for the treatment of pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN)

2 . Criteria

Product Name:Koselugo	
Diagnosis	Neurofibromatosis Type 1
Approval Length	6 Month(s) [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neurofibromatosis type 1

AND

2 - Patient has plexiform neurofibromas that are both of the following:

- Inoperable [B]
- Causing significant morbidity (e.g., disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment)

AND

3 - One of the following:

3.1 Patient is less than 18 years of age

OR

3.2 Both of the following:

- Patient is 18 years of age or older
- Patient is continuing therapy [C]

AND

4 - Patient is able to swallow a capsule whole

Product Name:Koselugo	
Diagnosis	Neurofibromatosis Type 1

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

Approval Criteria

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

3 . Endnotes

A. The initial authorization duration of 6 months is to allow for assessment of adverse reactions (e.g., cardiomyopathy) without interruption of therapy [1,2].
B. Inoperable plexiform neurofibromas are defined as those that could not be completely removed without risk for substantial morbidity due to encasement of, or close proximity to, vital structures, invasiveness, or high vascularity of the PN [1].
C. It is the recommendation of the consultant that the medication should not be discontinued due to patient's age [2].

4 . References

1. Koselugo Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. January 2024.
2. Per clinical consult with oncologist, May 27, 2020.

Prior Authorization Guideline

Guideline Name	Krystexxa (pegloticase)

Guideline Note:

Effective Date:	9/1/2024

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. 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 - Patient demonstrates positive clinical response to therapy as 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. November 2022.
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.

Prior Authorization Guideline

Guideline Name	Lamzede (velmanase alfa-tycv)

Guideline Note:

Effective Date:	7/1/2025

1 . Indications

Drug Name: Lamzede (velmanase alfa-tycv)
Alpha - Mannosidosis Indicated for the treatment of non-central nervous system manifestations of alpha-mannosidosis in adult and pediatric patients.

2 . Criteria

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

Approval Criteria

1 - Diagnosis of alpha-mannosidosis

AND

2 - Disease is confirmed by one of the following: [5, 6]

- Deficiency in alpha-mannosidase enzyme activity as measured in fibroblasts or leukocytes
- Molecular genetic testing confirms mutations in the MAN2B1 gene

AND

3 - Treatment is only for non-central nervous system disease manifestations (e.g., large head, prominent forehead, protruding jaw, skeletal abnormalities)

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

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy as evidenced by one of the following:

- Reduction in serum oligosaccharide concentration from baseline
- Improvement in clinical signs and symptoms from baseline (e.g., 3-minute stair climbing test, 6-minute walking test, pulmonary function, quality of life)

3 . References

1. Lamzede Prescribing Information. Chiesi USA, Inc. Cary, NC. February 2023.
2. ClinicalTrials.gov. A Placebo-Controlled Phase 3 Trial of Repeated Lamazym Treatment of Subjects With Alpha-Mannosidosis. Available at: https://www.clinicaltrials.gov/ct2/show/NCT01681953?term=nct01681953&draw=2&rank=1. Accessed March 30, 2023.
3. ClinicalTrials.gov. Trial on Safety and Efficacy of Velmanase Alfa Treatment in Pediatric Patients With Alpha-Mannosidosis (rhLaman-08). Available at: https://www.clinicaltrials.gov/ct2/show/NCT02998879?term=NCT02998879&draw=2&rank=1. Accessed March 30, 2023.
4. Bordwardt, L., Guffon, N., et al. Efficacy and safety of Velmanase alfa in the treatment of patients with alpha-mannosidosis: results from the core and extension phase analysis of a phase III multicentre, double-blind, randomised, placebo-controlled trial. Avaiable at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6326984/. Accessed March 30, 2023.
5. Malm, D, Nilssen, O. Alpha-Mannosidosis. Available at: https://www.ncbi.nlm.nih.gov/books/NBK1396/. Accessed March 30, 2023.
6. Alpha Mannosidosis. Available at : https://rarediseases.org/rare-diseases/alpha-mannosidosis/. Accessed March 30, 2023.

Prior Authorization Guideline

Guideline Name	Leqvio (inclisiran) - PA, NF

Guideline Note:

Effective Date:	11/1/2024

1 . Indications

Drug Name: Leqvio (inclisiran) injection, for subcutaneous use
Primary Hyperlipidemia Indicated as an adjunct to diet and statin therapy for the treatment of adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce low-density lipoprotein cholesterol (LDL-C).

2 . Criteria

Product Name:Leqvio	
Diagnosis	Primary Hyperlipidemia [Including 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:

- Heterozygous familial hypercholesterolemia (HeFH)
- Atherosclerotic cardiovascular disease (ASCVD)
- Primary hyperlipidemia

AND

2 - One of the following: [4]

- Patient has been receiving at least 12 consecutive weeks of highest tolerable dose of statin therapy
- Patient is statin intolerant as evidenced by an inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (e.g., creatine kinase)
- Patient has an FDA labeled contraindication to all statins

AND

3 - One of the following:

- Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy
- 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 PCSK9 inhibitor (Repatha, Praluent) therapy as adjunct to maximally tolerated lipid lowering therapy (e.g., statins, ezetimibe)

AND

4.1.2 Despite adherence to PCSK9 inhibitor (Repatha, Praluent) 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 with ASCVD [7]
- LDL-C greater than or equal to 100 mg/dL without ASCVD [3]

OR

4.2 Patient is unable to maintain adherence to PCSK9 inhibitor (Repatha, Praluent) 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 PCSK9 inhibitor (Repatha, Praluent) 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	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD)]
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 LDL-C reduction from baseline

AND

2 - One of the following:

- Patient continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at the maximally tolerated dose
- Patient has a documented inability to take other lipid-lowering therapy (e.g., statins, ezetimibe)

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 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

4.1.2 Despite adherence to Repatha therapy, patient was 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 with ASCVD [7]
- LDL-C greater than or equal to 100 mg/dL without ASCVD [3]

OR

4.2 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

4.3 Patient has experienced a hypersensitivity reaction, defined as angioedema, vasculitis, urticaria, to Repatha therapy

AND

3 - 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. July 2023.
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.
7. Lloyd-Jones D, Morris P, et al. 2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk. J Am Coll Cardiol. 2022 Oct, 80 (14) 1366–1418. https://doi.org/10.1016/j.jacc.2022.07.006

Prior Authorization Guideline

Guideline Name	Linezolid

Guideline Note:

Effective Date:	5/1/2024

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

AND

3 - One of the following if requesting oral solution:

- Pediatric member age 10 or under
- Documented inability of the member to use the preferred tablet formulation

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, 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.

Prior Authorization Guideline

Guideline Name	Livdelzi (seladelpar lysine)

Guideline Note:

Effective Date:	1/10/2025

1 . Criteria

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

Approval Criteria

1 - Diagnosis of primary biliary cholangitis (PBC) confirmed by two of the following:

- Biochemical evidence of cholestasis based on ALP elevation
- Presence of AMA or other PBC-specific autoantibodies
- Histology confirmation after biopsy

AND

2 - Submission of medical records (e.g., chart notes) confirming at least 12 months of inadequate response to ursodiol

AND

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

- Hepatologist
- Gastroenterologist

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

Approval Criteria

1 - Submission of medical records (e.g., chart notes or paid claims) confirming adherence to the medication

AND

2 - Attestation of clinical benefit and continued need

Prior Authorization Guideline

Guideline Name	Loqtorzi (toripalimab-tpzi)

Guideline Note:

Effective Date:	4/1/2025

1 . Indications

Drug Name: Loqtorzi (toripalimab-tpzi)
Nasopharyngeal carcinoma (NPC) Indicated, in combination with cisplatin and gemcitabine, for the first-line treatment of adults with metastatic or with recurrent, locally advanced NPC. Indicated, as a single agent, for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy.

2 . Criteria

Product Name:Loqtorzi	
Diagnosis	Nasopharyngeal carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of nasopharyngeal carcinoma (NPC)

AND

2 - Disease is one of the following:

- metastatic
- recurrent and locally advanced

AND

3 - One of the following:

3.1 All of the following:

3.1.1 Loqtorzi is being used as first line NPC treatment

AND

3.1.2 Loqtorzi is being used in combination with cisplatin and gemcitabine

AND

3.1.3 Treatment duration of Loqtorzi has not exceeded a total of 24 months during the patient's lifetime

OR

3.2 Both of the following:

3.2.1 Loqtorzi is being used as recurrent NPC treatment

AND

3.2.2 Disease has progressed on or after a platinum containing chemotherapy

Product Name:Loqtorzi	
Diagnosis	Nasopharyngeal carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Loqtorzi is being used as first line NPC treatment

AND

1.2 Patient does not show evidence of progressive disease while on therapy

AND

1.3 Treatment duration of Loqtorzi has not exceeded a total of 24 months during the patient's lifetime

OR

2 - Both of the following:

2.1 Loqtorzi is being used as recurrent NPC treatment

AND

2.2 Patient does not show evidence of progressive disease while on therapy

3 . References

1. Loqtorzi Prescribing Information.Coherus BioSciences, Inc. Redwood City, CA. October 2024.

Prior Authorization Guideline

Guideline Name	Lumizyme (alglucosidase alfa)

Guideline Note:

Effective Date:	7/1/2025

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 - Patient demonstrates 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 - Patient demonstrates 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. December 2024.
2. Kronn DF, Day-Salvatore D, Hwu WL, et al. Management of Confirmed Newborn-Screened Patients With Pompe Disease Across the Disease Spectrum. Pediatrics. 2017; 140 (Supplement 1): S24–S45.
3. Kishani PS, Steiner RD, Bali, D. ACMG Practice Guideline. Pompe disease diagnosis and management guideline. Genet Med. 2006;8(5):267-88.
4. Barba-Romero MA, Barrot E, Bautista-Lorite J, et al. Clinical guidelines for late-onset Pompe disease. Rev Neurol 2012; 54 (8): 497-507.

Prior Authorization Guideline

Guideline Name	Luxturna (voretigene neparvovec)

Guideline Note:

Effective Date:	8/1/2025

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 OptumRx 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/BloodVaccinesandOtherBiologics/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.

Prior Authorization Guideline

Guideline Name	Mepsevii (vestronidase alfa-vjbk)

Guideline Note:

Effective Date:	7/1/2025

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 - Patient demonstrates positive clinical response to therapy

3 . References

1. Mepsevii Prescribing Information. Ultragenyx Pharmaceutical Inc. Novato CA. December 2020.

Prior Authorization Guideline

Guideline Name	Mitoxantrone

Guideline Note:

Effective Date:	8/1/2025

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	When approved; no reauthorization required
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 (of a minimum 4-week supply), contraindication, or intolerance to two disease-modifying therapies for MS (e.g., Kesimpta [Ofatumumab], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod]): [B, 3, 11]

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 - A lifetime cumulative dose less than 140mg/m^2

AND

6 - Prescribed by or in consultation with a neurologist

Notes	For reauthorization request, bypass criteria review and approve t hrough 12/31/2039 For initial authorization request, approve through 12/31/2039

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

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]

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. October 2024.
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 12, 2025
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.

Prior Authorization Guideline

Guideline Name	Molluscum Contagiosum Agents

Guideline Note:

Effective Date:	7/1/2025

1 . Indications

Drug Name: Ycanth (cantharidin solution)
Molluscum contagiosum Indicated for the topical treatment of molluscum contagiosum in adult and pediatric patients 2 years of age and older.
Drug Name: Zelsuvmi (berdazimer) topical gel
Molluscum contagiosum Indicated for the topical treatment of molluscum contagiosum in adults and pediatric patients 1 year of age and older.

2 . Criteria

Product Name:Ycanth	
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of molluscum contagiosum

AND

2 - Patient is 2 years of age or older

AND

3 - Patient has single or multiple, 2- to 5-mm-diameter, flesh-colored to translucent, dome-shaped papules, some with central umbilication [2]

AND

4 - One of the following [4]:

- Patient has eczema (e.g., atopic dermatitis)
- Patient is immunocompromised
- Patient has extensive involvement or experiences bleeds, secondary infections or discomfort from the lesions

AND

5 - Lesions have not resolved within six months of diagnosis [4]

AND

6 - One of the following:

6.1 Patient is treating new lesions that have not previously been treated with Ycanth

OR

6.2 Lesions have previously been treated with Ycanth and will not exceed a total of 4 treatments of Ycanth [A]

AND

7 - Medication is not being used concurrently with other FDA approved therapies (e.g., Zelsuvmi) on the same lesion for the treatment of molluscum contagiosum [3]

AND

8 - Prescribed by or in consultation with a dermatologist

Product Name:Zelsuvmi	
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of molluscum contagiosum

AND

2 - Patient is 1 year of age or older

AND

3 - Patient has single or multiple, 2- to 5-mm-diameter, flesh-colored to translucent, dome-shaped papules, some with central umbilication [2]

AND

4 - One of the following [4]:

- Patient has eczema (e.g., atopic dermatitis)
- Patient is immunocompromised
- Patient has extensive involvement or experiences bleeds, secondary infections or discomfort from the lesions

AND

5 - Lesions have not resolved within six months of diagnosis [4]

AND

6 - Patient is treating new lesions that have not previously been treated with Zelsuvmi

AND

7 - Medication is not being used concurrently with other FDA approved therapies (e.g., Ycanth) on the same lesion for the treatment of molluscum contagiosum [3]

AND

8 - Prescribed by or in consultation with a dermatologist

3 . Endnotes

A. Subjects' lesions were treated with either YCANTH or vehicle at intervals of approximately 21 days until complete clearance of the lesion or for a maximum of 4 applications

4 . References

1. Ycanth Prescribing Information. Verrica Pharmaceuticals Inc. West Chester, PA. July 2023.
2. American Academy of Pediatrics. Molluscum contagiosum. In: Kimberlin DW, Barnett ED, Lynfield R, Sawyer MH, eds. Red Book: 2021–2024 Report of the Committee on Infectious Diseases. 32nd ed. Itasca, IL: American Academy of Pediatrics; 2021: 535-537.
3. Per clinical consult with dermatologist regarding Zelsuvmi, July 31, 2024.
4. Molluscum contagiosum: Diagnosis and treatment. www.aad.org. https://www.aad.org/public/diseases/a-z/molluscum-contagiosum-treatment
5. Zelsuvmi Prescribing Information. LNHC, Inc. Durham, NC 27703. January 2024.

Prior Authorization Guideline

Guideline Name	Monoclonal Antibody Agents for Alzheimer's Disease - PA, NF

Guideline Note:

Effective Date:	8/16/2024

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:

1.1 Based on the National Institute on Aging and the Alzheimer's Association (NIA-AA) criteria, one of the following: [16,17,24]

- 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: [18-19]

- 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 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

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 [20]

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: [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

1.2 Submission of medical records (e.g., chart notes) confirming both of the following: [18-19]

- 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:Leqembi	
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 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:Leqembi	
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]

5 . References

1. Kisunla Prescribing Information. Eli Lilly and Company. Indianapolis, IN. July 2024.
2. Alzheimer's Association: Criteria for Diagnosis and Staging of Alzheimer's Disease. Available at: https://www.alz.org/research/for_researchers/diagnostic-criteria-guidelines. Accessed July 22, 2024.

3. Jack Jr, Clifford, Andrews, J Scott, Beach, T., et al. Revised criteria for diagnosis and staging of Alzheimer's disease: Alzheimer's Association Workgroup. Available at: https://alz-journals.onlinelibrary.wiley.com/doi/epdf/10.1002/alz.13859. Accessed July 22, 2024.
4. Barthelemy, N., Salvado, G., Schindler, S., et al. Highly accurate blood test for Alzheimer's disease is similar or superior to clinical cerebrospinal fluid tests. Available at: https://www.nature.com/articles/s41591-024-02869-z. Accessed July 22, 2024.
5. Schneider, Tamara. Alzheimer's blood test performs as well as FDA- approved spinal fluid tests. Available at: https://medicine.wustl.edu/news/alzheimers-blood-test-performs-as-well-as-fda-approved-spinal-fluid-tests/. Accessed July 22, 2024.
6. AlMansoori, M., Jemimah, S., Abuhantash, F., et al. Predicitng early Alzheimer's with blood biomarkers and clinical features. Available at: https://www.nature.com/articles/s41598-024-56489-1. Accessed July 22, 2024.
7. Sims, J., Zimmer, J., Evans, C., et al. Donanemab in Early Symptomatic Alzheimer Disease, The Trailblazer-ALZ 2 Randomized Clinical Trial. Available at: Donanemab in Early Symptomatic Alzheimer Disease: The TRAILBLAZER-ALZ 2 Randomized Clinical Trial | Dementia and Cognitive Impairment | JAMA | JAMA Network. Accessed July 22, 2024.
8. ClinicalTrials.gov. A Study of Donanemab (LY3002813) in Participants With Early Alzheimer's Disease (TRAILBLAZER-ALZ 2). Available at: https://clinicaltrials.gov/study/NCT04437511#participation-criteria. Accessed July 22, 2024.
9. Leqembi Prescribing Information. Eisai, Inc. Nutley, NJ. July 2023.
10. 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.
11. 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.
12. A Study to Confirm Safety and Efficacy of Lecanemab in Participants With Early Alzheimer's Disease (Clarity AD): https://www.clinicaltrials.gov/ct2/show/NCT03887455. Accessed January 6, 2023.
13. A study to Evaluate Safety, Tolerability, and Efficacy of Lecanemab in Subjects with Early Alzheimer's Disease. https://www.clinicaltrials.gov/ct2/show/NCT01767311. Accessed January 6, 2023.
14. Oudart, Jean., Djerada, Z., et al. Incremental Value of CSF Biomarkers in Clinically Diagnosed AD and Non-AD Dementia. Available at: Incremental Value of CSF

Biomarkers in Clinically Diagnosed AD and Non-AD Dementia - PMC (nih.gov). Accessed July 20, 2023.
15. Anoop, A., Singh, P., et al. CSF Biomarkers for Alzeheimer's Disease Diagnosis. Available at: CSF Biomarkers for Alzheimer's Disease Diagnosis - PMC (nih.gov). Accessed July 20, 2023
16. 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.
17. 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.
18. ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT02477800.
19. ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT02484547.
20. Aducanumab [unapproved dossier], Cambridge, MA: Biogen; 2020.
21. 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.
22. 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.
23. Sevigny, J., Chiao, P., Bussière, T. et al. The antibody aducanumab reduces Aβ plaques in Alzheimer's disease. Nature 537, 50–56 (2016).
24. Per clinical consult with neurologist, January 21, 2021.
25. Aduhelm prescribing information. Biogen, Inc. Cambridge, MA. February 2023.
26. Blennow K, Mattsson N, Scholl M, et al. Amyloid biomarkers in Alzheimer's disease. Trends Pharmacol Sci 2015;36:297–309.
27. ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT01677572.
28. ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT04241068.
29. Wolk DA, Dickerson BC. Clinical features and diagnosis of Alzheimer disease. UpToDate Web site. http://www.uptodate.com. Accessed February 1, 2023.

Prior Authorization Guideline

Guideline Name	Multiple Sclerosis (MS) Agents - PA, NF

Guideline Note:

Effective Date:	8/1/2025

1 . Indications

Drug Name: Aubagio (teriflunomide), Avonex (interferon beta-1a), Bafiertam (monomethyl fumarate), Betaseron (interferon beta-1b), Briumvi (ublituximab-xiiy), Copaxone (glatiramer acetate), Extavia (interferon beta-1b), Glatopa (glatiramer acetate)
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: Kesimpta (ofatumumab), Mayzent (siponimod), Plegridy (peginterferon beta-1a), Ponvory (ponesimod), Rebif (interferon beta-1a), Vumerity (diroximel fumarate)
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: 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: Ocrevus (ocrelizumab), Ocrevus Zunovo (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: 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 40mg/mL, Generic glatiramer acetate, Glatopa, Kesimpta, Mayzent, Generic Teriflunomide, Vumerity	
Approval Length	When approved; no reauthorization required
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 (of a minimum 4-week supply), or intolerance to generic teriflunomide

Notes	For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Brand Copaxone 20mg/mL	
Approval Length	When approved; no reauthorization required
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 - Trial and failure (of a minimum 4-week supply), or intolerance to generic glatiramer acetate

Notes	If patient meets criteria above, please approve at GPI-14 For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Extavia, Plegridy, Ponvory, Rebif	
Approval Length	When approved; no reauthorization required
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 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to two disease-modifying therapies for MS (e.g., Kesimpta [Ofatumumab], Mavenclad [Cladribine], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod], Vumerity [diroximel fumarate], Bafiertam [monomethyl fumarate], Copaxone [glatiramer acetate])

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

Notes	For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Tascenso ODT	
Approval Length	When approved; no reauthorization required
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 Patient is unable to swallow solid oral dosage forms (e.g., oral tablet, capsule) due to one of the following:

- Age
- Physical impairment (e.g., difficulties with motor or oral coordination)
- Dysphagia
- Patient is using a feeding tube or nasal gastric tube

AND

3.1.3 One of the following:

3.1.3.1 For continuation of therapy

OR

3.1.3.2 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to two disease-modifying therapies for MS (e.g., Kesimpta [Ofatumumab], Mavenclad [Cladribine], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod], Vumerity [diroximel fumarate], Bafiertam [monomethyl fumarate], Copaxone [glatiramer acetate])

OR

3.2 Both of the following:

3.2.1 Patient is younger than 18 years of age

AND

3.2.2 One of the following:

3.2.2.1 Both of the following:

- Patient weighs greater than or equal to 40kg
- Trial and failure (of a minimum 4-week supply) or intolerance to generic fingolimod

OR

3.2.2.2 Both of the following:

- Patient weighs less than 40kg
- Trial and failure (of a minimum 4-week supply) or intolerance to Gilenya (fingolimod)

OR

3.3 Patient is unable to swallow solid oral dosage forms (e.g., oral tablet, capsule) due to one of the following:

- Age
- Physical impairment (e.g., difficulties with motor or oral coordination)
- Dysphagia
- Patient is using a feeding tube or nasal gastric tube

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

Notes	For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Extavia, Plegridy, Ponvory, Rebif	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a 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 Patient demonstrates 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 trial and failure (of a minimum 4-week supply), contraindication, or intolerance to at least three disease-modifying therapies for MS (e.g., Kesimpta [Ofatumumab], Mavenclad [Cladribine], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod], Vumerity [diroximel fumarate], Bafiertam [monomethyl fumarate], Copaxone [glatiramer acetate])

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)
Guideline Type	Non Formulary

Approval Criteria

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

3.1.2.1.1 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

3.1.2.1.2 Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

OR

3.1.2.2 Patient is unable to swallow solid oral dosage forms (e.g., oral tablet, capsule) due to one of the following:

- Age
- Physical impairment (e.g., difficulties with motor or oral coordination)
- Dysphagia
- Patient is using a feeding tube or nasal gastric tube

OR

3.1.2.3 All of the following:

3.1.2.3.1 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) with generic fingolimod that has the same active ingredient

AND

3.1.2.3.2 Submission of medical records confirming generic fingolimod has not been effective AND valid clinical justification provided explaining how Tascenso ODT is expected to provide benefit when generic fingolimod has not been shown to be effective despite having the same active ingredient

AND

3.1.2.3.3 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure (of a minimum 4-week supply), contraindication, or intolerance to at least two of the following disease-modifying therapies for MS (e.g., Kesimpta [Ofatumumab], Mavenclad [Cladribine], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod], Vumerity [diroximel fumarate], Bafiertam [monomethyl fumarate], Copaxone [glatiramer acetate])

OR

3.2 Both of the following:

3.2.1 Patient is younger than 18 years of age

AND

3.2.2 One of the following:

3.2.2.1 All of the following:

3.2.2.1.1 Patient weighs greater than or equal to 40kg

AND

3.2.2.1.2 Submission of medical records (e.g., chart notes) confirming lack of adequate clinical response (with related symptoms) with generic fingolimod

AND

3.2.2.1.3 Submission of medical records confirming generic fingolimod has not been effective AND valid clinical justification provided explaining how the Tascenso ODT is expected to provide benefit when generic fingolimod has not been shown to be effective despite having the same active ingredient

OR

3.2.2.2 All of the following:

3.2.2.2.1 Patient weighs less than 40kg

AND

3.2.2.2.2 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) to Gilenya 0.25mg (fingolimod)

AND

3.2.2.2.3 Submission of medical records confirming Gilenya 0.25mg has not been effective AND valid clinical justification provided explaining how the Tascenso ODT is expected to provide benefit when Gilenya 0.25mg (fingolimod) has not been shown to be effective despite having the same active ingredient

OR

3.2.2.3 Submission of medical records confirming patient is unable to swallow solid oral dosage forms (e.g., oral tablet, capsule) due to one of the following:

- Age
- Physical impairment (e.g., difficulties with motor or oral coordination)
- Dysphagia
- Patient is using a feeding tube or nasal gastric tube

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:Briumvi

Approval Length	When approved; no reauthorization required
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 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to two disease-modifying therapies for MS (e.g., Kesimpta [Ofatumumab], Mavenclad [Cladribine], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod], Vumerity [diroximel fumarate], Bafiertam [monomethyl fumarate], Copaxone [glatiramer acetate])

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

Notes	For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Lemtrada	
Approval Length	When approved; no reauthorization required
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 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to two disease-modifying therapies for MS (e.g., Kesimpta [Ofatumumab], Mavenclad [Cladribine], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod], Vumerity [diroximel fumarate], Bafiertam [monomethyl fumarate], Copaxone [glatiramer acetate])

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

Notes	For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Mavenclad	
Approval Length	When approved; no reauthorization required
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 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to one disease-modifying therapy for MS (e.g., Kesimpta [Ofatumumab], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod], Vumerity [diroximel fumarate], Bafiertam [monomethyl fumarate], Copaxone [glatiramer acetate])

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

Notes	For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Ocrevus, Ocrevus Zunovo	
Diagnosis	Relapsing Forms of MS
Approval Length	When approved; no reauthorization required
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 Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to one disease-modifying therapy for MS (e.g., Kesimpta [Ofatumumab], Mavenclad

[Cladribine], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod], Vumerity [diroximel fumarate], Bafiertam [monomethyl fumarate], Copaxone [glatiramer acetate])

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

Notes	For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Ocrevus, Ocrevus Zunovo	
Diagnosis	Primary Progressive Multiple Sclerosis (PPMS)

Approval Length	When approved; no reauthorization required
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

Notes	For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Ocrevus Zunovo	
Diagnosis	Relapsing Forms of MS

Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming 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)

AND

2 - One of the following:

2.1 Submission of medical records (e.g., chart notes) or paid claims confirming a trial and failure (of a minimum 4-week supply), contraindication, or intolerance to three disease-modifying therapy for MS (e.g., Kesimpta [Ofatumumab], Mavenclad [Cladribine], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod], Vumerity [diroximel fumarate], Bafiertam [monomethyl fumarate], Copaxone [glatiramer acetate])

OR

2.2 Both of the following:

2.2.1 Submission of medical records (e.g., chart notes) or paid claims confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy for continuation of therapy

AND

2.2.2 Patient demonstrates positive clinical response to 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])

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 Zunovo	
Diagnosis	Primary Progressive Multiple Sclerosis (PPMS)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming 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

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. July 2023.
2. Betaseron Prescribing Information. Bayer. Whippany, NJ. July 2023.
3. Copaxone Prescribing Information. Teva Pharmaceuticals. North Wales, PA. January 2025.
4. Extavia Prescribing Information. Novartis. East Hanover, NJ. July 2023.
5. Rebif Prescribing Information. Serono Inc. Rockland, MA. July 2023.
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 April 5, 2024
8. Per clinical consultation with MS specialist, December 29, 2010.
9. Plegridy Prescribing Information. Biogen Idec Inc. Cambridge, MA. November 2024.
10. Aubagio Prescribing Information. Genzyme Corporation. Cambridge, MA. June 2024.
11. Lemtrada Prescribing Information. Genzyme Corporation. Cambridge, MA. May 2024.
12. Glatopa Prescribing Information. Sandoz Inc. Princeton, NJ. February 2025.
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. November 2024.
15. Mayzent Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. August 2024.
16. Mavenclad Prescribing Information. EMD Serono, Inc. Rockland, MA. May 2024.
17. Vumerity Prescribing Information. Biogen Inc. Cambridge, MA. November 2024.
18. Bafiertam Prescribing Information. Banner Life Sciences. High Point, NC. March 2024.
19. Kesimpta Prescribing Information. Novartis Pharmaceuticals Corporation. East NJ. April 2024.
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. August 2024.

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. January 2025.
25. Briumvi Prescribing Information. TG Therapeutics, Inc. Morrisville, NC. November 2024.
26. Ocrevus Zunovo Prescribing Information. Genentech, Inc. San Francisco, CA. November 2024.

Prior Authorization Guideline

Guideline Name	Myobloc (rimabotulinumtoxin B)

Guideline Note:

Effective Date:	10/1/2024

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	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	All indications listed above
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 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.

Prior Authorization Guideline

Guideline Name	Naglazyme (galsulfase injection)

Guideline Note:

Effective Date:	8/1/2024

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 - Patient demonstrates positive clinical response to therapy

3 . References

1. Naglazyme Prescribing Information. BioMarin Pharmaceuticals Inc. April 2020.

Prior Authorization Guideline

Guideline Name	Nexletol (bempedoic acid) and Nexlizet (bempedoic acid-ezetimibe)

Guideline Note:

Effective Date:	11/1/2024

1 . Indications

Drug Name: Nexletol (bempedoic acid)
HeFH or primary hyperlipidemia Indicated as an adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH). **Established CVD or high risk for a CVD event but without established CVD** Indicated to reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with: established cardiovascular disease (CVD), or a high risk for a CVD event but without established CVD.
Drug Name: Nexlizet (bempedoic acid-ezetimibe)
HeFH or primary hyperlipidemia Indicated as an adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).

Established CVD or high risk for a CVD event but without established CVD Indicated to reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with: established cardiovascular disease (CVD), or a high risk for a CVD event but without established CVD.

2 . Criteria

Product Name:Nexletol, Nexlizet	
Diagnosis	Heterozygous familial hypercholesterolemia (HeFH) or primary hyperlipidemia
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Heterozygous familial hypercholesterolemia (HeFH)
- Primary Hyperlipidemia

AND

2 - One of the following:

- Patient has been receiving at least 12 consecutive weeks of highest tolerable dose of statin therapy
- Patient is statin intolerant as evidenced by an inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (e.g., creatine kinase)
- Patient has an FDA labeled contraindication to all statins

AND

3 - One of the following LDL-C values while on maximally tolerated statin therapy within the last 120 days:

- LDL-C greater than or equal to 55 mg/dL with ASCVD
- LDL-C greater than or equal to 100 mg/dL without ASCVD

AND

4 - One of the following:

4.1 For Nexletol, ONE of the following:

- Patient has been receiving at least 12 consecutive weeks of generic ezetimibe therapy as adjunct to maximally tolerated statin therapy
- Patient has a history of contraindication or intolerance to ezetimibe

OR

4.2 For Nexlizet, patient has been receiving at least 12 consecutive weeks of generic ezetimibe therapy as adjunct to maximally tolerated statin therapy

Product Name:Nexletol, Nexlizet	
Diagnosis	Heterozygous familial hypercholesterolemia (HeFH) or primary hyperlipidemia
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 a reduction in LDL-C levels from baseline while on therapy

AND

2 - One of the following:

- Patient continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at the maximally tolerated dose
- Patient has a documented inability to take other lipid-lowering therapy (e.g., statins, ezetimibe)

Product Name:Nexletol, Nexlizet	
Diagnosis	Established cardiovascular disease (CVD) or high risk for a CVD event but without established CVD
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Established cardiovascular disease (CVD) (e.g., coronary artery disease, symptomatic peripheral arterial disease, cerebrovascular atherosclerotic disease)
- A high risk for a CVD event but without established CVD [e.g., diabetes mellitus (type 1 or type 2) in females over 65 years of age or males over 60 years of age]

AND

2 - One of the following:

- Patient is statin intolerant as evidenced by an inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (e.g., creatine kinase)
- Patient has an FDA labeled contraindication to all statins

AND

3 - One of the following LDL-C values within the last 120 days:

- LDL-C greater than or equal to 55 mg/dL with ASCVD
- LDL-C greater than or equal to 100 mg/dL without ASCVD

AND

4 - One of the following:

4.1 For Nexletol, ONE of the following:

- Patient has been receiving at least 12 consecutive weeks of generic ezetimibe therapy
- Patient has a history of contraindication or intolerance to ezetimibe

OR

4.2 For Nexlizet, patient has been receiving at least 12 consecutive weeks of generic ezetimibe therapy

Product Name:Nexletol, Nexlizet	
Diagnosis	Established cardiovascular disease (CVD) or high risk for a CVD event but without established CVD
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

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. [3]

4 . References

1. Nexletol Prescribing Information. Esperion Therapeutics, Inc. Ann Arbor, MI. March 2024.
2. Nexlizet Prescribing Information. Esperion Therapeutics, Inc. Ann Arbor, MI. March 2024.
3. 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.
4. Alonso R, Cuevas A, Cafferata A. Diagnosis and Management of Statin Intolerance. J Atheroscler Thromb. 2019 Mar 1;26(3):207-215. doi: 10.5551/jat.RV17030. Epub 2019 Jan 19. PMID: 30662020; PMCID: PMC6402887.
5. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2017 Focused Update of the 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk. J Am Coll Cardiol. 2017;70:1785-1822.
6. Cannon CP, Blazing MA, Giugliano RP, et al. Ezetimibe added to statin therapy after acute coronary syndromes. N Engl J Med. 2015;372:2387-97.
7. Harada-Shiba M, Arai H, Ishigaki Y, Ishibashi S, Okamura T, Ogura M, Dobashi K, Nohara A, Bujo H, Miyauchi K, Yamashita S, Yokote K; Working Group by Japan Atherosclerosis Society for Making Guidance of Familial Hypercholesterolemia. Guidelines for Diagnosis and Treatment of Familial Hypercholesterolemia 2017. J

Atheroscler Thromb. 2018 Aug 1;25(8):751-770. doi: 10.5551/jat.CR003. Epub 2018 Jun 7. PMID: 29877295; PMCID: PMC6099072.

Prior Authorization Guideline

Guideline Name	Nexviazyme (avalglucosidase alfa-ngpt)

Guideline Note:

Effective Date:	11/1/2024

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

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

Approval Criteria

1 - Patient demonstrates 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. September 2023.
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.

Prior Authorization Guideline

Guideline Name	Niktimvo (axatilimab-csfr)- PA, NF

Guideline Note:

Effective Date:	8/1/2025

1 . Indications

Drug Name: Niktimvo (axatilimab-csfr)
Chronic Graft Versus Host Disease (cGVHD) Indicated for the treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg.

2 . Criteria

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

Approval Criteria

1 - Diagnosis of chronic graft versus host disease (cGVHD)

AND

2 - Trial and failure of at least two other systemic therapies [e.g., corticosteroids (e.g., prednisone, methylprednisolone), mycophenolate]

AND

3 - Patient weighs at least 40kg

Product Name:Niktimvo	
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:Niktimvo	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of chronic graft versus host disease (cGVHD)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure of at least two other systemic therapies [e.g., corticosteroids (e.g., prednisone, methylprednisolone), mycophenolate]

AND

3 - Submission of medical records (e.g., chart notes) confirming patient weighs at least 40kg

3 . References

1. Niktimvo Prescribing Information. Incyte Corporation. Wilmington, DE 19803. January 2025.
2. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology. Hematopoietic Cell Transplantation (HCT). V2.2024. NCCN Web site. https://www.nccn.org/professionals/physician_gls/pdf/hct.pdf. Accessed February 14, 2025.
3. Wolff D, Cutler C, Lee SJ, et al. Axatilimab in Recurrent or Refractory Chronic Graft-versus-Host Disease. N Engl J Med. 2024;391(11):1002-1014.

Prior Authorization Guideline

Guideline Name	Nplate (romiplostim)

Guideline Note:

Effective Date:	4/1/2025

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 - Patient demonstrates positive 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 January 8 2025.
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 January 9, 2025.

Prior Authorization Guideline

Guideline Name	Nucala (mepolizumab)

Guideline Note:

Effective Date:	7/1/2025

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 - One of the following [2-4, D]:

4.1 Both of the following:

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 [4]:

- 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]:

- 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:Nucala	
Diagnosis	Severe Asthma
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) [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 [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., 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 - Patient is 18 years of age or older

AND

3 - 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

4 - Used in combination with another agent for CRSwNP [J]

AND

5 - 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 - Patient demonstrates 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) unless there is a contraindication or intolerance to corticosteroid therapy [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 - Patient demonstrates 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 is 12 years of age or older

AND

3 - Patient has been diagnosed for at least 6 months

AND

4 - Verification that other non-hematologic secondary causes have been ruled out (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy)

AND

5 - Patient is Fip1-like1-platelet-derived growth factor receptor alpha (FIP1L1-PDGFRA)-negative

AND

6 - 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

7 - 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

8 - 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 - Patient demonstrates 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 [5]

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.

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 2. Low, medium and high daily doses of inhaled corticosteroids in children 6 – 11 years [5]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	100-200	> 200-400	> 400
Beclometasone dipropionate (pMDI, extrafine particle, HFA)	50-100	> 100-200	> 200
Budesonide (DPI, or pMDI, standard particle, HFA)	100-200	> 200-400	> 400
Budesonide (nebules)	250-500	>500-1000	>1000
Ciclesonide (pMDI, extrafine particle*, HFA)	80	>80-160	>160
Fluticasone furoate (DPI)	50		n.a.
Fluticasone propionate (DPI)	50-100	> 100-200	> 200
Fluticasone propionate (pMDI, standard particle, HFA)	50-100	> 100-200	> 200
Mometasone furoate (pMDI, standard particle, HFA)	100		200

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. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention (2023 update). 2023 www.ginasthma.org. Accessed April 20234

6. 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.
7. 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.
8. ClinicalTrials.gov Web site. https://clinicaltrials.gov/ct2/show/NCT03085797. Accessed August 15, 2021.
9. 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.
10. 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.

Prior Authorization Guideline

Guideline Name	Nulibry (fosdenopterin)

Guideline Note:

Effective Date:	6/1/2025

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. October 2022.
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. 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

Prior Authorization Guideline

Guideline Name	Octreotide Products - PA, NF

Guideline Note:

Effective Date:	6/1/2025

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 Brand 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 - Patient demonstrates 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 - Submission of medical records (e.g., chart notes) confirming 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 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 - Submission of medical records (e.g., chart notes) confirming 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 LAR, Generic octreotide LAR	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming 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 - All of the following (Applies to Brand Sandostatin LAR only):

4.1 Patient has had a trial of short-acting generic octreotide and responded to and tolerated therapy

AND

4.2 Submission of medical records (e.g., chart notes) confirming the patient has experienced intolerance (e.g., allergy to excipient) with generic octreotide LAR

AND

4.3 Submission of medical records confirming generic octreotide LAR has not been effective AND valid clinical justification provided explaining how Brand Sandostatin is expected to provide benefit when generic octreotide LAR 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	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 Brand 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 - Submission of medical records (e.g., chart notes) confirming 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 LAR, Generic octreotide LAR	
Diagnosis	Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes

AND

2 - Submission of medical records (e.g., chart notes) confirming patient has had a trial of short-acting generic octreotide and responded to and tolerated therapy

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 Brand Sandostatin LAR and generic octreotide LAR only)

OR

2.2 Trial and failure, or intolerance to generic octreotide (Applies to Brand Sandostatin)

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 - Patient demonstrates positive clinical response as evidenced by 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

Product Name:Brand Sandostatin LAR, Generic octreotide LAR	
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 - Submission of medical records (e.g., chart notes) confirming patient has had a trial of short-acting generic octreotide and responded to and tolerated therapy

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. September 2023.

Prior Authorization Guideline

Guideline Name	Oncology Admin - Optum Specialty Fusion & Cancer Guidance Program (MBM)

Guideline Note:

Effective Date:	3/1/2025

Note:

This guideline should be used for clients who have elected to participate in the Optum Specialty Fusion program or Medical Benefit Management (MBM) Cancer Guidance Program to review in scope drugs when used for cancer indications.

1 . Criteria

Product Name:In Scope Drug	
Diagnosis	Cancer Indications
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria	

1 - The drug is being used as indicated by National Comprehensive Cancer Network (NCCN) guidelines with a Category of Evidence and Consensus of 1, 2A, or 2B

Prior Authorization Guideline

Guideline Name	Oncology Injectable

Guideline Note:

Effective Date:	8/1/2025

1 . Criteria

Product Name:Adcetris, Aliqopa, Arzerra, Bavencio, Beleodaq, Besponsa, Bizengri, Blincyto, Columvi, Cyramza, Danyelza, Datroway, Elahere, Elrexfio, Elzonris, Empliciti, Emrelis, Enhertu, Epkinly, Erbitux, Eribulin mesylate, Firmagon, Folotyn, Fyarro, Brand Pralatrexate, Gazyva, Halaven, Imfinzi, Imjudo, Istodax, Romidepsin, Jemperli, Kadcyla, Keytruda, Kimmtrak, Kyprolis, Libtayo, Lumoxiti, Lunsumio, Margenza, Monjuvi, Mylotarg, Opdivo, Opdivo Qvantig, Opdualag, Padcev, Perjeta, Phesgo, Polivy, Portrazza, Poteligeo, Provenge, Rylaze, Sarclisa, Tecentriq, Tecentriq Hybreza, Tecvayli, Tivdak, Vyloy, Yervoy, Zaltrap, Zepzelca, Zynyz	
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

Product Name:Abecma, Aucatzyl, Breyanzi, Carvykti, Kymriah, Tecartus, Yescarta	
Approval Length	1 Time Authorization in Lifetime
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 All 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

AND

1.1.3 Patient has not previously received CAR-T Cell Therapy for the requested indication

OR

1.2 Meets the off-label administrative guideline criteria

Prior Authorization Guideline

Guideline Name	Onpattro (patisiran) & Tegsedi (inotersen)

Guideline Note:

Effective Date:	6/1/2025

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 - Presence of a transthyretin (TTR) mutation (e.g., V30M) as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [1-4]

AND

3 - One of the following [2, 4]:

- Patient has a baseline polyneuropathy disability (PND) score less than or equal to 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

4 - Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy) [2, 4]

AND

5 - Patient has not had a liver transplant

AND

6 - Requested drug is not used in combination with a TTR silencer (e.g., Amvuttra) or a TTR stabilizer (e.g., Vyndaqel)

AND

7 - Prescribed by or in consultation with a neurologist

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

Approval Criteria

1 - Patient demonstrates positive clinical response to 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 less than or equal to 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

AND

3 - Patient has not had a liver transplant

AND

4 - Requested drug is not used in combination with a TTR silencer (e.g., Amvuttra) or a TTR stabilizer (e.g., Vyndaqel)

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.

Prior Authorization Guideline

Guideline Name	Opfolda (miglustat)

Guideline Note:

Effective Date:	1/1/2024

1 . Indications

Drug Name: Opfolda (miglustat)
Late-Onset Pompe disease Indicated, in combination with Pombiliti, a hydrolytic lysosomal glycogen-specific enzyme, for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy (ERT).

2 . Criteria

Product Name:Opfolda	
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)

AND

2 - Disease is confirmed by one of the following: [2, 4-5]

- 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
- Molecular genetic testing confirms mutations in the GAA gene

AND

3 - Presence of clinical signs and symptoms of the disease (e.g., respiratory distress, skeletal muscle weakness, etc.) [A]

AND

4 - Medication is used in combination with Pombiliti (cipaglucosidase alfa-atga)

AND

5 - Patient weight is greater than or equal to 40 kg

AND

6 - Trial and inadequate response to one of the following:

- Lumizyme
- Nexviazyme

AND

7 - Opfolda is not substituted with other miglustat products (i.e., Zavesca, Yargesa)

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

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improvement in FVC, improvement in 6-minute walk distance [6MWD])

AND

2 - Medication is used in combination with Pombiliti (cipaglucosidase alfa-atga)

AND

3 - Opfolda is not substituted with other miglustat products (i.e., Zavesca, Yargesa)

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 [2, 4-5].

4 . References

1. Opfolda Prescribing Information. Amicus Therapeutics US, LLC. Philadelphia, PA. Sept 2023.
2. Diaz, C., Diaz-Manera, J. Therapeutic Options for the Management of Pompe Disease: Current Challenges and Clinical Evidence in Therapeutics and Clinical Risk Management. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9759116/. Accessed November 2, 2023.
3. Cleveland Clinic - Pompe Disease. Available at: https://my.clevelandclinic.org/health/diseases/15808-pompe-disease. Accessed November 2, 2023.
4. Cupler, E., Berger, K., Leshner, R., et al. Consensus Treatment Recommendations for Late-Onset Pompe Disease. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3534745/. Accessed November 2, 2023.
5. Barba-Romero MA, Barrot E, Bautista-Lorite J, et al. Clinical guidelines for late-onset Pompe disease. Available at: https://www.orpha.net/data/patho/Cpg/en/PompeLateOnset_ES_en_CPG_ORPHA420429.pdf. Accessed November 2, 2023.

Prior Authorization Guideline

Guideline Name	Opioid Risk Management

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 ap

	proved 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 acetaminophen, alone or in combination with other agents, which will exceed a total of 4 grams of acetaminophen per day. **NOTE: Published biomedical literature may be used as evidence to support safety and additional efficacy at higher than maximum doses for the diagnosis provided.

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 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: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 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: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 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: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 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: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 member does not meet the medical necessity reauthorization a uthorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time f or the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative treatment.

2 . References

1. Zohydro ER Prescribing Information.Currax Pharmaceuticals LLC. October 2019.

Prior Authorization Guideline

Guideline Name	Otezla (apremilast)

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.

Prior Authorization Guideline

Guideline Name	Oxlumo (lumasiran)

Guideline Note:

Effective Date:	4/1/2025

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 - Patient demonstrates 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. September 2023.
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#H2667808272. Accessed January 3, 2024.

Prior Authorization Guideline

Guideline Name	Palynziq (pegvaliase-pqpz) - PA, NF

Guideline Note:

Effective Date:	1/1/2025

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	24 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.

Prior Authorization Guideline

Guideline Name	Pedmark (sodium thiosulfate injection, solution)

Guideline Note:

Effective Date:	1/1/2025

1 . Indications

Drug Name: Pedmark (sodium thiosulfate injection, solution)
Prophylaxis of Cisplatin-Induced Ototoxicity. Indicated to reduce the risk of ototoxicity associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors. Limitations of Use: The safety and efficacy of Pedmark have not been established when administered following cisplatin infusions longer than 6 hours. Pedmark may not reduce the risk of ototoxicity when administered following longer cisplatin infusions, because irreversible ototoxicity may have already occurred.

2 . Criteria

Product Name:Pedmark	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of solid tumors

AND

2 - Disease is BOTH of the following:

- Localized
- Non-Metastatic

AND

3 - Used for the prevention of ototoxicity due to cisplatin-based chemotherapy

AND

4 - Patient is 1 month of age or older

AND

5 - Prescribed by or in consultation with an oncologist

3 . References

1. Pedmark Prescribing Information. Fennec Pharmaceuticals, Inc. Hoboken, NJ. September 2022.
2. Clinical Consult - Pediatric Hematology/Oncology specialist. November 15, 2022.

Prior Authorization Guideline

Guideline Name	Piasky (crovalimab)

Guideline Note:

Effective Date:	3/1/2025

1 . Indications

Drug Name: Piasky (crovalimab)
Paroxysmal nocturnal hemoglobinuria (PNH) Indicated for the treatment of adult and pediatric patients 13 years and older with paroxysmal nocturnal hemoglobinuria (PNH) and body weight of at least 40 kg.

2 . Criteria

Product Name:Piasky	
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 13 years of age or older

AND

3 - Patient weighs at least 40 kg

AND

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

- Soliris (eculizumab)
- Ultomiris (ravulizumab)

AND

5 - Prescribed by or in consultation with a hematologist/oncologist

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

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions)

AND

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

- Soliris (eculizumab)
- Ultomiris (ravulizumab)

Product Name:Piasky	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

AND

2 - Patient is 13 years of age or older

AND

3 - Patient weighs at least 40 kg

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:

- Soliris (eculizumab)
- Ultomiris (ravulizumab)

AND

5 - Prescribed by or in consultation with a hematologist/oncologist

3 . References

1. Piasky Prescribing Information. Genentech, Inc. San Francisco, CA. June 2024.

Prior Authorization Guideline

Guideline Name	Pombiliti (cipaglucosidase alfa-atga)

Guideline Note:

Effective Date:	1/1/2024

1 . Indications

Drug Name: Pombiliti (cipaglucosidase alfa-atga)
Late-Onset Pompe disease Indicated, in combination with Opfolda, an enzyme stabilizer, for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy (ERT).

2 . Criteria

Product Name:Pombiliti	
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)

AND

2 - Disease is confirmed by one of the following: [2, 4-5]

- 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
- Molecular genetic testing confirms mutations in the GAA gene

AND

3 - Presence of clinical signs and symptoms of the disease (e.g., respiratory distress, skeletal muscle weakness, etc.) [A]

AND

4 - Medication is used in combination with Opfolda (miglustat)

AND

5 - Patient weight is greater than or equal to 40 kg

AND

6 - Trial and inadequate response to one of the following:

- Lumizyme
- Nexviazyme

AND

7 - Not to be used in combination with other miglustat products (i.e., Zavesca, Yargesa)

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

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improvement in FVC, improvement in 6-minute walk distance [6MWD])

AND

2 - Medication is used in combination with Opfolda (miglustat)

AND

3 - Not to be used in combination with other miglustat products (i.e., Zavesca, Yargesa)

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 [2, 4-5].

4 . References

1. Pombiliti Prescribing Information. Amicus Therapeutics US, LLC. Philadelphia, PA. Sept 2023.
2. Diaz, C., Diaz-Manera, J. Therapeutic Options for the Management of Pompe Disease: Current Challenges and Clinical Evidence in Therapeutics and Clinical Risk Management. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9759116/. Accessed November 2, 2023.
3. Cleveland Clinic - Pompe Disease. Available at: https://my.clevelandclinic.org/health/diseases/15808-pompe-disease. Accessed November 2, 2023.
4. Cupler, E., Berger, K., Leshner, R., et al. Consensus Treatment Recommendations for Late-Onset Pompe Disease. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3534745/. Accessed November 2, 2023.
5. Barba-Romero MA, Barrot E, Bautista-Lorite J, et al. Clinical guidelines for late-onset Pompe disease. Available at: https://www.orpha.net/data/patho/Cpg/en/PompeLateOnset_ES_en_CPG_ORPHA420429.pdf. Accessed November 2, 2023.

Prior Authorization Guideline

Guideline Name	Prior Authorization Administrative Guideline

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.

Prior Authorization Guideline

Guideline Name	Pulmonary Arterial Hypertension Agents

Guideline Note:

Effective Date:	8/1/2025

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: Opsynvi (macitentan/ tadalafil) Tablets

Pulmonary Arterial Hypertension Indicated for the chronic treatment of adults with pulmonary arterial hypertension (PAH, WHO Group I and WHO Functional Class (FC) II–III). Macitentan reduces the risk of clinical worsening events and hospitalization. Tadalafil improves exercise ability.

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 underlie 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%).

Drug Name: Winrevair (sotatercept-csrk) Injection
Pulmonary Arterial Hypertension Indicated for the treatment of adults with pulmonary arterial hypertension (PAH, WHO Group I) to increase exercise capacity, improve WHO functional class (FC) and reduce the risk of clinical worsening events.

Drug Name: Yutrepia (treprostinil) capsule
Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability. Studies establishing effectiveness predominately included 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 interstitial lung disease (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%).

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, Ventavis inhalation solution, Yutrepia capsule	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	When approved; no reauthorization required
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

Notes	Operational Note: For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Brand Adcirca tablet, Tadliq oral suspension	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	When approved; no reauthorization required
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

Notes	Operational Note: For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve through 12/31/2039

Product Name:Brand Letairis tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	When approved; no reauthorization required
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

Notes	Operational Note: For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Opsynvi tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	When approved; no reauthorization required
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

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

AND

2 - One of the following:

2.1 Trial and failure, contraindication or intolerance to generic ambrisentan

OR

2.2 Patient is currently being treated with a macitentan-containing product

AND

3 - Patient is unable to take Opsumit and generic tadalafil separately due to intolerance with Opsumit (e.g., allergy to excipient)

AND

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

- Pulmonologist
- Cardiologist

Notes	Operational Note: For initial authorization request, approve through 12/31/2039

	For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Brand Remodulin injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	When approved; no reauthorization required
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

Notes	Operational Note: For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Brand Revatio tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	When approved; no reauthorization required
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

Notes	Operational Note: For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Brand Tracleer tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	When approved; no reauthorization required
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

Notes	Operational Note: For initial authorization request, approve through 12/31/2039

	For reauthorization request, bypass criteria review and approve through 12/31/2039

Product Name:Brand Revatio injection or Generic sildenafil injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	When approved; no reauthorization required
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]

AND

6 - For Brand Revatio injection, trial and failure or intolerance to generic sildenafil injection

Notes	Operational Note: For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Liqrev, Brand Revatio oral suspension or Generic sildenafil oral suspension	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	When approved; no reauthorization required
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 - For Brand Revatio oral suspension, trial and failure, or intolerance to both of the following:

- Generic sildenafil tablets
- Generic sildenafil oral suspension

AND

6 - For Liqrev, trial and failure or intolerance to generic sildenafil suspension

Notes	Operational Note: For initial authorization request, approve through 12/31/2039

	For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Adempas tablet	
Diagnosis	Chronic Thromboembolic Pulmonary Hypertension (CTEPH)
Approval Length	When approved; no reauthorization required
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

Notes	Operational Note: For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Tyvaso inhalation solution, Tyvaso Refill inhalation solution, or Tyvaso Start inhalation solution, Tyvaso DPI, Yutrepia capsule	
Diagnosis	Pulmonary Hypertension associated with Interstitial Lung Disease
Approval Length	When approved; no reauthorization required
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

Notes	Operational Note: For initial authorization request, approve through 12/31/2039

	For reauthorization request, bypass criteria review and approve through 12/31/2039

Product Name:Uptravi tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	When approved; no reauthorization required
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 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

Notes	Operational Note: For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Uptravi injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	When approved; no reauthorization required
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 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

6 - Patient is unable to take oral medications [13]

Notes	Operational Note: For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Winrevair Injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	When approved; no reauthorization required
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - Patient is currently on at least two therapies indicated for the treatment of pulmonary arterial hypertension from the following different mechanisms of action, unless there is a contraindication or intolerance:

- Endothelin receptor antagonists (i.e., Bosentan, ambrisentan or macitentan)
- Phosphodiesterase 5 inhibitors (i.e., Tadalafil or sildenafil)

AND

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

- Pulmonologist
- Cardiologist

Notes	Operational Note: For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

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. October 2023.
2. Revatio Prescribing Information. Viatris Specialty LLC. Morgantown, WV. 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. October 2023.
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. June 2023.
11. Adempas Prescribing Information. Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ. September 2021.
12. Orenitram Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. August 2023.
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. June 2023.
16. Tadliq Prescribing Information. CMP Pharma, Inc. Farmville, NC. October 2023.
17. Liqrev Prescribing Information. CMP Pharma, Inc. Farmville, NC. April 2023.
18. Winrevair Prescribing Information. Merck Sharp & Dohme LLC. March 2023
19. Opsynvi Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. April 2024.
20. Yutrepia Prescribing Information. Liquidia Technologies, Inc. Morrisville, NC 27560. June 2025.

Prior Authorization Guideline

Guideline Name	Qalsody (tofersen)

Guideline Note:

Effective Date:	9/1/2024

1 . Indications

Drug Name: Qalsody (tofersen)
Amyotrophic Lateral Sclerosis Indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene. This indication is approved under accelerated approval based on reduction in plasma neurofilament light chain (NfL) observed in patients treated with Qalsody. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

2 . Criteria

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

Approval Criteria

1 - Diagnosis amyotrophic lateral sclerosis (ALS)

AND

2 - Molecular genetic testing confirms mutation in the SOD1 gene

AND

3 - Patient's baseline functional ability has been documented prior to initiating treatment (e.g., speech, walking, climbing stairs, etc.)

AND

4 - Patient has a percent (%) slow vital capacity (%SVC) greater than or equal to 50% at the start of treatment [A]

AND

5 - Patient does not require permanent noninvasive ventilation or invasive ventilation

AND

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

Product Name:Qalsody	
Approval Length	6 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates slowed disease progression from baseline

AND

2 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis of ALS

3 . Endnotes

A. Those in the faster-progressing subgroup, which the primary and key secondary endpoints were formally tested, were required to have a slow vital capacity (SVC) greater than or equal to 65% of predicted value for sex, age, and height (from the sitting position) at screening. [2]

4 . References

1. Qalsody Prescribing Information. Biogen MA Inc. Cambridge, MA. April 2023.
2. Miller TM, Cudkowicz ME, Genge A, et al. Trial of Antisense Oligonucleotide Tofersen for SOD1 ALS. New England Journal of Medicine. 2022;387(12):1099-1110.

Prior Authorization Guideline

Guideline Name	Qfitlia (fitusiran)

Guideline Note:

Effective Date:	6/1/2025

1 . Indications

Drug Name: Qfitlia (fitusiran)
Prevention or to reduce the frequency of bleeding episodes Indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients aged 12 years and older with hemophilia A or B with or without factor VIII or IX inhibitors.

2 . Criteria

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

Approval Criteria

1 - Diagnosis of one of the following:

- hemophilia A with or without factor VIII inhibitors
- hemophilia B with or without factor IX inhibitors

AND

2 - Drug will be used for prophylaxis to prevent or reduce the frequency of bleeding episodes

AND

3 - Patient is 12 years of age or older

AND

4 - Presence of antithrombin (AT) activity greater than 60 percent (%) as detected by an FDA -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [A]

AND

5 - Prescribed by or in consultation with a hematologist/oncologist

AND

6 - One of the following: (applies to Hemophilia A only)

6.1 For continuation of prior therapy

OR

6.2 Trial and inadequate response, intolerance, or contraindication to Hemlibra (emicizumab-kxwh)

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

Approval Criteria

1 - Drug continues to be used for prophylaxis to prevent or reduce the frequency of bleeding episodes

AND

2 - Patient demonstrates positive clinical response to therapy (e.g., reduced bleeding episodes)

3 . Endnotes

A. Measure antithrombin (AT) activity prior to initiation of Qfitlia. Do not initiate Qfitlia dosing if AT activity is less than 60%. Monitor AT activity using an FDA-cleared test [1].

4 . References

1. Qfitlia Prescribing Information. Genzyme Corporation. Cambridge, MA. March 2025.

Prior Authorization Guideline

Guideline Name	Quantity Limit General

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 acetaminophen, alone or in combination with other agents, which will exceed a total of 4 grams of acetaminophen per day.

Prior Authorization Guideline

Guideline Name	Radicava (edaravone)

Guideline Note:

Effective Date:	2/1/2025

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:Brand Radicava IV, generic edaravone 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

AND

5 - Patient is not dependent on invasive ventilation or tracheostomy

Product Name:Brand Radicava IV, generic edaravone IV, Radicava ORS	
Diagnosis	Amyotrophic Lateral Sclerosis (ALS)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates 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. December 2022.
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. Edaravone Injection Prescribing Information. Piramal Crtical Care, Inc. Bethlehem, PA. May 2024.

Prior Authorization Guideline

Guideline Name	Reblozyl (luspatercept-aamt)

Guideline Note:

Effective Date:	4/1/2025

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. **Myelodysplastic Syndromes Associated Anemia** Indicated for the treatment of anemia without previous erythropoiesis stimulating agent use (ESA-naïve) in adult patients with very low- to intermediate-risk myelodysplastic syndromes (MDS) who may 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.

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 - Patient demonstrates 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
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of very low- to intermediate-risk myelodysplastic syndromes (MDS)

AND

2 - Patient does not have previous erythropoiesis stimulating agent use (ESA-naïve)

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

Approval Criteria

1 - Patient demonstrates 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. May 2024.
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.

Prior Authorization Guideline

Guideline Name	Repository Corticotropin Gel Products - PA, NF

Guideline Note:

Effective Date:	5/1/2025

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 80 unit/mL vial, Purified Cortrophin Gel [off-label]	
Diagnosis	Infantile Spasms (West Syndrome)
Approval Length	4 Week(s)
Guideline Type	Prior Authorization

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

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 one high dose corticosteroid treatment (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

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 suppor t the use of Acthar or Purified Cortrophin Gel [A]

Product Name:Acthar Gel 80 unit/mL vial, Purified Cortrophin Gel [off-label]	
Diagnosis	Infantile Spasms (West Syndrome)
Approval Length	4 Week(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming 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	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of acute exacerbation of multiple sclerosis

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming 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 one high dose corticosteroid treatment (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	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 suppor t 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. June 2024.
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. October 2023.

Prior Authorization Guideline

Guideline Name	Retinal Vascular Disease Agents

Guideline Note:

Effective Date:	6/1/2025

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. **Diabetic Macular Edema (DME)** Indicated for the treatment of patients with diabetic macular edema (DME) who have previously responded to at least two intravitreal injections of a 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

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 - Patient demonstrates 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	Neovascular (Wet) Age-Related Macular Degeneration, 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)

AND

2 - Trial and failure, or intolerance to Eylea

Product Name:Susvimo	
Diagnosis	Neovascular (Wet) Age-Related Macular Degeneration, Diabetic Macular Edema
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:Beovu, Byooviz, Cimerli, Lucentis, Susvimo, Vabysmo	
Diagnosis	All Indications
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)

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

1. Beovu Prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, New Jersey. May 2022.
2. Eylea Prescribing Information. Regeneron Pharmaceuticals, Inc. Tarrytown, NY. February 2023.
3. Lucentis Prescribing information. Genentech, Inc. South San Francisco, CA. October 2020.
4. FDA Final Guidance on Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application Guidance for Industry. January 2018. Available at: https://www.fda.gov/media/90986/download. Accessed April 7,2021.
5. Compounding-American Academy of Ophthalmology - AAO.org. Available at: https://www.aao.org/headline/compounding. Accessed April 7, 2021.
6. Susvimo Prescribing information. Genentech, Inc. South San Francisco, CA. February 2025.
7. Vabysmo Prescribing information. Genentech, Inc. South San Francisco, CA. October 2023.
8. Byooviz Prescribing Information. Biogen, Inc. Cambridge, MA. April 2022.
9. Cimerli Prescribing Information. Coherus BioSciences, Inc. Redwood City, CA. August 2022.
10. Johnston, S. Retinopathy of Prematuity (ROP). Available at: https://www.childrenshospital.org/conditions/retinopathy-prematurity-rop. Accessed Feb 28, 2023.

11. Hartnett, M. Managing Retinopathy of Prematurity. Available at: https://www.aao.org/eyenet/article/managing-retinopathy-of-prematurity. Accessed February 28, 2023.
12. Coats, D. Retinopathy of prematurity: Treatment and prognosis. Available at: https://www.uptodate.com/contents/retinopathy-of-prematurity-treatment-and-prognosis. Accessed February 27, 2023.
13. Fierson W., et al. Screening Examination of Premature Infants for Retinopathy of Prematurity. American Academy of Pediatrics. Vol 142, Issue 6, Dec 2018. Available at https://publications.aap.org/pediatrics/article/142/6/e20183061/37478/Screening-Examination-of-Premature-Infants-for?autologincheck=redirected. Accessed March 14, 2023.
14. Wong, R., Ventura, C. et al. Training fellows for retinopathy of prematurity care: A Web-based survey. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3338950/. Accessed March 14, 2023.
15. Eylea HD Prescribing Information. Regeneron Pharmaceuticals, Inc. Tarrytown, NY. August 2023.
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.

Prior Authorization Guideline

Guideline Name	Revcovi (elapegademase-lvlr)

Guideline Note:

Effective Date:	4/1/2025

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. Chiesi USA, Inc. Cary, NC 27518. August 2022
2. Immune Deficiency Foundation Patient & Family Handbook for Primary Immunodeficiency Diseases. Fifth Edition. 2013.

Prior Authorization Guideline

Guideline Name	Rezzayo (rezafungin)

Guideline Note:

Effective Date:	11/1/2024

1 . Indications

Drug Name: Rezzayo (rezafungin)
Candidemia and invasive candidiasis Indicated in patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis. Approval of this indication is based on limited clinical safety and efficacy data for Rezzayo. Limitations of Use Rezzayo has not been studied in patients with endocarditis, osteomyelitis, and meningitis due to Candida.

2 . Criteria

Product Name:Rezzayo	
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of candidemia or invasive candidiasis with limited or no alternative options

AND

2 - Patient is 18 years of age or older

AND

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

- generic caspofungin
- generic micafungin

3 . References

1. Rezzayo Prescribing Information. Melinta Therapeutics LLC. Lincolnshire, IL. June 2023.
2. Peter G. Pappas, Carol A. Kauffman, David R. Andes, Cornelius J. Clancy, Kieren A. Marr, Luis Ostrosky-Zeichner, Annette C. Reboli, Mindy G. Schuster, Jose A. Vazquez, Thomas J. Walsh, Theoklis E. Zaoutis, Jack D. Sobel, Clinical Practice Guideline for the Management of Candidiasis: 2016 Update by the Infectious Diseases Society of America, Clinical Infectious Diseases, Volume 62, Issue 4, 15 February 2016, Pages e1–e50, https://doi.org/10.1093/cid/civ933

Prior Authorization Guideline

Guideline Name	Rinvoq (upadacitinib)

Guideline Note:

Effective Date:	11/1/2024

1 . Indications

Drug Name: Rinvoq (upadacitinib) extended-release (ER) tablets, Rinvoq LQ solution
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. **Polyarticular Juvenile Idiopathic Arthritis (PJIA)** Indicated for the treatment of patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (pJIA) who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Rinvoq/Rinvoq LQ in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended. **Non-radiographic Axial Spondyloarthritis (nr-AxSpA)** Indicated for the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy. Limitations of Use: Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as

azathioprine and cyclosporine.

Crohn's Disease (CD) Indicated for the treatment of adult patients with moderately to severely active Crohn's disease 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 Crohn's disease, or with potent immunosuppressants such as azathioprine and cyclosporine.

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 cortic osteroids (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 cortic osteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Rinvoq	
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 (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 [4]:

- leflunomide
- methotrexate

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, etanercept)

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 cortic osteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Rinvoq	
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, 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 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 cortic osteroids (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 cortic osteroids (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 cortic osteroids (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 cortic osteroids (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 cortic osteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Rinvoq	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-AxSpA)
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, 6]

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 [6]

AND

5 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., certolizumab pegol)

AND

6 - 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 cortic osteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Rinvoq	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-AxSpA)
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 improvement from baseline for at 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 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 cortic osteroids (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 cortic osteroids (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 cortic osteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Rinvoq	
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

AND

2 - Prescribed by or in consultation with a gastroenterologist

AND

3 - One of the following [7, 8]:

- 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

4 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [7, 8]:

- 6-mercaptopurine
- Azathioprine
- Corticosteroids (e.g., prednisone)
- Methotrexate

AND

5 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol)

AND

6 - Not used in combination with other JAK inhibitors, biological therapies for CD, 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 cortic osteroids (equivalent to 10 mg or less of prednisone daily).

Product Name:Rinvoq	
Diagnosis	Crohn's Disease (CD)
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, 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 other JAK inhibitors, biological therapies for CD, 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 cortic osteroids (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 cortic osteroids (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 cortic osteroids (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.
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. 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.
6. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.
7. 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.
8. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014; 71(1):116-32.
9. European Task Force on Atopic Dermatitis. Severity scoring of atopic dermatitis: the SCORAD index. Consensus report of the European Task Force on atopic dermatitis. Dermatology. 1993; 186:23-31.
10. Blauvelt A, de Bruin-Weller M, Gooderham M, et al. Long-term management of moderate-to-severe atopic dermatitis with dupilumab and concomitant topical corticosteroids (CHRONOS): a 1-year, randomised, double-blinded, placebo-controlled, phase 3 trial. Lancet 2017; 389(10086)(suppl):2287-2303.
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.

Prior Authorization Guideline

Guideline Name	Rituxan Hycela (rituximab and hyaluronidase human)

Guideline Note:

Effective Date:	6/1/2025

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

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

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

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.
2. Habermann TM, Weller EA, Morrison VA, et al. Rituximab-CHOP versus CHOP alone or with maintenance rituximab in older patients with diffuse large B-cell lymphoma. J Clin Oncol. 2006;24(19):3121-3127.

3. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 25, 2024.
4. 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.

Prior Authorization Guideline

Guideline Name	Rituximab - PA, NF

Guideline Note:

Effective Date:	6/1/2025

Note:

For review process only: Refer to the Client Biosimilar Formulary Strategy List at the following link for carrier-specific formulary products: https://uhgazure.sharepoint.com/sites/ClinicalServices-UtilizationManagement/Internal%20Documents/Forms/AllItems.aspx?viewpath=%2Fsites%2FClinicalServices%2DUtilizationManagement%2FInternal%20Documents%2FForms%2FAllItems%2Easpx

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.

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.

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.

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).

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.

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]

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/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 therapy, defined as no more than a 45-day gap in therapy

AND

5 - Trial and failure or intolerance to Ruxience

Notes	*Includes attestation that a total of two TNF inhibitors have alre ady been tried in the past, and the patient should not be made to try a third TNF 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/XR (tofacitinib/ER)

OR

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

Notes	*Includes attestation that a total of two TNF inhibitors have alre ady been tried in the past, and the patient should not be made to try a third TNF 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 - Patient demonstrates 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 - Submission of medical records (e.g., chart notes) confirming 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/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 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

Notes	*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF 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

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

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]

- Submission of medical records (e.g., chart notes) confirming diagnosis of diffuse large B-cell, CD20-positive, non-Hodgkin’s lymphoma
- Paid claims or submission of medical records (e.g., chart notes) confirming requested medication is being 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:

- Submission of medical records (e.g., chart notes) confirming diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma
- Paid claims or submission of medical records (e.g., chart notes) confirming requested medication is being used as first-line treatment in combination with chemotherapy

OR

1.3 All of the following:

- Submission of medical records (e.g., chart notes) confirming diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma
- Submission of medical records (e.g., chart notes) confirming patient achieved a complete or partial response to a rituximab product in combination with chemotherapy
- Submission of medical records (e.g., chart notes) confirming requested medication will be followed by rituximab used as monotherapy for maintenance therapy

OR

1.4 Both of the following: [1]

1.4.1 Submission of medical records (e.g., chart notes) confirming diagnosis of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma

AND

1.4.2 One of the following:

- Submission of medical records (e.g., chart notes) confirming patient has stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy
- Submission of medical records (e.g., chart notes) confirming patient achieved a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy

OR

1.5 Submission of medical records (e.g., chart notes) confirming 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 Submission of medical records (e.g., chart notes) confirming 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 Submission of medical records (e.g., chart notes) confirming requested medication is 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

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

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

Product Name:Riabni, Truxima	
Diagnosis	Chronic Lymphocytic Leukemia
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of chronic lymphocytic leukemia [2, 12, 15-19]

AND

2 - Submission of medical records (e.g., chart notes) confirming requested medication is being 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

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 - 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

3 - 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

Product Name:Rituxan	
Diagnosis	Pemphigus Vulgaris
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to 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)

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

Product Name:Riabni, Truxima	
Diagnosis	Wegener's Granulomatosis and Microscopic Polyangiitis
Approval Length	3 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming 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

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 18, 2024.
2. AHFS Drug Information (Adult and Pediatric) [Internet database]. Hudson, Ohio: Lexicomp. Accessed January 18, 2024.
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.
17. Schulz H, Klein SK, Rehwald U, et al. Phase 2 study of a combined immunochemotherapy using rituxumab and fludarabine in patients with chronic lymphocytic leukemia. Blood. 2002;100:3115-3120.
18. Keating MJ, O'Brien S, Albitar M, et al. Early results of a chemoimmunotherapy regimen of fludarabine, cyclophosphamide, and rituxumab as initial therapy for chronic lymphocytic leukemia. J Clin Oncol. 2005;23:4079-4088.

19. National Comprehensive Cancer Network. Practice Guidelines in Oncology - v. 1.2024. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed January 18, 2024.
20. Truxima Prescribing Information. Teva Pharmaceuticals USA, Inc. North Wales, PA. November 2022.
21. Ruxience Prescribing Information. Pfizer Ireland Pharmaceuticals USA, Inc. Cork, Ireland. October 2023.
22. U.S. Food and Drug Administration (FDA). Biosimilar and Interchangeable Products. Silver Spring, MD: FDA; December 13, 2022. Available at: https://www.fda.gov/drugs/biosimilars/review-and-approval. Accessed January 18, 2024.
23. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. B-Cell Lymphomas. v.6.2023. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed January 18, 2024.
24. Riabni Prescribing Information. Amgen, Inc. Thousand Oaks, CA. June 2022.
25. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Pediatric Aggressive Mature B-Cell Lymphomas. v.1.2023. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/ped_b-cell.pdf. Accessed January 18, 2024.
26. 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.
27. 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.

Prior Authorization Guideline

Guideline Name	Rivfloza (nedosiran)

Guideline Note:

Effective Date:	7/1/2025

1 . Indications

Drug Name: Rivfloza (nedosiran)
Primary Hyperoxaluria Type 1 (PH1) Indicated to lower urinary oxalate levels in children 2 years of age and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function, e.g., eGFR ≥ 30 mL/min/1.73 m2.

2 . Criteria

Product Name:Rivfloza	
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 - Disease has been confirmed by both of the following: [2]

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 is 2 years of age or older [1]

AND

4 - Patient has preserved kidney function (e.g., eGFR greater than or equal to 30mL/min/1.73m^2)

AND

5 - Patient has not received a liver transplant [A, 2]

AND

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

- Hepatologist
- Nephrologist
- Urologist
- Geneticist
- Specialist with expertise in the treatment of PH1

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

Approval Criteria

1 - Patient demonstrates 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 . Endnotes

A. Liver transplantation provides the definitive cure for PH type 1 by restoring the missing enzyme, which lowers oxalate production to the normal range. [2]

4 . References

1. Rivfloza prescribing information. Pyramid Laboratories. Costa Mesa, CA. March 2025.
2. UptoDate: Primary hyperoxaluria. Available at https://www.uptodate.com/contents/primary-hyperoxaluria?search=Primary%20Hyperoxaluria%20Type%201%20&sectionRank=1&usage_type=default&anchor=H2111703101&source=machineLearning&selectedTitle=1%7E150&display_rank=1#H2111703101. Accessed April 13, 2025.

Prior Authorization Guideline

Guideline Name	Roctavian (valoctocogene roxaparvovec-rvox)

Guideline Note:

Effective Date:	2/1/2025

1 . Indications

Drug Name: Roctavian (valoctocogene roxaparvovec-rvox)
Hemophilia A indicated for the treatment of adults with severe hemophilia A (congenital factor VIII deficiency with factor VIII activity < 1 IU/dL) without pre-existing antibodies to adeno-associated virus serotype 5 detected by an FDA-approved test.

2 . Criteria

Product Name:Roctavian	
Diagnosis	Hemophilia A
Approval Length	1 Time Authorization in Lifetime
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe Hemophilia A

AND

2 - Factor VIII (FVIII) assay baseline level of less than 1 IU/dL

AND

3 - Patient is 18 years of age or older

AND

4 - Patient does not have pre-existing immunity to the AAV5 capsid as detected by the FDA-approved companion diagnostic test [B]

AND

5 - Patient does not have a history of inhibitors based on results from a modified Nijmegen Bethesda assay of less than 0.6 Bethesda Units (BU) on 2 consecutive occasions at least 1 week apart within the past 12 months [1]

AND

6 - Treatment logs including both factor infusions and bleeding episodes confirming BOTH of the following: [1]

6.1 Patient has been on prophylactic FVIII replacement therapy for at least 12 months

AND

6.2 Patient has been treated/exposed to FVIII concentrates for a minimum 150 exposure days (EDs) [1, A]

AND

7 - One of the following:

7.1 Patient does not exhibit significant liver dysfunction as defined by abnormal elevation of ONE of the following: [1]

- alanine transaminase (ALT) greater than 1.25 times the upper limit of normal
- aspartate aminotransferase (AST) greater than 1.25 times the upper limit of normal
- gamma-glutamyl transferase (GGT) greater than 1.25 times the upper limit of normal
- alkaline phosphatase (ALP) greater than 1.25 times the upper limit of normal
- bilirubin greater than 1.25 times the upper limit of normal
- international normalized ratio (INR) greater than or equal to 1.4

OR

7.2 Patient has had a consultation with a hepatologist to assess eligibility for Roctavian

AND

8 - Patient does not have an active infection or any immunosuppressive disorder [1]

AND

9 - Patient has never received valoctocogene roxaparvovec treatment in their lifetime

AND

10 - Prescribed by a hematologist affiliated with a comprehensive hemophilia treatment center (HTC)

AND

11 - Prescriber attests that the patient has been counseled and has agreed to adhere to post-treatment monitoring and follow-ups with their hematologist and HTC [5]

3 . Endnotes

A. The incidence rate of inhibitor development in patients with hemophilia A who have been previously treated for at least 150 EDs has been estimated to be approximately 2–5 per 1000 patient-years.[3]
B. About 20% of the people with Hemophilia A in U.S are estimated to produce antibodies, which could make the ineligible for the AAV5-mediated gene therapy [4]

4 . References

1. Pasi K.J., Rangarajan S, Mitchell N, et al. Multiyear follow-up of AAv5-hFVIII-SQ gene therapy for hemophilia A. New Eng J of Med. 2020;382:29-40.
2. Rangarajan S, Walsh L, Lester W, et al. AAV5–factor VIII gene transfer in severe hemophilia A. N Engl J Med 2017;377:2519-30.
3. Hermans C, Astermark J, de Moerloose P. Exposure to factor VIII and prediction of inhibitor development: exposure days vs.danger days, or both?J Thromb Haemost 2012;10:2194.
4. Biomarin's Valrox, possible 1st gene therapy for hemophilia A, Under FDA priority review. Hemophilia News Today; February 2020. Available at: https://hemophilianewstoday.com/2020/02/24/biomarins-valrox-possible-first-gene-therapy-hemophila-a-under-fda-priority-review-marketing-application-accepted/
5. Per clinical consult with hematologist, May 29, 2020.

6. Roctavian Prescribing Information. BioMarin Pharmaceutical Inc. Novato, CA. June 2023.

Prior Authorization Guideline

Guideline Name	Rybrevant (amivantamab)

Guideline Note:

Effective Date:	12/1/2024

1 . Indications

Drug Name: Rybrevant (amivantamab)
First-Line Treatment of NSCLC with EGFR Exon 20 Insertion Mutations Indicated in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test. 2) Indicated in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test. **First-Line Treatment of NSCLC with EGFR Exon 19 Deletions or Exon 21 L858R Substitution Mutations** Indicated in combination with lazertinib for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test. **Previously Treated NSCLC with EGFRExon 19 Deletions or Exon 21 L858R Substitution Mutations** Indicated in combination with carboplatin and pemetrexed, is indicated for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, whose

disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor

Previously Treated non-small Cell Lung Cancer (NSCLC) with EGFR Exon 20 Insertion Mutations Indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

2 . Criteria

Product Name:Rybrevant	
Approval Length	12 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 - One of the following:

3.1 Both of the following:

3.1.1 Presence of epidermal growth factor receptor (EGFR) exon 20 insertion mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3.1.2 One of the following:

3.1.2.1 Disease has progressed on or after platinum-based chemotherapy (e.g., carboplatin, cisplatin)

OR

3.1.2.2 Both of the following:

- Used as first-line treatment of NSCLC
- Used in combination with carboplatin and pemetrexed

OR

3.2 Both of the following:

3.2.1 Presence of epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test

AND

3.2.2 One of the following:

3.2.2.1 Both of the following:

- Used as first line treatment of NSCLC

- Used in combination with Lazcluze (lazertinib)

OR

3.2.2.2 Both of the following:

- Disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor (e.g., osimertinib)
- Used in combination with carboplatin and pemetrexed

AND

3.2.3 Used in combination with Lazcluze (lazertinib)

Product Name:Rybrevant	
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. Rybrevant Prescribing Information. Janssen Biotech, Inc. Horsham, PA. September 2024.

Prior Authorization Guideline

Guideline Name	Ryplazim (plasminogen, human-tvmh)

Guideline Note:

Effective Date:	1/1/2025

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 - Patient demonstrates 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. January 2024
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

Prior Authorization Guideline

Guideline Name	Rystiggo (rozanolixizumab)

Guideline Note:

Effective Date:	10/1/2024

1 . Indications

Drug Name: Rystiggo (rozanolixizumab)
Generalized Myasthenia Gravis (gMG) Indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

2 . Criteria

Product Name:Rystiggo	
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 - One of the following:

2.1 Both of the following:

2.1.1 Patient is anti-acetylcholine receptor (AChR) antibody positive

AND

2.1.2 One of the following: [2]

2.1.2.1 Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

OR

2.1.2.2 Both of the following:

2.1.2.2.1 Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

AND

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

- Chronic plasmapheresis or plasma exchange (PE)

- Intravenous immunoglobulin (IVIG)

OR

2.2 Both of the following:

2.2.1 Patient is anti-muscle-specific tyrosine kinase (MuSK) antibody positive

AND

2.2.2 One of the following: [2]

2.2.2.1 Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

OR

2.2.2.2 Both of the following:

2.2.2.2.1 Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

AND

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

- Chronic plasmapheresis or plasma exchange (PE)
- Intravenous immunoglobulin (IVIG)
- Rituximab [3]

AND

3 - Prescribed by or in consultation with a neurologist

Product Name:Rystiggo	
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. Rystiggo Prescribing Information. UCB, Inc., Smyrna, GA. June 2024.
2. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis. Neurology. 2016;87(4):419-25.
3. Alhaidar MK, Abumurad S, Soliven B, Rezania K. Current Treatment of Myasthenia Gravis. J Clin Med. 2022 Mar 14;11(6):1597.

Prior Authorization Guideline

Guideline Name	Rytelo (imetelstat)

Guideline Note:

Effective Date:	9/1/2024

1 . Indications

Drug Name: Rytelo (imetelstat)
Anemia Associated with Myelodysplastic Syndrome (MDS) Indicated for the treatment of adult patients with low- to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia requiring 4 or more red blood cell units over 8 weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESA).

2 . Criteria

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

Approval Criteria

1 - Diagnosis of myelodysplastic syndrome

AND

2 - Disease is low to intermediate-1 risk [A]

AND

3 - All of the following:

- Hemoglobin less than 10 g/dL
- Baseline absolute neutrophil count of 1.5 x 10^9 /L or greater
- Baseline platelet count of 75 x 10^9 /L or greater

AND

4 - Both of the following:

- Patient does not have a confirmed mutation with deletion 5q [del(5q)]
- Patient has not received prior treatment with Revlimid (lenalidomide) or hypomethylating agents (e.g., azacitidine, decitabine)

AND

5 - Patient requires 4 or more red blood cell units over 8 weeks

AND

6 - One of the following:

- Previous treatment with an erythropoiesis stimulating agent shows no response
- Previous treatment with an erythropoiesis stimulating agent shows loss of response
- Patient is ineligible for treatment with an erythropoiesis stimulating agent

Product Name:Rytelo	
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 . Definitions

Definition	Description
Myelodysplastic Syndromes (MDS)	Myelodysplastic syndromes (MDS) are an uncommon group of disorders characterized by abnormal blood-forming cells in the bone marrow, resulting in the reduction of peripheral blood cells, an elevated risk of acute myeloid leukemia (AML), and reduced survival. Anemia (low red blood cell counts), thrombocytopenia (low platelet counts), and leukopenia (low white blood cell counts) are common among patients with MDS [3]
The International Prognostic Scoring System (IPSS)	IPSS uses three "prognostic indicators" to predict the course of the patient's disease: • The percentage of leukemic blast cells in the marrow • The type of chromosomal changes, if any, in the marrow cells (cytogenetics) • The presence of one or

	more low blood cell counts (cytopenias) These 3 prognostic indicators are then assigned a total risk score from low, intermediate risk-1, intermediate risk -2, or high. [4]

4 . Endnotes

A. Disease was determined as low to intermediate-1 risk based on the The International Prognostic Scoring System (IPSS). [1,4]

5 . References

1. Rytelo Prescribing Information. Catalent Indiana, LLC. Bloomington, IN. June 2024.
2. ClinicalTrials.gov. Study to Evaluate Imetelstat (GRN163L) in Subjects With International Prognostic Scoring System (IPSS) Low or Intermediate-1 Risk Myelodysplastic Syndrome (MDS). Available at: https://www.clinicaltrials.gov/study/NCT02598661?cond=NCT02598661&rank=1. Accessed July 28, 2024.
3. ICER: Anemia in Myelodysplastic Syndrome. Available at: https://icer.org/assessment/myelodysplastic-syndrome-2024. Accessed July 28, 2024.
4. Leukemia and Lymphoma Society: The International Prognostic Scoring System. Available at: https://www.lls.org/myelodysplastic-syndromes/diagnosis/international-prognostic-scoring-system. Accessed July 28, 2024.
5. NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes v3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed July 29, 2024.

Prior Authorization Guideline

Guideline Name	Saphnelo (anifrolumab-fnia)

Guideline Note:

Effective Date:	12/1/2024

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 - Patient demonstrates 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. August 2024.
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. Fanouriakis A, Kostopoulou M, Andersen J, et al. EULAR recommendations for the management of systemic lupus erythematosus: 2023 update. Ann Rheum Dis. 2024 Jan 2;83(1):15-29.

Prior Authorization Guideline

Guideline Name	Scenesse (afamelanotide)

Guideline Note:

Effective Date:	6/1/2025

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 - Patient demonstrates 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. August 2024.
2. Per clinical consult with dermatologist, December 19, 2019.

Prior Authorization Guideline

Guideline Name	Signifor, Signifor LAR (pasireotide) - PA, NF

Guideline Note:

Effective Date:	1/1/2025

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 - Patient demonstrates 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 - Patient demonstrates 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 - Submission of medical records (e.g., chart notes) confirming a 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 OptumRx 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. Bridgewater, NJ. July 2024.
2. Signifor Prescribing Information. Recordati Rare Diseases Inc. Bridgewater, NJ. July 2024.

Prior Authorization Guideline

Guideline Name	Skin Cancer Agents

Guideline Note:

Effective Date:	7/1/2025

1 . Indications

Drug Name: Klisyri (tirbanibulin) ointment
Actinic Keratosis indicated for the topical treatment of actinic keratosis on the face or scalp.

2 . Criteria

Product Name:Klisyri	
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, contraindication, or intolerance to both of the following generics:

- fluorouracil
- imiquimod

3 . References

1. American Academy of Dermatology. Actinic Keratosis: diagnosis and treatment. https://www.aad.org/public/diseases/scaly-skin/actinic-keratosis#treatment. Accessed April 8, 2025
2. Klisyri Prescribing Information. Almirall, LLC. Exton, PA. June 2024.

Prior Authorization Guideline

Guideline Name	Somatuline Depot (lanreotide)

Guideline Note:

Effective Date:	4/1/2025

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-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. **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:Brand Somatuline Depot, Generic 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 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and intolerance to generic lanreotide (Applies to Brand Somatuline Depot 120 mg only)

Product Name:Brand Somatuline Depot, Generic lanreotide	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy, such as a reduction or normalization of IGF-1/GH level for same age and sex

AND

2 - Trial and intolerance to generic lanreotide (Applies to Brand Somatuline Depot 120 mg only)

Product Name:Brand Somatuline Depot 120mg/0.5mL, Generic 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 intolerance to generic lanreotide (Applies to Brand Somatuline Depot 120 mg only)

Product Name:Brand Somatuline Depot 120mg/0.5mL, Generic 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

AND

2 - Trial and intolerance to generic lanreotide (Applies to Brand Somatuline Depot 120 mg only)

Product Name:Brand Somatuline Depot 120mg/0.5mL, Generic 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 - Prescribed by or in consultation with one of the following:

- Endocrinologist

- Oncologist

AND

4 - Trial and intolerance to generic lanreotide (Applies to Brand Somatuline Depot 120 mg only)

Product Name:Brand Somatuline Depot 120mg/0.5mL, Generic lanreotide 120mg/0.5ml [off-label]	
Diagnosis	Carcinoid Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Trial and intolerance to generic lanreotide (Applies to Brand Somatuline Depot 120 mg only)

3 . References

1. Somatuline Depot Prescribing Information. Ipsen Biopharmaceuticals, Inc. Cambridge, MA. July 2024.
2. Lanreotide Injection Prescribing Information. Cipla USA Inc. Warren, NJ. July 2024.

Prior Authorization Guideline

Guideline Name	Spevigo (spesolimab-sbzo)

Guideline Note:

Effective Date:	2/1/2025

1 . Indications

Drug Name: Spevigo (spesolimab-sbzo)
Generalized Pustular Psoriasis (GPP) Indicated for the treatment of generalized pustular psoriasis (GPP) in adults and pediatric patients 12 years of age and older and weighing at least 40 kg.

2 . Criteria

Product Name:Spevigo IV	
Approval Length	14 Days [A]
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of generalized pustular psoriasis (GPP)

AND

2 - Patient has a moderate to severe GPP flare based on one of the following:

- Presence of fresh pustules (new appearance or worsening of pustules)
- At least 5% of body surface area (BSA) covered with erythema and the presence of pustules
- A Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of at least 3 (moderate) [B]
- GPPPGA pustulation sub score of at least 2 (mild)

AND

3 - Both of the following:

- Patient is 12 years of age or older
- Patient weighs at least 40kg

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - Patient has not already received two infusions of Spevigo for a single flare

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

Approval Criteria

1 - Diagnosis of generalized pustular psoriasis (GPP) as defined by both of the following [2]:

- Primary, sterile, macroscopically visible pustules (excluding cases where pustulation is restricted to psoriatic plaques)
- Disease is relapsing (>1 episode) or persistent (>3 months)

AND

2 - Subcutaneous formulation will not be used to treat GPP flare

AND

3 - Both of the following:

- Patient is 12 years of age or older
- Patient weighs at least 40kg

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name:Spevigo SC	
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 number of flares)

3 . Endnotes

A. Spevigo is administered as a single intravenous infusion. If GPP flare symptoms persist, an additional intravenous dose may be administered one week after the initial dose [1].
B. The total Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) score ranges from 0 (clear) to 4 (severe) [1].

4 . References

1. Spevigo Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. March 2024.
2. Navarini AA, Burden AD, Capon F, Mrowietz U, Puig L, Köks S, Kingo K, Smith C, Barker JN1.2. Navarini AA, Burden AD, Capon F, et al; ERASPEN Network. European consensus statement on phenotypes of pustular psoriasis. J Eur Acad Dermatol Venereol. 2017 Nov;31(11):1792-1799. doi: 10.1111/jdv.14386. Epub 2017 Aug 29.
3. Armstrong AW, Elston CA, Elewski BE, Ferris LK, Gottlieb AB, Lebwohl MG; Medical Board of the National Psoriasis Foundation. Generalized pustular psoriasis: A consensus statement from the National Psoriasis Foundation. J Am Acad Dermatol. 2024 Apr;90(4):727-730. doi: 10.1016/j.jaad.2023.09.080. Epub 2023 Oct 13.

Prior Authorization Guideline

Guideline Name	Spinraza (nusinersen)

Guideline Note:

Effective Date:	8/1/2025

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 Part 2 (HINE-2) (infant to early childhood)
- Hammersmith Functional Motor Scale Expanded (HFMSE)
- Revised Upper Limb Module (RULM) 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 - Trial and failure or intolerance to Evrysdi

Notes	*Baseline assessments for patients less than 2 months of age r equesting nusinersen proactively are not necessary in order to n ot delay access to initial therapy in recently diagnosed infants. I nitial assessments shortly post-therapy can serve as baseline wi th respect to efficacy reauthorization assessment.

Product Name:Spinraza	
Diagnosis	Spinal Muscular Atrophy
Approval Length	12 Months [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates 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 RULM 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)

AND

8 - Trial and failure or intolerance to Evrysdi

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. April 2024.
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.
5. Markowitz JA, Sing P, Darras BT. Spinal muscular atrophy: a clinical and research update. Pediatr Neurol. 2012;46(1):1-12.
6. 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.
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. Haataja L, Mercuri E, Regev R, et al. Optimality score for the neurologic examination of the infant at 12 and 18 months of age. J Pediatr. 1999 Aug;135(2 Pt 1):153-61.

9. Glanzman AM, O'Hagen JM, McDermott MP, et al. Validation of the Expanded Hammersmith Functional Motor Scale in spinal muscular atrophy type II and III. J Child Neurol. 2011;26(12):1499-507.
10. O'Hagen JM, Glanzman AM, McDermott MP, et al. An expanded version of the Hammersmith Functional Motor Scale for SMA II and III patients. Neuromuscular disorders : NMD. 2007;17(9-10):693-7.
11. 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.
12. Pera , M., Coratti, G., Mazzone, E., et al. (2019). Revised upper limb module for spinal muscular atrophy: 12 month changes. Muscle Nerve. Apr;59(4):426-430.
13. Stolte B, Bois JM, Kizina K, et al. Minimal clinically important differences in functional motor scores in adults with spinal muscular atrophy. Eur. J. Neurol. 2020; 0:1-9.
14. 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.
15. Kirschner J, Bernert G, Butoianu N, et al. 2024 update: European consensus statement on gene therapy for spinal muscular atrophy. Eur J Paediatr Neurol. 2024;51:73-78. doi:10.1016/j.ejpn.2024.06.001

Prior Authorization Guideline

Guideline Name	Spravato (esketamine) - PA, NF

Guideline Note:

Effective Date:	7/1/2025

1 . Indications

Drug Name: Spravato (esketamine)
Depression Indicated, as monotherapy or in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults. Indicated, in conjunction with an oral antidepressant, for the treatment of 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:

- Diagnosis of major depressive disorder
- 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 [1-6, A-C]

OR

1.2 All 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

1.2.3 Used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline)

AND

2 - 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 - Patient demonstrates positive clinical response to therapy.

AND

2 - For major depressive disorder (MDD) with depressive symptoms and acute suicidal ideation or behavior: 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:

- Diagnosis of major depressive disorder
- 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 [1-6, A-C]

OR

1.2 Submission of medical records (e.g. chart notes) or paid claims documenting all 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

1.2.3 Used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline)

AND

2 - 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]
C. Requirement of inadequate response to antidepressant specific to current depressive episode mirrors Spravato clinical trial inclusion criteria. [1]

4 . References

1. Spravato Prescribing Information. Janssen Pharmaceuticals, Inc. Titusville, NJ. January 2025.
2. American Psychiatric Association. Practice guideline for the treatment of patients with major depressive disorder (3rd Edition). October 2010. Available at: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf. Accessed April 7, 2025.
3. Rush AJ, Trivedi MH, Wisniewski SR, et al. Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR*D report. Am J Psychiatry. 2006;163(11):1905-17.
4. Per clinical consult with psychiatrist, April 25, 2019.
5. Per clinical consult with psychiatrist, April 18, 2019.
6. Thase M, Connolly KR. Unipolar depression in adults: Choosing treatment for resistant depression. Solomon D, ed. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com (Accessed on April 7, 2025).

Prior Authorization Guideline

Guideline Name	Sunlenca (lenacapavir)

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

Prior Authorization Guideline

Guideline Name	Syfovre (pegcetacoplan)

Guideline Note:

Effective Date:	6/1/2025

1 . Indications

Drug Name: Syfovre (pegcetacoplan)
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 - 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.

Prior Authorization Guideline

Guideline Name	Sylvant (siltuximab)

Guideline Note:

Effective Date:	9/1/2024

1 . Indications

Drug Name: Sylvant (siltuximab)
Multicentric Castleman's Disease Indicated for the treatment of patients with multicentric Castleman’s disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative. Limitation of use: Sylvant was not studied in patients with MCD who are HIV positive or HHV-8 positive because Sylvant did not bind to virally produced IL-6 in a nonclinical study.

2 . Criteria

Product Name:Sylvant	
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multicentric Castleman's disease (MCD)

AND

2 - Patient is human immunodeficiency virus (HIV) negative

AND

3 - Patient is human herpesvirus-8 (HHV-8) negative

Product Name:Sylvant	
Approval Length	6 Months [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - Patient is human immunodeficiency virus (HIV) negative

AND

3 - Patient is human herpesvirus-8 (HHV-8) negative

3 . Endnotes

A. Patients should be evaluated for response to the drug every 3-6 months. A length of authorization of 6 months would be reasonable. [2]

4 . References

1. Sylvant Prescribing Information. Janssen Biotech, Inc. Horsham PA. April 2022.
2. Per clinical consult with hematologist/oncologist, June 5, 2014.

Prior Authorization Guideline

Guideline Name	Synagis (palivizumab)

Guideline Note:

Effective Date:	11/17/2023

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.

AND

4 - Patient has not received Beyfortus (nirsevimab) for the current RSV season [4]

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.

AND

7 - Patient has not received Beyfortus (nirsevimab) for the current RSV season

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

AND

4 - Patient has not received Beyfortus (nirsevimab) for the current RSV season

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

AND

6 - Patient has not received Beyfortus (nirsevimab) for the current RSV season

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 - Prescriber attests that patient is immunocompromised

AND

2 - Age < 24 months

AND

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

- Pediatric pulmonologist
- Infectious disease specialist
- Pediatric intensivist

AND

4 - 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

AND

5 - Patient has not received Beyfortus (nirsevimab) for the current RSV season

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	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]

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

AND

4 - Patient has not received Beyfortus (nirsevimab) for the current RSV season

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.

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.
4. Jones JM, Fleming-Dutra KE, Prill MM, et al. Use of nirsevimab for the prevention of respiratory syncytial virus disease among infants and young children: recommendations of the Advisory Committee on Immunization Practices – United States, 2023. MMWR Morb Mortal Wkly Rep. 2023;72(34):920-925

Prior Authorization Guideline

Guideline Name	Talvey (talquetamab-tgvs)

Guideline Note:

Effective Date:	12/1/2024

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.

Prior Authorization Guideline

Guideline Name	Tepezza (teprotumumab-trbw)

Guideline Note:

Effective Date:	5/1/2025

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 - Trial and failure (minimum 4 weeks), contraindication or intolerance to at least one oral or IV glucocorticosteroid (e.g., prednisone, methylprednisolone)

AND

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

- Endocrinologist
- Ophthalmologist

AND

4 - Treatment with Tepezza has not exceeded a total of 8 infusions [A, 1]

3 . Endnotes

A. In the pivotal trials, patients were given intravenous infusions (10 mg/kg for first infusion and 20 mg/kg for the remaining 7 infusions) every 3 weeks for a total of 8 infusions. [1]

4 . 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. 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.
4. 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%7E74&usage_type=default&display_rank=2. Accessed February 21, 2024.
5. Burch, H., Perros, P., Bednarczuk, T., et al. Management of Thyroid Eye Disease: A Consensus Statement by the American Thyroid Associati.n and the European Thyroid Association. Available at: https://www.liebertpub.com/doi/10.1089/thy.2022.0251. Accessed February 21, 2024.

Prior Authorization Guideline

Guideline Name	Tevimbra (tislelizumab)

Guideline Note:

Effective Date:	5/1/2025

1 . Indications

Drug Name: Tevimbra (tislelizumab)
Esophageal Squamous Cell Carcinoma (1) Indicated for the treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor (2) In combination with platinum-containing chemotherapy, indicated for first-line treatment of adults with unresectable or metastatic esophageal squamous cell carcinoma whose tumors express PD-L1 (≥1) **Gastric or Gastroesophageal Junction Adenocarcinoma** Indicated for the first-line treatment of adults with unresectable or metastatic HER2- negative gastric or gastroesophageal junction adenocarcinoma (G/GEJ) whose tumors express PD-L1 (≥1)

2 . Criteria

Product Name:Tevimbra	
Diagnosis	Esophageal Squamous Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of esophageal squamous cell carcinoma

AND

2 - Disease is one of the following:

- Unresectable
- Metastatic

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Patient has received prior systemic chemotherapy

AND

3.1.2 Patient has not previously been treated with a PD-(L)1 inhibitor (e.g., Keytruda, Opdivo

OR

3.2 Used in combination with platinum-containing chemotherapy (e.g., carboplatin, cisplatin, oxaliplatin)

Product Name:Tevimbra	
Diagnosis	Gastric or gastroesophageal junction adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastric or gastroesophageal junction adenocarcinoma

AND

2 - Disease is one of the following:

- Unresectable
- Metastatic

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

4 - Tumor(s) express PD-L1 as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

5 - Used in combination with platinum (e.g., carboplatin, cisplatin, oxaliplatin) and fluoropyrimidine (e.g., fluorouracil) -based chemotherapy

Product Name:Tevimbra	
Diagnosis	All indications listed above
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. Tevimbra Prescribing Information. BeiGene USA, Inc. San Mateo, CA. March 2025.

Prior Authorization Guideline

Guideline Name	Tezspire (tezepelumab-ekko) - PA

Guideline Note:

Effective Date:	6/1/2025

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 - One of the following: [2,3]

2.1 Patient has had two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months

OR

2.2 Prior asthma-related hospitalization within the past 12 months

AND

4 - Patient is 12 years of age or older

AND

3 - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

3.1 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 [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium])

OR

3.2 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]) [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 - Patient demonstrates positive clinical response to therapy (e.g., reduction in exacerbations, improvement in 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 [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., 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. May 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 (2023 update). 2023 www.ginasthma.org. Accessed 13 February 2024.

Prior Authorization Guideline

Guideline Name	Thyrogen (thyrotropin alfa for injection)

Guideline Note:

Effective Date:	5/1/2025

1 . Indications

Drug Name: Thyrogen (thyrotropin alfa for injection)
Adjunctive Diagnostic Tool for Serum Thyroglobulin Testing in Well Differentiated Thyroid Cancer Indicated for use as an adjunctive diagnostic tool for serum thyroglobulin (Tg) testing with or without radioiodine imaging in the follow-up of patients with well-differentiated thyroid cancer who have previously undergone thyroidectomy. Limitations of Use: Thyrogen-stimulated Tg levels are generally lower than, and do not correlate with, Tg levels after thyroid hormone withdrawal. Even when Thyrogen-stimulated Tg testing is performed in combination with radioiodine imaging, there remains a risk of missing a diagnosis of thyroid cancer or of underestimating the extent of disease. Anti-Tg antibodies may confound the Tg assay and render Tg levels uninterpretable. Therefore, in such cases, even with a negative or low-stage Thyrogen radioiodine scan, consideration should be given to further evaluating patients. **Adjunct to Treatment for Ablation in Well Differentiated Thyroid Cancer** Indicated for use as an adjunctive treatment for radioiodine ablation of thyroid tissue remnants in patients who have undergone a near-total or total thyroidectomy for well-differentiated thyroid cancer and who do not have evidence of distant metastatic thyroid cancer. Limitations of Use: The effect of Thyrogen on long-term thyroid cancer outcomes has not been determined. Due to the relatively small clinical experience

with Thyrogen in remnant ablation, it is not possible to conclude whether long-term thyroid cancer outcomes would be equivalent after use of Thyrogen or use of thyroid hormone withholding for TSH elevation prior to remnant ablation.

2 . Criteria

Product Name:Thyrogen	
Approval Length	1 course of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Thyrogen is being used as a diagnostic tool for serum thyroglobulin testing in well differentiated thyroid cancer

OR

1.2 All of the following:

1.2.1 Thyrogen is being used as an adjunctive treatment for radioiodine ablation of thyroid tissue remnants

AND

1.2.2 Patient has undergone a near-total or total thyroidectomy for well-differentiated thyroid cancer

AND

1.2.3 Patient does not have evidence of distant metastatic thyroid cancer

AND

2 - One of the following:

2.1 Patient is unable to tolerate thyroid hormone withdrawal (ie, intolerable hypothyroid symptoms) [1,2]

OR

2.2 Thyroid hormone withdrawal is medically contraindicated (ie, exacerbation of comorbid conditions) [1,2]

OR

2.3 Patient has inadequate thyroid stimulating hormone (TSH) response to thyroid hormone withdrawal [1]

OR

2.4 Patient has an undetectable Tg on thyroid hormone suppressive therapy, to exclude the diagnosis of residual or recurrent thyroid cancer [1]

3 . References

1. Thyrogen Package Insert. Genzyme Corporation. Cambridge, MA. February 2023.
2. Haugen, Alexander, et al. 2015 American Thyroid Association Management Guidelines for Adult Patients with Thyroid Nodules and Differentiated Thyroid Cancer: The American Thyroid Association Guidelines Task Force on Thyroid Nodules and Differentiated Thyroid Cancer. Thyroid. 2016, 26(1): 1-133.

Prior Authorization Guideline

Guideline Name	Tier Lowering Exceptions Process

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.

Prior Authorization Guideline

Guideline Name	Trastuzumab - PA, NF

Guideline Note:

Effective Date:	3/1/2025

1 . Indications

Drug Name: Herceptin (trastuzumab), Hercessi (trastuzumab-strf), Herzuma (trastuzumab-pkrb), Kanjinti (trastuzumab-anns), Ogivri (trastuzumab-dkst), Ontruzant (trastuzumab-dkst), Trazimera (trastuzumab-qyyp)
Adjuvant Breast Cancer Indicated for adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer: 1) as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel, 2) with docetaxel and carboplatin, 3) as a single agent following multi-modality anthracycline based therapy. **Metastatic Breast Cancer** Indicated: 1) In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer, 2) As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease. **Metastatic Gastric Cancer** Indicated in combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma, who have not received prior treatment for metastatic disease.

Drug Name: Herceptin Hylecta (trastuzumab and hyaluronidase-oysk)
Adjuvant Breast Cancer Indicated for adjuvant treatment of adults with HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer: 1) as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel, 2) as part of a treatment regimen with docetaxel and carboplatin, 3) as a single agent following multi-modality anthracycline based therapy. **Metastatic Breast Cancer** Indicated in adults: 1) In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer, 2) As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease.

2 . Criteria

Product Name:Kanjinti, Trazimera	
Diagnosis	Adjuvant or Neoadjuvant Breast Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2-overexpressing of breast cancer [A]

AND

2 - One of the following treatment regimens: [4, C]

- Adjuvant treatment
- Used in combination with Perjeta (pertuzumab)

Product Name:Kanjinti, Trazimera	
Diagnosis	Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2-overexpressing of breast cancer [A]

AND

2 - Disease is metastatic

AND

3 - One of the following treatment regimens: [3-5, 7, C]

- Used in combination with a taxane
- Used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease
- Used in combination with Perjeta (pertuzumab)

Product Name:Kanjinti, Trazimera	
Diagnosis	Metastatic Breast 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:Kanjinti, Trazimera	
Diagnosis	Metastatic Gastric Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2-overexpressing gastric or gastroesophageal junction adenocarcinoma (locally advanced, recurrent, or metastatic) [3-5, 7, A-C]

AND

2 - Used in combination with one of the following treatment regimens: [3-5, 7, C]

- Platinol (cisplatin) and Adrucil (5-fluorouracil)
- Platinol (cisplatin) and Xeloda (capecitabine)

Product Name:Kanjinti, Trazimera	
Diagnosis	Metastatic Gastric 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:Herceptin Hylecta	
Diagnosis	Adjuvant Breast Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2-overexpressing breast cancer [A]

AND

2 - One of the following:

2.1 Administered as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel

OR

2.2 Administered as part of a treatment regimen with docetaxel and carboplatin

OR

2.3 Administered as a single agent following multi-modality anthracycline based therapy

AND

3 - One of the following:

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

- Kanjinti
- Trazimera

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Herceptin Hylecta	
Diagnosis	Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2-overexpressing breast cancer [A]

AND

2 - Disease is metastatic

AND

3 - One of the following:

3.1 Administered in combination with paclitaxel for first-line treatment

OR

3.2 Administered as a single agent for treatment in patients who have received one or more chemotherapy regimens for metastatic disease

AND

4 - One of the following:

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

- Kanjinti
- Trazimera

OR

4.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Herceptin Hylecta	
Diagnosis	Metastatic Breast 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

AND

2 - One of the following:

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

- Kanjinti
- Trazimera

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Herceptin, Hercessi, Herzuma, Ogivri, Ontruzant	
Diagnosis	Adjuvant or Neoadjuvant Breast Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2-overexpressing of breast cancer [A]

AND

2 - One of the following treatment regimens: [4, C]

- Adjuvant treatment
- Used in combination with Perjeta (pertuzumab)

AND

3 - One of the following:

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

- Kanjinti
- Trazimera

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Herzuma, Ogivri, Ontruzant	
Diagnosis	Adjuvant or Neoadjuvant Breast Cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of HER2-overexpressing of breast cancer [A]

AND

2 - One of the following treatment regimens: [4, C]

- Adjuvant treatment
- Used in combination with Perjeta (pertuzumab)

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 both of the following:

- Kanjinti
- Trazimera

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

Product Name:Herceptin, Hercessi, Herzuma, Ogivri, Ontruzant	
Diagnosis	Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2-overexpressing of breast cancer [A]

AND

2 - Disease is metastatic

AND

3 - One of the following treatment regimens: [1, 4-6, 8-9, C]

- Used in combination with a taxane
- Used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease
- Used in combination with Perjeta (pertuzumab)

AND

4 - One of the following:

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

- Kanjinti
- Trazimera

OR

4.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Herceptin, Hercessi, Herzuma, Ogivri, Ontruzant	
Diagnosis	Metastatic Breast 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

AND

2 - One of the following:

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

- Kanjinti
- Trazimera

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Herzuma, Ogivri, Ontruzant	
Diagnosis	Metastatic Breast Cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of HER2-overexpressing of breast cancer [A]

AND

2 - Disease is metastatic

AND

3 - One of the following treatment regimens: [1, 4-6, 8-9, C]

- Used in combination with a taxane
- Used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease
- Used in combination with Perjeta (pertuzumab)

AND

4 - One of the following:

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to both of the following:

- Kanjinti
- Trazimera

OR

4.2 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

Product Name:Herceptin, Hercessi, Herzuma, Ogivri, Ontruzant	
Diagnosis	Metastatic Gastric Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2-overexpressing gastric or gastroesophageal junction adenocarcinoma (locally advanced, recurrent, or metastatic) [1, 4-6, 8-9, A-C]

AND

2 - Used in combination with one of the following treatment regimens: [1, 4-6, 8-9, C]

- Platinol (cisplatin) and Adrucil (5-fluorouracil)
- Platinol (cisplatin) and Xeloda (capecitabine)

AND

3 - One of the following:

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

- Kanjinti
- Trazimera

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Herceptin, Hercessi, Herzuma, Ogivri, Ontruzantt	
Diagnosis	Metastatic Gastric 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

AND

2 - One of the following:

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

- Kanjinti
- Trazimera

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name:Herzuma, Ogivri, Ontruzant	
Diagnosis	Metastatic Gastric Cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of HER2-overexpressing gastric or gastroesophageal junction adenocarcinoma (locally advanced, recurrent, or metastatic) [1, 4-6, 8-9, A-C]

AND

2 - Used in combination with one of the following treatment regimens: [1, 4-6, 8-9, C]

- Platinol (cisplatin) and Adrucil (5-fluorouracil)
- Platinol (cisplatin) and Xeloda (capecitabine)

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 both of the following:

- Kanjinti
- Trazimera

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

3 . Endnotes

A. Detection of HER2 protein overexpression is necessary for selection of patients appropriate for trastuzumab therapy because these are the only patients studied and for whom benefit has been shown. Due to differences in tumor histopathology, use FDA-approved tests for the specific tumor type (e.g. breast or gastric/gastroesophageal adenocarcinoma) to assess HER2 protein overexpression and HER2 gene amplification. Assessment of HER2 protein overexpression and HER2 gene amplification should be performed using FDA-approved tests specific for breast cancer by laboratories with demonstrated proficiency. Improper assay performance, including use of suboptimally fixed tissue, failure to utilize specified reagents, deviation from specific assay instructions, and failure to include appropriate controls for assay validation, can lead to unreliable results. Assessment of HER2 protein overexpression and HER2 gene amplification in metastatic gastric cancer should be performed using FDA-approved tests specifically for gastric cancers due to differences in gastric vs. breast histopathology, including incomplete membrane staining and more frequent heterogeneous expression of HER2 seen in gastric cancers. Study 7 demonstrated that gene amplification and protein overexpression were not as well correlated as with breast cancer. Treatment outcomes for metastatic gastric cancer (Study 7) are based on HER2 gene amplification (FISH) and HER 2 protein overexpression (IHC) test results. [1-3, 6-9]
B. Herceptin, Kanjinti, Ogivri, Trazimera, Herzuma and Ontruzant are indicated for the treatment of HER-2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. A pivotal study included patients previously untreated for metastatic gastric or gastroesophageal junction adenocarcinoma. [1, 3, 6-9]
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. [5]

4 . References

1. Herceptin Prescribing Information. Genentech, Inc. South San Francisco, CA. February 2021.

2. Herceptin Hylecta Prescribing Information. Genentech, Inc. South San Francisco, CA. February 2019.
3. Kanjinti Prescribing Information. Amgen Inc. Thousand Oaks, CA. October 2019.
4. The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium. Available at www.nccn.org. Accessed May 15, 2023.
5. U.S. Food and Drug Administration (FDA). Biosimilar and Interchangeable Products. Silver Spring, MD: FDA; October 23, 2017. Available at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm#biosimilar. Accessed May 14, 2021.
6. Ogivri Prescribing Information. Mylan Institutional LLC. Rockford, IL. February 2021.
7. Trazimera Prescribing Information. Pfizer Laboratories Div Pfizer Inc. New York, NY. November 2020.
8. Herzuma Prescribing Information. Celltrion, Inc. Incheon, Republic of Korea. May 2019.
9. Ontruzant Prescribing Information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. March 2020.
10. Hercessi Prescribing Information. Accord BioPharma Inc.Raleigh, NC. September 2024.

Prior Authorization Guideline

Guideline Name	Trodelvy (sacituzumab govitecan-hziy)

Guideline Note:

Effective Date:	2/1/2025

1 . Indications

Drug Name: Trodelvy (sacituzumab govitecan-hziy)
Breast Cancer Indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease. **Breast Cancer** Indicated for the treatment of adult patients with unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH−) breast cancer who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting.

2 . Criteria

Product Name:Trodelvy	
Diagnosis	Triple Negative Breast Cancer

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

Approval Criteria

1 - Diagnosis of triple negative breast cancer (TNBC) [A]

AND

2 - Disease is one of the following:

- Unresectable locally advanced
- Metastatic

AND

3 - Patient has received at least two prior therapies for at least one of which is for metastatic disease (e.g., chemotherapy with or without programmed cell death protein-1 (PD-1) inhibitor [e.g., Keytruda (pembrolizumab)], neoadjuvant/adjuvant therapy, poly-ADP ribose polymerase (PARP) inhibitor [e.g., Olaparib, talazoparib], etc.) [1-3]

Product Name:Trodelvy	
Diagnosis	HR-positive, HER2-negative Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Disease is one of the following:

- Unresectable locally advanced
- Metastatic

AND

3 - Disease is hormone-receptor (HR) - positive

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2) - negative

AND

5 - Both of the following:

5.1 Patient has received endocrine-based therapy (e.g., tamoxifen, aromatase inhibitors [e.g., Aromasin (exemestane), Femara (letrozole), Arimidex (anastrozole)], fulvestrant)

AND

5.2 Patient has received at least two additional systemic therapies in the metastatic setting (e.g., chemotherapy, poly-ADP ribose polymerase (PARP) inhibitor [e.g., olaparib, talazoparib], fam-trastuzumab deruxtecan-nxki) [B, 3]

Product Name:Trodelvy

Diagnosis	All indications listed above
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. Triple-negative breast cancer is defined by a lack of tumor-cell expression of the estrogen receptor, progesterone receptor, and human epidermal growth factor receptor 2 (HER2). [2]
B. Adjuvant or neoadjuvant therapy for early-stage disease will qualify as one of the required prior regimens if the development of unresectable, locally advanced or metastatic disease occurred within 12 months of adjuvant therapy. [1]

4 . References

1. Trodelvy Prescribing Information. Immunomedics, Inc. Morris Plains, NJ. November 2024.
2. Bardia A, Mayer IA, Vahdat LT, et al. Sacituzumab govitecan-hziy in refractory metastatic triple-negative breast cancer. N Engl Med. 2019;380:741-51.
3. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 23, 2023.

Prior Authorization Guideline

Guideline Name	Tryngolza (olezarsen sodium)

Guideline Note:

Effective Date:	4/1/2025

1 . Indications

Drug Name: Tryngolza (olezarsen sodium)
Familial chylomicronemia syndrome (FCS) Indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS)

2 . Criteria

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

Approval Criteria

1 - Diagnosis of familial chylomicronemia syndrome (FCS) (type 1 hyperlipoproteinemia)

AND

2 - One of the following:

2.1 Genetic confirmation of biallelic pathogenic variants in FCS-causing genes (i.e., LPL, GPIHBP1, APOA5, APOC2, or LMF1)

OR

2.2 A North American FCS (NAFCS) Score of greater than or equal to 45 [4]

AND

3 - Both of the following:

3.1 One of the following:

3.1.1 Patient has tried or will receive treatment with standard of care triglyceride lowering therapy (i.e., prescription omega-3 fatty acid and a fibrate)

OR

3.1.2 Patient has an intolerance to standard of care triglyceride lowering therapy (i.e., prescription omega-3 fatty acid and a fibrate)

AND

3.2 Baseline fasting triglyceride levels are greater than or equal to 880 mg/dL prior to treatment with requested drug

AND

4 - Requested drug will be used as adjunct to a low-fat diet

AND

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

- Cardiologist
- Endocrinologist
- Gastroenterologist
- Lipid specialist (lipidologist)

Product Name:Tryngolza	
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 triglyceride levels from baseline)

3 . References

1. Tryngolza Prescribing Information. Ionis Pharmaceuticals, Inc. Carlsbad, CA 92010. December 2024.
2. Stroes ESG, Alexander VJ, Karwatowska-Prokopczuk E, et al. Olezarsen, Acute Pancreatitis, and Familial Chylomicronemia Syndrome. N Engl J Med. 2024;390(19):1781-1792. doi:10.1056/NEJMoa2400201
3. Study Details | A Study of Olezarsen (Formerly Known as AKCEA-APOCIII-LRx) Administered to Patients With Familial Chylomicronemia Syndrome (FCS) |

ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT04568434. Accessed January 10, 2024.
4. Hegele RA, Ahmad Z, Ashraf A, et al. Development and validation of clinical criteria to identify familial chylomicronemia syndrome (FCS) in North America. J Clin Lipidol. Published online November 12, 2024. doi:10.1016/j.jacl.2024.09.008

Prior Authorization Guideline

Guideline Name	Tysabri (natalizumab)

Guideline Note:

Effective Date:	7/1/2025

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	When approved; no reauthorization required
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 (of a minimum 4-week supply), contraindication, or intolerance to one disease-modifying therapy for MS (e.g., Kesimpta [Ofatumumab], Mavenclad [Cladribine], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b], Mayzent [Siponimod], Zeposia [ozanimod])

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

Notes	For initial authorization request, approve through 12/31/2039 For reauthorization request, bypass criteria review and approve t hrough 12/31/2039

Product Name:Tysabri	
Diagnosis	Crohn’s Disease (CD)
Approval Length	3 Months [D]
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) [1,3]

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., certolizumab pegol, adalimumab)

AND

5 - Not used in combination with TNF inhibitors (e.g., certolizumab pegol, adalimumab) or immunosuppressants (e.g., 6-MP, azathioprine, cyclosporine, or methotrexate) [A, C]

AND

6 - Prescribed by or in consultation with a gastroenterologist

Product Name:Tysabri	
Diagnosis	Crohn's Disease (CD)
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, 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 TNF inhibitors (e.g., certolizumab pegol, adalimumab) or immunosuppressants (e.g., 6-MP, azathioprine, cyclosporine, or methotrexate) [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. 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]
D. Tysabri should be discontinued in patients with Crohn's disease who have not experienced therapeutic benefit by 12 weeks of induction therapy. For patients with Crohn's disease who start Tysabri while on chronic oral corticosteroids, steroid tapering should begin as soon as a therapeutic benefit of Tysabri has occurred. Tysabri should be discontinued if patients cannot be tapered off of oral corticosteroids within six months of starting Tysabri. Other than the initial six-month taper, prescribers should consider discontinuing Tysabri for patients who require additional steroid use that exceeds three months in a calendar year to control their Crohn's disease. [1]

4 . References

1. Tysabri Prescribing Information. Biogen Inc. Cambridge, MA. October 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.

Prior Authorization Guideline

Guideline Name	Ultomiris (ravulizumab-cwvz)

Guideline Note:

Effective Date:	5/1/2025

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). Limitations of Use: Ultomiris 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** Indicated for the treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) 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 - Patient demonstrates positive clinical response to therapy (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions)

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 - Patient demonstrates positive clinical response to therapy (e.g., normalization of platelet count, improvement in serum creatinine from baseline)

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]

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 - Patient demonstrates positive clinical response to therapy

Product Name:Ultomiris	
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 - Prescribed by or in consultation with one of the following:

- Neurologist
- Ophthalmologist

Product Name:Ultomiris	
Diagnosis	Neuromyelitis Optica Spectrum Disorder (NMOSD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . References

1. Ultomiris Prescribing Information. Alexion Pharmaceuticals, Inc. Boston, MA. March 2024.

2. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis. Neurology. 2016;87(4):419-25.
3. Alhaidar MK, Abumurad S, Soliven B, Rezania K. Current Treatment of Myasthenia Gravis. Journal of Clinical Medicine. 2022;11(6):1597. doi:https://doi.org/10.3390/jcm11061597

Prior Authorization Guideline

Guideline Name	Unituxin (dinutuximab)

Guideline Note:

Effective Date:	9/1/2024

1 . Indications

Drug Name: Unituxin (dinutuximab)
Neuroblastoma Indicated, in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA), for the treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to prior first-line multiagent, multimodality therapy.

2 . Criteria

Product Name:Unituxin	
Diagnosis	Neuroblastoma
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of high-risk neuroblastoma

AND

2 - Used in combination with all of the following:

- Granulocyte-macrophage colony-stimulating factor (GM-CSF) [e.g., Leukine (sargramostim)]
- Interleukin-2 (IL-2) [e.g., Proleukin (aldesleukin)]
- 13-cis-retinoic acid (RA) [e.g., isotretinoin]

AND

3 - Patient responded to prior first-line multiagent, multimodality therapy (e.g., chemotherapy, surgery, stem cell transplant, radiation therapy)

3 . References

1. Unituxin Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. April 2024.

Prior Authorization Guideline

Guideline Name	Uplizna (inebilizumab-cdon)

Guideline Note:

Effective Date:	8/1/2025

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. **Immunoglobulin G4-Related Disease (IgG4-RD)** Indicated for the treatment of Immunoglobulin G4-related disease (IgG4-RD) in adult patients.

2 . Criteria

Product Name:Uplizna	
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 - 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	
Diagnosis	Immunoglobulin G4-Related Disease (IgG4-RD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Immunoglobulin G4-Related Disease (IgG4-RD)

AND

2 - Presence of disease involving two or more organ systems or sites (e.g., Pancreas, Submandibular gland, Lymph node(s), Kidneys, Bile Duct, Lungs or Lacrimal glands)

AND

3 - One of the following: [3]

3.1 Patient is currently being treated with a glucocorticoid (e.g., prednisone, methylprednisolone)

OR

3.2 Trial and failure, contraindication or intolerance to a glucocorticoid (e.g., prednisone, methylprednisolone)

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

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . References

1. Uplizna Prescribing Information. Horizon Therapeutics USA, Inc. Deerfield, IL. April 2025
2. Stone, John H., et al. “Inebilizumab for Treatment of IgG4-Related Disease.” New England Journal of Medicine, vol. 392, no. 12, 14 Nov. 2024, https://doi.org/10.1056/nejmoa2409712.
3. Khosroshahi, A., Wallace, Z.S., Crowe, J.L., Akamizu, T., Azumi, A., Carruthers, M.N., Chari, S.T., Della-Torre, E., Frulloni, L., Goto, H., Hart, P.A., Kamisawa, T., Kawa, S., Kawano, M., Kim, M.H., Kodama, Y., Kubota, K., Lerch, M.M., Löhr, M., Masaki, Y., Matsui, S., Mimori, T., Nakamura, S., Nakazawa, T., Ohara, H., Okazaki, K., Ryu, J.H., Saeki, T., Schleinitz, N., Shimatsu, A., Shimosegawa, T., Takahashi, H., Takahira, M., Tanaka, A., Topazian, M., Umehara, H., Webster, G.J., Witzig, T.E., Yamamoto, M., Zhang, W., Chiba, T. and Stone, J.H. (2015), International Consensus Guidance Statement on the Management and Treatment of IgG4-Related Disease. Arthritis & Rheumatology, 67: 1688-1699.

Prior Authorization Guideline

Guideline Name	Veopoz (pozelimab-bbfg)

Guideline Note:

Effective Date:	12/1/2024

1 . Indications

Drug Name: Veopoz (pozelimab-bbfg)
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	
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 less than or equal to 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
- Gastroenterologist

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

Approval Criteria

1 - Patient demonstrates 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. March 2024.

Prior Authorization Guideline

Guideline Name	Viltepso (viltolarsen) - PA, NF

Guideline Note:

Effective Date:	12/1/2024

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 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 with expertise in the treatment of DMD

AND

4 - Dose will not exceed 80 milligrams per kilogram of body weight infused once weekly

AND

5 - Patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair) [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 with expertise in the treatment of DMD

AND

4 - Patient is maintaining ambulatory status without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair)

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 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 with expertise in the treatment of DMD

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 without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair) [2, 3]

3 . References

1. Viltepso Prescribing Information. NS Pharma, Inc. Paramus, NJ. January 2023.

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 19, 2024.
3. Per Clinical Consultation with a Pediatrician, April 25, 2019 and January 22, 2020.

Prior Authorization Guideline

Guideline Name	Vimizim (elosulfase alfa)

Guideline Note:

Effective Date:	10/1/2024

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	12 month(s)
Therapy Stage	Initial Authorization
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 for mutations in the GALNS gene.

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

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy

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.

Prior Authorization Guideline

Guideline Name	Vyondys 53 (golodirsen) - PA, NF

Guideline Note:

Effective Date:	4/1/2025

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 with expertise in the treatment of DMD

AND

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

AND

6 - Patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.) [2, 3]

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 with expertise in the treatment of DMD

AND

4 - Patient is maintaining ambulatory status without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)

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 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 with expertise in the treatment of DMD

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 without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.) [2, 3]

3 . References

1. Vyondys 53 Prescribing Information. Sarepta Therapeutics, Inc. Cambridge, MA. June 2024.
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.

Prior Authorization Guideline

Guideline Name	Vyvgart (efgartigimod alfa-fcab)

Guideline Note:

Effective Date:	6/1/2025

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.
Drug Name: Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)
Generalized Myasthenia Gravis (gMG) Indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. **Chronic inflammatory demyelinating polyneuropathy (CIDP)** Indicated for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP)

2 . Criteria

Product Name:Vyvgart, Vyvgart Hytrulo	
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:

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, Vyvgart Hytrulo	
Diagnosis	Generalized myasthenia gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name:Vyvgart Hytrulo	
Diagnosis	Chronic inflammatory demyelinating polyneuropathy (CIDP)
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 [3]:

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 one of the following standard of care treatments [3][4]:

- Corticosteroids (minimum 3 month trial duration)
- Immunoglobulin
- Plasma exchange

AND

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

- Immunologist
- Neurologist
- Hematologist

Product Name:Vyvgart Hytrulo	
Diagnosis	Chronic inflammatory demyelinating polyneuropathy (CIDP)
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 INCAT or aINCAT score)

AND

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

- Immunologist
- Neurologist
- Hematologist

3 . References

1. Vyvgart Prescribing Information. Argenx US, Inc. Boston, MA. October 2024.
2. Vyvgart Hytrulo Prescribing Information. Argenx US, Inc. Boston, MA. April 2025.
3. Koller H, Kieseier BC, Jander S, et al. Chronic inflammatory demyelinating polyneuropathy. N Engl J Med. 2005;352(13):1343-56.
4. Van den Bergh PYK, van Doorn PA, Hadden RDM et al. European Academy of Neurology/Peripheral Nerve Society guideline on diagnosis and treatment of

chronic inflammatory demyelinating polyradiculoneuropathy: Report of a joint Task Force-Second revision. Eur J Neurol. 2021 Nov;28(11):3556-3583. doi: 10.1111/ene.14959. Epub 2021 Jul 30.

Prior Authorization Guideline

Guideline Name	Vyxeos (daunorubicin and cytarabine)

Guideline Note:

Effective Date:	9/1/2023

1 . Indications

Drug Name: Vyxeos (daunorubicin and cytarabine)
Newly-diagnosed therapy-related AML (t-AML) or AML with myelodysplasia-related changes (AML-MRC) Indicated for the treatment of newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) in adults and pediatric patients 1 year and older.

2 . Criteria

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

Approval Criteria

1 - One of the following diagnoses: [1-3]

- Newly-diagnosed therapy-related acute myeloid leukemia (t-AML)
- Newly-diagnosed acute myeloid leukemia with myelodysplasia-related changes (AML-MRC)

Product Name:Vyxeos	
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. Vyxeos Prescribing Information. Jazz Pharmaceuticals. Palo Alto, CA. April 2021.
2. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium. Available by subscription at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed May 28,2021.
3. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia v.3.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed May 28, 2021.

Prior Authorization Guideline

Guideline Name	Xenpozyme (olipudase alfa)

Guideline Note:

Effective Date:	1/1/2025

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 Disease 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.

Prior Authorization Guideline

Guideline Name	Xeomin (incobotulinumtoxinA)

Guideline Note:

Effective Date:	10/1/2024

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. **Cosmetic Uses [Non-approvable Use]** 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 - Patient demonstrates positive clinical response to therapy

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 - Patient demonstrates positive clinical response to therapy

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 - Patient demonstrates positive clinical response to therapy

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 - Patient demonstrates positive clinical response to therapy

AND

2 - At least 4 months have elapsed or will have elapsed since the last treatment [E]

Product Name:Xeomin	
Diagnosis	Cosmetic Use
Guideline Type	Prior Authorization

Approval Criteria

1 - Requests for coverage of any Xeomin 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. 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. July 2024.
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.

Xiaflex (collagenase clostridium histolyticum)

Prior Authorization Guideline

Guideline Name	Xiaflex (collagenase clostridium histolyticum)

Guideline Note:

Effective Date:	6/1/2025

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. August 2022.

Prior Authorization Guideline

Guideline Name	Xipere (triamcinolone acetonide injectable suspension)

Guideline Note:

Effective Date:	4/1/2025

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 - Patient demonstrates 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.

6. UpToDate: Uveitis: Etiology, clinical manifestations, and diagnosis. Available at: https://www.uptodate.com/contents/uveitis-etiology-clinical-manifestations-and-diagnosis?search=macular%20edema%20asscoiated%20with%20uveitis&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1. Accessed January 4, 2024.
7. Uptodate: Uveitis: Treatment. Available at: Uveitis: https://www.uptodate.com/contents/uveitis-treatment?search=macular%20edema%20asscoiated%20with%20uveitis&topicRef=5581&source=see_link. Accessed January 4, 2024.
8. Ozurdex Prescribing Information. Allergan USA, Inc. Madison, NJ. December 2022.
9. Iluvien Prescribing Information. Alimera Sciences, Inc. Alpharetta, GA. November 2016.
10. Retisert Prescribing Information. Bausch & Lomb Inc. Waterford, Ireland. May 2011.

Prior Authorization Guideline

Guideline Name	Xphoza (tenapanor HCl)

Guideline Note:

Effective Date:	3/1/2024

1 . Criteria

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

Approval Criteria

1 - Diagnosis of hyperphosphatemia

AND

2 - Member has chronic kidney disease with one of the following:

- Chronic maintenance hemodialysis 3x per week for at least 3 months
- Chronic peritoneal dialysis for a minimum of 6 months

AND

3 - Member is 18 years or older

AND

4 - Prescribed by, or in consultation with, a nephrologist

AND

5 - All of the following other potential contributing factors for hyperphosphatemia been addressed by treating provider:

- Serum parathyroid hormone <1200 pg/mL
- Active vitamin D or calcimimetic dose stable for the last 4 weeks
- Dietary restrictions are in place to limit phosphate intake

AND

6 - Member has continued to have elevated serum phosphate levels (≥5.5 to ≤10mg/dL) despite use of at least 3 different phosphate binder agents (calcium acetate, sevelamer, lanthanum) used at therapeutic doses with adherence to therapy (at least 80% adherence based on fill history) AND medication is intended for use as add-on therapy with phosphate binder therapy

AND

7 - Member does not have contraindication to requested therapy (e.g., history of inflammatory bowel disease or irritable bowel syndrome with diarrhea)

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

Approval Criteria

1 - Documentation of continued effectiveness of the requested medication

Prior Authorization Guideline

Guideline Name	Ziihera (zanidatamab-hrii)

Guideline Note:

Effective Date:	2/1/2025

1 . Indications

Drug Name: Ziihera (zanidatamab-hrii) injection
Biliary tract cancer (BTC) indicated for the treatment of adults with previously treated, unresectable, or metastatic HER2-positive (IHC 3+) biliary tract cancer (BTC), as detected by an FDA-approved test. This indication is approved under accelerated approval based on overall response rate and duration 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:Ziihera	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of biliary tract cancer (BTC)

AND

2 - Disease is one of the following:

- Unresectable
- Metastatic

AND

3 - Presence of human epidermal growth factor receptor (HER2) - positive (Immunohistochemistry [IHC] 3+) as detected by a U.S. Food and Drug Administration (FDA) - approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - Patient has been previously treated (e.g., chemotherapy)

Product Name:Ziihera	
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. Ziihera Prescribing Information. Jazz Pharmaceuticals, Inc. Palo Alto, CA. November 2024.
2. Center. List of Cleared or Approved Companion Diagnostic Devices. U.S. Food and Drug Administration. Published 2024. Accessed December 17, 2024. http://www.fda.gov/CompanionDiagnostics

Prior Authorization Guideline

Guideline Name	Zoladex (goserelin)

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

Prior Authorization Guideline

Guideline Name	Zolgensma (onasemnogene abeparvovec-xioi) - PA, NF

Guideline Note:

Effective Date:	8/1/2025

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. February 2025.
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.

Prior Authorization Guideline

Guideline Name	Zulresso (brexanolone)

Guideline Note:

Effective Date:	7/1/2025

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]

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/Drugs/PsychopharmacologicDrugsAdvisoryCommittee/UCM624643.pdf. Accessed March 27, 2024.
3. ClinicalTrials.gov. A Multicenter, Randomized, Double-Blind, Parallel-Group, PlaceboControlled Study Evaluating the Efficacy, Safety, and Pharmacokinetics of SAGE-547 Injection in the Treatment of Adult Female Subjects with Severe Postpartum Depression and Adult Female Subjects with Moderate Postpartum Depression. Available at: https://cdn.clinicaltrials.gov/large-docs/04/NCT02942004/SAP_001.pdf. Accessed April 23, 2025.

Prior Authorization Guideline

Guideline Name	Zurzuvae (zuranolone)

Guideline Note:

Effective Date:	7/2/2024

1 . Criteria

Product Name:Zurzuvae	
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

- Diagnosis of moderate to severe postpartum depression (PPD)
- Submission of medical records (e.g., chart notes) of validated screening tool result(s) (e.g. EPDS, PHQ-9) that will be used to monitor a patient's response to Zurzuvae therapy

AND

2 - Patient is 18 years or older

AND

3 - Physician attest that patient has not had a major depressive episode prior to third trimester of pregnancy and no later than the first 4 weeks following delivery

AND

4 - Patient is less than or equal to 6 months postpartum

AND

5 - Patient has a trial and failure to generic SSRI or SNRI for PPD

AND

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

- Psychiatrist
- Obstetrician or Gynecologist

Prior Authorization Guideline

Guideline Name	Zynlonta (loncastuximab tesirine-lpyl)

Guideline Note:

Effective Date:	10/1/2024

1 . Indications

Drug Name: Zynlonta (loncastuximab tesirine-lpyl)
Large B-cell lymphoma Indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low-grade lymphoma, and high-grade B-cell lymphoma. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2 . Criteria

Product Name:Zynlonta	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Diffuse large B-cell lymphoma (DLBCL)
- DLBCL arising from low-grade lymphoma
- High-grade B-cell lymphoma

AND

2 - Disease is one of the following:

- Relapsed
- Refractory

AND

3 - Patient has received at least two prior systemic therapies (e.g. chemotherapy, immunotherapy) [2]

Product Name:Zynlonta	
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. Zynlonta Prescribing Information. ADC Therapeutics America. Murray Hill, NJ. October 2022.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: B-Cell Lymphomas. v.2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed July 23, 2024