Samaritan Health Plans

B vs D Prior Authorization Criteria

Samaritan Advantage Health Plans
(HMO)

Updated on 03/26/2024. 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.

H3811_BvD_C

Prior Authorization Guideline

Guideline Name Akynzeo (netupitant/palonosetron)

Formulary 2024 Samaritan Advantage Health Plans (HMO)

Formulary Note

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	
P&T Revision Date:	4/19/2023

1 . Indications

Drug Name: Akynzeo (netupitant/palonosetron) capsules
Chemotherapy induced nausea and vomiting Indicated in combination with dexamethasone in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy.

2 . Criteria

Product Name: Akynzeo capsules	
Guideline Type	Part B

Approval Criteria

1 - Oral anti-emetic drug administered with cancer chemotherapy treatment that is initiated within 2 hours of the administration of the chemotherapy and continued for a period not to exceed 48 hours from that time

AND

2 - Oral anti-emetic drug is used as a full therapeutic replacement for IV anti-emetic drugs that would have been administered at the time of the cancer chemotherapy treatment

AND

3 - Used in combination with oral dexamethasone [2]

AND

4 - Patient is receiving one of the following anti-cancer chemotherapeutic agents:

- Alemtuzumab
- Azacitidine
- Bendamustine
- Carboplatin
- Carmustine
- Cisplatin
- Clofarabine
- Cyclophosphamide
- Cytarabine
- Dacarbazine
- Daunorubicin
- Doxorubicin
- Epirubicin
- Idarubicin
- Ifosfamide

- Irinotecan
- Lomustine
- Mechlorethamine
- Oxaliplatin
- Streptozocin

Product Name: Akynzeo capsules	
Approval Length	12 month(s)
Guideline Type	Part D

Approval Criteria

1 - Patient does not meet criteria for Part B above

AND

2 - Used for the prevention of nausea and vomiting associated with cancer chemotherapy

AND

3 - Used in combination with dexamethasone

3 . References

1. Akynzeo capsules prescribing information. Helsinn Therapeutics (U.S.), Inc. Iselin, NJ. January 2021.
2. Centers for Medicare & Medicaid Services. Local Coverage Article: Oral Antiemetic Drugs (Replacement for Intravenous Antiemetics) (A52480). Available at: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33827. Accessed February 9, 2022.

4 . Revision History

Date	Notes
8/11/2023	2024 Medicare Implementation - No Changes

Prior Authorization Guideline

Guideline Name Anti-Parkinson's Agents

Formulary 2024 Samaritan Advantage Health Plans (HMO)

Formulary Note

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	
P&T Revision Date:	4/19/2023

1 . Indications

Drug Name: Benztropine mesylate
Parkinsonism Indicated for use as an adjunct in the therapy of all forms of parkinsonism. Useful also in the control of extrapyramidal disorders (except tardive dyskinesia) due to neuroleptic drugs (e.g., phenothiazines).
Drug Name: Duopa (carbidopa and levodopa) enteral suspension

Parkinson's Disease Indicated for the treatment of motor fluctuations in patients with advanced Parkinson's disease.
Drug Name: Trihexyphenidyl hydrochloride
Parkinsonism Indicated as an adjunct in the treatment of all forms of parkinsonism (postencephalitic, arteriosclerotic, and idiopathic). It is often useful as adjuvant therapy when treating these forms of parkinsonism with levodopa. Additionally, it is indicated for the control of extrapyramidal disorders caused by central nervous system drugs such as the dibenzoxazepines, phenothiazines, thioxanthenes, and butyrophenones.

2 . Criteria

Product Name: Duopa [2, B]	
Guideline Type	Part B

Approval Criteria

1 - Drug is administered using an infusion pump*

AND

2 - Infusion pump paid for by Medicare*

AND

3 - Drug is administered at home (not including facility providing skilled nursing care)

AND

4 - Diagnosis of idiopathic Parkinson's disease [3]

AND

5 - Diagnosis confirmed by the presence of both of the following: [3]

- Bradykinesia
- One other cardinal Parkinson's disease feature (tremor, rigidity, postural instability)

AND

6 - Patient is levodopa responsive with clearly defined "On" periods [3]

AND

7 - Persistent motor complications with disabling "Off" periods for a minimum of 3 hours/day [3]

AND

8 - Disabling "Off" periods occur despite medical therapy with both of the following: [3]

- Levodopa-carbidopa
- One other class of anti-Parkinson's disease therapy (ie, COMT inhibitor or MAO-B inhibitor)

AND

9 - Patient has been evaluated by a neurologist, who prescribes and manages treatment with Duopa [3]

Notes	*If the infusion pump AND the drug administered via that pump are not covered by Part B, then consideration of coverage for the drug is done under Part D pursuant to Part D formulary. [2, A]

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

Approval Criteria

1 - One of the following:

1.1 Patient does not meet criteria for Part B coverage above

OR

1.2 Patient is in a long-term care facility (e.g., hospital or skilled nursing facility where patient is receiving skilled care)*

AND

2 - Diagnosis of Parkinson's disease

AND

3 - Patient is levodopa-responsive [1, 5, C, D]

AND

4 - Patient experiences disabling "Off" periods for a minimum of 3 hours/day [1, 5, D]

AND

5 - Disabling "Off" periods occur despite therapy with both of the following: [1, 5, C, E]

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

AND

6 - Prescribed by or in consultation with a neurologist

Notes	*Long term care facility includes the following: a) hospital, b) skilled nu rsing facility (SNF) or a distinct part SNF, c) a nursing home that is du

	ally certified as both Medicare SNF and a Medicaid nursing facility, d) a Medicaid only nursing facility that primarily furnishes skilled care, e) a non-participating nursing home (neither Medicaid or Medicare) that provided primarily skilled care, and f) an institution that has a distinct p art SNF and which also primarily furnishes skilled care. [4]

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

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: benztropine, trihexyphenidyl	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient age is less than 65 years

OR

1.2 All of the following:

1.2.1 One of the following:

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

OR

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

AND **1.2.2** The prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication	
Notes	Please check the formulary status of the drug. If the product is NON-FORMULARY, please use the Medicare Part D non-formulary administrative guideline.

3 . Endnotes

A. The fact that coverage is available for a particular drug under Part B with the use of an infusion pump does not mean that coverage under Part D using some other method of administration automatically can be denied. There is no Part B coverage in the home for infusion drugs administered without an infusion pump (e.g., IV push). There is also no Part B coverage in the home for infusion drugs administered with an infusion pump unless the drug is specifically covered under the local coverage policy of the applicable Medicare DME MAC. Therefore, determinations about Part D sponsor payment for these other methods of administration and for drugs administered with an infusion pump but not covered by the local DME MAC policy should be based on the question of whether the drug is on the sponsor's formulary. [2]

B. Drugs that require administration by the use of a piece of covered DME (eg, a nebulizer, external or implantable pump) are covered under Part B. The statute does not explicitly cover DME drugs; they are covered as a supply necessary for the DME to perform its function. Examples of such drugs include: (1) inhalation drugs that are administered in the home through the use of a nebulizer (e.g., albuterol sulfate, ipratropium bromide); or (2) drugs for which administration with an infusion pump in the home is medically necessary (eg, some chemotherapeutic agents). [2]

C. The efficacy of Duopa was established in a randomized, double-blind, double-dummy, active controlled, parallel group, 12-week study in patients with advanced Parkinson's disease who were levodopa-responsive and had persistent motor fluctuations while on treatment with oral immediate-release carbidopa-levodopa and other Parkinson's disease medications. [1, 5]

D. Patients were eligible for participation in the studies if they were experiencing 3 hours or more of "Off" time on their current Parkinson's disease drug treatment and they demonstrated a clear responsiveness to treatment with levodopa. [1, 5]

E. Most patients (89%) were taking at least one concomitant medication for Parkinson's disease (e.g., dopaminergic agonist, COMT-inhibitor, MAO B inhibitor) in addition to oral immediate-release carbidopa-levodopa. [1, 5]

4 . References

1. Duopa Prescribing Information. AbbVie Inc. North Chicago, IL. December 2019.
2. Medicare Prescription Drug Benefit Manual. Chapter 6-Part D drugs and formulary requirements. Available at:https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. Accessed January 28, 2021.
3. Local Coverage Determination (LCD) for External Infusion Pumps (L33794). Available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33794&ver=121&keyword=infusion%20pumps&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1. Accessed January 18, 2022.
4. Centers for Medicaid & Medicare Services. Medicare Parts B/D Coverage Issues. Available at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/PartsBDCoverageSummaryTable_041806.pdf. Accessed January 18, 2022.
5. Olanow CW, Kieburtz K, Odin P, et al. Continuous intrajejunal infusion of levodopa-carbidopa intestinal gel for patients with advanced Parkinson's disease: a randomised, controlled, double-blind, double-dummy study. Lancet Neurol. 2014 Feb;13(2):141-9.
6. Benztropine Prescribing Information. Cipla USA, Inc. Warren, NJ. May 2020.
7. Trihexyphenidyl Prescribing Information. Mikart, LLC. Atlanta, GA. July 2019.

5 . Revision History

Date	Notes
8/18/2023	2024 Medicare Implementation - No Changes

Prior Authorization Guideline

Guideline Name Blincyto (blinatumomab)

Formulary 2024 Samaritan Advantage Health Plans (HMO)

Formulary Note

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	2/18/2015
P&T Revision Date:	4/19/2023

1 . Indications

Drug Name: Blincyto (blinatumomab)
Minimal residual disease (MRD)-positive B-cell precursor ALL Indicated for the treatment of CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1% in adults and children. This indication is approved under accelerated approval based on MRD response rate and hematological relapse-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) Indicated for the treatment of relapsed or refractory CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) in adults and children.

2 . Criteria

Product Name: Blincyto* [A]	
Diagnosis	All Indications
Guideline Type	Part B

Approval Criteria

1 - Drug is administered using an infusion pump*

AND

2 - Infusion pump paid for by Medicare*

AND

3 - Drug is administered at home (not including facility providing skilled nursing care)

AND

4 - One of the following:

4.1 For patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) (ICD-10 diagnosis code C91.02) [4]

OR

4.2 For patients with B-cell precursor ALL in first or second complete remission with minimal residual disease greater than or equal to 0.1% (ICD-10 diagnosis code C91.01)

Notes	Please refer to local coverage determination. *If the infusion pump AND the drug administered via that pump are not covered by Part B, then consideration of coverage for the drug is done under Part D pursuant to Part D formulary. [3, B]

Product Name: Blincyto*	
Diagnosis	Relapsed or Refractory B-Cell Precursor Acute Lymphoblastic Leukemia (ALL)
Approval Length	12 Month [C]
Guideline Type	Part D Prior Authorization - Applies to New Starts Only

Approval Criteria

1 - One of the following:

1.1 Patient does not meet criteria for Part B coverage above

OR

1.2 Patient is in a long-term care facility (e.g., hospital or skilled nursing facility where patient is receiving skilled care)**

AND

2 - One of the following

2.1 Both of the following:

2.1.1 Diagnosis of relapsed or refractory CD19-positive B-cell precursor acute lymphoblastic leukemia/acute lymphoblastic lymphoma [D]

AND

2.1.2 Prescribed by or in consultation with a hematologist/oncologist

OR

2.2 For continuation of prior therapy

Notes	*Prior Authorization may not apply depending on the plan. **Long ter m care facility includes the following: a) hospital, b) skilled nursing faci lity (SNF) or a distinct part SNF, c) a nursing home that is dually certifi ed as both Medicare SNF and a Medicaid nursing facility, d) a Medicai d only nursing facility that primarily furnishes skilled care, e) a non-par ticipating nursing home (neither Medicaid or Medicare) that provided p rimarily skilled care, and f) an institution that has a distinct part SNF a nd which also primarily furnishes skilled care. [5]

Product Name: Blincyto*	
Diagnosis	Minimal Residual Disease (MRD)-Positive B-cell Precursor Acute Lymphoblastic Leukemia (ALL)
Approval Length	6 Month [E]
Guideline Type	Part D Prior Authorization - Applies to New Starts Only

Approval Criteria

1 - One of the following:

1.1 Patient does not meet criteria for Part B coverage above

OR

1.2 Patient is in a long-term care facility (e.g., hospital or skilled nursing facility where patient is receiving skilled care)**

AND

2 - One of the following:

2.1 All of the following:

2.1.1 Diagnosis of CD19-positive B-cell precursor ALL [D]

AND

2.1.2 Patient is in their first or second complete remission

AND **2.1.3** Documentation of MRD greater than or equal to 0.1% **AND** **2.1.4** Prescribed by or in consultation with a hematologist/oncologist **OR** **2.2** For continuation of prior therapy	
Notes	*Prior Authorization may not apply depending on the plan. **Long term care facility includes the following: a) hospital, b) skilled nursing facility (SNF) or a distinct part SNF, c) a nursing home that is dually certified as both Medicare SNF and a Medicaid nursing facility, d) a Medicaid only nursing facility that primarily furnishes skilled care, e) a non-participating nursing home (neither Medicaid or Medicare) that provided primarily skilled care, and f) an institution that has a distinct part SNF and which also primarily furnishes skilled care. [5]

3 . Endnotes

A. Drugs that require administration by the use of a piece of covered DME (eg, a nebulizer, external or implantable pump) are covered under Part B [3]. The statute does not explicitly cover DME drugs; they are covered as a supply necessary for the DME to perform its function. Examples of such drugs include: (1) inhalation drugs that are administered in the home through the use of a nebulizer (e.g., albuterol sulfate, ipratropium bromide); or (2) drugs for which administration with an infusion pump in the home is medically necessary (eg, some chemotherapeutic agents). In the case of a beneficiary in a hospital, or a SNF bed, (1) who does not have Part A coverage, (2) whose Part A coverage for the stay has run out, or (3) whose stay is non-covered, infusible DME supply drugs are not covered under Part B because the law limits coverage under Part B's DME benefit to those items that are furnished for use in a patient's home, and specifies that a hospital or SNF cannot be considered the beneficiary's “home” for this purpose. In this case, coverage for the drugs would be available under Part D.
B. The fact that coverage is available for a particular drug under Part B with the use of an infusion pump does not mean that coverage under Part D using some other method of

administration automatically can be denied. There is no Part B coverage in the home for infusion drugs administered without an infusion pump (e.g., IV push). There is also no Part B coverage in the home for infusion drugs administered with an infusion pump unless the drug is specifically covered under the local coverage policy of the applicable Medicare DME MAC. Therefore, determinations about Part D sponsor payment for these other methods of administration and for drugs administered with an infusion pump but not covered by the local DME MAC policy should be based on the question of whether the drug is on the sponsor's formulary. [3]

C. A single cycle of treatment of Blincyto consists of 4 weeks of continuous intravenous infusion, followed by a 2-week treatment-free interval. A treatment course consists of up to 2 cycles of Blincyto for induction, followed by 3 additional cycles for consolidation treatment (up to a total of 5 cycles). [1]
D. The World Health Organization (WHO) 2008 classification lists acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma as the same entity, distinguished only by the primary location of the disease. Patients with lymphoblastic lymphoma generally benefit from treatment with ALL-like regimens. [2]
E. For MRD-positive B-cell precursor ALL, a treatment course consists of 1 cycle for induction followed by up to 3 additional cycles for consolidation (up to a total of 4 cycles). Each cycle consists of a total of 42 days (28 days of treatment and 14 days of treatment-free interval). [1]

4 . References

1. Blincyto Prescribing Information. Amgen, Inc. Thousand Oaks, CA. February 2022.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Acute Lymphoblastic Leukemia v1.2020. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed February 24, 2020.
3. Centers for Medicaid & Medicare Services. Medicare Prescription Drug Benefit Manual. Chapter 6 - Appendix C - Summary of Coverage Policy: Medicare Part B Versus Part D Coverage Issues. Available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. Accessed February 24, 2020.
4. Local Coverage Determination (LCD) for External Infusion Pumps (L33794). Available at: http://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed February 9, 2023.
5. Centers for Medicaid & Medicare Services. Medicare Parts B/D Coverage Issues. Available at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/PartsBDCoverageSummaryTable_041806.pdf. Accessed February 24, 2020.

5 . Revision History

Date	Notes
8/30/2023	2024 Guideline Loading created from HPMS Submission file

Prior Authorization Guideline

Guideline Name Brovana (arformoterol)

Formulary 2024 Samaritan Advantage Health Plans (HMO)

Formulary Note

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	
P&T Revision Date:	4/19/2023

1 . Indications

Drug Name: Brovana (arformoterol) inhalation solution
Maintenance treatment of chronic obstructive pulmonary disease (COPD) Indicated for the long-term, twice daily (morning and evening) maintenance treatment of bronchoconstriction in patients with COPD, including chronic bronchitis and emphysema. Brovana inhalation solution is for use by nebulization only. Important Limitations of Use: Brovana is not indicated to treat acute deteriorations of COPD. Brovana is not indicated to treat asthma. The safety and effectiveness of Brovana in asthma have not been established.
Drug Name: Arformoterol tartrate inhalation solution

Maintenance Treatment of chronic obstructive pulmonary disease (COPD Indicated for the long-term, twice daily (morning and evening) maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. Arformoterol tartrate inhalation solution is for use by nebulization only. Important Limitations of Use: Arformoterol tartrate inhalation solution is not indicated to treat acute deteriorations of COPD. Arformoterol tartrate inhalation solution is not indicated to treat asthma. The safety and effectiveness of arformoterol tartrate inhalation solution in asthma have not been established.

2 . Criteria

Product Name: Brand Brovana inhalation solution, generic arformoterol inhalation solution	
Guideline Type	Part B
Approval Criteria **1** - Drug is administered using a nebulizer* **AND** **2** - Drug is administered at home (not including facility providing skilled nursing care) **AND** **3** - For patients with obstructive pulmonary disease** [2]	
Notes	*Please refer to relevant local coverage determinations for more information. **ICD-10 codes for obstructive pulmonary disease: J41.0, J41.1, J41.8, J42, J43.0, J43.1, J43.2, J43.8, J43.9, J44.0, J44.1, J44.9, J45, J45.2, J45.20, J45.21, J45.22, J45.3, J45.30, J45.31, J45.32, J45.4, J45.40, J45.41, J45.42, J45.5, J45.50, J45.51, J45.52, J45.9, J45.901, J45.902, J45.909, J45.99, J45.990, J45.991, J45.998, J47.0, J47.1, J47.9, J60, J61, J62.0, J62.8, J63.0, J63.1, J63.2, J63.3, J63.4, J63.5, J63.6, J64, J65, J66.0, J66.1, J66.2, J66.8, J67.0, J67.1, J67.2, J67.3, J67.4, J67.5, J67.6, J67.7, J67.8, J67.9, J68.0, J68.1, J68.2, J68.3, J68.4, J68.8, J68.9, J69.0, J69.1, J69.8, J70.0, J70.1, J70.2, J70.3, J70.4, J70.5, J70.8, J70.9.

Product Name: generic arformoterol inhalation solution	
Approval Length	12 month(s)
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient does not meet criteria for Part B coverage above

OR

1.2 Patient is in a long-term care facility (eg, hospital or skilled nursing facility where patient is receiving skilled nursing care)**

AND

2 - Diagnosis of chronic obstructive pulmonary disease (COPD)

AND

3 - Used for maintenance treatment of bronchoconstriction in patients with COPD, including chronic bronchitis and emphysema

Notes	**Long term care facility includes the following: a) hospital, b) skilled nursing facility (SNF) or a distinct part SNF, c) a nursing home that is dually certified as both Medicare SNF and a Medicaid nursing facility, d) a Medicaid only nursing facility that primarily furnishes skilled care, e) a non-participating nursing home (i.e., neither Medicaid nor Medicare) that provides primarily skilled care, and f) an institution which has a distinct part SNF and which also primarily furnishes skilled care. [3, 4]

Product Name: Brand Brovana inhalation solution	
Approval Length	12 month(s)
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient does not meet criteria for Part B coverage above

OR

1.2 Patient is in a long-term care facility (eg, hospital or skilled nursing facility where patient is receiving skilled nursing care)**

AND

2 - Diagnosis of chronic obstructive pulmonary disease (COPD)

AND

3 - Used for maintenance treatment of bronchoconstriction in patients with COPD, including chronic bronchitis and emphysema

AND

4 - Trial and failure, contraindication, or intolerance to Perforomist (formoterol fumarate)

Notes	**Long term care facility includes the following: a) hospital, b) skilled nursing facility (SNF) or a distinct part SNF, c) a nursing home that is dually certified as both Medicare SNF and a Medicaid nursing facility, d) a Medicaid only nursing facility that primarily furnishes skilled care, e) a non-participating nursing home (i.e., neither Medicaid nor Medicare) that provides primarily skilled care, and f) an institution which has a distinct part SNF and which also primarily furnishes skilled care. [3, 4]

3 . References

1. Brovana Prescribing Information. Sunovion Pharmaceuticals, Inc. Marlborough, MA. May 2021.
2. Centers for Medicaid & Medicare Services. Medicare Coverage Database. Available at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Accessed August 24, 2021.

3. Centers for Medicaid & Medicare Services. Medicare Part B/D Coverage Issues. http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/BvsDCoverageIssues.pdf. Accessed August 4, 2021.
4. Centers for Medicaid & Medicare Services. Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements. http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter6.pdf. Accessed September 12, 2019.
5. Arformoterol Prescribing Information. Glenmark Pharmaceuticals Inc., USA. Mahwah, NJ . December 2020.

4 . Revision History

Date	Notes
8/15/2023	2024 Medicare Implementation - No Changes

Prior Authorization Guideline

Guideline Name Cannabinoids

Formulary 2024 Samaritan Advantage Health Plans (HMO)

Formulary Note

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	
P&T Revision Date:	4/19/2023

1 . Indications

Drug Name: Marinol (dronabinol) capsule, Syndros (dronabinol) oral solution
Chemotherapy-induced nausea and vomiting Indicated in adults for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments. **Anorexia in patients with AIDS** Indicated in adults for the treatment of anorexia associated with weight loss in patients with Acquired Immune Deficiency Syndrome (AIDS).

2 . Criteria

Product Name: Generic dronabinol, Brand Marinol, or Syndros	
Guideline Type	Part B

Approval Criteria

1 - Oral anti-emetic drug administered with chemotherapy treatment that is initiated within 2 hours of the administration of chemotherapy and continued for a period not to exceed 48 hours from that time [1, 4-7]

AND

2 - Oral anti-emetic drug is used as a full therapeutic replacement for IV anti-emetic drugs that would have been administered at the time of the chemotherapy treatment [1, 4-7]

Product Name: Brand Marinol, Generic dronabinol, or Syndros	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	6 month(s)
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Patient does not meet criteria for Part B above

AND

1.1.2 Patient is receiving cancer chemotherapy

AND

1.1.3 Trial and failure, contraindication, or intolerance to one 5HT-3 receptor antagonist (e.g., Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]) [3]

AND

1.1.4 Trial and failure, contraindication, or intolerance to one of the following: [3]

- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Zyprexa (olanzapine)

OR

1.2 Both of the following:

1.2.1 As continuation of therapy for treatment covered under Part B

AND

1.2.2 Patient is receiving cancer chemotherapy

Product Name: Brand Marinol, Generic dronabinol, or Syndros	
Diagnosis	Anorexia in Patients with AIDS
Approval Length	3 month(s)
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Diagnosis of anorexia with weight loss in patients with AIDS

AND

2 - Patient is on antiretroviral therapy [8, 9]

Product Name: Generic dronabinol*, Brand Marinol*, or Syndros*	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	6 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Quantity requests exceeding the limited amount will be evaluated on an individual basis by a clinical pharmacist for patients on ongoing chemotherapy

Notes	*Quantity limit may not apply depending on the plan.

Product Name: Generic dronabinol* (2.5 mg, 5 mg), Brand Marinol* (2.5 mg, 5 mg)	
Diagnosis	Anorexia with weight loss in patients with AIDS and All other diagnoses - for requests less than or equal to the maximum dose specified in the prescribing information
Approval Length	3 month(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 For titration purposes

OR

2.2 Requested strength/dose is commercially unavailable

OR

2.3 Patient is on a dose alternating schedule

OR

2.4 There is a medically necessary justification why patient cannot use a higher commercially available strength to achieve the same dosage and remain within the same dosing frequency (e.g., patient requires smaller tablet size)

Notes	*Quantity limit may not apply depending on the plan. Not to exceed m aximum FDA-approved dose.

Product Name: Generic dronabinol*, Brand Marinol*, or Syndros*	
Diagnosis	Anorexia with weight loss in patients with AIDS and All other diagnoses - for requests greater than the maximum dose specified in the prescribing information
Approval Length	3 month(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** Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information **OR** **2.2** Higher dose or quantity is supported by one of the two Medicare approved compendia: • American Hospital Formulary Service Drug Information • DRUGDEX Information System

Notes	*Quantity limit may not apply depending on the plan. **Published biomedical literature may be used as evidence to support safety and additional efficacy at higher than maximum doses for the diagnosis provided.

3 . References

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6. Medicare Prescription Drug Benefit Manual, Chapter 6 - Part D Drugs and Formulary Requirements. Available at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. Accessed March 9, 2022.
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4 . Revision History

Date	Notes
8/15/2023	2024 Medicare Implementation - No Changes

Prior Authorization Guideline

Guideline Name Cyclophosphamide and Methotrexate 2.5 mg Part B v D

Formulary 2024 Samaritan Advantage Health Plans (HMO)

Formulary Note

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	
P&T Revision Date:	4/19/2023

1 . Criteria

Product Name: Cyclophosphamide capsule/tablet, generic methotrexate 2.5 mg tablet	
Guideline Type	Part B
Approval Criteria **1** - One of the following:	

1.1 For patients who are being treated for a cancer that has the same indications, including unlabeled uses*, as the non-self-administered (e.g., intravenous) product. [A]

OR

1.2 For patients who were enrolled in Medicare Part A at the time of the organ transplant, whether or not Medicare paid for the transplant (i.e., heart, lung, kidney, liver, intestinal, kidney-pancreas transplant, bone marrow/stem cell transplant)

Product Name: Cyclophosphamide capsule/tablet	
Guideline Type	Part D

Approval Criteria

1 - For patients who are not being treated for cancer [A]

AND

2 - One of the following:

2.1 Diagnosis of Nephrotic Syndrome in children

OR

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

Product Name: Generic methotrexate 2.5 mg tablet	
Guideline Type	Part D

Approval Criteria

1 - For patients who are not being treated for cancer [A]

AND

2 - One of the following:

2.1 Diagnosis of one of the following:

- Psoriasis
- Rheumatoid arthritis
- Polyarticular-course juvenile rheumatoid arthritis

OR

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

2 . Endnotes

A. For an oral anti-cancer drug to be covered under Part B, it must 1) be prescribed by a physician or other practitioner licensed under State law to prescribe such drugs as anti-cancer chemotherapeutic agents; 2) Be a drug or biological that has been approved by the Food and Drug Administration (FDA); 3) Have the same active ingredients as a non-self-administrable anti-cancer chemotherapeutic drug or biological that is covered when furnished incident to a physician's service. The oral anti-cancer drug and the non-self-administrable drug must have the same chemical/generic name as indicated by the FDA's "Approved Drug Products" (Orange Book), "Physician's Desk Reference" (PDR), or an authoritative drug compendium; 4) Be used for the same indications, including unlabeled uses, as the non-self-administrable version of the drug; and 5) Be reasonable and necessary for the individual patient. [1] The following drugs are generally considered Part D exclusions and may not be reviewed for Part D coverage for cancer chemotherapy: Alkeran (melphalan), Hycamtin (topotecan), Temodar (temozolomide), Vepesid (etoposide), Xeloda (capecitabine). For non-cancer indications, the Part D off-label policy may be applied.

3 . References

1. Centers for Medicaid & Medicare services. Medicare Benefit Policy Manual. Chapter 15 – Covered Medical and Other Services. Section 50.5.3. http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf. Accessed July 30, 2019.

4 . Revision History

Date	Notes
8/11/2023	2024 Medicare Implementation - No Changes

Prior Authorization Guideline

Guideline Name Durable Medical Equipment (DME) Supply Drugs (Inhalation Solutions)

Formulary 2024 Samaritan Advantage Health Plans (HMO)

Formulary Note

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	
P&T Revision Date:	4/19/2023

1 . Indications

Drug Name: AccuNeb (albuterol 0.63 mg/3 mL, 1.25 mg/3 mL) inhalation solution
Bronchospasm Indicated for the relief of bronchospasm in patients 2 to 12 years of age with asthma (reversible obstructive airway disease).
Drug Name: Albuterol (0.083%, 0.5%) inhalation solution
Bronchospasm Indicated for the relief of bronchospasm in patients 2 years of age and older with reversible obstructive airway disease and acute attacks of bronchospasm.

Drug Name: Acetylcysteine inhalation solution
Abnormal, viscid, or inspissated mucous secretions Indicated as adjuvant therapy for patients with abnormal, viscid, or inspissated mucous secretions in such conditions as: chronic bronchopulmonary disease (chronic emphysema, emphysema with bronchitis, chronic asthmatic bronchitis, tuberculosis, bronchiectasis and primary amyloidosis of the lung), acute bronchopulmonary disease (pneumonia, bronchitis, tracheobronchitis), pulmonary complications of cystic fibrosis, tracheostomy care, pulmonary complications associated with surgery, use during anesthesia, post-traumatic chest conditions, atelectasis due to mucous obstruction, diagnostic bronchial studies (bronchograms, bronchospirometry, and bronchial wedge catheterization).
Drug Name: Bethkis (tobramycin) inhalation solution
Management of cystic fibrosis Indicated for the management of cystic fibrosis patients with Pseudomonas aeruginosa. Safety and efficacy have not been demonstrated in patients under the age of six years, patients with FEV1 less than 40% or greater than 80% predicted, or patients colonized with Burkholderia cepacia
Drug Name: Cromolyn inhalation solution
Bronchial asthma Indicated in the management of patients with bronchial asthma. In patients whose symptoms are sufficiently frequent to require a continuous program of medication, cromolyn sodium is given by inhalation on a regular daily basis. The effect of cromolyn sodium is usually evident after several weeks of treatment, although some patients show an almost immediate response. In patients who develop acute bronchoconstriction in response to exposure to exercise, toluene diisocyanate, environmental pollutants, etc., cromolyn sodium should be given shortly before exposure to the precipitating factor.
Drug Name: Duoneb (ipratropium/albuterol) inhalation solution
Bronchospasm Indicated for the treatment of bronchospasm associated with COPD in patients requiring more than one bronchodilator.
Drug Name: Ipratropium inhalation solution
Bronchospasm Indicated as a bronchodilator for maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema.
Drug Name: Kitabis Pak (tobramycin) inhalation solution
Management of Cystic Fibrosis Indicated for the management of cystic fibrosis in adults and pediatric patients 6 years of age and older with P. aeruginosa. Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with FEV1 <25% or >75% predicted, or patients colonized with Burkholderia cepacia.
Drug Name: NebuPent (pentamidine) inhalation solution

Pneumocystis jiroveci pneumonia (PJP) Indicated for the prevention of Pneumocystis jiroveci pneumonia (PJP) in high-risk, HIV-infected patients defined by one or both of the following criteria: (i) a history of one or more episodes of PJP, (ii) a peripheral CD4+ (T4 helper/inducer) lymphocyte count less than or equal to 200/mm3. These indications are based on the results of an 18-month randomized, dose-response trial in high risk HIV-infected patients and on existing epidemiological data from natural history studies.
Drug Name: Nebusal (sodium chloride) inhalation solution, HyperSal (sodium chloride) inhalation solution
Sputum production Used in conjunction with a nebulizer for the induction of sputum production where sputum production is indicated.
Drug Name: Pentamidine inhalation solution
Pneumocystis jiroveci pneumonia (PJP) Pentamidine Isethionate is indicated for the prevention of Pneumocystis jiroveci pneumonia (PJP) in high-risk, HIV-infected patients defined by one or both of the following criteria: (I) a history of one or more episodes of PJP (ii) a peripheral CD4+ (T4 helper/inducer) lymphocyte count less than or equal to 200/mm3.
Drug Name: Perforomist (formoterol) inhalation solution
Maintenance treatment of chronic obstructive pulmonary disease (COPD) Indicated for the long term, twice daily (morning and evening) administration in the maintenance treatment of bronchoconstriction in patients with COPD, including chronic bronchitis and emphysema. Important limitations of use: Perforomist is not indicated to treat acute deteriorations of COPD. Perforomist is not indicated to treat asthma. The safety and effectiveness of Perforomist in asthma have not been established.
Drug Name: Pulmicort Respules (budesonide) inhalation suspension
Maintenance treatment of asthma Indicated for the maintenance treatment of asthma and as prophylactic therapy in children 12 months to 8 years of age. Important limitations of use: Pulmicort Respules is not indicated for the relief of acute bronchospasm.
Drug Name: TOBI (tobramycin) inhalation solution
Management of Cystic Fibrosis Indicated for the management of cystic fibrosis patients with P. aeruginosa. Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with forced expiratory volume in 1 second (FEV1) <25% or >75% predicted, or patients colonized with Burkholderia cepacia.
Drug Name: Xopenex (levalbuterol) inhalation solution
Bronchospasm Indicated for the treatment or prevention of bronchospasm in adults, adolescents, and children 6 years of age and older with reversible obstructive airway disease.
Drug Name: Yupelri (revefenacin) inhalation solution

Maintenance treatment of chronic obstructive pulmonary disease (COPD) Indicated for the maintenance treatment of patients with COPD.

2 . Criteria

Product Name: Bethkis Inhalation Solution, Kitabis Pak Inhalation Solution, Brand TOBI Inhalation Solution, Generic tobramycin inhalation solution	
Guideline Type	Part B
Approval Criteria **1** - Drug is administered using a nebulizer* **AND** **2** - Drug is administered at home (not including facility providing skilled nursing care)** **AND** **3** - For patients with cystic fibrosis or bronchiectasis (ICD-10 diagnosis code E84.0, J47.9, J47.1, J47.0, Q33.4, A15.0)	
Notes	*Please refer to relevant local coverage determinations for more infor mation. **Please refer to the PRC code in RxClaims for the nebulizer solution prior to asking prescriber where the member is administering the drug. PRC 03 and 09 are long term care facility locations.

Product Name: Brand Accuneb inhalation solution, Generic albuterol inhalation solution, Generic budesonide inhalation suspension, cromolyn inhalation solution, Brand DuoNeb inhalation solution, ipratropium inhalation solution, Generic ipratropium/albuterol inhalation solution, Generic levalbuterol inhalation solution, Brand Perforomist inhalation solution, Generic formoterol inhalation solution, Brand Pulmicort Respules inhalation suspension, Brand Xopenex inhalation solution, or Yupelri inhalation solution	
Guideline Type	Part B
Approval Criteria	

1 - Drug is administered using a nebulizer*

AND

2 - Drug is administered at home (not including facility providing skilled nursing care)**

AND

3 - For patients with obstructive pulmonary disease*** [3]

AND

4 - Drug is NOT a compounded nebulizer solution [3]

Notes	*Please refer to relevant local coverage determinations for more information. **Please refer to the PRC code in RxClaims for the nebulizer solution prior to asking prescriber where the member is administering the drug. PRC 03 and 09 are long term care facility locations. ***ICD-10 codes for obstructive pulmonary disease: J41.0, J41.1, J41.8, J42, J43.0, J43.1, J43.2, J43.8, J43.9, J44.0, J44.1, J44.9, J45, J45.2, J45.20, J45.21, J45.22, J45.3, J45.30, J45.31, J45.32, J45.4, J45.40, J45.41, J45.42, J45.5, J45.50, J45.51, J45.52, J45.9, J45.901, J45.902, J45.909, J45.99, J45.990, J45.991, J45.998, J47.0, J47.1, J47.9, J60, J61, J62.0, J62.8, J63.0, J63.1, J63.2, J63.3, J63.4, J63.5, J63.6, J64, J65, J66.0, J66.1, J66.2, J66.8, J67.0, J67.1, J67.2, J67.3, J67.4, J67.5, J67.6, J67.7, J67.8, J67.9, J68.0, J68.1, J68.2, J68.3, J68.4, J68.8, J68.9, J69.0, J69.1, J69.8, J70.0, J70.1, J70.2, J70.3, J70.4, J70.5, J70.8, J70.9.

Product Name: Acetylcysteine inhalation solution	
Guideline Type	Part B

Approval Criteria

1 - Drug is administered using a nebulizer*

AND

2 - Drug is administered at home (not including facility providing skilled nursing care)**

AND

3 - For patients with persistent thick or tenacious pulmonary secretions*** [3]

AND

4 - Drug is NOT a compounded nebulizer solution [3]

Notes	*Please refer to relevant local coverage determinations for more information. **Please refer to the PRC code in RxClaims for the nebulizer solution prior to asking prescriber where the member is administering the drug. PRC 03 and 09 are long term care facility locations. ***ICD-10 codes for persistent thick or tenacious pulmonary secretions: A22.1, A37.01, A37.11, A37.81, A37.91, A48.1, B25.0, B44.0, B77.81, E84.0, J09.X1, J09.X2, J09.X3, J09.X9, J10.00, J10.01, J10.08, J10.1, J10.2, J10.81, J10.82, J10.83, J10.89, J11.00, J11.08, J11.1, J11.2, J11.81, J11.82, J11.83, J11.89, J12.0, J12.1, J12.2, J12.3, J12.81, J12.89, J12.9, J13, J14, J15.0, J15.1, J15.20, J15.211, J15.212, J15.29, J15.3, J15.4, J15.5, J15.6, J15.7, J15.8, J15.9, J16.0, J16.8, J18.0, J18.1, J18.8, J18.9, J40, J41.0, J41.1, J41.8, J42, J43.0, J43.1, J43.2, J43.8, J43.9, J44.0, J44.1, J44.9, J45.20, J45.21, J45.22, J45.30, J45.31, J45.32, J45.40, J45.41, J45.42, J45.50, J45.51, J45.52, J45.901, J45.902, J45.909, J45.990, J45.991, J45.998, J47.0, J47.1, J47.9, J60, J61, J62.0, J62.8, J63.0, J63.1, J63.2, J63.3, J63.4, J63.5, J63.6, J64, J65, J66.0, J66.1, J66.2, J66.8, J67.0, J67.1, J67.2, J67.3, J67.4, J67.5, J67.6, J67.7, J67.8, J67.9, J68.0, J68.1, J68.2, J68.3, J68.4, J68.8, J68.9, J69.0, J69.1, J69.8, J70.0, J70.1, J70.2, J70.3, J70.4, J70.5, J70.8, J70.9.

Product Name: NebuPent Inhalation Solution, Generic pentamidine inhalation solution	
Guideline Type	Part B

Approval Criteria

1 - Drug is administered using a nebulizer*

AND

2 - Drug is administered at home (not including facility providing skilled nursing care)**

AND

3 - For patients with HIV, pneumocystosis, or complications of organ transplants*** [3]

AND

4 - Drug is NOT a compounded nebulizer solution [3]

Notes	*Please refer to relevant local coverage determinations for more infor mation. **Please refer to the PRC code in RxClaims for the nebulizer solution prior to asking prescriber where the member is administering the drug. PRC 03 and 09 are long term care facility locations. ***ICD-10 code for HIV: B20; ICD-10 code for pneumocystosis: B59; I CD-10 codes for complications of organ transplants: T86.00, T86.01, T86.02, T86.03, T86.09, T86.10, T86.11, T86.12, T86.13, T86.19, T86 .20, T86.21, T86.22, T86.23, T86.290, T86.298, T86.30, T86.31, T86. 32, T86.33, T86.39, T86.40, T86.41, T86.42, T86.43, T86.49, T86.5, T 86.810, T86.811, T86.812, T86.818, T86.819, T86.830, T86.831, T86. 832, T86.838, T86.839, T86.850, T86.851, T86.852, T86.858, T86.85 9, T86.890, T86.891, T86.892, T86.898, T86.899, T86.90, T86.91, T8 6.92, T86.93, T86.99.

Product Name: Brand HyperSal inhalation solution, Brand Nebusal inhalation solution, or Generic sodium chloride inhalation solution	
Guideline Type	Part B

Approval Criteria

1 - Drug is administered using a nebulizer*

AND

2 - Drug is administered at home (not including facility providing skilled nursing care)**

AND

3 - For patients with cystic fibrosis, bronchiectasis, a tracheostomy, or a tracheobronchial stent*** [3]	
Notes	*Please refer to relevant local coverage determinations for more infor mation. **Please refer to the PRC code in RxClaims for the nebulizer solution prior to asking prescriber where the member is administering the drug. PRC 03 and 09 are long term care facility locations. ***ICD-10 code for cystic fibrosis: E84.0; ICD-10 codes for bronchiect asis: A15.0, J47.0, J47.1, J47.9, Q33.4; ICD-10 codes for tracheosto my: Z43.0, Z93.0; ICD-10 codes for tracheobronchial stent: J39.8, J98 .09.

Product Name: Formulary inhalation solutions or suspensions	
Guideline Type	Part D

Approval Criteria

1 - One of the following:

1.1 Patient does not meet criteria for Part B coverage above

OR

1.2 Patient is in a long-term care facility (eg, hospital or skilled nursing facility where patient is receiving skilled nursing care)**

AND

2 - One of the following:

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

OR

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

Notes	**INTERNAL NOTE: 1) Long term care facility includes the following: a) hospital, b) skilled nursing facility (SNF) or a distinct part SNF, c) a nursing home that is dually certified as both Medicare SNF and a Med icaid nursing facility, d) a Medicaid only nursing facility that primarily fu

	rnishes skilled care, e) a non-participating nursing home (i.e., neither Medicaid nor Medicare) that provides primarily skilled care, and f) an i nstitution which has a distinct part SNF and which also primarily furnis hes skilled care. [1,2] 2) Please refer to the PRC code in RxClaims for the nebulizer solution prior to asking prescriber where the member is administering the drug. PRC 03 and 09 are long term care facility locations. 3) For compounded nebulizer solutions that do not meet Part B criteri a, use the Compound Administrative Guideline.

3 . Background

Benefit/Coverage/Program Information
Durable Medical Equipment (DME) - Part B coverage [1,2] Drugs that require administration by the use of a piece of covered DME (e.g., a nebulizer, external or implantable pump) are covered under Part B. The statute does not explicitly cover DME drugs; they are covered as a supply necessary for the DME to perform its function. Examples of such drugs include: (1) Inhalation drugs that are administered in the home through the use of a nebulizer (e.g., albuterol sulfate, ipratropium bromide); or (2) Drugs for which administration with an infusion pump in the home is medically necessary (e.g., some chemotherapeutic agents). **Inhalation Drugs - Part B coverage [1,2]** Certain inhalation drugs are generally covered under Part B when used with a nebulizer in the home. These drugs would not be covered under Part D for use with a nebulizer. However, if these drugs were delivered with a metered dose inhaler or other non-nebulizer administration, they would be Part D drugs. In the case of a beneficiary, in a hospital, or a SNF bed, (1) who does not have Part A coverage, (2) whose Part A coverage for the stay has run out or (3) whose stay is non-covered -- inhalation DME supply drugs are not covered under Part B because the law limits coverage under Part B's DME benefit to those items that are furnished for use in a patient's home, and specifies that a hospital or SNF cannot be considered the beneficiary's "home" for this purpose. In this case, coverage for the drugs would be available under Part D.

4 . References

1. Centers for Medicaid & Medicare Services. Medicare Part B/D Coverage Issues. http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/BvsDCoverageIssues.pdf. Accessed May 5, 2021.
2. Centers for Medicaid & Medicare Services. Medicare Prescription Drug Benefit Manual Chapter 6 - Part D Drugs and Formulary Requirements.

http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter6.pdf. Accessed May 5, 2021.
3. Centers for Medicaid & Medicare Services. Medicare Coverage Database. Available at: https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52466. Accessed May 5, 2021.
4. Accuneb Prescribing Information. Mylan Pharmaceuticals Inc., January 2013.
5. Albuterol 0.083% Prescribing Information. Bausch & Lomb Incorporated. October 2004.
6. Albuterol 0.5% Prescribing Information. Bausch & Lomb Incorporated. August 2013.
7. Acetylcysteine Prescribing Information. American Regent, Inc., November 2005.
8. Cromolyn Prescribing Information. Cardinal Health, June 2004.
9. Duoneb Prescribing Information. Dey Pharma L.P., June 2012.
10. Ipratropium Prescribing Information. Mylan Pharmaceuticals, Inc. July 2012.
11. Nebupent Prescribing Information. APP Pharmaceuticals, LLC. December 2010.
12. Nebusal Prescribing Information. PharmaCaribe, September 2013.
13. Perforomist Prescribing Information. Mylan Specialty L.P. Morgantown, WV. May 2019.
14. Pulmicort Respules Prescribing Information. AstraZeneca. Wilmington, DE. October 2019.
15. Xopenex Prescribing Information. Akorn, Inc. Lake Forest, IL. December 2018.
16. Xopenex Concentrate Prescribing Information. Akorn, Inc. Lake Forest, IL. December 2018.
17. Bethkis Prescribing Information. Chiesi USA, Inc. Woodstock, IL. December 2019.
18. Kitabis Pak Prescribing Information. Pari Respiratory Equipment, Inc. Midlothian, VA. November 2019.
19. Tobi Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. October 2018.
20. Yupelri Prescribing Information. Mylan Specialty LP. Morgantown, WV. May 2019.
21. Pentamidine Isethionate Prescribing Information. Seton Pharmaceuticals, LLC. Wall, NJ. August 2019.

5 . Revision History

Date	Notes
8/11/2023	2024 Medicare Implementation - No Changes

Prior Authorization Guideline

Guideline Name Emend (aprepitant)

Formulary 2024 Samaritan Advantage Health Plans (HMO)

Formulary Note

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	
P&T Revision Date:	4/19/2023

1 . Indications

Drug Name: Emend (aprepitant)
Prevention of Chemotherapy Induced Nausea and Vomiting (CINV) 1) Emend for oral suspension is indicated in combination with other antiemetic agents, in patients 6 months of age and older for prevention of: (a) acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin; (b) nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC). 2) Emend capsules is indicated in combination with other antiemetic agents, in patients 12 years of age and older for prevention of: (a) acute and delayed nausea and vomiting associated with initial and repeat courses of

highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin; (b) nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC).

Prevention of Postoperative Nausea and Vomiting (PONV)- capsules only Indicated in adults for the prevention of postoperative nausea and vomiting.

2 . Criteria

Product Name: Brand Emend capsules, Generic aprepitant capsules, Brand Emend oral suspension	
Guideline Type	Part B

Approval Criteria

1 - Initiated within 2 hours of the administration of chemotherapy and continued for a period not to exceed 48 hours from that time [5-9]

AND

2 - Used as a full therapeutic replacement for IV anti-emetic therapy that would have been administered at the time of the cancer chemotherapy treatment [5-9]

AND

3 - Used in combination with both of the following: [4,11]

- An oral 5HT3 antagonist (e.g., Anzemet [dolasetron], granisetron, Zofran [ondansetron])
- Oral dexamethasone

AND

4 - Patient is receiving one of the following anti-cancer chemotherapeutic agents:

- Alemtuzumab

- Azacitidine
- Bendamustine
- Carboplatin
- Carmustine
- Cisplatin
- Clofarabine
- Cyclophosphamide
- Cytarabine
- Dacarbazine
- Daunorubicin
- Doxorubicin
- Epirubicin
- Idarubicin
- Ifosfamide
- Irinotecan
- Lomustine
- Mechlorethamine
- Oxaliplatin
- Streptozocin

Product Name: Brand Emend capsules, Generic aprepitant capsules, Brand Emend oral suspension	
Diagnosis	Chemotherapy-Induced Nausea and Vomiting
Approval Length	12 month(s)
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Patient does not meet criteria for Part B above

AND

2 - Used for the prevention of nausea and vomiting associated with cancer chemotherapy

AND

3 - Patient is concurrently on both of the following medications: [1-3,10]

- Dexamethasone

- 5-HT3 receptor antagonist (e.g., Aloxi [palonosetron], Anzemet [dolasetron], granisetron, Zofran [ondansetron])

Product Name: Brand Emend capsules, Generic aprepitant capsules	
Diagnosis	Prevention of Postoperative Nausea and Vomiting
Approval Length	1 month(s)
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Patient does not meet criteria for Part B above

AND

2 - Used for the prevention of postoperative nausea and vomiting when administered prior to the induction of anesthesia [1]

3 . References

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4 . Revision History

Date	Notes
8/11/2023	2024 Medicare Implementation - No Changes

Prior Authorization Guideline

Guideline Name End-Stage Renal Disease (ESRD) Products

Formulary 2024 Samaritan Advantage Health Plans (HMO)

Formulary Note

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	
P&T Revision Date:	04/19/2023 ; 11/16/2023

1 . Criteria

Product Name: Always ESRD-related products*	
Guideline Type	Excluded Use
Approval Criteria **1** - Will be excluded from Part B and Part D coverage for patients with ESRD on dialysis for any indication related or unrelated to treatment of ESRD since the payment for the drug is included in the ESRD PPS payment bundle [8]	

Notes	*See Background section for "Always ESRD-related Products" list.

2 . Background

Clinical Practice Guidelines

Drugs Subject to Consolidated Billing for ESRD PPS [3, 4, 7, B]

Category	HCPCS	Title
Access Management	C9121	INJ ARGATROBAN
	J1642	INJ HEPARIN SODIUM PER 10 U
	J1644	INJ HEPARIN SODIUM PER 1000U
	J1945	LEPIRIDUN
	J2993	RETEPLASE INJECTION
	J2997	ALTEPLASE RECOMBINANT
	J3364	UROKINASE 5000 IU INJECTION
	J3365	UROKINASE 250,000 IU INJ
Anemia Management	J0882	DARBEPOETIN
	J0886	EPO
	J0887	INJ. EPOETIN BETA (FOR ESRD ON DIALYSIS), 1 MCG
	J1439	INJ FERRIC CARBOXYMALTOSE,
	J1750	IRON DEXTRAN
	J1756	IRON SUCROSE INJECTION
	J2916	NA FERRIC GLUCONATE
	J3420	VITAMIN B12 INJECTION
	Q0139	FERUMOXYTOL
	Q9976	INJ. FERRIC PYROPHOSPHATE
	Q4081	EPO
Bone and Mineral Metabolism	J0610	CALCIUM GLUCONATE INJECTION
	J0630	CA CITONIN SALMON INJECTION
	J0635	CALCITRIOL
	J0636	INJ CALCITRIOL PER 0.1 MCG
	J0895	DEFEROXAMINE MESYLATE INJ
	J1270	INJECTION, DOXERCALCIFEROL
	J1740	IBANDRONATE SODIUM
	J2430	PAMIDRONATE DISODIUM /30 MG
	J2501	PARICALCITOL
	J3487	ZOLEDRONIC ACID
	S0169	CALCITRIOL
Cellular Management	J1955	INJ LEVOCARNITINE PER 1 GM

Anti-Infectives	J0879	INJECTION, DIFELIKEFALIN, 0.1
Composite Rate Drugs and Biologicals	A4802	INJ PROTAMINE SULFATE
	J0670	INJ MEPIVACAINE HYDROCHLORIDE
	J1200	INJ DIPHENHYDRAMINE HCL
	J1205	INJ CHLOROTHIAZIDE SODIUM
	J1240	INJ DIMENHYDRINATE
	J1940	INJ FUROSEMIDE
	J2001	INJ LIDOCAINE HCL FOR INTRAVENOUS INFUSION, 10 MG
	J2150	INJ MANNITOL
	J2720	INJ PROTAMINE SULFATE
	J2795	INJ ROPIVACAINE HYDROCHLORIDE
	J3410	INJ HYDROXYZINE HCL
	J3480	INJ. POTASSIUM CHLORIDE, PER 2 MEQ.
	Q0163	DIPHENHYDRAMINE HYDROCHLORIDE

Always ESRD-related Products:

Always ESRD-related products link:
https://uhgazure.sharepoint.com/:f:/r/sites/CST/CSDM/Shared%20Documents/UHCMR%20Formulary%20Exc

Activase (alteplase) injection
Aranesp (darbepoetin) injection
argatroban injection
Benadryl (diphenhydramine) capsule/injection
Boniva (ibandronate) injection
calcitriol injection
calcium gluconate injection
Carbocaine (mepivacaine) injection
Carnitor (levocarnitine) injection
Cathflo Activase (alteplase) injection
Desferal (deferoxamine) injection
Dexferrum (iron dextran) injection
Dimenhydrinate injection
Epogen (epoetin alfa) injection
Feraheme (ferumoxytol)
Ferric carboxymaltose injection

Ferric pyrophosphate citrate injection
Ferrlecit (sodium ferric gluconate) injection
Fortical (calcitonin) nasal spray
Furosemide injection
Hectorol (doxercalciferol) capsules/injection
Heparin injection [A]
hydroxocobalamin injection
hydroxyzine injection
Infed (iron dextran) injection
Jesduvroq (daprodustat) oral tablets
Kinlytic (urokinase) injection
Miacalcin (calcitonin) injection/nasal spray
Mircera (methoxy polyethylene glycol-epoetin beta)
Naropin (ropivacaine)
Nascobal (cyanocobalamin) nasal spray
Osmitrol (mannitol) injection
pamidronate injection
Parsabiv (etelcalcetide) injection
Polocaine (mepivacaine) injection
Potassium chloride injection
Potassium chloride/NaCl injection
Potassium chloride/dextrose injection
Procrit (epoetin alfa) injection
Protamine injection
Refludan (lepirudin) injection
Retacrit (epoetin alfa-epbx) injection
Retavase (reteplase) injection
Rocaltrol (calcitriol) capsules/oral solution
Sensipar (cinacalcet) tablets
Sodium Diuril (chlorothiazide) injection
Venofer (iron sucrose) injection
Vitamin B-12 (cyanocobalamin) injection
Xylocaine (lidocaine) injection
Zemplar (paricalcitol) capsules/injection
Zometa (zoledronic acid) injection

Benefit/Coverage/Program Information

ESRD Prospective Payment System (PPS) bundle [4,7,9]

All drugs and biologicals used for the treatment of ESRD are included in the ESRD PPS and are not separatel
(1) Drugs and biologicals included under the composite rate as of December 31, 2010 (discussed below);

(2) Former separately billable Part B injectable drugs;
(3) Oral or other forms of injectable drugs used for the treatment of ESRD formerly billed under Part D; and
(4) Oral or other forms of drugs and biologicals without an injectable form. (Implementation delayed until Janua

Drug Categories Always Considered to be ESRD Related [4,6,7]

Drugs and biologicals always considered to be ESRD-related are those used for access management, anemia ESRD facilities are responsible for furnishing these drugs directly or under arrangement. This includes any dru ESRD facility.

Injectable Drugs and Biologicals [4]

All injectable drugs or biologicals used for the treatment of ESRD-related conditions are included in the ESRD prior to the implementation of the ESRD PPS were separately billable under Part B. However, ESRD facilities r payment for these drugs and biologicals under the composite rate portion of the blend during the transition.

Oral or Other Forms of Injectable Drugs and Biologicals [4]

The ESRD PPS includes certain drugs and biologicals that were previously paid under Part D. Oral or other fo Levocarnitine, antibiotics or any other oral or other form of injectable drug or biological furnished for ESRD-rela

Oral Forms of Non-Injectable Drugs [4,7]

ESRD-related oral forms of non-injectable drugs and biologicals will be included in the ESRD PPS as a Part B NOTE: Implementation of ESRD-related oral-only drugs has been delayed until January 1, 2025.

Drugs and Biologicals Under the Composite Rate [4]

Prior to the implementation of the ESRD PPS, certain drugs used in furnishing outpatient maintenance dialysi these drugs are included in the ESRD PPS and are not paid separately under the composite rate portion of the implementation of the ESRD PPS remained after implementation unless otherwise noted.

3 . Definitions

Definition	Description
Chronic Renal Failure [2]	Progressive loss of kidney function and development of complications. Renal failure is defined as a GFR less than 15 mL/min/1.73m2) which is accompanied in most cases by signs and symptoms of uremia, or as the need for initiation of kidney replacement therapy (dialysis or transplantation) for management of complications of a decreased GFR.
End Stage Renal Disease [2]	An administrative term based on the conditions for health care payment by the Medicare ESRD Program for patients requiring treatment by replacement therapy (dialysis or transplantation), irrespective of the level of GFR.

Access Management [1,5]	Drugs used to ensure access by removing clots from grafts, reverse anticoagulation if too much medication is given, and provide anesthetic for access placement.
Anemia Management [1,5]	Drugs used to stimulate red blood cell production and/or treat or prevent anemia.
Bone and Mineral Metabolism [1,5]	Drugs used to prevent/treat bone disease secondary to dialysis.
Cellular Management [1,5]	Drugs used for deficiencies of naturally occurring substances needed for cellular management.
Antiemetic [1,5]	Drugs used to prevent or treat nausea and vomiting secondary to dialysis, excluding antiemetics used in conjunction with chemotherapy as these are covered under a a separate benefit category.
Anti-infectives [1,5]	Drugs used to treat infections. These may include antibacterial and antifungal drugs.
Antipruritic [1,5]	Drugs in this category have multiple clinical indications, but are included for their action to treat itching secondary to dialysis.
Anxiolytic [1,5]	Drugs in this category have multiple actions, but are included for the treatment of restless leg syndrome secondary to dialysis.
Excess fluid management [1,5]	Drugs/fluids used to treat fluid excess/overload.
Fluid and electrolyte management including volume expanders [1,5]	Intravenous drugs/fluids used to treat fluid and electrolyte needs.
Pain management [1,5]	Drugs used to treat graft site pain and to treat pain medication overdose.

4 . Endnotes

A. Access management drugs include heparin sodium injection 1000-Unit/mL (GPI: 83100020202015) used specifically in ESRD or dialysis settings.
B. Drugs and biologicals identified for consolidated billing are designated as always ESRD-related and therefore no separate payment is made to ESRD facilities or other providers when these drugs are furnished to ESRD beneficiaries. This list is used to enforce consolidated billing edits which ensure that payment is not made for ESRD-related drugs and biologicals outside of the ESRD PPS. This is not an all-inclusive list and any drug or biological that is used for the same purpose as those drugs and biologicals on the list are also included under the ESRD PPS. Providers other than ESRD facilities furnishing those drugs must look to the ESRD facility for payment. [4]

5 . References

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6 . Revision History

Date	Notes
10/23/2023	update guideline

Prior Authorization Guideline

Guideline Name Erythropoietic Agents

Formulary 2024 Samaritan Advantage Health Plans (HMO)

Formulary Note

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	3/1/2000
P&T Revision Date:	04/19/2023 ; 11/16/2023

1 . Indications

Drug Name: Aranesp (darbepoetin alfa)
Anemia Due to Chronic Kidney Disease Indicated for the treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and patients not on dialysis. **Anemia Due to Chemotherapy in Patients with Cancer** Indicated for treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of 2 additional months of planned chemotherapy. Limitations of Use: Aranesp has not been shown to improve quality of life, fatigue, or patient well-being. Aranesp is not indicated for use: (1) In

patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy; (2) In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure; (3) In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion; and (4) As a substitute for red blood cell (RBC) transfusions in patients who require immediate correction of anemia.

Off Label Uses: Anemia in patients with Myelodysplastic Syndrome (MDS) Has been used for the treatment of anemia in patients with MDS. [20]

Drug Name: Epogen (epoetin alfa), Procrit (epoetin alfa), and Retacrit (epoetin alfa-epbx)

Anemia Due to Chronic Kidney Disease Indicated for the treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and not on dialysis to decrease the need for red blood cell (RBC) transfusion.

Anemia Due to Zidovudine in Patients with HIV-infection Indicated for the treatment of anemia due to zidovudine administered at less than or equal to 4200 mg/week in patients with HIV-infection with endogenous serum erythropoietin levels of less than or equal to 500 mUnits/mL.

Anemia Due to Chemotherapy in Patients with Cancer Indicated for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy and upon initiation, there is a minimum of 2 additional months of planned chemotherapy. Limitations of Use: Epoetin alfa has not been shown to improve quality of life, fatigue, or patient well-being. Epoetin alfa is not indicated for use: (1) In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy; (2) In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure; (3) In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion; (4) As a substitute for red blood cell (RBC) transfusions in patients who require immediate correction of anemia.

Reduction of Allogeneic Red Blood Cell Transfusions in Patients Undergoing Elective, Noncardiac, Nonvascular Surgery Indicated to reduce the need for allogeneic RBC transfusions among patients with perioperative hemoglobin greater than 10 to less than or equal to 13 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery. Epoetin alfa is not indicated for patients who are willing to donate autologous blood preoperatively. Limitations of Use: Epoetin alfa has not been shown to improve quality of life, fatigue, or patient well-being. Epoetin alfa is not indicated for use: (1) In patients scheduled for surgery who are willing to donate autologous blood; (2) In patients undergoing cardiac or vascular surgery.

Off Label Uses: Anemia associated with HIV infection Have been used for the treatment of anemia associated with HIV infection in patients not receiving zidovudine. [5]

Anemia in Hepatitis C virus (HCV) infected patients due to combination therapy of ribavirin and interferon or peg-interferon Have been used for the treatment of anemia in patients with hepatitis C virus (HCV) infection who are being treated with the combination of

ribavirin and interferon or peginterferon alfa. [20]

Anemia in patients with Myelodysplastic Syndrome (MDS) Have been used for the treatment of anemia in patients with MDS. [5, 20]

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	Part D

Approval Criteria

1 - Patient does not meet Excluded Use criteria for End-Stage Renal Disease

AND

2 - Diagnosis of chronic kidney disease (CKD)

AND

3 - Verification of iron evaluation for adequate iron stores [A, J]

AND

4 - Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request: [1-3, 9, 13-17, 33, B]

- Hematocrit (Hct) less than 30%
- Hemoglobin (Hgb) less than 10 g/dL

AND

5 - One of the following:

5.1 Both of the following:

5.1.1 Patient is on dialysis

AND

5.1.2 Patient is without ESRD

OR

5.2 All of the following:

5.2.1 Patient is not on dialysis

AND

5.2.2 The rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion

AND

5.2.3 Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal

Notes	*Refer to End-Stage Renal Disease (ESRD) Products guideline for ESRD criteria

Product Name: Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia due to Chronic Kidney Disease (CKD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Part D

Approval Criteria

1 - Patient does not meet Excluded Use criteria for End-Stage Renal Disease

AND

2 - Diagnosis of chronic kidney disease (CKD)

AND

3 - One of the following:

3.1 All of the following:

- Patient is on dialysis
- Patient is without ESRD
- Most recent or average Hct over 3 months is 33% or less (Hgb 11 g/dL or less)

OR

3.2 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

3.3 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

4 - Patient demonstrates positive clinical response to therapy from pre-treatment level

AND

5 - Verification of iron evaluation for adequate iron stores [A, J]

Notes	*Refer to End-Stage Renal Disease (ESRD) Products guideline for ESRD criteria

Product Name: Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in Patients with Human Immunodeficiency Virus (HIV)-Infection
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Part D

Approval Criteria

1 - Patient does not meet Excluded Use criteria for End-Stage Renal Disease

AND

2 - Verification of iron evaluation for adequate iron stores [2, 3, 33]

AND

3 - Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request:

- Hemoglobin (Hgb) less than 12 g/dL [11, 25-28, K]
- Hematocrit (Hct) less than 36%

AND

4 - Serum erythropoietin level less than or equal to 500 mU/mL [2-3, 24, 26, 33]

AND

5 - One of the following:

- Patient is receiving zidovudine therapy [2, 3, 33]
- Diagnosis of HIV [off-label] [5, 11, 24-28]

Notes	*Refer to End-Stage Renal Disease (ESRD) Products guideline for ESRD criteria

Product Name: Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in Patients with Human Immunodeficiency Virus (HIV)-Infection
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Part D

Approval Criteria

1 - Patient does not meet Excluded Use criteria for End-Stage Renal Disease

AND

2 - 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

3 - Patient demonstrates positive clinical response to therapy from pre-treatment level

Notes	*Refer to End-Stage Renal Disease (ESRD) Products guideline for ESRD criteria

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	Part D

Approval Criteria

1 - Patient does not meet Excluded Use criteria for End-Stage Renal Disease

AND

2 - Other causes of anemia have been ruled out [1-3, 23, 33, M]

AND

3 - 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

4 - Verification of iron evaluation for adequate iron stores [1-3, 8, 33, G]

AND

5 - Cancer is a non-myeloid malignancy [1-3, 33, F]

AND

6 - Patient is receiving chemotherapy [1-3, 33, D]

Notes	*Refer to End-Stage Renal Disease (ESRD) Products guideline for ESRD criteria

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	Part D

Approval Criteria

1 - Patient does not meet Excluded Use criteria for End-Stage Renal Disease

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]

- Hemoglobin (Hgb) less than 10 g/dL
- Hematocrit (Hct) less than 30% [10, 18-19]

AND

3 - Patient demonstrates positive clinical response to therapy from pre-treatment level

AND

4 - Patient is receiving chemotherapy [D]

Notes	*Refer to End-Stage Renal Disease (ESRD) Products guideline for ESRD criteria

Product Name: Epogen, Procrit, or Retacrit	
Diagnosis	Preoperative use for reduction of allogeneic blood transfusion in patients undergoing surgery
Approval Length	1 Month [2, 3, 33]
Guideline Type	Part D

Approval Criteria

1 - Patient does not meet Excluded Use criteria for End-Stage Renal Disease

AND

2 - Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery

AND

3 - Hemoglobin (Hgb) is greater than 10 to less than or equal to 13 g/dL

AND

4 - Patient is at high risk for perioperative transfusions

AND

5 - Patient is unwilling or unable to donate autologous blood pre-operatively

AND

6 - Verification of iron evaluation for adequate iron stores [2, 3, 33]

Notes	*Refer to End-Stage Renal Disease (ESRD) Products guideline for ESRD criteria

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	Part D

Approval Criteria

1 - Patient does not meet Excluded Use criteria for End-Stage Renal Disease

AND

2 - Diagnosis of Myelodysplastic Syndrome (MDS) [4]

AND

3 - One of the following: [4]

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

AND

4 - Verification of iron evaluation for adequate iron stores [4, A, H]

Notes	*Refer to End-Stage Renal Disease (ESRD) Products guideline for ESRD criteria

Product Name: Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in Myelodysplastic Syndrome (MDS) patients [off-label] [4-6, 20]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Part D

Approval Criteria

1 - Patient does not meet Excluded Use criteria for End-Stage Renal Disease

AND

2 - Verification of anemia as defined by one of the following: [4, E]

- 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

3 - Patient demonstrates positive clinical response to therapy from pre-treatment level

Notes	*Refer to End-Stage Renal Disease (ESRD) Products guideline for ESRD criteria

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	Part D

Approval Criteria

1 - Patient does not meet Excluded Use criteria for End-Stage Renal Disease

AND

2 - Diagnosis of hepatitis C virus (HCV) infection [12, 20]

AND

3 - Verification of iron evaluation for adequate iron stores [2, 3, 33]

AND

4 - 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 12g/dL

AND

5 - Both of the following:

5.1 Patient is receiving ribavirin

AND

5.2 Patient is receiving one of the following:

- interferon alfa
- peg-interferon alfa

Notes	*Refer to End-Stage Renal Disease (ESRD) Products guideline for ESRD criteria

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 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	Part D

Approval Criteria

1 - Patient does not meet Excluded Use criteria for End-Stage Renal Disease

AND

2 - 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

3 - Patient demonstrates positive clinical response to therapy from pre-treatment level	
Notes	*Refer to End-Stage Renal Disease (ESRD) Products guideline for ESRD criteria

Product Name: Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Other Off-Label Uses
Guideline Type	Part D
Approval Criteria **1** - Patient does not meet Excluded Use criteria for End-Stage Renal Disease **AND** **2** - Off-label guideline approval criteria have been met **AND** **3** - 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	*Refer to End-Stage Renal Disease (ESRD) Products guideline for ESRD criteria

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, and Retacrit Prescribing Information states that dialysis, and non-dialysis patients with symptomatic anemia considered for therapy should have a hemoglobin less than 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 less than 30 ng/mL and TSAT less than 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 greater than 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. As of January 1, 2011, ESAs that are furnished to individuals for the treatment of end stage renal disease are considered "renal dialysis services" and are included in the ESRD Prospective Payment System (PPS) bundle. The PPS provides a single payment to a provider of services or a renal dialysis facility for all renal dialysis services. Separate payment outside of the PPS bundle for ESAs under either Part B or Part D in this circumstance will no longer be made. The products must be billed by the renal dialysis facility. [21]
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]

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5 . Revision History

Date	Notes
11/20/2023	2023 annual review: update to standard reauth language "patient de monstrates positive clinical response..." with no change to clinical int ent.

Prior Authorization Guideline

Guideline Name Immune Globulins

Formulary 2024 Samaritan Advantage Health Plans (HMO)

Formulary Note

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	
P&T Revision Date:	05/18/2023 ; 12/13/2023

Note:

THIS GUIDELINE IS USED TO DETERMINE PART B VS PART D COVERAGE

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: Dermatomyositis [8, 34-38] In patients with treatment-resistant dermatomyositis, IVIG therapy resulted in improvements in muscle strength and neuromuscular symptoms.

Multifocal Motor Neuropathy (MMN) [39-43] In placebo-controlled trials, IVIG has been shown to improve strength and reduce disability and conduction block in patients with MMN.

HIV [8, 44-46, 81] 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 [8, 47-49] Considered to be equally effective as plasma exchange for the treatment of Guillain-Barre Syndrome.

Lambert-Eaton Myasthenic Syndrome [50] Shown to produce short-term improvement in strength in patients with Lambert-Eaton Myasthenic Syndrome.

Myasthenia Gravis [8, 76, 77] 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.

Stiff-Person Syndrome [8, 89, 90] The efficacy of IVIG for the treatment of stiff-person syndrome was demonstrated in a randomized, double-blind, placebo-controlled, crossover trial.

Polymyositis [8, 70] Found to be effective in reversing chronic polymyositis previously unresponsive to immunosuppressive therapy.

Multiple Myeloma [8] A randomized, placebo-controlled study with intravenous immune globulin (IVIG) demonstrated beneficial effects when given to outpatients with stable-phase multiple myeloma.

Pure Red Cell Aplasia [8] Reticulocyte count increased in an infant with pure red cell aplasia treated with immune globulin.

Fetal Alloimmune Thrombocytopenia [8] Antenatal therapy with IV immune globulin (1 g/kg over 4 to 7 hours weekly), with or without dexamethasone 3 to 5 mg daily, was reported effective in increasing fetal platelet counts in severe neonatal alloimmune thrombocytopenia.

Hemolytic Disease of the Newborn [8] IV immune globulin was effective as prenatal therapy following severe Rh immunization, improving the outcome of pregnancy, in two patients. It is suggested that IV immune globulin may prevent intrauterine death in Rh immunized patients, alleviating the need for fetal transfusion, plasmapheresis, or premature delivery.

Autoimmune Blistering Disease [8] Monotherapy with intravenous immune globulin (IVIG) 40mg/kg/day for 5 consecutive days effected progressive improvement in two male patients (aged 18 and 60 years) with refractory epidermolysis bullosa acquisita.

Solid Organ Transplant [8] IVIG contains anti-idiopathic antibodies that are potent inhibitors of donor-specific human leukocyte antigen alloantibodies, thus preventing organ rejection episodes.

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 (cytomegalovirus immune globulin [Human])

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: HyQvia (immune globulin with recombinant human hyaluronidase) for subcutaneous administration

Primary Immunodeficiency Disorders Indicated for the treatment of Primary Immunodeficiency (PI) in adults and pediatric patients two years of age and older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies. Limitation of Use: Safety and efficacy of chronic use of recombinant human hyaluronidase in HyQvia have not been established in conditions other than PI.

Drug Name: Hizentra (immune globulin [Human]) for subcutaneous administration

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 immune globulins (IVIG)	
Diagnosis	Primary Immunodeficiency Syndrome
Guideline Type	Part B

Approval Criteria

1 - For patients with a primary immunodeficiency syndrome (ICD-10 diagnosis codes G11.3, D80.0, D80.2, D80.3, D80.4, D80.5, D80.6, D80.7, D81.0, D81.1, D81.2, D81.5, D81.6, D81.7, D81.89, D81.9, D82.0, D82.1, D82.4, D83.0, D83.1, D83.2, D83.8, D83.9) [78, 79, A, J]

AND

2 - Drug is administered in the patient's home [A, H, J]

Product Name: Subcutaneous immune globulins (SCIG)	
Diagnosis	Primary Immunodeficiency Syndrome, Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
Guideline Type	Part B

Approval Criteria

1 - One of the following:

1.1 For patients with a primary immunodeficiency syndrome (ICD-10 diagnosis codes G11.3, D80.0, D80.2, D80.3, D80.4, D80.5, D80.6, D80.7, D81.0, D81.1, D81.2, D81.5, D81.6, D81.7, D81.89, D81.9, D82.0, D82.1, D82.4, D83.0, D83.1, D83.2, D83.8, D83.9, G11.3) [78, 79, F, I]

OR

1.2 For patients with a diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP, ICD-10 diagnosis code G61.81) that has responded to IVIg treatment

AND

2 - Drug is administered in the patient's home

AND

3 - Drug is administered using an infusion pump* [G]

AND

4 - Infusion pump is paid for by Medicare*

Notes	*If the infusion pump AND the drug administered via that pump are not covered by Part B, then consideration of coverage for the drug is done under Part D pursuant to Part D formulary.

Product Name: Intravenous immune globulins (IVIG)	
Diagnosis	Primary Immunodeficiency Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient does not meet criteria for Part B coverage above

OR

1.2 Patient is in a long-term care facility

AND

2 - One of the following diagnoses:

2.1 Common variable immunodeficiency

OR

2.2 Congenital agammaglobulinemia (X-linked or autosomal recessive)

OR

2.3 Severe combined immunodeficiencies

OR

2.4 Wiskott-Aldrich syndrome

OR

2.5 Other primary immunodeficiency (PI) with both of the following:

2.5.1 An immunologic evaluation including IgG levels below the normal laboratory value for the patient's age at the time of diagnosis

AND

2.5.2 The patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine)

AND

3 - Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis

AND

4 - Ig is being used intravenously (IV)

AND

5 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

AND

6 - For Privigen only: Patient does not have hyperprolinemia

AND

7 - For Octagam only: Patient does not have an allergy to corn

AND

8 - For Gammaplex only, one of the following:

8.1 Patient does not have hereditary intolerance to fructose

OR

8.2 Patient is not an infant for whom sucrose or fructose tolerance has not been established

AND

9 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulins (IVIG)	
Diagnosis	B-cell Chronic Lymphocytic Leukemia (CLL) [5, 24-26, 84]
Approval Length	12 month(s)
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Diagnosis of B-cell chronic lymphocytic leukemia (CLL) [5]

AND

2 - One of the following:

2.1 Immune globulin level less than 500 mg/dL

OR

2.2 History of recurrent bacterial infections

AND

3 - Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis

AND

4 - Ig is being used intravenously (IV)

AND

5 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

AND

6 - For Privigen only: Patient does not have hyperprolinemia

AND

7 - For Octagam only: Patient does not have an allergy to corn

AND

8 - For Gammaplex only, one of the following:

8.1 Patient does not have hereditary intolerance to fructose

OR

8.2 Patient is not an infant for whom sucrose or fructose tolerance has not been established

AND

9 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulins (IVIG)	
Diagnosis	HIV (off-label) [44-46, 81, 85, 86]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Diagnosis of HIV infection [44, 81, K]

AND

2 - Patient is less than or equal to 12 years of age

AND

3 - One of the following:

3.1 Immune globulin level less than 400 mg/dL [46, 81, L]

OR

3.2 Patient has active bleeding or a platelet count less than 10 x 109/L

AND

4 - Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis

AND

5 - Ig is being used intravenously (IV)

AND

6 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

AND

7 - For Privigen only: Patient does not have hyperprolinemia

AND

8 - For Octagam only: Patient does not have an allergy to corn

AND

9 - For Gammaplex only, one of the following:

9.1 Patient does not have hereditary intolerance to fructose

OR

9.2 Patient is not an infant for whom sucrose or fructose tolerance has not been established

AND

10 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Multiple Myeloma (off-label) [8]
Approval Length	12 month(s)
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma in plateau phase

AND

2 - Patient has hypogammaglobulinemia

AND

3 - Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis

AND

4 - Ig is being used intravenously (IV)

AND

5 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

AND

6 - For Privigen only: Patient does not have hyperprolinemia

AND

7 - For Octagam only: Patient does not have an allergy to corn

AND

8 - For Gammaplex only, one of the following:

8.1 Patient does not have hereditary intolerance to fructose

OR

8.2 Patient is not an infant for whom sucrose or fructose tolerance has not been established

AND

9 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Acquired (pure) red cell aplasia (PRCA) (off-label) [8]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of acquired (pure) red cell aplasia (PRCA) that is immunologic

AND

1.2 Patient had failure, contraindication, or intolerance to both of the following:

- A corticosteroid
- An immunosuppressant (i.e., cyclophosphamide, cyclosporine)

AND

2 - Patient has viral PRCA caused by parvovirus B19

AND

3 - Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis

AND

4 - Ig is being used intravenously (IV)

AND

5 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

AND

6 - For Privigen only: Patient does not have hyperprolinemia

AND

7 - For Octagam only: Patient does not have an allergy to corn

AND

8 - For Gammaplex only, one of the following:

8.1 Patient does not have hereditary intolerance to fructose

OR

8.2 Patient is not an infant for whom sucrose or fructose tolerance has not been established

AND

9 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)

Diagnosis	Fetal Alloimmune Thrombocytopenia (off-label) [8]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Diagnosis of fetal alloimmune thrombocytopenia

AND

2 - Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis

AND

3 - Ig is being used intravenously (IV)

AND

4 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

AND

5 - For Privigen only: Patient does not have hyperprolinemia

AND

6 - For Octagam only: Patient does not have an allergy to corn

AND

7 - For Gammaplex only, one of the following:

7.1 Patient does not have hereditary intolerance to fructose

OR

7.2 Patient is not an infant for whom sucrose or fructose tolerance has not been established

AND

8 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Hemolytic disease of the newborn (off-label) [8]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Diagnosis of hemolytic disease of the newborn

AND

2 - Patient has established hyperbilirubinemia

AND

3 - Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis

AND

4 - Ig is being used intravenously (IV)

AND

5 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

AND

6 - For Privigen only: Patient does not have hyperprolinemia

AND

7 - For Octagam only: Patient does not have an allergy to corn

AND

8 - For Gammaplex only, one of the following:

8.1 Patient does not have hereditary intolerance to fructose

OR

8.2 Patient is not an infant for whom sucrose or fructose tolerance has not been established

AND

9 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulins (IVIG)	
Diagnosis	Idiopathic Thrombocytopenic Purpura (ITP) [2, 3, 5, 9-18, 66]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Diagnosis of idiopathic thrombocytopenic purpura (ITP) [2, 3, 5, 66]

AND

2 - One of the following:

2.1 Patient had failure, contraindication or intolerance to a corticosteroid

OR

2.2 A platelet count less than 30,000 cells/mm3

AND

3 - Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis

AND

4 - Ig is being used intravenously (IV)

AND

5 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

AND

6 - For Privigen only: Patient does not have hyperprolinemia

AND

7 - For Octagam only: Patient does not have an allergy to corn

AND

8 - For Gammaplex only, one of the following:

8.1 Patient does not have hereditary intolerance to fructose

OR

8.2 Patient is not an infant for whom sucrose or fructose tolerance has not been established

AND

9 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [27-32, 60, 63, 83, C, E, N]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient does not meet criteria for Part B coverage above

OR

1.2 Patient is in a long-term care facility

AND

1 - Diagnosis of chronic inflammatory demyelinating polyneuropathy

AND

2 - Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis

AND

3 - Ig is being used intravenously (IV)

AND

4 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

AND

5 - For Privigen only: Patient does not have hyperprolinemia

AND

6 - For Octagam only: Patient does not have an allergy to corn

AND

7 - For Gammaplex only, one of the following:

7.1 Patient does not have hereditary intolerance to fructose

OR

7.2 Patient is not an infant for whom sucrose or fructose tolerance has not been established

AND

9 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Guillain-Barre Syndrome (off-label) [47-49]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Diagnosis of Guillain-Barre Syndrome

AND

2 - Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis

AND

3 - Ig is being used intravenously (IV)

AND

4 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

AND

5 - For Privigen only: Patient does not have hyperprolinemia

AND

6 - For Octagam only: Patient does not have an allergy to corn

AND

7 - For Gammaplex only, one of the following:

7.1 Patient does not have hereditary intolerance to fructose

OR

7.2 Patient is not an infant for whom sucrose or fructose tolerance has not been established

AND

8 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Dermatomyositis and Polymyositis (off-label) [8, 34-38, 68]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - One of the following diagnoses: [38]

- Dermatomyositis
- Polymyositis

AND

2 - History of failure, contraindication, or intolerance to both of the following: [38, M]

- A corticosteroid
- An immunosuppressant (i.e., azathioprine, methotrexate, cyclosporine A, cyclophosphamide, or tacrolimus)

AND

3 - Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis

AND

4 - Ig is being used intravenously (IV)

AND

5 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

AND

6 - For Privigen only: Patient does not have hyperprolinemia

AND

7 - For Octagam only: Patient does not have an allergy to corn

AND

8 - For Gammaplex only, one of the following:

8.1 Patient does not have hereditary intolerance to fructose

OR

8.2 Patient is not an infant for whom sucrose or fructose tolerance has not been established

AND

9 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Lambert-Eaton Myasthenic Syndrome (off-label) [50]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Diagnosis of Lambert-Eaton Myasthenic Syndrome [50]

AND

2 - History of failure, contraindication, or intolerance to both of the following: [87, 88]

- A corticosteroid
- An immunosuppressant (e.g., azathioprine)

AND

3 - Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis

AND

4 - Ig is being used intravenously (IV)

AND

5 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

AND

6 - For Privigen only: Patient does not have hyperprolinemia

AND

7 - For Octagam only: Patient does not have an allergy to corn

AND

8 - For Gammaplex only, one of the following:

8.1 Patient does not have hereditary intolerance to fructose

OR

8.2 Patient is not an infant for whom sucrose or fructose tolerance has not been established

AND

9 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Multifocal Motor Neuropathy (off-label) [39-43]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Diagnosis of multifocal motor neuropathy (MMN) [82, O]

AND

2 - Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis

AND

3 - Ig is being used intravenously (IV)

AND

4 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

AND

5 - For Privigen only: Patient does not have hyperprolinemia

AND

6 - For Octagam only: Patient does not have an allergy to corn

AND

7 - For Gammaplex only, one of the following:

7.1 Patient does not have hereditary intolerance to fructose

OR

7.2 Patient is not an infant for whom sucrose or fructose tolerance has not been established

AND

8 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulins (IVIG)	
Diagnosis	Myasthenia Gravis (off-label) [52-56]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Diagnosis of myasthenia gravis with one of the following: [D, P]

- Severe exacerbations
- Myasthenic crises

AND

2 - Patient had failure, contraindication, or intolerance to both of the following:

- A corticosteroid

- An immunosuppressant (i.e., azathioprine, cyclosporine, cyclophosphamide, or mycophenolate mofetil)

AND

3 - Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis

AND

4 - Ig is being used intravenously (IV)

AND

5 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

AND

6 - For Privigen only: Patient does not have hyperprolinemia

AND

7 - For Octagam only: Patient does not have an allergy to corn

AND

8 - For Gammaplex only, one of the following:

8.1 Patient does not have hereditary intolerance to fructose

OR

8.2 Patient is not an infant for whom sucrose or fructose tolerance has not been established

AND

9 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Stiff Person Syndrome (off-label)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Diagnosis of stiff-person syndrome [58, 89, 90]

AND

2 - History of failure, contraindication or intolerance to at least 2 standard therapies (i.e., benzodiazepines, muscle relaxants, or anti-convulsants)

AND

3 - Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis

AND

4 - Ig is being used intravenously (IV)

AND

5 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

AND

6 - For Privigen only: Patient does not have hyperprolinemia

AND

7 - For Octagam only: Patient does not have an allergy to corn

AND

8 - For Gammaplex only, one of the following:

8.1 Patient does not have hereditary intolerance to fructose

OR

8.2 Patient is not an infant for whom sucrose or fructose tolerance has not been established

AND

9 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Autoimmune blistering disease (off-label) [8]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Diagnosis of autoimmune blistering disease

AND

2 - Patient had failure, contraindication, or intolerance to both of the following:

- A corticosteroid
- An immunosuppressant (i.e., cyclophosphamide, dapsone, methotrexate, azathioprine, or mycophenolate mofetil)

AND

3 - Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis

AND

4 - Ig is being used intravenously (IV)

AND

5 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

AND

6 - For Privigen only: Patient does not have hyperprolinemia

AND

7 - For Octagam only: Patient does not have an allergy to corn

AND

8 - For Gammaplex only, one of the following:

8.1 Patient does not have hereditary intolerance to fructose

OR

8.2 Patient is not an infant for whom sucrose or fructose tolerance has not been established

AND

9 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulins (IVIG)	
Diagnosis	Kawasaki syndrome [5, 19-21, 59]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Diagnosis of Kawasaki syndrome [5, 19-21]

AND

2 - Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis

AND

3 - Ig is being used intravenously (IV)

AND

4 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

AND

5 - For Privigen only: Patient does not have hyperprolinemia

AND

6 - For Octagam only: Patient does not have an allergy to corn

AND

7 - For Gammaplex only, one of the following:

7.1 Patient does not have hereditary intolerance to fructose

OR

7.2 Patient is not an infant for whom sucrose or fructose tolerance has not been established

AND

8 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulins (IVIG)	
Diagnosis	Solid Organ Transplant (off-label) [8]
Approval Length	4 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Diagnosis of solid organ transplant

AND

2 - One of the following:

2.1 IVIG is being used for CMV prophylaxis

OR

2.2 Both of the following:

- Patient is a kidney transplant recipient
- Patient has donor specific antibodies

OR

2.3 Both of the following:

- Patient has steroid-resistant rejection
- Patient had failure, contraindication, or intolerance to standard therapies

AND

3 - Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis

AND

4 - Ig will be used intravenously (IV)

AND

5 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

AND

6 - For Privigen only: Patient does not have hyperprolinemia

AND

7 - For Octagam only: Patient does not have an allergy to corn

AND

8 - For Gammaplex only, one of the following:

8.1 Patient does not have hereditary intolerance to fructose

OR

8.2 Patient is not an infant for whom sucrose or fructose tolerance has not been established

AND

9 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Subcutaneous immune globulin (SCIG) - Gamunex-C, Gammagard Liquid, Gammaked only	
Diagnosis	Primary Immunodeficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient does not meet criteria for Part B coverage above

OR

1.2 Patient is in a long-term care facility

AND

2 - Diagnosis of one of the following primary immunodeficiency (PI) diagnoses:

2.1 Common variable immunodeficiency

OR

2.2 Congenital agammaglobulinemia (X-linked or autosomal recessive)

OR

2.3 Severe combined immunodeficiencies

OR

2.4 Wiskott-Aldrich syndrome

OR

2.5 Other PI with both of the following:

2.5.1 An immunologic evaluation including IgG levels below the normal laboratory value for the patient's age at the time of diagnosis

AND

2.5.2 Patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine)

AND

3 - Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis

AND

4 - Immune globulin is being used subcutaneously

AND

5 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

AND

6 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Intravenous immune globulin (IVIG), Subcutaneous immune globulin (SCIG) - Gamunex-C, Gammagard Liquid, Ganmaked only	
Diagnosis	Non-Oncology Renewal
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - The patient has experienced an objective improvement on immune globulin therapy

AND

2 - The immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy

AND

3 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

AND

4 - For Privigen only: Patient does not have hyperprolinemia

AND

5 - For Octagam only: Patient does not have an allergy to corn

AND

6 - For Gammaplex only, one of the following:

6.1 Patient does not have hereditary intolerance to fructose

OR

6.2 Patient is not an infant for whom sucrose or fructose tolerance has not been established

AND

7 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Subcutaneous immune globulin (SCIG) - Hizentra, HyQvia, Cuvitru, Cutaquig, Xembify only	
Diagnosis	Primary Immunodeficiency

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

Approval Criteria

1 - One of the following:

1.1 Patient does not meet criteria for Part B coverage above

OR

1.2 Patient is in a long-term care facility

AND

2 - One of the following FDA-approved or literature supported diagnoses:

2.1 Common variable immunodeficiency (CVID)

OR

2.2 Congenital agammaglobulinemia (X-linked or autosomal recessive)

OR

2.3 Severe combined immunodeficiencies (SCID)

OR

2.4 Wiskott-Aldrich syndrome

OR

2.5 Other primary immunodeficiency with both of the following:

2.5.1 An immunologic evaluation including IgG levels below the normal laboratory value for the patient's age at the time of diagnosis

AND

2.5.2 Patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine)

AND

3 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

AND

4 - For Hizentra only: Patient does not have hyperprolinemia

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on SCIG therapy (e.g., immunologist, hematologist, neurologist)

AND

6 - For Hyqvia only: Patient is age 2 years or older

Product Name: Subcutaneous immune globulin (SCIG) - Hizentra, HyQvia (off-label), Cuvitru (off-label), Cutaquig (off-label), Xembify (off-label) only	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient does not meet criteria for Part B coverage above

OR

1.2 Patient is in a long-term care facility

AND

2 - Diagnosis of chronic inflammatory demyelinating polyneuropathy

AND

3 - Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis

AND

4 - Ig is being used subcutaneously (SC)

AND

5 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

AND

6 - For Hizentra only: Patient does not have hyperprolinemia

AND

7 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on SCIG therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Subcutaneous immune globulin (SCIG) - Hizentra, HyQvia, Cuvitru, Cutaquig, Xembify only	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Patient has experienced an objective improvement on immune globulin therapy

AND

2 - Immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy

AND

3 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

AND

4 - For Hizentra only: Patient does not have hyperprolinemia

AND

5 - Prescribed by or in consultation with a physician who has specialized expertise in managing patients on SCIG therapy (e.g., immunologist, hematologist, neurologist)

Product Name: Gamastan	
Approval Length	3 Month

Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Patient requires immunization for hepatitis A, measles, rubella, or varicella

AND

2 - Immune globulin is being used intramuscularly

AND

3 - Immune globulin will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis

AND

4 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

Product Name: Cytogam	
Approval Length	4 month(s)
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient requires prophylaxis for CMV infection following kidney transplantation and both of the following:

- Patient is CMV-seronegative
- Organ donor is CMV-seropositive

OR

1.2 Both of the following:

1.2.1 Patient requires prophylaxis for CMV infection following liver, heart, lung, or pancreas transplantation and both of the following:

- Patient is CMV-seronegative
- Organ donor is CMV-seropositive

AND

1.2.2 Patient will receive concomitant therapy with ganciclovir or valganciclovir unless patient has a hypersensitivity or intolerance, or therapy is deemed inappropriate

AND

2 - Patient does not have contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication)

3 . Endnotes

A. The Medicare Modernization Act created a benefit for the provision of intravenous immune globulin (IVIG) for beneficiaries with a diagnosis of primary immune deficiency disease. [7] Coverage is provided if a physician determines that the administration of IVIG in the patient's home is medically appropriate. Payment is limited to that for the IVIG itself and does not cover items and services related to administration of the product.
B. Based on inclusion criteria from Molica et al. [26]
C. According to published data, there appears to be no difference in efficacy among IVIG, plasma exchange, and corticosteroids. [27, 29, 32]
D. 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. [55] IVIG may be as effective as plasma exchange for patients with acute exacerbations of myasthenia gravis. [52] 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. [64] 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.

E. Treatment for CIDP includes corticosteroids such as prednisone, which may be prescribed alone or in combination with immunosuppressant drugs. [63] 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.
F. Durable Medical Equipment (DME) Supply Drugs. These are drugs that require administration by the use of a piece of covered DME (e.g., a nebulizer, external or implantable pump). The statute does not explicitly cover DME drugs; they are covered as a supply necessary for the DME to perform its function. Medicare covers as a DME supply include drugs for which administration with an infusion pump in the home is medically necessary (e.g. some chemotherapeutic agents).
G. 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. [8]
H. Intravenous immune globulin (IVIG) will be covered under Part B provided it will be used in the home for individual with diagnosis of primary immune deficiency disease. IVIG provided in the home for other diagnoses would be a Part D benefit. [78]
I. Coverage of subcutaneous immune globulin using external infusion pump applies only to those products that are specifically labeled as subcutaneous administration products. Intravenous immune globulin products are not covered under this LCD. [79]
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. [80]
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. IVIG also has been used in HIV-infected adults. 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. [81]
L. The ACIP, AAP, 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. [81]
M. Per expert consultant regarding dermatomyositis: It is reasonable to ask a patient to try steroids prior to treatment with IVIG [92].

N. 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 [92].
O. Per expert consultant regarding multifocal motor neuropathy: the EFNS guidelines [91] 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. [109]
P. 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. [92]

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5 . Revision History

Date	Notes
11/29/2023	GPI update

Prior Authorization Guideline

Guideline Name Injectable Durable Medical Equipment (DME)

Formulary 2024 Samaritan Advantage Health Plans (HMO)

Formulary Note

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	5/17/2005
P&T Revision Date:	04/20/2022 ; 10/19/2022 ; 10/18/2023 ; 10/18/2023

Note:

THIS GUIDELINE IS USED TO DETERMINE PART B VS PART D COVERAGE

1 . Criteria

Product Name: Injectable Durable Medical Equipment (DME) supply drugs [A, B]	
Guideline Type	Part B

Approval Criteria

1 - DME supply drugs listed in endnote B will be covered under Part B based on the following criterion:

1.1 Drug is administered using an infusion pump*^

AND

1.2 One of the following:

1.2.1 Infusion pump paid for by Medicare*^

OR

1.2.2 All of the following: [2]

1.2.2.1 Patient is using a subcutaneous insulin pump [excluding disposable drug delivery systems (e.g., OmniPod, V-Go)] [D]

AND

1.2.2.2 One of the following:

1.2.2.2.1 Patient is enrolled in a comprehensive diabetes program with one of the following symptoms:

- Hemoglobin level (HbA1C) greater than 7 percent
- History of recurring hypoglycemia
- Fluctuations in blood glucose
- Dawn phenomenon
- History of severe glycemic excursions

OR

1.2.2.2.2 Patient has been on an external insulin infusion pump prior to enrollment in Medicare and has documented frequency of glucose self-testing an average of at least 4 times per day

AND

1.2.2.3 One of the following:

1.2.2.3.1 A fasting blood sugar less than or equal to 225 mg/dL

OR

1.2.2.3.2 Beta cell autoantibody test is positive

AND

1.3 Drug is administered at home (not including facility providing skilled nursing care)

Notes	Please refer to local coverage determination. *If the infusion pump AND the drug administered via that pump are not covered by Part B, then consideration of coverage for the drug is done under Part D pursuant to Part D formulary. [1, C] ^Examples of infusion pumps include IV infusion pump for morphine or chemotherapy administration, subcutaneous insulin infusion pump, parenteral pumps for milrinone/dopamine, etc. [2]

Product Name: Injectable Durable Medical Equipment (DME) supply drugs [A, B]	
Approval Length	12 months or as applicable based on drug-specific or administrative guideline.
Guideline Type	Part D

Approval Criteria

1 - DME supply drugs listed in endnote B will be covered under Part D based on all of the following criteria:

1.1 One of the following:

1.1.1 Patient does not meet criteria for Part B coverage above

OR

1.1.2 Patient is in a long-term care facility (e.g., hospital or skilled nursing facility where patient is receiving skilled care)**

AND

1.2 One of the following:

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

OR

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

AND

1.3 Patient meets criteria in applicable drug-specific or administrative guidelines (e.g., non-formulary exceptions)

Notes	**Long term care facility includes the following: a) hospital, b) skilled nursing facility (SNF) or a distinct part SNF, c) a nursing home that is dually certified as both Medicare SNF and a Medicaid nursing facility, d) a Medicaid only nursing facility that primarily furnishes skilled care, e) a non-participating nursing home (neither Medicaid or Medicare) that provided primarily skilled care, and f) an institution that has a distinct part SNF and which also primarily furnishes skilled care

Product Name: Mealtime Insulins Processing Under Part D (Admelog [insulin lispro], Apidra [insulin glulisine], Fiasp [insulin aspart], Fiasp cartridge [insulin aspart], Humalog [insulin lispro], Humulin R [insulin regular (human)], Insulin Aspart cartridge [insulin aspart], Lyumjev [insulin lispro-aabc], Novolog [insulin aspart], Novolog cartridge [insulin aspart], Novolin R [insulin regular (human)], Novolin R Relion [insulin regular (human)])	
Guideline Type	Part D
Approval Criteria **1** - Patient does not meet criteria for Part B coverage above*	
Notes	*Meal-time insulins that are processing under Part D at point-of-sale can be canceled (would not undergo diagnosis review) once it is determined the member does not meet Part B.

2 . Endnotes

A. Drugs that require administration by the use of a piece of covered DME (e.g., a nebulizer, external or implantable pump) are covered under Part B [1]. The statute does not explicitly cover DME drugs; they are covered as a supply necessary for the DME to perform its function. Examples of such drugs include: (1) inhalation drugs that are administered in the home through the use of a nebulizer (e.g., albuterol sulfate, ipratropium bromide); or (2) drugs for which administration with an infusion pump in the home is medically necessary (e.g., some chemotherapeutic agents). In the case of a beneficiary in a hospital, or a SNF bed, (1) who does not have Part A coverage, (2) whose Part A coverage for the stay has run out, or (3) whose stay is non-covered, infusible DME supply drugs are not covered under Part B because the law limits coverage under Part B's DME benefit to those items that are furnished for use in a patient's home, and specifies that a hospital or SNF cannot be considered the beneficiary's "home" for this purpose. In this case, coverage for the drugs would be available under Part D.

B. DME supply drugs requiring B vs. D review include: [2] (1) Anticancer Chemotherapy Drugs (Bleomycin, Cladribine, Cytarabine, Doxorubicin [non-liposomal], Fluorouracil, Vinblastine, Vincristine); (2) Antifungal, Antiviral Drugs (Acyclovir, Amphotericin B, Foscarnet, Ganciclovir); (3) Chronic Iron Overload Therapy (Deferoxamine); (4) Parenteral Inotropic Therapy (Milrinone); (5) Anti-Spasmodic Drugs (Baclofen); (6) Analgesic Drugs (Ziconotide); (7) Gallium nitrate; (8) Opioid Drugs for Treatment of Chronic Intractable Pain (Sublimaze [fentanyl citrate] injection, Hydromorphone injection, Morphine Sulfate injection); (9) Insulin (Admelog [insulin lispro], Apidra [insulin glulisine], Fiasp [insulin aspart], Humalog [insulin lispro], Humulin R [insulin regular (human)], Lyumjev [insulin lispro-aabc], Novolog [insulin aspart], Novolin R [insulin regular (human)]) [of note, this guideline has a separate Part D section for insulin products]

C. The fact that coverage is available for a particular drug under Part B with the use of an infusion pump does not mean that coverage under Part D using some other method of administration automatically can be denied. There is no Part B coverage in the home for infusion drugs administered without an infusion pump (e.g., IV push). There is also no Part B coverage in the home for infusion drugs administered with an infusion pump unless the drug is specifically covered under the local coverage policy of the applicable Medicare DME MAC. Therefore, determinations about Part D sponsor payment for these other methods of administration and for drugs administered with an infusion pump but not covered by the local DME MAC policy should be based on the question of whether the drug is on the sponsor's formulary. [1]

D. Disposable drug delivery systems are non-covered devices under Part B because they do not meet the Medicare definition of durable medical equipment. Drugs and supplies used with disposable drug delivery systems are also non-covered items under Part B. OmniPod and V-Go are disposable drug delivery systems. [2]

3 . References

1. Centers for Medicaid & Medicare Services. Medicare Prescription Drug Benefit Manual. Chapter 6 - Appendix C - Summary of Coverage Policy: Medicare Part B Versus Part D Coverage Issues. Available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. Accessed August 5, 2022.
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4 . Revision History

Date	Notes
11/30/2023	No criteria changes. Updated 2024 GL to incorporate background an d GPI updates from October 2023 annual review.

Prior Authorization Guideline

Guideline Name Injectable Immunosuppressants

Formulary 2024 Samaritan Advantage Health Plans (HMO)

Formulary Note

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	
P&T Revision Date:	04/19/2023 ; 11/16/2023

1 . Criteria

Product Name: Generic azathioprine inj, Brand CellCept Inj, generic mycophenolate inj, Brand Solu-Medrol inj, Generic methylprednisolone sodium succinate inj	
Guideline Type	Part B
Approval Criteria **1** - For patients who were enrolled in Medicare Part A at the time of the organ transplant,	

whether or not Medicare paid for the transplant (i.e., heart, lung, kidney, liver, intestinal, kidney-pancreas transplant, or bone marrow/stem cell transplant)* [A]	
Notes	*Note: If the prescriber indicates that the transplant was performed at a facility that is not a Medicare certified facility (e.g., a facility outside of the United States), then the drug is not eligible for Part B coverage and should be reviewed under the Part D benefit [12, B].

Product Name: Generic azathioprine inj, Brand CellCept Inj, generic mycophenolate inj	
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Patient does not meet criteria for Part B above

AND

2 - One of the following:

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

OR

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

Product Name: Transplant Corticosteroids Processing Under Part D (Brand Solu-Medrol inj, Generic methylprednisolone sodium succinate inj)	
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Patient does not meet criteria for Part B above*

Notes	*Corticosteroids used for transplant purposes that are processing under Part D at point-of-sale can be canceled (would not undergo diagnosis review) once it is determined the member does not meet Part B.

2 . Endnotes

A. Medicare covers immunosuppressive drugs for a beneficiary who has received an organ transplant, provided that the beneficiary receiving the drug was enrolled in Medicare Part A at the time of the organ transplant. Medicare will make payment for medically necessary immunosuppressive drugs for such a beneficiary regardless of whether Medicare made payment for the transplant itself. [9]
B. Prescription drugs used in immunosuppressive therapy are covered only if the transplant met Medicare coverage criteria in effect at the time (e.g., approved facility for kidney, heart, intestinal, liver, lung, or heart/lung transplant; national and/or local medical necessity criteria; etc.). [12]

3 . References

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4 . Revision History

Date	Notes
10/25/2023	2023 UM Annual Review. No criteria changes

Prior Authorization Guideline

Guideline Name Onpattro (patisiran) & Tegsedi (inotersen)

Formulary 2024 Samaritan Advantage Health Plans (HMO)

Formulary Note

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	10/17/2018
P&T Revision Date:	04/19/2023 ; 12/13/2023

1 . Indications

Drug Name: Onpattro (patisiran), Tegsedi (inotersen)
Hereditary transthyretin-mediated amyloidosis Indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

2 . Criteria

Product Name: Onpattro	
Guideline Type	Part B

Approval Criteria

1 - Drug is administered using an infusion pump*

AND

2 - Infusion pump paid for by Medicare*

AND

3 - Drug is administered at home (not including facility providing skilled nursing care)

Notes	*If the infusion pump AND the drug administered via that pump are not covered by Part B, then consideration of coverage for the drug is done under Part D pursuant to Part D formulary. [3, B]

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

Approval Criteria

1 - One of the following:

1.1 Patient does not meet criteria for Part B coverage above

OR

1.2 Patient is in a long-term care facility (e.g., hospital or skilled nursing facility where patient is receiving skilled care)*

AND

2 - Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) with polyneuropathy

AND

3 - Patient has a transthyretin (TTR) mutation (e.g., V30M) [1, 2, 5, 6]

AND

4 - Prescribed by or in consultation with a neurologist

AND

5 - One of the following [2, 6]:

- Patient has a baseline polyneuropathy disability (PND) score ≤ IIIb
- Patient has a baseline familial amyloidotic polyneuropathy (FAP) stage of 1 or 2
- Patient has a baseline neuropathy impairment score (NIS) between 5 and 130

AND

6 - Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy) [2, 6]

Notes	*Long term care facility includes the following: a) hospital, b) skilled nu rsing facility (SNF) or a distinct part SNF, c) a nursing home that is du ally certified as both Medicare SNF and a Medicaid nursing facility, d) a Medicaid only nursing facility that primarily furnishes skilled care, e) a non-participating nursing home (neither Medicaid or Medicare) that provided primarily skilled care, and f) an institution that has a distinct p art SNF and which also primarily furnishes skilled care. [4]

Product Name: Onpattro	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

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

Approval Criteria

1 - Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) with polyneuropathy

AND

2 - Patient has a transthyretin (TTR) mutation (e.g., V30M) [1, 2, 5, 6]

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - One of the following [2, 6]:

- Patient has a baseline polyneuropathy disability (PND) score ≤ IIIb
- Patient has a baseline familial amyloidotic polyneuropathy (FAP) stage of 1 or 2
- Patient has a baseline neuropathy impairment score (NIS) between 10 and 130

AND

5 - Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy) [2, 6]

Product Name: Tegsedi	
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. Drugs that require administration by the use of a piece of covered DME (e.g., a nebulizer, external or implantable pump) are covered under Part B. [3] The statute does not explicitly cover DME drugs; they are covered as a supply necessary for the DME to perform its function. Examples of such drugs include: (1) inhalation drugs that are administered in the home through the use of a nebulizer (e.g., albuterol sulfate, ipratropium bromide); or (2) drugs for which administration with an infusion pump in the home is medically necessary (e.g., some chemotherapeutic agents). In the case of a beneficiary in a hospital, or a SNF bed, (1) who does not have Part A coverage, (2) whose Part A coverage for the stay has run out, or (3) whose stay is non-covered, infusible DME supply drugs are not covered under Part B because the law limits coverage under Part B's DME benefit to those items that are furnished for use in a patient's home, and specifies that a hospital or SNF cannot be considered the beneficiary's “home” for this purpose. In this case, coverage for the drugs would be available under Part D.

B. The fact that coverage is available for a particular drug under Part B with the use of an infusion pump does not mean that coverage under Part D using some other method of administration automatically can be denied. There is no Part B coverage in the home for infusion drugs administered without an infusion pump (e.g., IV push). There is also no Part B coverage in the home for infusion drugs administered with an infusion pump unless the drug is specifically covered under the local coverage policy of the applicable Medicare DME MAC. Therefore, determinations about Part D sponsor payment for these other methods of administration and for drugs administered with an infusion pump but not covered by the local DME MAC policy should be based on the question of whether the drug is on the sponsor's formulary. [3]

4 . References

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4. Centers for Medicaid & Medicare Services. Medicare Parts B/D Coverage Issues. Available at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/PartsBDCoverageSummaryTable_041806.pdf. Accessed March 5, 2021.
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5 . Revision History

Date	Notes
11/21/2023	Stage 5 criteria update

Prior Authorization Guideline

Guideline Name Oral 5-HT3 Receptor Antagonists

Formulary 2024 Samaritan Advantage Health Plans (HMO)

Formulary Note

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	
P&T Revision Date:	4/19/2023

1 . Indications

Drug Name: Anzemet (dolasetron)
Prevention of chemotherapy-induced nausea and vomiting Indicated for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy, including initial and repeat courses in adults and children 2 years and older. **Off Label Uses: Prevention of postoperative nausea and vomiting** Used orally for the prevention of postoperative nausea and vomiting. [5,16] **Prevention and treatment of radiation-induced nausea and vomiting** Used for the

prevention and treatment of nausea and vomiting induced by radiation therapy. [5,6,15]

Treatment of chemotherapy-induced nausea and vomiting Used for the treatment of nausea and vomiting induced by chemotherapy. [5,15]

Drug Name: Granisetron tablet

Prevention of chemotherapy-induced nausea and vomiting Indicated for the prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high-dose cisplatin.

Prevention of radiation-induced nausea and vomiting Indicated for the prevention of nausea and vomiting associated with radiation, including total body irradiation and fractionated abdominal radiation.

Off Label Uses: Prevention of postoperative nausea and vomiting Used for the prevention of postoperative nausea and vomiting. [7]

Treatment of chemotherapy-induced nausea and vomiting Used for the treatment of nausea and vomiting induced by chemotherapy. [7,15]

Treatment of radiation-induced nausea and vomiting Used for the treatment of nausea and vomiting induced by radiation therapy. [7,15]

Drug Name: Zofran (ondansetron), Zuplenz (ondansetron oral soluble film)

Prevention of highly emetogenic cancer chemotherapy-induced nausea and vomiting Indicated for the prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy, including cisplatin greater than or equal to 50 mg/m2.

Prevention of moderately emetogenic cancer chemotherapy-induced nausea and vomiting Indicated for the prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.

Prevention of radiation-induced nausea and vomiting Indicated for the prevention of nausea and vomiting associated with radiotherapy in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen.

Prevention of postoperative nausea and/or vomiting Indicated for the prevention of postoperative nausea and/or vomiting. As with other antiemetics, routine prophylaxis is not recommended for patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and/or vomiting must be avoided postoperatively, Zofran tablets, Zofran ODT tablets, Zofran oral solution, and Zuplenz are recommended even where the incidence of postoperative nausea and/or vomiting is low.

Off Label Uses: Treatment of chemotherapy-induced nausea and vomiting Used for the treatment of nausea and vomiting induced by chemotherapy. [15,17]

Treatment of radiation-induced nausea and vomiting Used for the treatment of nausea and vomiting induced by radiation therapy. [15,17]

2 . Criteria

Product Name: Anzemet, granisetron, Generic ondansetron, Brand Zofran, or Zuplenz	
Guideline Type	Part B

Approval Criteria

1 - Oral anti-emetic drug administered with cancer chemotherapy treatment that is initiated within 2 hours of the administration of chemotherapy and continued for a period not to exceed 48 hours from that time [8-11]

AND

2 - Oral anti-emetic drug is used as a full therapeutic replacement for IV anti-emetic drugs that would have been administered at the time of the cancer chemotherapy treatment [8-11]

Product Name: Anzemet, granisetron, Generic ondansetron, Brand Zofran, or Zuplenz	
Diagnosis	Chemotherapy-Induced Nausea and Vomiting
Approval Length	12 month(s)
Guideline Type	Part D

Approval Criteria

1 - Patient does not meet criteria for Part B above

AND

2 - Used for the prevention or treatment of nausea and vomiting associated with cancer chemotherapy

Product Name: Anzemet, granisetron, Generic ondansetron, Brand Zofran, or Zuplenz

Diagnosis	Radiation-Induced Nausea and Vomiting
Approval Length	3 month(s)
Guideline Type	Part D

Approval Criteria

1 - Patient does not meet criteria for Part B above

AND

2 - Used for the prevention or treatment of nausea and vomiting associated with radiotherapy (total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen)

Product Name: Anzemet, granisetron, Generic ondansetron, Brand Zofran, or Zuplenz	
Diagnosis	Post-Operative Nausea and/or Vomiting
Approval Length	1 month(s)
Guideline Type	Part D

Approval Criteria

1 - Patient does not meet criteria for Part B above

AND

2 - Used for the prevention of postoperative nausea and/or vomiting when administered prior to induction of anesthesia

Product Name: Anzemet*, granisetron*, Generic ondansetron*, Brand Zofran*, or Zuplenz*	
Guideline Type	Quantity Limit

Approval Criteria

1 - Quantity requests exceeding the limited amount will be evaluated on an individual basis by a clinical pharmacist for patients on ongoing chemotherapy or radiotherapy, or for patients undergoing more than one surgical procedure in any one month period. [3-4]

Notes	*Quantity limits may not apply depending on the plan.

3 . References

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4 . Revision History

Date	Notes
8/11/2023	2024 Medicare Implementation - No Changes

Prior Authorization Guideline

Guideline Name Oral Antiemetics for Chemotherapy

Formulary 2024 Samaritan Advantage Health Plans (HMO)

Formulary Note

Guideline Note:

Effective Date:	11/1/2023
P&T Approval Date:	
P&T Revision Date:	04/19/2023 ; 10/18/2023

1 . Criteria

Product Name: Generic Aller-Cap capsule, Generic Banophen capsule, Generic chlorpromazine tablet, Brand Decadron tablet, Generic dexamethasone elixir, Generic Dexamethasone Intensol oral solution, Generic dexamethasone tablet, Generic dexamethasone oral solution, Brand Dexpak, Generic dexamethasone pack, Generic diphenhydramine capsule and elixir, Brand Dxevo, Hemady, Brand Hidex, Generic hydroxyzine pamoate, Generic perphenazine tablet, Generic prochlorperazine tablet, Generic promethazine tablet and syrup, Brand Taperdex	
Guideline Type	Part B

Approval Criteria

1 - Oral anti-emetic drug administered with cancer chemotherapy treatment that is initiated within 2 hours of the administration of chemotherapy and continued for a period not to exceed 48 hours from that time [1-4]

AND

2 - Oral anti-emetic drug is used as a full therapeutic replacement for IV anti-emetic drugs that would have been administered at the time of the cancer chemotherapy treatment [1-4]

Product Name: Generic Aller-Cap capsule, Generic Banophen capsule, Generic chlorpromazine tablet, Brand Decadron tablet, Generic dexamethasone elixir, Generic Dexamethasone Intensol oral solution, Generic dexamethasone tablet, Generic dexamethasone oral solution, Brand Dexpak, Generic dexamethasone pack, Generic diphenhydramine capsule and elixir, Brand Dxevo, Hemady, Brand Hidex, Generic hydroxyzine pamoate, Generic perphenazine tablet, Generic prochlorperazine tablet, Generic promethazine tablet and syrup, Brand Taperdex	
Approval Length	12 month(s)
Guideline Type	Part D

Approval Criteria

1 - Patient does not meet criteria for Part B above

AND

2 - One of the following:

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

OR

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

2 . References

1. Medicare Parts B/D Coverage Issues. Available at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/BvsDCoverageIssues.pdf. Accessed August 3, 2022.
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3 . Revision History

Date	Notes
10/20/2023	Added Hemady to guideline.

Prior Authorization Guideline

Guideline Name Oral Chemotherapy Agents

Formulary 2024 Samaritan Advantage Health Plans (HMO)

Formulary Note

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	
P&T Revision Date:	04/19/2023 ; 11/16/2023

1 . Indications

Drug Name: Alkeran (melphalan) tablet
Multiple Myeloma, Epithelial Carcinoma of the Ovary Indicated for the palliative treatment of multiple myeloma and for the palliation of non-resectable epithelial carcinoma of the ovary. **Off Label Uses: Amyloidosis** Has been used in the treatment of amyloidosis. [3]
Drug Name: Myleran (busulfan) tablet

Chronic myelogenous leukemia Indicated for the palliative treatment of chronic myelogenous (myeloid, myelocytic, granulocytic) leukemia.

Off Label Uses: Essential thrombocythemia Has been used for the treatment of essential thrombocythemia. [6]

2 . Criteria

Product Name: Brand Alkeran tablet, Generic melphalan tablet, Myleran tablet, Trexall, Hycamtin capsules, Brand Temodar capsules, Generic temzolomide capsules, Generic etoposide capsules, Brand Xeloda tablets, Generic capecitabine tablets	
Guideline Type	Part B
Approval Criteria **1** - For patients who are being treated for a cancer	
Notes	*For an off-label indication, refer to the off-label guideline criteria [C]

Product Name: Brand Alkeran tablet, Generic melphalan tablet	
Guideline Type	Part D
Approval Criteria **1** - One of the following: **1.1** Both of the following: **1.1.1** Patient does not meet criteria for Part B above **AND** **1.1.2** If requested for an off-label indication, the off-label guideline approval criteria have been met **OR**	

1.2 Diagnosis of amyloidosis [3]

Product Name: Myleran tablet	
Guideline Type	Part D

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Patient does not meet criteria for Part B above

AND

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

OR

1.2 Diagnosis of essential thrombocythemia [5, B]

Product Name: Trexall	
Guideline Type	Part D

Approval Criteria

1 - Patient does not meet criteria for Part B above

AND

2 - One of the following:

2.1 Diagnosis of one of the following:

- Psoriasis
- Rheumatoid arthritis

- Polyarticular-course juvenile rheumatoid arthritis

OR

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

Product Name: Hycamtin capsules, Brand Temodar capsules, Generic temzolomide capsules, Generic etoposide capsules, Brand Xeloda tablets, Generic capecitabine tablets	
Guideline Type	Part D

Approval Criteria

1 - Patient does not meet criteria for Part B above

AND

2 - One of the following:

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

OR

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

3 . Endnotes

A. For an oral anti-cancer drug to be covered under Part B, it must 1) be prescribed by a physician or other practitioner licensed under State law to prescribe such drugs as anti-cancer chemotherapeutic agents; 2) Be a drug or biological that has been approved by the Food and Drug Administration (FDA); 3) Have the same active ingredients as a non-self-administrable anti-cancer chemotherapeutic drug or biological that is covered when furnished incident to a physician's service. The oral anti-cancer drug and the non-self-administrable drug must have the same chemical/generic name as indicated by the FDA's "Approved Drug Products" (Orange Book), "Physician's Desk Reference" (PDR), or an authoritative drug compendium; 4) Be used for the same indications, including

unlabeled uses, as the non-self-administrable version of the drug; and 5) Be reasonable and necessary for the individual patient. [1] The following drugs are generally considered Part D exclusions and may not be reviewed for Part D coverage for cancer chemotherapy: Alkeran (melphalan), Hycamtin (topotecan), Temodar (temozolomide), Vepesid (etoposide), Xeloda (capecitabine).

B. Based on Maximus appeal overturn, essential thrombocythemia is a medically accepted indication as cited in a Medicare approved journal [5]. Per Maximus decision, this indication does not meet Part B rule regarding coverage for an oral anticancer drug. Specifically, there are no citations in Medicare approved publications that support the use of intravenous busulfan for the treatment of thrombocythemia and therefore should be covered under Part D.

C. The plan provides coverage for the requested medication when it is being used for a U.S. Food and Drug Administration (FDA)-approved indication and/or a medical condition that is supported by medical compendia or published literature (that is, peer-reviewed medical journals) that is not otherwise excluded from Medicare Part D. Medical compendia are a collection of medical references recognized by healthcare professionals. Examples of Medicare-recognized compendia for the treatment of cancer include: American Hospital Formulary Service Drug Information (AHFS DI), Micromedex DRUGDEX Information System, the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Clinical Pharmacology, or Wolters Kluwer Lexi-Drugs. [1]

4 . References

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3. 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 November 2, 2023.
4. Myleran prescribing information. Waylis Therapeutics LLC. Wixom, MI. May 2023.
5. Shvidel L, Sigler E, Haran M, et al. Busulphan is safe and efficient treatment in elderly patients with essential thrombocythemia. Leukemia. 2007; 21, 2071-72.
6. Renso R, Aroldi A, et al. Long-term and low-dose of busulfan is a safe and effective second-line treatment in elderly patients with essential thrombocythemia resistant or intolerant to hydroxyurea. Blood Cancer J. 2018;8(6):56. Published 2018 Jun 11.doi:10.1038/s41408-018-0091-6

5 . Revision History

Date	Notes
11/2/2023	Annual Review. No changes

Prior Authorization Guideline

Guideline Name Oral Immunosuppressants

Formulary 2024 Samaritan Advantage Health Plans (HMO)

Formulary Note

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	
P&T Revision Date:	4/19/2023

1 . Criteria

Product Name: Astagraf XL capsules, Brand Azasan tablets, Generic azathioprine tablets, Brand Cellcept oral suspension, Brand Cellcept capsules, Brand Cellcept tablets, Generic cyclosporine capsules, Generic cyclosporine modified capsules, Generic cyclosporine modified oral solution, Brand Deltasone tablets, Envarsus XR, Gengraf capsules, Gengraf solution, Brand Imuran tablets, Brand Medrol tablets, Generic methylprednisolone tablets, Millipred DP, Millipred solution, Millipred tablets, Generic prednisolone tablets, Generic mycophenolate mofetil capsules, Generic mycophenolate mofetil tablets, Generic mycophenolate mofetil oral suspension, Brand Myfortic tablets, Generic mycophenolate sodium tablets, Brand Neoral capsules, Brand Neoral oral solution, Brand Orapred ODT, Brand Pediapred, Generic prednisone oral solution, Generic prednisone oral solution, Generic

prednisone packs, Generic prednisone tablets, generic prednisolone solution, generic prednisolone ODT, Brand Prograf capsules, Prograf granules packet for oral suspension, Brand Rapamune oral solution, Brand Rapamune oral tablets, Rayos tablets, Brand Sandimmune oral capsules, Sandimmune oral solution, Generic sirolimus oral solution, Generic sirolimus tablets, Generic tacrolimus capsules, Brand Veripred solution, Brand Zortress tablets, or Generic Everolimus tablets	
Guideline Type	Part B
Approval Criteria **1** - For patients who were enrolled in Medicare Part A at the time of the organ transplant, whether or not Medicare paid for the transplant (i.e., heart, lung, kidney, liver, intestinal, kidney-pancreas transplant, bone marrow/stem cell transplant)* [2-3, A]	
Notes	*Note: If the prescriber indicates that the transplant was performed at a facility that is not a Medicare certified facility (e.g., a facility outside o f the United States), then the drug is not eligible for Part B coverage a nd should be reviewed under the Part D benefit [4, B].

Product Name: Astagraf XL capsules, Brand Azasan tablets, Generic azathioprine tablets, Brand Cellcept oral suspension, Brand Cellcept capsules, Brand Cellcept tablets, Generic cyclosporine capsules, Generic cyclosporine modified capsules, Generic cyclosporine modified oral solution, Envarsus XR, Gengraf capsules, Gengraf solution, Brand Imuran tablets, Generic mycophenolate mofetil capsules, Generic mycophenolate mofetil tablets, Generic mycophenolate mofetil oral suspension, Brand Myfortic tablets, Generic mycophenolate sodium tablets, Brand Neoral capsules, Brand Neoral oral solution, Brand Prograf capsules, Prograf granules packet for oral suspension, Brand Rapamune oral solution, Brand Rapamune oral tablets, Brand Sandimmune oral capsules, Sandimmune oral solution, Generic sirolimus oral solution, Generic sirolimus tablets, or Generic tacrolimus capsules, Brand Zortress tablets, generic everolimus tablets	
Guideline Type	Part D Prior Authorization
Approval Criteria **1** - Patient does not meet criteria for Part B above **AND** **2** - One of the following: **2.1** Requested drug is FDA-approved for the condition being treated	

OR **2.2** If requested for an off-label indication, the off-label guideline approval criteria have been met

Product Name: Transplant Corticosteroids Processing Under Part D (Brand Deltasone tablets, Brand Medrol tablets, Generic methylprednisolone tablets, Millipred DP, Millipred solution, Millipred tablets, Generic prednisolone tablets, Brand Orapred ODT, Brand Pediapred solution, Generic prednisolone solution, Generic prednisolone tablets, Generic prednisone oral solution, Generic prednisone intensol oral solution, Generic prednisone packs, Generic prednisone tablets, Rayos tablets, Brand Veripred solution)	
Guideline Type	Part D Prior Authorization
Approval Criteria **1** - Patient does not meet criteria for Part B above*	
Notes	*Corticosteroids used for transplant purposes that are processing under Part D at point-of-sale can be canceled (would not undergo diagnosis review) once it is determined the member does not meet Part B.

2 . Endnotes

A. Medicare covers immunosuppressive drugs for a beneficiary who has received an organ transplant, provided that the beneficiary receiving the drug was enrolled in Medicare Part A at the time of the organ transplant. Medicare will make payment for medically necessary immunosuppressive drugs for such a beneficiary regardless of whether Medicare made payment for the transplant itself. [3]
B. Prescription drugs used in immunosuppressive therapy are covered only if the transplant met Medicare coverage criteria in effect at the time (e.g., approved facility for kidney, heart, intestinal, liver, lung, or heart/lung transplant; national and/or local medical necessity criteria; etc.). [4]

3 . References

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2. Medicare Claims Processing Manual. Chapter 17 - Drugs and Biologicals. Section 80.3, pages 46-49. Available at: http://www.cms.gov/manuals/downloads/clm104c17.pdf. Accessed on October 19, 2021.
3. Centers for Medicare & Medicaid Services (CMS). Adjudicating Claims for Immunosuppressive Drugs When Medicare Did Not Pay for the Original Transplant. CMS Website. http://www.cms.gov/transmittals/downloads/R1448CP.pdf. Published February 15, 2008. Accessed November 29, 2018.
4. Centers for Medicare & Medicaid Services (CMS). Local Coverage Article for Immunosuppressive Drugs - Policy Article (A52474) (cms.gov). https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=52474&ver=26&bc=CAAAAAAAAAAA. Published January 1, 2020. Accessed October 19, 2021.

4 . Revision History

Date	Notes
8/11/2023	2024 Medicare Implementation - No Changes

Prior Authorization Guideline

Guideline Name Parenteral Nutrition

Formulary 2024 Samaritan Advantage Health Plans (HMO)

Formulary Note

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	
P&T Revision Date:	4/19/2023

1 . Criteria

Product Name: Drugs (NDC) used in the parenteral nutrition [A, B, C]	
Guideline Type	Part B
Approval Criteria **1** - Patient has a permanent non-functioning digestive tract	

AND

2 - ONE of the following:

2.1 The provider has considered and ruled out enteral nutrition

OR

2.2 Enteral nutrition has been tried and found ineffective

OR

2.3 Enteral nutrition exacerbates gastrointestinal tract dysfunction

AND

3 - Patient has one of the following:

3.1 A condition involving the small intestine and/or its exocrine glands which significantly impairs the absorption of nutrients

OR

3.2 A disease of the stomach and/or intestine which is a motility disorder and impairs the ability of nutrients to be transported through and absorbed by the gastrointestinal (GI) system

Product Name: Drugs (NDC) used in the parenteral nutrition	
Guideline Type	Part D

Approval Criteria

1 - Patient does not meet criteria for Part B coverage above

2 . Endnotes

A. Parenteral nutritions are covered under the prosthetic benefit. They are available to beneficiaries who cannot absorb nutrition through their intestinal tract. [1] The same drug (NDC) provided by an infusion/DME supplier may be covered under Part B or Part D depending on the characteristics of the beneficiary or method of administration. The supplier would need to know whether the therapy was being provided because of a non-functioning digestive tract. If so, Part B would be billed. Otherwise this would be a Part D drug. Parenteral nutrition, including Intraperitoneal Nutrition (IPN), or Intradialytic Parenteral Nutrition (IDPN) is covered under Part B if the member has a 'permanent' non-functioning digestive tract. Parenteral nutrition is not covered under Part B in situations of temporary impairment. [2] For beneficiaries with ESRD on dialysis and a permanent non-functioning digestive tract IPN is covered under Part B, however the dialysate itself is not covered. The dialysate is to be covered by the dialysis center as part of their bundled services. [3]
B. As stipulated in the Medicare Benefit Policy Manual (CMS Pub. 100-02), Chapter 15 Section 120, coverage of parenteral nutrition requires that a beneficiary must have a permanent impairment. However, this does not require a determination that there is no possibility that the beneficiary's condition may improve sometime in the future. If the medical record, including the judgment of the treating practitioner, indicates that the impairment will be of long and indefinite duration, the test of permanence is considered met. [4]
C. When nutritional support other than the oral route is necessary, enteral nutrition (EN) is usually initially preferable to parenteral nutrition for the following reasons: (1) In a fluid restricted beneficiary, EN permits delivery of all necessary nutrients in a more concentrated volume than parenteral nutrition; (2) EN allows for safer home delivery Created on 12/30/2021. Page 3 of 12 of nutrients; and (3) EN lowers the risk of Central Line-Associated Bloodstream Infections (CLABSI). [5]

3 . References

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2. Centers for Medicaid & Medicare Services. Medicare Prescription Drug Benefit Manual. Chapter 6 – Part D Drugs and Formulary Requirements. Available at https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf. Accessed December 30, 2020.
3. Centers for Medicaid & Medicare Services. IDPN/IPN Coverage under Medicare Part D. October 5, 2012. http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/IDPN-IPNCoverageunderMedicarePart-D.pdf. Accessed December 29, 2020.

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5. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): Parenteral Nutrition (L38953). Available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38953&ver=4&keyword=L38953&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1. Accessed December 22, 2022.

4 . Revision History

Date	Notes
8/11/2023	2024 Medicare Implementation - No Changes

Prior Authorization Guideline

Guideline Name Pulmonary Arterial Hypertension Agents

Formulary 2024 Samaritan Advantage Health Plans (HMO)

Formulary Note

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	2/15/2011
P&T Revision Date:	6/19/2023

Note:

THIS GUIDELINE IS USED TO DETERMINE PART B VS PART D COVERAGE FOR THE FOLLOWING AGENTS: Flolan (epoprostenol) injection, Generic epoprostenol injection, Remodulin (treprostinil) injection, Tyvaso (treprostinil) inhalation solution, Tyvaso (treprostinil) Refill inhalation solution, Tyvaso (treprostinil) Start inhalation solution, Veletri (epoprostenol) injection, or Ventavis (iloprost) inhalation solution

1 . Indications

Drug Name: Adcirca (tadalafil) Tablets, Alyq (tadalafil) Tablets, Tadliq (tadalafil) Oral Suspension
Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) to improve exercise ability. Studies establishing effectiveness included predominately patients with New York Heart Association (NYHA) Functional Class II–III symptoms and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (23%).
Drug Name: Adempas (riociguat) Tablets
Pulmonary Arterial Hypertension (PAH) Indicated for treatment of adults with PAH (WHO Group I) to improve exercise capacity, WHO Functional Class, and to delay clinical worsening. Efficacy was shown in patients on riociguat monotherapy or in combination with endothelin receptor antagonists or prostanoids. Studies establishing effectiveness included predominantly patients with WHO Functional Class II to III and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (25%). **Chronic-Thromboembolic Pulmonary Hypertension (CTEPH)** Indicated for treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH), (WHO Group 4) after surgical treatment, or inoperable CTEPH, to improve exercise capacity and WHO Functional Class.
Drug Name: Flolan (epoprostenol sodium) Injection
Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to improve exercise capacity. Studies establishing effectiveness included predominantly (97%) patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH (49%) or PAH associated with connective tissue diseases (51%).
Drug Name: Letairis (ambrisentan) Tablets
Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to 1) improve exercise ability and delay clinical worsening and 2) in combination with tadalafil to reduce the risks of disease progression and hospitalization for worsening PAH, and to improve exercise ability. Studies establishing effectiveness included predominantly patients with WHO Functional Class II-III symptoms and etiologies of idiopathic or heritable PAH (60%) or PAH associated with connective tissue diseases (34%).
Drug Name: Liqrev (sildenafil) suspension
Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) in adults to improve exercise ability and delay clinical worsening.
Drug Name: Opsumit (macitentan) Tablets

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to reduce the risks of disease progression and hospitalization for PAH. Effectiveness was established in a long-term study in PAH patients with predominantly WHO Functional Class II-III symptoms treated for an average of 2 years. Patients had idiopathic and heritable PAH (57%), PAH caused by connective tissue disorders (31%), and PAH caused by congenital heart disease with repaired shunts (8%).

Drug Name: Orenitram (treprostinil) Tablets

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to delay disease progression and to improve exercise capacity. The studies that established effectiveness included predominately patients with WHO functional class II-III symptoms and etiologies of idiopathic or heritable PAH (66%) or PAH associated with connective tissue disease (26%).

Drug Name: Remodulin (treprostinil sodium) Injection

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to diminish symptoms associated with exercise. Studies establishing effectiveness included patients with NYHA Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (58%), PAH associated with congenital systemic-to-pulmonary shunts (23%), or PAH associated with connective tissue diseases (19%). Indicated to diminish the rate of clinical deterioration in patients with PAH requiring transition from epoprostenol. Consider the risks and benefits of each drug prior to transition.

Drug Name: Revatio (sildenafil) Injection, Tablets, Oral Suspension

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I): 1) In adults to improve exercise ability and delay clinical worsening. 2) in pediatric patients 1 to 17 years old to improve exercise ability and, in pediatric patients too young to perform standardized exercise testing, pulmonary hemodynamics thought to underly improvements in exercise.

Drug Name: Tracleer (bosentan) Tablets, Tablets for Suspension

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I): 1) In adults to improve exercise ability and to decrease clinical worsening. Studies establishing effectiveness included predominantly patients with WHO Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (60%), PAH associated with connective tissue diseases (21%), and PAH associated with congenital heart disease with left-to right shunts (18%). 2) In pediatric patients aged 3 years and older with idiopathic or congenital PAH to improve pulmonary vascular resistance (PVR), which is expected to result in an improvement in exercise ability.

Drug Name: Tyvaso (treprostinil) Inhalation Solution, Tyvaso (treprostinil) DPI Inhalation Powder

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to improve exercise ability. Studies establishing effectiveness included predominately patients

with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with connective tissue diseases (33%). The effects diminish over the minimum recommended dosing interval of 4 hours; treatment timing can be adjusted for planned activities. While there are long-term data on use of treprostinil by other routes of administration, nearly all controlled clinical experience with inhaled treprostinil has been on a background of bosentan (an endothelin receptor antagonist) or sildenafil (a phosphodiesterase type 5 inhibitor). The controlled clinical experience was limited to 12 weeks in duration.

Pulmonary Hypertension Associated with Interstitial Lung Disease (ILD) Indicated for the treatment of pulmonary hypertension associated with ILD (PH-ILD; WHO Group 3) to improve exercise ability. The study establishing effectiveness predominately included patients with etiologies of idiopathic interstitial pneumonia (IIP) (45%) inclusive of idiopathic pulmonary fibrosis (IPF), combined pulmonary fibrosis and emphysema (CPFE) (25%), and WHO Group 3 connective tissue disease (22%).

Drug Name: Veletri (epoprostenol) Injection

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I) to improve exercise capacity. Studies establishing effectiveness included predominantly patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases.

Drug Name: Ventavis (iloprost) Inhalation Solution

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to improve a composite endpoint consisting of exercise tolerance, symptoms (NYHA Class), and lack of deterioration. Studies establishing effectiveness included predominately patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH (65%) or PAH associated with connective tissue diseases (23%).

Drug Name: Uptravi (selexipag) Tablets and Injection

Pulmonary Arterial Hypertension Indicated for the treatment of PAH (WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH. Effectiveness was established in a long-term study in PAH patients with WHO Functional Class II-III symptoms. Patients had idiopathic and heritable PAH (58%), PAH associated with connective tissue disease (29%), PAH associated with congenital heart disease with repaired shunts (10%).

2 . Criteria

Product Name: Brand Flolan injection, Generic epoprostenol injection, Brand Remodulin injection, Generic treprostinil injection, or Veletri injection

Guideline Type	Part B

Approval Criteria

1 - Patients with pulmonary hypertension*

AND

2 - Pulmonary hypertension is not secondary to any of the following:

- pulmonary venous hypertension (e.g., left sided atrial or ventricular disease, left sided valvular heart disease)
- disorders of the respiratory system (e.g., chronic obstructive pulmonary disease, interstitial lung disease, obstructive sleep apnea or other sleep disordered breathing, alveolar hypoventilation disorders)

AND

3 - One of the following:

3.1 Patients with primary pulmonary hypertension

OR

3.2 Patients with pulmonary hypertension secondary to one of the following conditions:

- Connective tissue disease
- Thromboembolic disease of the pulmonary arteries
- Human immunodeficiency virus (HIV) infection
- Cirrhosis
- Diet drugs
- Congenital left to right shunts

AND

4 - Pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition

AND

5 - Mean pulmonary artery pressure is greater than 25 mm Hg at rest or greater than 30 mm Hg with exertion

AND

6 - Patient has significant symptoms from the pulmonary hypertension (e.g., severe dyspnea on exertion, and either fatigability, angina, or syncope)

AND

7 - Treatment with oral calcium channel blocking agents has been tried and failed, or has been considered and ruled out

AND

8 - Drug is administered at home (not including facility providing skilled nursing care)

AND

9 - Both of the following:

9.1 Drug is administered using an infusion pump

AND

9.2 Infusion pump paid for by Medicare**

Notes	*Pulmonary hypertension includes arterial hypertension (PAH). **If the infusion pump AND the drug administered via that pump are not cover ed by Part B, then consideration of coverage for the drug is done und er Part D pursuant to Part D formulary. [13, A]

Product Name: Ventavis inhalation solution

Guideline Type	Part B

Approval Criteria

1 - Patients with pulmonary artery hypertension

AND

2 - Pulmonary hypertension is not secondary to any of the following:

- pulmonary venous hypertension (e.g., left sided atrial or ventricular disease, left sided valvular heart disease)
- disorders of the respiratory system (e.g., chronic obstructive pulmonary disease, interstitial lung disease, obstructive sleep apnea or other sleep disordered breathing, alveolar hypoventilation disorders)

AND

3 - One of the following:

3.1 Patients with primary pulmonary hypertension

OR

3.2 Patients with pulmonary hypertension secondary to one of the following conditions:

- Connective tissue disease
- Human immunodeficiency virus (HIV) infection
- Cirrhosis
- Diet drugs
- Congenital left to right shunts

AND

4 - Pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition

AND

5 - Mean pulmonary artery pressure is greater than 25 mm Hg at rest or greater than 30 mm Hg with exertion

AND

6 - Patient has significant symptoms from the pulmonary hypertension (e.g., severe dyspnea on exertion, and either fatigability, angina, or syncope)

AND

7 - Treatment with oral calcium channel blocking agents has been tried and failed, or has been considered and ruled out

AND

8 - Drug is administered at home (not including facility providing skilled nursing care)

AND

9 - Drug is administered using the device supplied with Ventavis [i.e., I-neb Adaptive Aerosol Delivery (AAD) System] or a controlled dose inhalation drug delivery system [3, 16]

Product Name: Tyvaso inhalation solution, Tyvaso Refill inhalation solution, or Tyvaso Start inhalation solution	
Diagnosis	Pulmonary Hypertension associated with Interstitial Lung Disease
Guideline Type	Part B

Approval Criteria

1 - Diagnosis of pulmonary hypertension associated with interstitial lung disease

AND

2 - The presence of interstitial lung disease has been confirmed by a high-resolution CT scan of the chest

AND

3 - Mean pulmonary artery pressure is greater than or equal to 25 mm Hg

AND

4 - Pulmonary capillary wedge pressure or left ventricular end-diastolic pressure is less than or equal to 15 mm Hg

AND

5 - Pulmonary vascular resistance is greater than or equal to 3 Wood Units at rest

AND

6 - Patient has significant symptoms of pulmonary hypertension (e.g., dyspnea on exertion, fatigability)

AND

7 - Drug is administered at home (not including facility providing skilled nursing care)

AND

8 - Drug is administered using the device supplied with the Tyvaso Inhalation System or a small volume ultrasonic nebulizer [4, 16]

Product Name: Tyvaso inhalation solution, Tyvaso Refill inhalation solution, or Tyvaso Start inhalation solution	
Diagnosis	Pulmonary Arterial Hypertension
Guideline Type	Part B

Approval Criteria

1 - Patients with pulmonary artery hypertension

AND

2 - Disease is NOT secondary to any of the following:

- pulmonary venous hypertension (e.g., left sided atrial or ventricular disease, left sided valvular heart disease)
- disorders of the respiratory system* (e.g., chronic obstructive pulmonary disease, obstructive sleep apnea or other sleep disordered breathing, alveolar hypoventilation disorders)

AND

3 - One of the following:

3.1 Patients with primary pulmonary hypertension

OR

3.2 Pulmonary hypertension is secondary to one of the following conditions:

- Connective tissue disease
- Human immunodeficiency virus (HIV) infection
- Cirrhosis
- Diet drugs
- Congenital left to right shunts

AND

4 - Pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition

AND

5 - Mean pulmonary artery pressure is greater than 25 mm Hg at rest or greater than 30 mm Hg with exertion

AND

6 - Patient has significant symptoms from the pulmonary hypertension (e.g., severe dyspnea on exertion, and either fatigability, angina, or syncope)

AND

7 - Treatment with oral calcium channel blocking agents has been tried and failed, or has been considered and ruled out

AND

8 - Drug is administered at home (not including facility providing skilled nursing care)

AND

9 - Drug is administered using the device supplied with the Tyvaso Inhalation System or a small volume ultrasonic nebulizer [4, 16]

Notes	*If interstitial lung disease, review using the “Pulmonary Hypertension Associated with Interstitial Lung Disease” Part B section above.

Product Name: Tyvaso inhalation solution, Tyvaso Refill inhalation solution, or Tyvaso Start inhalation solution	
Diagnosis	Pulmonary Hypertension associated with Interstitial Lung Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient does not meet criteria for Part B coverage above

OR

1.2 Patient is in a long-term care facility (e.g., hospital or skilled nursing facility where patient is receiving skilled care)*

AND

2 - Diagnosis of pulmonary hypertension associated with interstitial lung disease

AND

3 - 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

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

- Pulmonologist
- Cardiologist

Notes	*Long-term care facility includes the following: a) hospital, b) skilled nu rsing facility (SNF) or a distinct part SNF, c) a nursing home that is du ally certified as both Medicare SNF and a Medicaid nursing facility, d) a Medicaid only nursing facility that primarily furnishes skilled care, e) a non-participating nursing home (neither Medicaid or Medicare) that provided primarily skilled care, and f) an institution that has a distinct p art SNF and which also primarily furnishes skilled care. [14]

Product Name: Tyvaso inhalation solution, Tyvaso Refill inhalation solution, or Tyvaso Start inhalation solution

Diagnosis	Pulmonary Hypertension associated with Interstitial Lung Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name: Brand Flolan injection, Generic epoprostenol injection, Brand Remodulin injection, Generic treprostinil injection, Tyvaso inhalation solution, Tyvaso Refill inhalation solution, Tyvaso Start inhalation solution, Veletri injection, or Ventavis inhalation solution	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient does not meet criteria for Part B coverage above

OR

1.2 Patient is in a long-term care facility (e.g., hospital or skilled nursing facility where patient is receiving skilled care)*

AND

2 - Diagnosis of pulmonary arterial hypertension

AND

3 - Pulmonary arterial hypertension is symptomatic

AND

4 - One of the following:

4.1 Diagnosis of pulmonary arterial hypertension confirmed by right heart catheterization [B]

OR

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

AND

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

- Pulmonologist
- Cardiologist

Notes	*Long term care facility includes the following: a) hospital, b) skilled nu rsing facility (SNF) or a distinct part SNF, c) a nursing home that is du ally certified as both Medicare SNF and a Medicaid nursing facility, d) a Medicaid only nursing facility that primarily furnishes skilled care, e) a non-participating nursing home (neither Medicaid or Medicare) that provided primarily skilled care, and f) an institution that has a distinct p art SNF and which also primarily furnishes skilled care. [14]

Product Name: Brand Revatio injection or Generic sildenafil injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension confirmed by right heart catheterization [B]

OR

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

AND

4 - Patient is unable to take oral medications [2]

AND

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

- Pulmonologist
- Cardiologist

Product Name: Tyvaso DPI	
Diagnosis	Pulmonary Hypertension associated with Interstitial Lung Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary hypertension associated with interstitial lung disease

AND

2 - Diagnosis of pulmonary hypertension associated with interstitial lung disease was confirmed by diagnostic test(s) (e.g., right heart catheterization, doppler echocardiogram, computerized tomography imaging)

AND

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

- Pulmonologist
- Cardiologist

Product Name: Tyvaso DPI	
Diagnosis	Pulmonary Hypertension associated with Interstitial Lung Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name: Brand Adcirca* tablet, Generic tadalafil* tablet, Generic Alyq* tablet, Tadliq oral suspension*, Adempas tablet, Brand Letairis tablet, Generic ambrisentan, Opsumit tablet, Orenitram tablet, Brand Revatio* tablet, Generic sildenafil* tablet, Brand Tracleer tablet, Generic bosentan tablet, or Tracleer tablet for suspension, Tyvaso DPI	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension confirmed by right heart catheterization [B]

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	*If the member does not have a valid Part D diagnosis, please check if the plan has an enhanced exclusion benefit where the drug may be co vered.

Product Name: Brand Adcirca* tablet, Generic tadalafil* tablet, Generic Alyq* tablet, Tadliq oral suspension*, Adempas tablet, Brand Flolan injection, Generic epoprostenol injection, Brand Letairis tablet, Generic ambrisentan tablet, Opsumit tablet, Orenitram tablet, Brand Remodulin injection, Generic treprostinil injection, Brand Revatio injection, Generic sildenafil injection, Brand Revatio* tablet, Generic sildenafil* tablet, Brand Tracleer tablet, Generic bosentan tablet, Tracleer tablet for suspension, Tyvaso inhalation solution, Tyvaso Refill inhalation solution, Tyvaso Start inhalation solution, Tyvaso DPI, Veletri injection, or Ventavis inhalation solution	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Notes	*If the member does not have a valid Part D diagnosis, please check if the plan has an enhanced exclusion benefit where the drug may be co vered.

Product Name: Liqrev, Brand Revatio oral suspension or Generic sildenafil oral suspension	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension confirmed by right heart catheterization [B]

OR

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

AND

4 - One of the following:

4.1 Intolerance to generic Revatio tablets

OR

4.2 Patient is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to one of the following:

- Age
- Oral-motor difficulties
- Dysphagia

AND

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

- Pulmonologist
- Cardiologist

Product Name: Liqrev, Brand Revatio oral suspension or Generic sildenafil oral suspension	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name: Uptravi tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [B]

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:

- PDE5 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), or Tracleer (bosentan)]

OR

4.2 For continuation of prior therapy

AND

5 - Not taken in combination with a prostanoid/prostacyclin analogue [e.g., Flolan (epoprostenol), Ventavis (iloprost), Tyvaso/Remodulin/Orenitram (treprostinil)]

AND

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

- Pulmonologist
- Cardiologist

Product Name: Uptravi injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [B]

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:

- PDE5 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), or Tracleer (bosentan)]

OR

4.2 For continuation of prior therapy

AND

5 - Not taken in combination with a prostanoid/prostacyclin analogue [e.g., Flolan (epoprostenol), Ventavis (iloprost), Tyvaso/Remodulin/Orenitram (treprostinil)]

AND

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

- Pulmonologist
- Cardiologist

AND

7 - Patient is unable to take oral medications [15]

Product Name: Uptravi tablet/injection	
Diagnosis	Pulmonary Arterial Hypertension
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 taken in combination with a prostanoid/prostacyclin analogue [e.g., Flolan (epoprostenol), Ventavis (iloprost), Tyvaso/Remodulin/Orenitram (treprostinil)]

Product Name: Adempas tablet	
Diagnosis	Chronic Thromboembolic Pulmonary Hypertension (CTEPH)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of inoperable or persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH)

AND

1.1.2 CTEPH is symptomatic

OR

1.2 Patient is currently on any therapy for the diagnosis of CTEPH

AND

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

- Pulmonologist
- Cardiologist

Product Name: Adempas tablet	
Diagnosis	Chronic Thromboembolic Pulmonary Hypertension (CTEPH)
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. The fact that coverage is available for a particular drug under Part B with the use of an infusion pump does not mean that coverage under Part D using some other method of administration automatically can be denied. There is no Part B coverage in the home for

infusion drugs administered without an infusion pump (e.g., IV push). There is also no Part B coverage in the home for infusion drugs administered with an infusion pump unless the drug is specifically covered under the local coverage policy of the applicable Medicare Durable Medical Equipment Medicare Administrative Contractor (DME MAC). Therefore, determinations about Part D sponsor payment for these other methods of administration and for drugs administered with an infusion pump but not covered by the local DME MAC policy should be based on the question of whether the drug is on the sponsor's formulary. [13]

B. Require right heart catheterization in order to confirm pulmonary arterial hypertension diagnosis: Per clinical consult with cardiologist, PAH specialist, and P&T committee recommendation, February 20, 2014.

4 . References

1. Flolan Prescribing Information. GlaxoSmithKline. Research Triangle Park, NC. August 2021.
2. Revatio Prescribing Information. Pfizer Inc. New York, NY. January 2023.
3. Ventavis Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. March 2022.
4. Tyvaso Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. May 2022.
5. Remodulin Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. July 2021.
6. Veletri Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. July 2022.
7. Adcirca Prescribing Information. Eli Lilly and Company. Indianapolis, IN. September 2020.
8. Tracleer Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. July 2022.
9. Letairis Prescribing Information. Gilead Sciences, Inc. Foster City, CA. August 2019.
10. Opsumit Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. July 2022.
11. Adempas Prescribing Information. Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ. September 2021.
12. Orenitram Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. May 2021.
13. Centers for Medicaid & Medicare Services. Medicare Prescription Drug Benefit Manual. Chapter 6 - Appendix C - Summary of Coverage Policy: Medicare Part B Versus Part D Coverage Issues. Available at http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter6.pdf. Accessed January 4, 2023.
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15. Uptravi Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. July 2022.

16. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): Nebulizers (L33370). Available at: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33370&ver=24&articleId=52466&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD%7cEd&PolicyType=Both&s=All&KeyWord=inhalation&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAACABAAAA&. Accessed January 4, 2023.
17. Alyq Prescribing Information. Teva Pharmaceuticals USA, Inc. North Wales, PA. September 2021.
18. Tyvaso DPI Prescribing Information. United Therapeutics Corporation. Research Triangle Park, NC. May 2022.
19. Tadliq Prescribing Information. CMP Pharma, Inc. Farmville, NC. June 2022.
20. Liqrev Prescribing Information. CMP Pharma, Inc. Farmville, NC. April 2023.

5 . Revision History

Date	Notes
8/16/2023	2024 Medicare Implementation

Prior Authorization Guideline

Guideline Name Pulmozyme (dornase alfa)

Formulary 2024 Samaritan Advantage Health Plans (HMO)

Formulary Note

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	
P&T Revision Date:	4/19/2023

1 . Indications

Drug Name: Pulmozyme (dornase alfa) Inhalation Solution
Cystic fibrosis Indicated, in conjunction with standard therapies, for the management of pediatric and adult patients with cystic fibrosis (CF) to improve pulmonary function. In CF patients with an FVC ≥ 40% of predicted, daily administration of PULMOZYME has also been shown to reduce the risk of respiratory tract infections requiring parenteral antibiotics.

2 . Criteria

Product Name: Pulmozyme Inhalation Solution	
Guideline Type	Part B

Approval Criteria

1 - Drug is administered using a nebulizer*

AND

2 - Drug is administered at home (not including facility providing skilled nursing care)

AND

3 - For patients with cystic fibrosis (ICD-9 diagnosis code 277.02)

Notes	ICD-10 diagnosis code for cystic fibrosis E84.0: *Please refer to relev ant local coverage determinations for more information.

Product Name: Pulmozyme Inhalation Solution	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Part D

Approval Criteria

1 - One of the following:

1.1 Patient does not meet criteria for Part B coverage above

OR

1.2 Patient is in a long-term care facility (e.g., hospital or skilled nursing facility where patient is receiving skilled nursing care)**

AND **2** - Diagnosis of Cystic Fibrosis

Notes	**Long term care facility includes the following: a) hospital, b) skilled nursing facility (SNF) or a distinct part SNF, c) a nursing home that is dually certified as both Medicare SNF and a Medicaid nursing facility, d) a Medicaid only nursing facility that primarily furnishes skilled care, e) a non-participating nursing home (neither Medicaid or Medicare) that provided primarily skilled care, and f) an institution that has a distinct part SNF and which also primarily furnishes skilled care

Product Name: Pulmozyme Inhalation Solution	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Part D

Approval Criteria

1 - Diagnosis of Cystic Fibrosis

AND

2 - Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations)

3 . Endnotes

A. BENEFIT COVERAGE Drugs that require administration by the use of a piece of covered durable medical equipment (DME) (e.g., a nebulizer, external or implantable pump) are covered under Part B.(1) The statute does not explicitly cover DME drugs; they are covered as a supply necessary for the DME to perform its function. Examples of such drugs include: * Inhalation drugs that are administered in the home through the use of a nebulizer (e.g., albuterol sulfate, ipratropium bromide); or * Drugs for which administration with an infusion pump in the home is medically necessary (e.g., some chemotherapeutic agents). Certain inhalation drugs are generally covered under Part B when used with a nebulizer in the home. These drugs would not be covered under Part

D for use with a nebulizer. However, if these drugs were delivered with a metered dose inhaler or other non-nebulizer administration, they would be Part D drugs. In the case of a beneficiary, in a hospital, or a SNF bed, (1) who does not have Part A coverage, (2) whose Part A coverage for the stay has run out or (3) whose stay is non-covered -- inhalation DME supply drugs are not covered under Part B because the law limits coverage under Part B's DME benefit to those items that are furnished for use in a patient's home, and specifies that a hospital or SNF cannot be considered the beneficiary's "home" for this purpose. In this case, coverage for the drugs would be available under Part D.

4 . References

1. Centers for Medicaid & Medicare Services. Medicare Part B Versus Part D Coverage Issues. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/PartsBDCoverageSummaryTable_041806.pdf. Accessed March 15, 2021.
2. Pulmozyme Prescribing Information. Genentech, Inc. South San Francisco, CA. July 2021.
3. Centers for Medicaid & Medicare Services. LCD - Nebulizers (L33370). Available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33370&ver=42&keyword=dornase&keywordType=starts&areaId=all&docType=NCA%2cCAL%2cNCD%2cMEDCAC%2cTA%2cMCD%2c6%2c3%2c5%2c1%2cF%2cP&contractOption=all&sortBy=relevance&bc=1. Accessed March 9, 2023. .cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33370&ver=30&keyword=dornase&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1. Accessed March 17, 2022.
4. Centers for Medicaid & Medicare Services. Medicare Part D Manual. Appendix C Medicare Part B versus Part D Coverage Issues. Available at: https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf. Accessed March 17, 2022.

5 . Revision History

Date	Notes
8/11/2023	2024 Medicare Implementation - No Changes

Prior Authorization Guideline

Guideline Name Tigan (trimethobenzamide) capsules

Formulary 2024 Samaritan Advantage Health Plans (HMO)

Formulary Note

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	
P&T Revision Date:	4/19/2023

1 . Indications

Drug Name: Tigan (trimethobenzamide) capsules
Post-operative Nausea and Vomiting and Nausea Associated with Gastroenteritis Indicated in adults for the treatment of postoperative nausea and vomiting and for nausea associated with gastroenteritis. Limitation of use: Tigan is not recommended for use in pediatric patients due to the risk of extrapyramidal signs and symptoms and other serious central nervous system (CNS) effects, and the risk of exacerbation of the underlying disease in pediatric patients with Reye's syndrome or other hepatic impairment.

2 . Criteria

Product Name: Brand Tigan capsules or Generic trimethobenzamide capsules	
Guideline Type	Part B

Approval Criteria

1 - Oral anti-emetic drug administered with cancer chemotherapy treatment that is initiated within 2 hours of the administration of chemotherapy and continued for a period not to exceed 48 hours from that time [2-4]

AND

2 - Oral anti-emetic drug is used as a full therapeutic replacement for IV anti-emetic drugs that would have been administered at the time of the cancer chemotherapy treatment [2-4]

Product Name: Brand Tigan capsules or Generic trimethobenzamide capsules	
Approval Length	1 month(s)
Guideline Type	Part D

Approval Criteria

1 - Patient does not meet criteria for Part B above

AND

2 - One of the following:

2.1 Used for the treatment of postoperative nausea and vomiting

OR

2.2 Used for the treatment of nausea associated with gastroenteritis

3 . References

1. Tigan capsules prescribing information. Pfizer Inc. New York, NY. November 2020.
2. Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services. Available at: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf. Accessed March 9, 2022.
3. Medicare Claims Processing Manual, Chapter 17 - Drugs and Biologicals. Available at: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf. Accessed March 9, 2022.
4. Medicare Prescription Drug Benefit Manual, Chapter 6 - Part D Drugs and Formulary Requirements. Available at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. Accessed March 9, 2022.

4 . Revision History

Date	Notes
8/16/2023	2024 Medicare Implementation - No Changes

Prior Authorization Guideline

Guideline Name Vaccines

Formulary 2024 Samaritan Advantage Health Plans (HMO)

Formulary Note

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	
P&T Revision Date:	6/19/2023

1 . Criteria

Product Name: Engerix-B, Heplisav-B, Prehevbrio, or Recombivax HB	
Guideline Type	Part B
Approval Criteria **1** - One of the following: [1] **1.1** Individuals with end-stage renal disease	

OR

1.2 Individuals with hemophilia who receive Factor VIII or IX concentrates

OR

1.3 Healthcare workers who have exposure to blood in the workplace

OR

1.4 Illicit injectable drug abusers

OR

1.5 Men who have sex with men

OR

1.6 Persons who live in the same household as a hepatitis B virus (HBV) carrier (includes long-term care facilities) [A]

OR

1.7 Clients and staff members of institutions for the mentally handicapped

OR

1.8 Persons diagnosed with diabetes mellitus

Product Name: Hepagam B, Nabi-HB, or Hyperhep B	
Guideline Type	Part B

Approval Criteria

1 - One of the following:

1.1 When given related to the treatment of an injury or direct exposure to Hepatitis B

OR

1.2 Used for the prevention of Hepatitis B recurrence following liver transplantation in HBsAg-positive transplant patients

Product Name: Other products	
Guideline Type	Part B

Approval Criteria

1 - When given related to the treatment of an injury or direct exposure to a disease or condition (e.g., tetanus, rabies)

Notes	NOTE: Pneumococcal and influenza vaccines are covered under Part B only.

Product Name: All vaccines	
Guideline Type	Part D

Approval Criteria

1 - Patient does not meet criteria for Part B above

AND

2 - One of the following:

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

OR

2.2 If requested for an off-label indication, the off-label guideline approval criteria have been met	
Notes	NOTE: Pneumococcal and influenza vaccines are covered under Part B only.

2 . Endnotes

A. Per communication with CMS and discussion with members of CPS.
B. There are a number of vaccines that remain covered under Part B. Pneumococcal and influenza vaccines are not covered under Part D because of Part B coverage. Hepatitis B vaccine is covered under Part B for individuals at high or intermediate risk; for all other individuals, it would be covered under a Part D benefit. Part B also covers certain vaccines reasonable and necessary for the treatment of an illness or injury. All other currently available vaccines and all future preventative vaccines could be covered under Part D. [1]

3 . References

1. Centers for Medicaid & Medicare Services. Covered Medical and Other Health Services – revised 3/24/2021. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf. Accessed May 5, 2023.

4 . Revision History

Date	Notes
8/16/2023	2024 Medicare Implementation - No Changes

Prior Authorization Guideline

Guideline Name Varubi (rolapitant)

Formulary 2024 Samaritan Advantage Health Plans (HMO)

Formulary Note

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	
P&T Revision Date:	4/19/2023

1 . Indications

Drug Name: Varubi (rolapitant) tablets
Prevention of chemotherapy-induced nausea and vomiting (CINV) Indicated in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy [1, A].

2 . Criteria

Product Name: Varubi tablets	
Guideline Type	Part B

Approval Criteria

1 - Initiated within 2 hours of the administration of chemotherapy and continued for a period not to exceed 48 hours from that time [10-15]

AND

2 - Used as a full therapeutic replacement for IV anti-emetic therapy that would have been administered at the time of the cancer chemotherapy treatment [10-15]

AND

3 - Used in combination with both of the following: [15]

- An oral 5HT3 antagonist (e.g., Anzemet [dolasetron], granisetron, Zofran [ondansetron])
- Oral dexamethasone

AND

4 - Patient is receiving one of the following anti-cancer chemotherapeutic agents: [15]

- alemtuzumab
- azacitidine
- bendamustine
- carboplatin
- carmustine
- cisplatin
- clofarabine
- cyclophosphamide
- cytarabine
- dacarbazine
- daunorubicin
- doxorubicin

- epirubicin
- idarubicin
- ifosfamide
- irinotecan
- lomustine
- mechlorethamine
- oxaliplatin
- streptozocin

Product Name: Varubi tablets	
Approval Length	12 month(s)
Guideline Type	Part D Prior Authorization

Approval Criteria

1 - Patient does not meet criteria for Part B above

AND

2 - Used for the prevention of delayed nausea and vomiting associated with cancer chemotherapy

AND

3 - Patient is concurrently on both of the following medications: [4-5, B]

- Dexamethasone
- 5-HT3 receptor antagonist (e.g., Aloxi [palonosetron], Anzemet [dolasetron], granisetron, Zofran [ondansetron])

3 . Endnotes

A. Three distinct types of chemotherapy-induced nausea and vomiting (CINV) have been defined: acute, delayed, and anticipatory. Emesis occurring during the first 24 hours (hrs) after chemotherapy is classified as acute. Emesis occurring more than 24 hrs after chemotherapy initiation is classified as delayed. Anticipatory emesis is a conditioned

response in patients who have developed significant nausea and vomiting during previous cycles of chemotherapy; it can be elicited by a variety of stimuli and cognitive activities in association with subsequent cycles of chemotherapy. [2-3] Clinical studies also often refer to an “overall phase”, which is defined as 0 to 120 hrs (ie, the overall at-risk period). [4-5]

B. It is recommended to administer Varubi in combination with dexamethasone and a 5-HT3 receptor antagonist. [1] Treatment guidelines currently recommend a multimodal approach that incorporates a prophylactic regimen prior to the start of chemotherapy. [6-8] A 3-drug regimen consisting of an NK1 receptor antagonist (eg, aprepitant, fosaprepitant, rolapitant); a serotonin-3 (5-HT3) receptor antagonist (eg, dolasetron, granisetron, ondansetron, palonosetron); and dexamethasone is recommended for patients receiving HEC (ie, cisplatin or AC). [6-8] For MEC, a 5-HT3 receptor antagonist and dexamethasone with or without an NK1 receptor antagonist is recommended. An NK1 receptor antagonist should be added for select patients with additional risk factors or who have failed previous therapy with a steroid and a 5-HT3 receptor antagonist alone. [6-8] The National Comprehensive Cancer Network Drugs and Biologics Compendium recommends rolapitant for use in combination with dexamethasone and a serotonin receptor antagonist with or without lorazepam, histamine-2 blockers, or proton pump inhibitors before parenteral anticancer therapy with high emetic risk (with or without olanzapine) or moderate emetic risk for select patients. [9]

4 . References

1. Varubi prescribing information. TerSera Therapeutics LLC. Deerfield, IL. August 2020.
2. Hesketh PJ. Pathophysiology and prediction of chemotherapy-induced nausea and vomiting. Available at: http://www.uptodate.com. Updated January 24, 2022. Accessed May 23, 2022.
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5. Schwartzberg LS, Modiano MR, Rapoport BL, et al. Safety and efficacy of rolapitant for prevention of chemotherapy-induced nausea and vomiting after administration of moderately emetogenic chemotherapy or anthracycline and cyclophosphamide regimens in patients with cancer: a randomised, active-controlled, double-blind, phase 3 trial. Lancet Oncol. 2015;16(9):1071-8.
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5 . Revision History

Date	Notes
8/16/2023	2024 Medicare Implementation - No Changes