ABILIFY® (aripiprazole), for injection

Product Affected

- *ABILIFY® (aripiprazole), for injection*

PA Criteria	Criteria Details
Billing code	J0401
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients with a history of severe hypersensitivity reaction to Abilify. Limitation of use: None.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply.
Prescriber Restrictions	Prescribed by or in consultation with a psychiatrist.
Coverage Duration	6 months
Other Criteria	

Reference: Abilify [package insert]. Tokyo, Japan: Otsuka Pharmaceutical Co.; 2016.

ABILIFY ASIMTUFII® (aripiprazole monohydrate), for injection

Product Affected

- *ABILIFY ASIMTUFII ® (aripiprazole monohydrate), for injection*

PA Criteria	Criteria Details
Billing code	J0402
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients with a history of severe hypersensitivity reaction to aripiprazole.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	For patients 18 years of age or older.
Prescriber Restrictions	Prescribed by or in consultation with a psychiatrist.
Coverage Duration	12 months
Other Criteria	

Reference:

Micromedex
Abilify Asimtufii [package insert]. Tokyo, Japan: Otsuka Pharmaceutical Co.; 2023.

Prior Authorization Criteria for Part B drugs
Effective Date: 01.01.2025
Utilization Management Committee Approval Date: 04.11.2024

ACTEMRA® (tocilizumab), for injection, for intravenous use

Product Affected

- *ACTEMRA® (tocilizumab), for injection, for intravenous use*

PA Criteria	Criteria Details
Billing code	J3262
Covered Uses	*All FDA approved and medically accepted indications.* *FDA indications:* • Moderately to severely active Rheumatoid Arthritis who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs), • Patient with Giant Cell Arteritis (GCA) • Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD • Polyarticular Juvenile Idiopathic Arthritis (PJIA) in patients ≥2 years • Systemic Juvenile Idiopathic Arthritis (SJIA in patients ≥2 years
Exclusion Criteria	Contraindication(s): • In patients with hypersensitivity to this medication. Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Diagnosis confirmation.** **Step Therapy Requirement (Only for New Patients in Therapy with Rheumatoid Arthritis)** a. The patient is considered a new start to the non-preferred product (defined as no use in the previous 365 days) **AND** b. Must try/fail, have contraindication to, or intolerance to one of the following: Inflectra, Renflexis or Avsola prior to receiving Actemra. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.

PA Criteria	Criteria Details
Age Restrictions	≥2 years for Polyarticular Juvenile Idiopathic Arthritis and Systemic Juvenile Idiopathic Arthritis. For all other conditions **≥ 18 years.**
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist.
Coverage Duration	Approve medication for 12 months.
Other Criteria	Discard live vaccines in previous month.

Reference:

1. ACTEMRA [package insert]. South San Francisco, CA: Genentech, Inc. 2022
2. ACTEMRA. In: Lexi-Drugs. UpToDate Inc; 2024. Updated May 10, 2024. Accessed May 17, 2024. http://online.lexi.com

ADAKVEO® (crizanlizumab-tmca), for injection

Product Affected

- *ADAKVEO® (crizanlizumab-tmca), for injection*

PA Criteria	Criteria Details
Billing code	J3590
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): None. Limitation of use: None.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **AND** Diagnosed with sickle cell disease (any genotype including HbSS, HbSC, HbSB0-thalassemia, HbSB+thalassemia, and others). **AND** Order CBC and monitor closely platelet count. **AND** **One** of the following criteria: • Patient has experienced at least 2 vaso occlusive crises (VOC) within the past 6 months while on hydroxyurea at up to maximally indicated dose. • Patient has intolerance or contraindication to hydroxyurea and has experienced at least 2 VOC within the past 12 months. **AND** Documentation of baseline incidence of VOC over the last twelve months. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply

PA Criteria	Criteria Details
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	6 months
Other Criteria	

Reference:

Lexicomp
Adakveo [package insert]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation.; 2019.

Adzynma® , lyophilized powder for injection, for intravenous use

Products Affected

- *Adzynma® (ADAMTS13, recombinant-krhn lyophilized powder for injection, for intravenous use – Takeda Pharmaceuticals U.S.A., Inc.)*

PA Criteria	Criteria Details
Billing Code	J7171
Covered Uses	*All FDA approved and medically accepted indications.* **FDA Indications:** Adult and pediatric patients with congenital thrombotic thrombocytopenic purpura (cTTP) • Prophylactic or on demand enzyme replacement therapy (ERT)
Exclusion Criteria	Contraindication(s): Patients who have manifested life-threatening hypersensitivity reactions to ADZYNMA or its components.
Required Medical Information	Congenital thrombotic thrombocytopenic purpura (cTTP) diagnostic. • Diagnostic laboratory testing including at least one of the following: o ADAMTS13 activity assay o ADAMTS13 functional inhibitor assay o Anti-ADAMTS13 antibody assay Note: May be useful as a means of distinguishing TTP from other TMAs and as a means of differentiation iTTP from cTTP.
Age Restrictions	No restrictions Safety and effectiveness have been established in pediatric patients; aged 2 years and older.
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	12 meses
Other Criteria	Ninguno

References:

1. Alvin Sherman Library. https://online-lexi-com.ezproxylocal.library.nova.edu/lco/action/doc/retrieve/docid/patch_f/7392964?cesid=7fMdFoF5DvE&searchUrl=%2Flco%2Faction%2Fsearch%3Fq%3DAdzynma%26t%3Dname%26acs%3Dfalse%26acq%3DAdzynma.
2. Takeda Pharmaceuticals. (n.d.). Product Information: ADZ. Retrieved from https://content.takeda.com/?contenttype=PI&product=ADZ&language=ENG&country=USA&documentnumber=1
3. Thita Chiasakul, Adam Cuker; Clinical and laboratory diagnosis of TTP: an integrated approach. Hematology Am Soc Hematol Educ Program 2018; 2018 (1): 530–538. doi: https://doi.org/10.1182/asheducation-2018.1.530

AKYNZEO® (fosnetupitant and palonosetron), for injection

Product Affected

- *Akynzeo® (fosnetupitant and palonosetron) for injection*

PA Criteria	Criteria Details
Billing code	J8540
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): None Limitation of use: For injection has not been studied for the prevention of nausea and vomiting associated with anthracycline plus cyclophosphamide chemotherapy.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	6 months
Other Criteria	

Reference:

Akynzeo [package insert]. Dublin, Ireland: Helsinn Birex Pharmaceuticals.; 2014.

ALDURAZYME (laronidase) for injection, for intravenous use

Products Affected

- ALDURAZYME (laronidase) for injection, for intravenous use

PA Criteria	Criteria Details
Billing code	J1931
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): Limitations of Use: • The risks and benefits of treating mildly affected patients with the Scheie form have not been established. • ALDURAZYME has not been evaluated for effects on the central nervous system manifestations of the disorder.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. Diagnosis of Hurler and Hurler-Scheie forms of Mucopolysaccharidosis I (MPS I) or Scheie form (moderate to severe); **AND** The following criteria: Initial request: o Genetic testing o Disease severity Continuation request o Tolerance and response to treatment: describe disease improvement or abatement. **AND** Confirm that the patient has not had previous surgical intervention for TED.
Age Restrictions	

PA Criteria	Criteria Details
Prescriber Restrictions	Prescribed by, or in consultation with, a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders
Coverage Duration	Initial approval: 6 months Subsequent approval: 12 months
Other Criteria	Encourage pregnant women with MPS I to enroll is the MPS I Registry

References:

Product Information: ALDURAZYME(R) intravenous injection, laronidase intravenous injection. Genzyme Corporation (per FDA), Cambridge, MA, 2019.

Alpha1-Proteinase Inhibitors

Products Affected

- ARALAST NP Alpha 1 -Proteinase Inhibitor (Human)
- GLASSIA Alpha1-Proteinase Inhibitor (Human)
- ZEMAIRA® Alpha1-Proteinase Inhibitor (Human)

PA Criteria	Criteria Details
Billing code	J0256 (Aralast NP) J0257 (Glassia, Zemaira)
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): Immunoglobulin A (IgA) deficient patients with antibodies against IgA History of anaphylaxis or other severe systemic reaction, to Alpha1-PI products. Limitation of use: The effect of augmentation therapy with any Alpha1 -PI, on pulmonary exacerbations and on the progression of emphysema in alpha 1 -antitrypsin deficiency has not been conclusively demonstrated in randomized, controlled clinical trials. Not indicated as therapy for lung disease in patients in whom severe Alpha1 -PI deficiency has not been established.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information Diagnosis of congenital alpha1-antitrypsin deficiency confirmed by one of the following: • Pi*ZZ, Pi*Z(null) or Pi*(null)(null) protein phenotypes (homozygous); or • Other rare AAT disease-causing alleles associated with serum alpha1-antitrypsin (AAT) level < 11 µmol/L [e.g., Pi(Malton, Malton)] **AND** **Step Therapy Requirement**

PA Criteria	Criteria Details
	a. The patient is considered a new start to the non-preferred product (defined as no use in the previous 365 days) **AND** **b.** Must try/fail, have contraindication to, or intolerance to Prolastin-C **AND** Dosing: 60 mg/kg body weight administered once weekly by intravenous infusion. **AND (If applicable)** **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

References:

Product Information: Zemaira(R) IV powder for solution, Alpha1-Proteinase Inhibitor (Human) IV powder for solution. CSL Behring LLC (per manufacturer), Kankakee, IL, 2019.

Product Information: GLASSIA intravenous injection, alpha1-proteinase inhibitor (human) intravenous injection. Takeda Pharmaceuticals USA Inc (per FDA), Lexington, MA, 2022.

Product Information: ARALAST NP(R) injection, alpha1-proteinase inhibitor (human) injection. Baxter Healthcare Corporation, Westlake Village, CA, 2010.

ALPHANATE® (antihemophilic factor/von willebrand factor complex [human]), for injection

Product Affected

- *ALPHANATE® (antihemophilic factor/von willebrand factor complex [human]), for injection*

PA Criteria	Criteria Details
Billing code	J7186
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components. Limitation of use: • Not indicated for patients with severe VWD (Type 3) undergoing major surgery.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	6 months
Other Criteria	

Reference:

Alphanate [package insert]. Los Angeles, California: Grifols Biologicals Inc.

ALPHANINE SD (antihemophilic factor IX (non-recombinant)), for injection

Product Affected

- *ALPHANINE SD (antihemophilic factor IX (non-recombinant)), for injection*

PA Criteria	Criteria Details
Billing code	J7193 J7194
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • None. Limitation of use: • Not indicated for the treatment of von Willebrand disease.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Age ≥ 16 years
Prescriber Restrictions	Prescribed by or in consultation with an hematologist.
Coverage Duration	6 months
Other Criteria	

Reference: Alphanine SD [package insert]. Los Angeles, CA: Bayer HealthCare LLC.; 2014.

AMELUZ® (aminolevulinic acid hydrochloride gel 10%), for topical

Product Affected

- *AMELUZ® (aminolevulinic acid hydrochloride gel 10%), for topical*

PA Criteria	Criteria Details
Billing code	J7345
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients with known hypersensitivity to porphyrins. • In patients with known hypersensitivity to any component of AMELUZ, which includes soybean phosphatidylcholine. • Porphyria. • Photodermatoses. Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply.
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist.
Coverage Duration	6 months
Other Criteria	

Reference: Ameluz [package insert]. Woburn, MA: Biofrontera Inc.; 2021.

AMICAR® (aminocaproic acid), for injection

Product Affected

- *AMICAR® (aminocaproic acid), for injection*

PA Criteria	Criteria Details
Billing code	S0017
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Active intravascular clotting process. Limitation of use: None.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **AND** Provide tests results to assure that patient does not have an active intravascular clotting process, the cause of bleeding is primary fibrinolysis or disseminated intravascular coagulation (DIC). AMICAR must not be used in the presence of DIC without concomitant heparin. **AND** Provide test results that determine the amount of fibrinolysis present. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist.
Coverage Duration	6 months

PA Criteria	Criteria Details
Other Criteria	

Reference: Amicar [package insert]. Florence, KY: Xanodyne Pharmaceuticals, Inc.

ANTIHEMOPHILIC FACTOR VII (recombiant), for injection

Product Affected

- *ANTIHEMOPHILIC FACTOR VII (recombiant), for injection*

PA Criteria	Criteria Details
Billing code	J7205 – Eloctate J7207 – Adynovate J7209 – Nuwiq J7210 – Afstyla J7211 – Kovaltry J7182 – NovoEight
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients who have manifested life-threatening hypersensitivity reactions, including anaphylaxis, to the product or its components. Limitation of use: • Not indicated for the treatment of von Willebrand disease.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	None.
Prescriber Restrictions	Prescribed by or in consultation with an hematologist.
Coverage Duration	6 months

PA Criteria	Criteria Details
Other Criteria	

Reference:

Lexicomp
Eloctate [package insert]. Cambridge, MA: Biogen Inc.; 2010.
Adynovate [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; 2023.
Nuwiq [package insert]. Elersvagen, Sweden: Octapharma AB.; 2015.
Afstyla [package insert]. Marburg, Germany: CSL Behring GmbH.; 2023.
Kovaltry [package insert]. Whippany, New Jersey: Bayer HealthCare LLC.; 2021.
Novoeight [package insert]. Novo Alle, Bagsvaerd: Novo Nordisk A/S.; 2018.

AREDIA® (pamidronate disodium), for injection

Product Affected

- *AREDIA® (pamidronate disodium), for injection*

PA Criteria	Criteria Details
Billing code	J2430
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients with clinically significant hypersensitivity to Aredia or other bisphosphonates. Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **AND** Provide results of serum creatinine prior to each treatment. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	6 months
Other Criteria	

Note:
All Oncology Cases must be review first by OncoHealth Team to provide an expert recommendation.

Reference: Aredia [package insert]. East Hanover, New Jersey: Novartis Pharmaceutical.; 2010.

Prior Authorization Criteria for Part B drugs
Effective Date: 01.01.2025
Utilization Management Committee Approval Date: 04.11.2024

ARISTADA™ (aripriprazole lauroxil), for extended-release injection

Product Affected

- *ARISTADA™ (aripriprazole lauroxil), for extended-release injection*

PA Criteria	Criteria Details
Billing code	J1944
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • For treatment of patients with dementia-related psychosis. Limitation of use: None.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **AND** Provide CBC results to monitor risk of neutropenia. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a psychiatrist.
Coverage Duration	6 months
Other Criteria	

Reference: Aristada [package insert]. Waltham, MA: Alkermes, Inc.; 2020.

ARISTADA INITIO® (aripiprazole lauroxil), for injection

Product Affected

- *ARISTADA INITIO® (aripiprazole lauroxil), for injection*

PA Criteria	Criteria Details
Billing code	J1943
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients with a history of severe hypersensitivity reaction to aripiprazole. Limitation of use: None.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a psychiatrist.
Coverage Duration	6 months
Other Criteria	

Reference: Aristada Initio [package insert]. Waltham, MA: Alkermes, Inc.; 2022.

ARTESUNATE, para inyección

Producto Afectado

- *ARTESUNATE, para inyección*

Criterios de PA	Detalles de los criterios
Código de facturación	J0391
Usos cubiertos	*Todas las indicaciones aprobadas por la FDA y medicamente aceptadas.*
Criterios de exclusión	Contraindicacion(es): • Historial de hipersensibilidad con artesunate.
Información médica requerida	Proveedor debe someter documentación de respaldo tales como: notas de progreso, resultados de laboratorio, tratamientos previos y cualquier otra información clínica relevante. Debe ir seguido de un ciclo completo de tratamiento del régimen antimalarial oral prescrito. La terapia concomitante con un agente antimalarial, como un 8-aminoquinolina, es necesaria para el tratamiento de la malaria grave debida a P. vivax o P. ovale.
Restricción de edad	Ninguna.
Restricciones de los prescriptores	Ninguna.
Duración de la cobertura	7 días
Otros Criterios	

Referencia:

Micromedex
ARTESUNATE [package insert] Amivas LLC, 1209 Orange St., Wilmington Delaware 19801 USA.

BELATACEPT® (Nulojix), for injection

Product Affected

- *BELATACEPT® (Nulojix), for injection*

PA Criteria	Criteria Details
Billing code	J0485
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Do not use in transplant recipients who are Epstein-Barr virus (EBV) seronegative or with unknown EBV serostatus due to the risk of post-transplant lymphoproliferative disorder (PTLD), predominantly involving the central nervous system (CNS). Limitation of use: • Use only in patients who are EBV seropositive. • Use of NULOJIX for the prophylaxis of organ rejection in transplanted organs other than kidney has not been established.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **AND** Provide documentation of concurrent use with Basiliximab induction, mycophenolate mofetil, and corticosteroid. **AND** Provide results of Epstein-Barr virus serology prior therapy. **AND** Provide results of TB screening prior therapy initiation. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply

PA Criteria	Criteria Details
Prescriber Restrictions	None
Coverage Duration	6 months
Other Criteria	

Reference: Belatacept [package insert]. Princeton, New Jersey: Bristol-Myers Squibb Company.; 2014.

BeneFIX® (factor IX recombinant), for injection

Product Affected

- *BeneFIX® (factor IX recombinant), for injection*

PA Criteria	Criteria Details
Billing code	J7195
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Do not use in patients who have manifested life-threatening, immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including hamster protein. Limitation of use: • Not indicated for induction of immune tolerance in patients with hemophilia B.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply.
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	6 months
Other Criteria	

Reference:

Benefix [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals LLC.; 2021.

BENLYSTA® (belimumab), for injection

Product Affected

- *BENLYSTA® (belimumab), for injection*

PA Criteria	Criteria Details
Billing code	J0490
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients who have had anaphylaxis with belimumab. Limitation of use: • It has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. • It has not been studied in combination with other biologics or intravenous cyclophosphamide.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with an rheumatologist
Coverage Duration	6 months
Other Criteria	

Reference:

Benlysta [package insert]. Rockville, MD: Human Genome Sciences, Inc.; 2012.

Prior Authorization Criteria for Part B drugs
Effective Date: 01.01.2025
Utilization Management Committee Approval Date: 04.11.2024

BEOVU (brolucizumab-dbll) for injection, for intravitreal use

Products Affected

- BEOVU (brolucizumab-dbll) for injection, for intravitreal use

PA Criteria	Criteria Details
Billing code	J0179
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Ocular or Periocular Infections • Active Intraocular Inflammation • Hypersensitivity (Continuation therapy)
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information Diagnosis of Neovascular (Wet) Age-Related Macular Degeneration (AMD); Diabetic Macular Edema (DME). **AND** The following criteria: Initial request: • Absence of contraindications • Previous therapy (if applicable) • Concurrent therapy **Continuation of therapy request:** Absence of contraindications Tolerance and response to treatment: describe disease improvement or abatement, e.g., Maintenance or improvement in visual acuity **AND** Dosing: AMD

PA Criteria	Criteria Details
	• 6 mg monthly (approximately 25-31 days) for the first 3 doses, followed by one dose every 8-12 weeks DME • 6 mg every six weeks (approximately 39-45 days) for the first 5 doses followed by one dose every 8-12 weeks
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist (retina specialist)
Coverage Duration	**AMD** • Initial approval: 3 months • Subsequent approvals: 6 months, considering dose frequency prescribed DME • Initial approval: first 5 doses • Subsequent approvals: 6 months, considering dose frequency prescribed
Other Criteria	Females of Reproductive Potential (15-49 years old): Highly effective forms of contraception should be implemented during treatment and for 1 (one) month following the last dose of BEOVU

Reference: Product Information: BEOVU(R) intravitreal injection, brolucizumab-dbll intravitreal injection. Novartis Pharmaceuticals Corporation (per FDA), East Hanover, NJ, 2022

Botulinum Toxin, injectable

Products Affected

- *Botox® (onabotulinumtoxinA injection – Allergan/AbbVie)*
- *Daxxify® (daxibotulinumtoxinA-lanm injection – Revance)*
- *Dysport® (abobotulinumtoxinA injection – Ipsen/Galderma)*
- *Myobloc® (rimabotulinumtoxinB injection – Solstice)*
- *Xeomin® (incobotulinumtoxinA injection – Merz)*

PA Criteria	Criteria Details
Preferred Products	Botox, Dysport
Non-Preferred Products	Myobloc, Xeomin, Daxxify
Billing Code	• Botox® J0585 • Daxxify® J0589 • Dysport® J0586 • Myobloc® J0587 • Xeomin® J0588
Covered Uses	*All FDA approved and medically accepted indications.* **FDA Indications:** **Botox, Xeomin**: • Blepharospasm associated with dystonia, including benign essential blepharospasm or seventh (VII) nerve disorders in patients **Botox, Daxxify, Dysport, Xeomin:** • Cervical dystonia, in adults to reduce the severity of abnormal head position and neck pain associated with cervical dystonia. **Botox:** • Hyperhidrosis, severe primary axillary which is inadequately managed with topical agents in adults. **Botox:** • Migraine headache prophylaxis (prevention), in adults with chronic migraine (≥ 15 days per month with headache lasting 4 hours a day or longer). **Botox:** • Neurogenic detrusor overactivity in pediatric patients ≥ 5 years of age who have had an inadequate response to or are intolerant of an anticholinergic medication.

PA Criteria	Criteria Details
	Botox: • Overactive bladder in patients who have an inadequate response to or are intolerant of an anticholinergic medication. **Botox, Dysport, Xeomin:** • Spasticity in patients **Botox:** • Strabismus in patients **Botox:** • Urinary incontinence due to detrusor **Xeomin:** • Sialorrhea, chronic **Xeomin:** • Excessive salivation, Chronic
Exclusion Criteria	Infection at the proposed injection sites • Keloidal scarring • Neuromuscular disorders • Botulinum toxin allergies • Body dysmorphic disorder • Pregnancy • Breastfeeding • Amyotrophic lateralizing sclerosis myopathies
Required Medical Information	Provider must submit supporting documentation such as progress notes (including weight and height), laboratory results, previous treatments, and other relevant clinical information. Step Therapy Requirement (Only for New Patients) **BOTOX** **A)** Migraine Headache Prevention. • Patient has ≥ 15 migraine headache days per month with headache lasting 4 hours per day or longer (prior to initiation of Botox therapy); AND Patient has tried at least one standard prophylactic (preventative) pharmacologic therapy Standard prophylactic (preventative) pharmacologic therapies include angiotensin receptor blocker, angiotensin converting enzyme inhibitor, anticonvulsant, beta-blocker, calcium channel blocker, tricyclic antidepressant, another antidepressant.

PA Criteria	Criteria Details
	• Patient has tried at least one standard prophylactic (preventative) pharmacologic therapy. A patient who has already tried a calcitonin gene-related peptide (CGRP) inhibitor indicated for the prevention of chronic migraine, is NOT required to try a standard prophylactic pharmacologic therapy. **B)** Hyperhidrosis, Primary Axillary. • Patient has tried at least one topical agent for axillary hyperhidrosis. (topical aluminum chloride, Qbrexza (glycopyrronium cloth 2.4% for topical use). **C)** Pediatric Neurognic Detrusor Overactivity (NDO) • Patient has tried at least one other pharmacologic therapy for the treatment of neurogenic detrusor overactivity (NDO). **D)** Overactive Bladder • Patient has tried at least one other pharmacologic therapy for the treatment of overactive bladder (OAB). **E)** Adult Urinary Incontinence Associated with a neurological Conditions. • Patient has tried at least one other pharmacologic therapy for the treatment of urinary incontinence. Diagnosis Confirmation (Laboratories)
Age Restrictions	Patient is ≥ 18 years of age, unless specified. **Botox:** Blepharospasm: patient is > 12 years of age. Neurogenic detrusor over-activity: Patient is ≥ 5 years of age Strabismus in patients ≥ 12 years of age. Upper limb spasticity: No age restriction **Dysport:** Spasticity: In patients ≥ 2 years of age. In pediatric patients 2 to 17 years of age, this excludes spasticity caused by cerebral palsy. **Xeomin:** Sialorrhea, chronic, in patients ≥ 2 years of age. Upper limb spasticity: In pediatric patients ≥ 2 years of age, excluding spasticity caused by cerebral palsy.

PA Criteria	Criteria Details
Prescriber Restrictions	Prescribed by or in consultation with a Urologist, Dermatologist, Neurologist, Ophthalmologist.
Coverage Duration	**New and Continuation:** Approve for 1 year **Botox, Dysport:** Spasticity: administered not more frequently than once every 12 weeks. **Xeomin:** Sialorrhea, chronic: administered not more frequently than once every 16 weeks. Upper limb spasticity: administered not more frequently than once every 12 weeks.
Other Criteria	**Continuation Criteria:** Progress Notes
Exception Criteria for Step Therapy	Myobloc: 1) Approve for 1 year if the patient meets the following (A and B): **A)** Patient meets the standard Botulinum Toxins – Myobloc Medicare Advantage Utilization Management Medical criteria; AND **B)** Patient meets ONE of the following conditions (i or ii): i) Patient has tried one of Botox, Daxxify, Dysport, Xeomin; OR ii) Patient is currently receiving Myobloc or has previously taken Myobloc within the past 365 days.

References:

1. Daxxify injection [prescribing information]. Newark, CA: Revance; August 2023.
2. Myobloc® injection [prescribing information]. Louisville, KY: Solstice; September 2020.
3. Botox® injection [prescribing information]. Madison, NJ: Allergan/AbbVie; August 2022.
4. Xeomin® injection [prescribing information]. Raleigh, NC: Merz; August 2021.

BRIUMVI™ (ublituximab-xiiy) injection, for intravenous use

Products Affected

- BRIUMVI™ (ublituximab-xiiy) injection, for intravenous use

PA Criteria	Criteria Details
Billing code	J2329
Covered Uses	*All FDA approved and medically accepted indications.* **FDA Indication:** Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults
Exclusion Criteria	Contraindication(s): Active hepatitis B virus infection History of life-threatening infusion reaction to BRIUMVI
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments and other relevant clinical information Confirmed diagnosis of multiple sclerosis (MS) as documented by an MRI. **AND** Patient has a diagnosis of a relapsing form of MS: • relapsing-remitting MS (RRMS) • active secondary progressive disease (SPMS) • clinically isolated syndrome (CIS) **AND** **1. Step Therapy Requirement** a. The patient is considered a new start to the non-preferred product (defined as no use in the previous 365 days) **AND** **b.** Try/fail, have contraindication to, or intolerance to two of the following: Avonex, Dimethyl furamate, Glatiramer, Mayzent, Ocrevus, or Tysabri **AND** Patient has been screened for the presence of Hepatitis B virus (HBV) prior to initiating treatment AND does not have active disease (i.e., positive HBsAg and anti-HBV tests)

PA Criteria	Criteria Details
	AND Dosing: • First Infusion: 150 mg intravenous infusion. • Second Infusion: 450 mg intravenous infusion two weeks after the first infusion. • Subsequent Infusions: 450 mg intravenous infusion 24 weeks after the first infusion and every 24 weeks thereafter.
Age Restrictions	Age ≥ 18 years
Prescriber Restrictions	Prescribed by or in consultation with a neurologist.
Coverage Duration	6 months
Other Criteria	

References:

Product Information: BRIUMVI(TM) intravenous injection, ublituximab-xiiy intravenous injection. TG Therapeutics Inc (per FDA), Morrisville, NC, 2022.

BUSULFEX® (busulfan), for injection

Product Affected

- *BUSULFEX® (busulfan), for injection*

PA Criteria	Criteria Details
Billing code	J0594
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients with a history of hypersensitivity to any of its components. Limitation of use: None.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	None.
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist.
Coverage Duration	6 months
Other Criteria	

Note:
All Oncology Cases must be review first by OncoHealth Team to provide an expert recommendation.

Reference:
Lexicomp
Busulfex [package insert]. Greenville, MC: DSM Pharmaceuticals, Inc.; 2015.

CABENUVA (cabotegravir extended release; rilpivirine extended-release) for injection, for intramuscular use

Products Affected

- CABENUVA (cabotegravir extended release; rilpivirine extended-release) for injection, for intramuscular use.

PA Criteria	Criteria Details
Billing code	J0741
Covered Uses	*All FDA-approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Hypersensitivity to cabotegravir or rilpivirine • Concurrent use of CYP3A4 inducers (carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, St. John's wort, dexamethasone (more than a single-dose treatment)
Required Medical Information	The provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information • Diagnosis of HIV-1 • Weight of > 35 kg • Virologically suppressed (HIV-1 RNA < 50 copies/mL) for 3-6 months • On stable antiretroviral regimen with no history of treatment failure • No known or suspected resistance to either cabotegravir or rilpivirine • Liver function test **AND** Prior to initiating treatment with CABENUVA, oral lead-in dosing **may** be considered to assess the tolerability of cabotegravir and rilpivirine with the recommended dosage used for approximately 1 month. **AND** Dosing: Monthly Regimen: • Initial Dose: 600 mg / 900 mg the first month • Maintenance Dose: 400 mg / 600 mg monthly

PA Criteria	Criteria Details
	OR Every Two-Month Regimen: • Initial Dose: 600 mg / 900 mg the monthly the first 2 months • Maintenance Dose: 600 mg / 900 mg every 2 months
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist
Coverage Duration	12 months
Other Criteria	Healthcare professionals should carefully select individuals who agree to the injection dosing schedule and counsel individuals about the importance of adherence to help maintain viral suppression and reduce the risk of viral rebound and potential development of resistance with missed doses

Reference:

Product Information: CABENUVA intramuscular extended-release suspension, cabotegravir intramuscular extended-release suspension, rilpivirine intramuscular extended-release suspension. Viiv Healthcare (per FDA), Research Triangle Park, NC, 2022.

Cantharidin (YCANTH™), for topical use

Products Affected

- *Cantharidin (YCANTH™), for topical use*

PA Criteria	Criteria Details
Billing Code	J7354
Covered Uses	*All FDA approved and medically accepted indications.* **FDA Indications:** • Molluscum contagiosum virus
Exclusion Criteria	Contraindication(s): None
Required Medical Information	Laboratory monitoring not necessary Diagnosis confirmation: Based on the person's history and physical exam or via skin biopsy or tissue scraping that shows the viral infection
Age Restrictions	≥ 2 years old
Prescriber Restrictions	Prescribed by or in consultation with a pathologist or a board-certified dermatologist.
Coverage Duration	12 months
Other Criteria	

References:

1. Ycanth (cantharidin) [prescribing information]. West Chester, PA: Verrica Pharmaceuticals Inc; July 2023.
2. Cantharidin. Lexi-Drugs. [updated 2024 Sep 13; cited 2024 Nov 4] In Lexicomp Online [Internet].
3. Isaacs S. Molluscum contagiosum. In: Hirsch M, Levy M, Rosen T, ed. *UpToDate,* 2024.

Capecitabine (Xeloda®), for Oral use

Products Affected

- *Capecitabine (Xeloda®), for oral use*

PA Criteria	Criteria Details
Billing Code	J8522
Covered Uses	**Breast cancer, advanced or metastatic**: • As a single agent: if an anthracycline- or taxane-containing chemotherapy is not indicated. • In combination with docetaxel) after disease progression on a prior anthracycline-containing regimen. **Colorectal cancer**: • Adjuvant treatment of stage 3 colon cancer, either as a single agent or as a component of a combination chemotherapy regimen. • Perioperative treatment of locally advanced rectal cancer in adults, as a component of chemoradiotherapy. • Treatment of unresectable or metastatic colorectal cancer, either as a single agent or as a component of a combination chemotherapy regimen. **Gastric, esophageal, or gastroesophageal junction cancer**: • Treatment of unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer in adults, as a component of a combination chemotherapy regimen. • Treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma in adults who have not received prior treatment for metastatic disease, as a component of a combination regimen. **Pancreatic cancer, adjuvant therapy:** • Adjuvant treatment of pancreatic adenocarcinoma in adults, as a component of a combination chemotherapy regimen.
Exclusion Criteria	Contraindication(s): Known hypersensitivity to capecitabine, fluorouracil, or any component of the formulation.
Required Medical Information	• CBC with differential (at baseline and prior to each cycle)

PA Criteria	Criteria Details
	• Hepatic function (as clinically indicated; more frequently if hepatotoxicity occurs) • Kidney function (at baseline and as clinically indicated) • Monitor INR closely/more frequently if receiving a concomitant vitamin K antagonist • Evaluate pregnancy status prior to treatment initiation (in patients who could become pregnant) • Monitor hydration status at baseline and as clinically indicated • Monitor for signs/symptoms of diarrhea, dehydration, hand-foot syndrome, new or worsening serious skin reactions (eg, Stevens-Johnson syndrome, toxic epidermal necrolysis), stomatitis, hepatotoxicity, nephrotoxicity, and cardiotoxicity. • Evaluate any symptoms suggestive of cardiotoxicity • Consider monitoring ECG in patients on concomitant QT-prolonging medications • Monitor adherence. HBV screening with hepatitis B surface antigen, hepatitis B core antibody, total Ig or IgG, and antibody to hepatitis B surface antigen prior to beginning (or at the beginning of) systemic anticancer therapy; do not delay treatment for screening/results. Detection of chronic or past HBV infection requires a risk assessment to determine antiviral prophylaxis requirements, monitoring, and follow-up.
Age Restrictions	≥ 18 years of age
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	

References:

1. Xeloda (capecitabine) [prescribing information]. South San Francisco, California: Genentech; April 2022.
2. Capecitabine. Lexi-Drugs. [updated 2024 Oct 26; cited 2024 Nov 6] In Lexicomp Online [Internet].
3. Capecitabine: Drug Information. UpToDate, 2024.

CEPROTIN® (protein C concentrate), for injection

Product Affected

- *CEPROTIN® (protein C concentrate), for injection*

PA Criteria	Criteria Details
Billing code	J2724
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): None Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	6 months
Other Criteria	

Reference:

Ceprotin [package insert]. Lexington, MA: Baxalta US Inc.; 2021.

CEREZYME® (imiglucerase), for injection

Product Affected

- *CEREZYME® (imiglucerase), for injection*

PA Criteria	Criteria Details
Billing code	J1786
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): None Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, oncologist or geneticist.
Coverage Duration	6 months
Other Criteria	

Reference:

Cerezyme [package insert]. Cambridge, MA: Genzyme Corporation.; 2021.

CIMZIA® (certolizumab pegol), for injection

Product Affected

- *CIMZIA® (certolizumab pegol), for injection*

PA Criteria	Criteria Details
Billing code	J0717
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): None Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **AND** Provide results for tuberculin skin test and most recent Chest X-Ray. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply.
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist, dermatologist or gastroenterologist
Coverage Duration	6 months
Other Criteria	

Reference: Cimzia [package insert]. Smyrna, GA: UCB, Inc.; 2016.

CINQAIR® (reslizumab) injection, for intravenous use

Products Affected

- CINQAIR® (reslizumab) injection, for intravenous use

PA Criteria	Criteria Details
Billing code	J2786
Covered Uses	*All FDA approved and medically accepted indications.* **FDA Indication:** Add-on maintenance treatment of severe asthma with an eosinophilic phenotype
Exclusion Criteria	Contraindication(s): Known hypersensitivity to reslizumab or any of its excipients. (Only for Continuation therapy) Limitations of Use: Treatment of other eosinophilic conditions. Relief of acute bronchospasm or status asthmaticus.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information Diagnosis of severe asthma with an eosinophilic phenotype **AND** **One** of the following types of requests: Initial request: • Concurrent medications, when used to treat the same indication • Absence of contraindications Continuation of therapy request: • Concurrent medications, when used to treat the same indication • Absence of contraindications • Tolerance and response to treatment: describe disease improvement or abatement **AND** Dosing: • 3 mg/kg once every 4 weeks

PA Criteria	Criteria Details
Age Restrictions	Age ≥ 18 years
Prescriber Restrictions	Prescribed by or in consultation with a pneumologist.
Coverage Duration	12 months
Other Criteria	

Reference: Product Information: CINQAIR(R) intravenous injection, reslizumab intravenous injection. Teva Pharmaceuticals (per manufacturer), Frazer, PA, 2016.

CINRYZE® (C1 Esterase Inhibitor [Human]), for injection

Product Affected

- *CINRYZE® (C1 Esterase Inhibitor [Human]), for injection*

PA Criteria	Criteria Details
Billing code	J0598
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): In patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product. Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **AND** Provide diagnosis of Hereditary Angioedema (HAE) **AND** History of at least two HAE attacks per month. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with an allergist, a hematologist or a immunologist
Coverage Duration	6 months
Other Criteria	

Reference: Cinryze [package insert]. Lexington, MA: ViroPharma Biologics LLC.; 2022.

CINVANTI® (aprepitant), for injectable emulsion

Product Affected

- *CINVANTI® (aprepitant), for injectable emulsion*

PA Criteria	Criteria Details
Billing code	J0185
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients who are hypersensitive to any component of the product. • In patients who are taking pimozide. Limitation of use: • For the treatment of established nausea and vomiting.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **AND** Provide documentation that patient is receiving a highly and/or moderately emetogenic chemotherapy. **AND** Provide documentation of use in combination with a corticosteroid (Dexamethasone) and a 5-HT3 antagonist (Ondansetron). **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a hematologist and/or oncologist.
Coverage Duration	According treatment protocol
Other Criteria	

Note: All Oncology Cases must be review first by OncoHealth Team to provide an expert recommendation.

Reference:

Cinvanti [package insert]. San Diego, CA: Heron Therapeutics, Inc.; 2018.

COAGADEX ® (factor X (human)), for injection

Product Affected

- *COAGADEX ® (factor X (human)), for injection*

PA Criteria	Criteria Details
Billing code	J7175
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Do not use in patients who have had life-threatening hypersensitivity reactions to COAGADEX. (**Continuation of Therapy Only**) Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	6 months
Other Criteria	

Reference:

Coagadex [package insert]. Borehamwood, United Kingdom: Bio Products Laboratory Ltd.; 2023.

CORIFACT® (factor XIII human), for injection

Product Affected

- *CORIFACT® (factor XIII human), for injection*

PA Criteria	Criteria Details
Billing code	J7180
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Do not use in patients who have manifested life-threatening, immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including hamster protein. Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement
Age Restrictions	None.
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	6 months
Other Criteria	

Reference: Corifact [package insert]. Marburg, Germany: CSL Behring GmbH.; 2020.

COSENTYX ®*(secukinumab), for intravenous use*

Product Affected

- COSENTYX *(secukinumab, for intravenous use*

PA Criteria	Criteria Details
Billing code	J3247
Covered Uses	*All FDA approved and medically accepted indications.* FDA indications: • Active ankylosing spondylitis in adults • Active non-radiographic axial spondylarthritis in adults with objective signs of inflammation • Active psoriatic arthritis in patients ≥2 years of age.
Exclusion Criteria	Contraindication(s): • In patients with hypersensitivity to this medication. Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Diagnosis confirmation** **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	≥ 2 years of age for Active psoriatic arthritis. For all others ≥18 of age, unless specified for a diagnosis.
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist or a rheumatologist.
Coverage Duration	Approve medication for 12 months.
Other Criteria	• Screening for TB latent infection is required before starting treatment.

PA Criteria	Criteria Details
	• These criteria only apply for the intravenous administration. The subcutaneous formulation must be evaluated according to the Article (A52571) Self-Administered Drug exclusion list.

Reference:

1. COSENTYX [package insert]. South San Francisco, CA: Genentech, Inc. 2021
2. COSENTYX. In: Lexi-Drugs. UpToDate Inc; 2024. Updated April 23, 2024. Accessed May 20, 2024. http://online.lexi.com

COSYNTROPIN (cosyntropin), for injection

Product Affected

- *COSYNTROPIN (cosyntropin), for injection*

PA Criteria	Criteria Details
Billing code	J0834
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients with a hypersensitivity reaction to cosyntropin injection, synthetic ACTH, or to any of the excipients. Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist.
Coverage Duration	6 months
Other Criteria	

Reference:

Cosyntropin [package insert]. Princeton, New Jersey: Sandoz, Inc.; 2018.

CRYSVITA® (berosumab-twza), for injection

Product Affected

- *CRYSVITA® (berosumab-twza), for injection*

PA Criteria	Criteria Details
Billing code	J0584
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients with oral phosphate and active vitamin D analogs. • Serum phosphorus is within or above the normal range for age. • In patients with severe renal impairment or end stage renal disease. Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **AND** Diagnosis of X-linked hypophosphatemia (XLH) confirmed by **one** of the following: • DNA testing confirms the presence of mutations in the PHEX gene • serum fibroblast growth factor 23 (FGF23) level >30 pg/mL **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by, or in consultation with, an endocrinologist or specialist experienced in the treatment of metabolic bone disorders
Coverage Duration	6 months
Other Criteria	

Reference: Crysvita [package insert]. Novato, CA: Ultragenyx Pharmaceutical, Inc.; 2018.

Prior Authorization Criteria for Part B drugs
Effective Date: 01.01.2025
Utilization Management Committee Approval Date: 04.11.2024

CYKLOKAPRON® (tranexamic acid), for injection

Product Affected

- *CYKLOKAPRON® (tranexamic acid), for injection*

PA Criteria	Criteria Details
Billing code	J 3490
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients with subarachnoid hemorrhage. • In patients with active intravascular clotting. • In patients with severe hypersensitivity reactions to tranexamic acid or any of the ingredients. Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	8 days
Other Criteria	

Reference: Cyklokapron [package insert]. New York, NY: Pharmacia & Upjohn Co.; 2021.

CYTOGAM® (cytomegalovirus immune globulin), for injection

Product Affected

- *CYTOGAM® (cytomegalovirus immune globulin), for injection*

PA Criteria	Criteria Details
Billing code	J0850
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients with a history of a prior severe reaction associated with the administration of this or other human immunoglobulin preparations. • Persons with selective immunoglobulin A deficiency have the potential for developing antibodies to immunoglobulin A and could have anaphylactic reactions to subsequent administration of blood products that contain immunoglobulin A, including CytoGam. Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **AND** Provide results for BUN and serum creatinine. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement
Age Restrictions	Apply
Prescriber Restrictions	
Coverage Duration	6 months

PA Criteria	Criteria Details
Other Criteria	

Reference: CytoGam [package insert].Roswell, GA: Saol Therapeutics, Inc.; 2020.

DACOGEN™ (decitabine), for injection

Product Affected

- *DACOGEN™ (decitabine), for injection*

PA Criteria	Criteria Details
Billing code	J0893 – Sun Pharma J0894
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients with a history of serious hypersensitivity to decitabine. Limitation of use: None.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply.
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist.
Coverage Duration	6 months
Other Criteria	

Note:
All Oncology Cases must be review first by OncoHealth Team to provide an expert recommendation.

Reference: Dacogen [package insert]. The Netherlands: Pharmachemie B.V.; 2006.

Prior Authorization Criteria for Part B drugs
Effective date: 01.01.2025
Utilization Management Committee Approval Date: 04.11.2024

DDAVP (desmopressin) for injection, for intravenous or subcutaneous use

Products Affected

- DDAVP (desmopressin) for injection, for intravenous or subcutaneous use

PA Criteria	Criteria Details
Billing code	J2597
Covered Uses	*All FDA approved and medically accepted indication.*
Exclusion Criteria	Contraindication(s): • Known hypersensitivity to desmopressin acetate or to any of the components (Continuation therapy); • Moderate to severe renal impairment defined as a creatinine clearance below 50mL/min; Hyponatremia or a history of hyponatremia; • Known or suspected syndrome of inappropriate antidiuretic hormone (SIADH) secretion; • Polydipsia; • Concomitant use with loop diuretics or systemic or inhaled glucocorticoids; • During illnesses that can cause fluid or electrolyte imbalance; • Heart failure or uncontrolled hypertension
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information Diagnosis of Central Diabetes Insipidus; Hemophilia A, or von Willebrand's disease **AND** The following criteria: **Diabetes Insipidus:** • Prior to treatment assess serum sodium, urine volume and osmolality. Intermittently during treatment, assess serum sodium, urine volume and osmolality or plasma osmolality. **Hemophilia A:** • Prior to treatment verify that factor VIII coagulant activity levels are >5% and exclude the presence of factor VIII autoantibodies. Also assess serum sodium and aPTT prior to treatment. In certain clinical

PA Criteria	Criteria Details
	situations, it may be justified to try Desmopressin acetate in patients with factor VIII levels between 2% to 5%; however, these patients should be carefully monitored. **von Willebrand's Disease (Type I):** • Prior to verify that factor VIII coagulant activity levels are >5% and exclude severe von Willebrand's disease (Type I) and presence of abnormal molecular form of factor VIII antigen. During treatment with Desmopressin acetate injection, assess serum sodium, bleeding time, factor VIII coagulant activity, ristocetin cofactor activity, and von Willebrand antigen to ensure that adequate levels are being achieved. **AND** Dosing: **Diabetes Insipidus:** • 2 – 4 mcg/d in one or divided doses administered IV or SC **Hemophilia A and von Willebrand's Disease (Type 1):** • 0.3 mcg/kg (maximum of 20mcg) administered IV
Age Restrictions	Apply
Prescriber Restrictions	None
Coverage Duration	1 months
Other Criteria	None

Reference: Product Information: DDAVP(R) injection, desmopressin acetate intravenous injection. Ferring Pharmaceuticals Inc (per FDA), Parsippany, NJ, 2018

DESFERAL® (deferoxamine mesylate), for injection

Product Affected

- *DESFERAL® (deferoxamine mesylate), for injection*

PA Criteria	Criteria Details
Billing code	J9155
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): In patients with severe renal disease or anuria. Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	6 months
Other Criteria	

Reference:

Desferal [package insert]. Stein, Switzerland: Novartis Pharma Stein AG.; 2007.

DUROLANE® (sodium hyaluronate), for injection

Product Affected

- *DUROLANE® (sodium hyaluronate), for injection*

PA Criteria	Criteria Details
Billing code	J7318
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Do not inject DUROLANE® with knee joint infections, infections, or skin disease in the area of the injection site. • Do not administer to patients with known hypersensitivity (allergy) to HA preparations. Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Diagnosis** of Osteoarthritis (OA) of the knee (Confirmatory Test) **AND** **Documentation** that the patient has failed to respond adequately to respond adequately conservative non-pharmacologic therapy or simple analgesics **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement
Age Restrictions	Apply
Prescriber Restrictions	
Coverage Duration	One Time per Knee
Other Criteria	

Reference:

Durolane [package insert]. Uppsala, Sweden: Bioventus LLC.; 2001.

DURYSTA® (bimatoprost implant), for intracameral

Product Affected

- *DURYSTA® (bimatoprost implant), for intracameral*

PA Criteria	Criteria Details
Billing code	J7351
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Ocular or periocular infections • Corneal endothelial cell dystrophy • Prior corneal transplantation • Absent or ruptured posterior lens capsule • Hypersensitivity Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement, e.g., Maintenance or improvement in visual acuity.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist
Coverage Duration	6 months
Other Criteria	None

Reference: Durysta [package insert]. Madison, New Jersey: Allergan, Inc.; 2020.

Prior Authorization Criteria for Part B drugs
Effective Date: 01.01.2025
Utilization Management Committee Approval Date: 04.11.2024

ELAPRASE (idursulfase) for injection, for intravenous use

Products Affected

- ELAPRASE (idursulfase) for injection, for intravenous use

PA Criteria	Criteria Details
Billing code	J1743
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments and other relevant clinical information Diagnosis of Hunter Syndrome (Mucopolysaccharidosis II, MPS II) with the following information: ▪ Presence of glycosaminoglycans (GAG) in the urine ▪ Deficiency in iduronate-2-sulfatase (IDS) enzyme activity ▪ Genetics testing **AND** Dosing: • 0.5 mg/kg once weekly **Continuation of Therapy** o Medical record documentation of stabilization of disease progression may include: ▪ Improvement in percent predicted FVC ▪ Improvement in 6-minute walk test ▪ Reduction in urinary GAG levels ▪ Reduction in liver or spleen size
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a geneticist

PA Criteria	Criteria Details
Coverage Duration	Initial request: 6 months Continuation request: 12 months
Other Criteria	None

Reference:

Product Information: ELAPRASE(R) intravenous injection, idursulfase intravenous injection. Shire Human Genetic Therapies Inc (per FDA), Lexington, MA, 2013.

ELELYSO® (taliglucerase alfa), for injection

Product Affected

- *ELELYSO® (taliglucerase alfa), for injection*

PA Criteria	Criteria Details
Billing code	J3060
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Do not use in patients who have manifested life-threatening, immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including hamster protein. Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a hematologist, oncologist or geneticist.
Coverage Duration	6 months
Other Criteria	

Reference: ELELYSO [package insert]. New York, NY: Pfizer Pharmaceuticals labs.; 2012.

ELFABRIO® (pegunigalsidase alfa-iwxj), for intravenous use

Product affected

- *Elfabrio® (pegunigalsidase alfa-iwxj), for intavenous use*

PA Criteria	Criteria details
Billing Code	J2508
Covered Uses	*All FDA-approved and medically accepted indications.* FDA Indications: • Fabry disease
Exclusion Criteria	Contraindication(s): • None Limitation of use: • Hypersensitivity: The patient may develop IgG antibodies within 26 weeks of initiation of therapy. Patients with previous enzyme replacement are at higher risk.
Required Medical Information	The provider must submit confirmation of diagnosis, supporting documentation such as progress notes, lab results, previous treatments, and other relevant clinical information. • ≤ 1% alpha-GAL enzyme activity • genetic testing **Continuation of therapy** Tolerance and response to treatment: describe the improvement or decrease of disease activity.
Restriction of age	Adults ≥ 18 years old
Prescriber restrictions	Prescribed by or in consultation with a geneticist, cardiologist, nephrologist, or gastroenterologist
Duration of Coverage	12 months
Other criteria	

Reference:

Elfabrio (pegunigalsidase alfa) [prescribing information]. Cary, NC: Chiesi USA; May 2023.

ELITEK® (rasburicase), for injection

Product Affected

- *ELITEK® (rasburicase), for injection*

PA Criteria	Criteria Details
Billing code	J2783
Covered Uses	*All FDA approved and medically accepted indications..*
Exclusion Criteria	Contraindication(s): • History of the following reactions to rasburicase: anaphylaxis, severe hypersensitivity, hemolysis, methemoglobinemia. • Glucose-6-phosphate dehydrogenase (G6PD) deficiency. Limitation of use: Elitek is indicated only for a single course of treatment
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **AND** Provide evidence of Glucose-6-phosphate dehydrogenase (G6PD) test.
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	5 days
Other Criteria	

Reference: ELITEK [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC.; 2009.

ENJAYMO® (sutimlimab-jome) injection, for intravenous use

Products Affected

- ENJAYMO® (sutimlimab-jome) injection, for intravenous use

PA Criteria	Criteria Details
Billing code	J1302
Covered Uses	All FDA approved and medically accepted indications. FDA Indication: Hemolysis in adults with cold agglutinin disease (CAD)
Exclusion Criteria	Contraindication(s): contraindicated in patients with known hypersensitivity to sutimlimab-jome or any of the inactive ingredients.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments and other relevant clinical information **Step Therapy Requirement** a. The patient is considered a new start to the non-preferred product (defined as no use in the previous 365 days) **AND** b. Must try/fail, have contraindication to, or intolerance to Rituximab (Truxima, Ruxience, Rituxan) Confirmed diagnosis of primary cold agglutinin disease (CAD) based on **all** of the following: 1. Evidence of hemolysis as indicated by both of the following: a. Lactate dehydrogenase (LDH) level above the upper limit of normal **and** b. Haptoglobin level below the lower limit of normal; **and** 2. Positive polyspecific direct antiglobulin test (DAT) result; **and** 3. Monospecific DAT result strongly positive for C3d; **and** 4. Cold agglutinin titer is above or equal to 1:64; **and** **5.** DAT result for IgG of ≤1+ **AND** AND Hemoglobin level <= 10.0 g/dL **AND** Bilirubin level above the normal reference range **AND**

PA Criteria	Criteria Details
	Secondary CAD has been ruled out (e.g., cold agglutinin syndrome secondary to infection, rheumatologic disease, or active hematologic malignancy). **AND** Dosing: • For body weight **39 kg to < 75 kg**: 6,500 mg (6 vials) on Day 0, Day 7, then every 2 weeks thereafter • For body weight **≥ 75 kg**: 7,500 mg (7 vials) on Day 0, Day 7, then every 2 weeks thereafter
Age Restrictions	Age ≥ 18 years
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist
Coverage Duration	6 months
Other Criteria	**Continuation of therapy:** Patient has experienced a disease response compared to pretreatment baseline: • Hemoglobin response defined as an increase from baseline in Hgb level ≥2 g/dL or aHgb level ≥12 g/dL without transfusion over a four week or longer time period; **OR** • Absence of packed RBC transfusion; **OR** • Patient had an increase in Hb and/or decrease in transfusion requirement, to a lesser extent than the above, **AND** also had an improvement in the signs and symptoms (e.g., fatigue, jaundice, shortness of breath) and/or markers of hemolysis (e.g., indirect bilirubin, reticulocyte count, LDH, haptoglobin, etc).

Referencia: Product Information: ENJAYMO(TM) intravenous injection, sutimlimab-jome intravenous injection. Bioverativ USA Inc (per FDA), Waltham, MA, 2024.https://products.sanofi.us/enjaymo/enjaymo.pdf

ENTYVIO ®*(vedolizumab) for injection, for intravenous use*

Product Affected

- ENTYVIO (vedolizumab) for injection, for intravenous use

PA Criteria	Criteria Details
Billing code	J3380
Covered Uses	*All FDA approved and medically accepted indications.* FDA Indications: • Moderate to severe active Crohn's Disease • Moderate to severe active Ulcerative Colitis
Exclusion Criteria	Contraindication(s): • In patients with hypersensitivity reaction to Entyvio or any of its excipients (Only for Continuation of Therapy) • Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Diagnosis confirmation** **Step Therapy Requirement (Only for New Patients in Therapy with Ulcerative Colitis)** a) The patient is considered a new start to the non-preferred product (defined as no use in the previous 365 days) **AND** b) Must try/fail, have contraindication to, or intolerance to one of the following: Inflectra, Renflexis or Avsola prior to receiving ENTYVIO. **Select one of the following types of requests:** **Initial request:** • Documentation of disease severity, activity, and risk • For Crohn's Disease (CD): Crohn's Disease Activity Index (CDAI) o Crohn's disease activity index (CDAI) ▪ Asymptomatic remission < 150

PA Criteria	Criteria Details
	▪ Mild to moderate 150 – 220 ▪ **Moderate to severe 221 – 450** ▪ Severely active to fulminate 451 – 1100 o CDAIcalculator: https://www.mdcalc.com/calc/3318/crohns-disease-activityindex-cdai o For Ulcerative Colitis (UC): Mayo Score / Disease Activity Index (DAI) ▪ The score can range from 0-12 with higher scores indicating worse severity. o Past, current, and concurrent medication trial, failure, contraindication, or intolerance when used to treat the same indication. ▪ Intolerant to tumor necrosis factor (TNF) blocker or immunomodulator; inadequate response with, are intolerant to, or demonstrated dependence on corticosteroids. o Negative Tuberculosis Test (PPD Test or Chest X-Ray) o Nonreactive Hepatitis B Panel o Recent vaccination history (within the last month; if applicable): Patient should have not received live vaccines in the past 4 weeks. **OR** **Continuation of Therapy:** • Documentation of change in disease severity: o CD (CDAI, indicators of severe disease) o UC (Mayo Score / DAI) • Concomitant therapy • Absence of contraindications • Negative test for tuberculosis (PPD Test or Chest X-Ray) • Tolerance and response to treatment: describe disease improvement or abatement. **AND** Select the Appropriate Dosing: • Initial dose: 300 mg at week 0, 2 and 6. • Maintenance dose: 300mg every 8 weeks
Age Restrictions	≥ 18 years of age.

PA Criteria	Criteria Details
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	Initial: 42 days Continuation of Therapy: 6 months
Other Criteria	None

Reference:
Product Information: ENTYVIO intravenous injection, vedolizumab intravenous injection. Takeda Pharmaceuticals America Inc (per FDA), Lexington, MA, 2022. Local Coverage Determination (A59074): Billing and Coding: Complex Drug Administration Coding

Feuerstein, J. D., Isaacs, K. L., Schneider, Y., Siddique, S. M., Falck–Ytter, Y., Singh, S., Chachu, K. A., Day, L. W., Lebwohl, B., Muniraj, T., Patel, A., Peery, A. F., Shah, R., Sultan, S., Singh, H., Spechler, S. J., Su, G. L., Thrift, A. P., Weiss, J. M., . . . Terdiman, J. P. (2020). AGA Clinical Practice Guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology, 158(5), 1450–1461. https://doi.org/10.1053/j.gastro.2020.01.006

Feuerstein, J. D., Ho, E. Y., Shmidt, E., Singh, H., Falck–Ytter, Y., Sultan, S., Terdiman, J. P., Sultan, S., Cohen, B. L., Chachu, K. A., Day, L. W., Davitkov, P., Lebwohl, B., Levin, T. R., Patel, A., Peery, A. F., Shah, R., Singh, S., Spechler, S. J., . . . Weiss, J. M. (2021). AGA Clinical Practice Guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's Disease. Gastroenterology, 160(7), 2496–2508. https://doi.org/10.1053/j.gastro.2021.04.022

ENVARSUS XR® (tacrolimus extended-release tablets), for oral

Product Affected

- *ENVARSUS XR® (tacrolimus extended-release tablets), for oral*

PA Criteria	Criteria Details
Billing code	J7503
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): In patients with known hypersensitivity to tacrolimus. Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	6 months
Other Criteria	

Reference: Envarsus XR [package insert]. North Rhine-Westphalia, Germany: Rottendorf Pharma GmbH.; 2018.

Erythropoiesis - Stimulating Agents, for intravenous and subcutaneous use

Products Affected

- *ARANESP® (darbepoetin alfa) injection, for intravenous or subcutaneous use*
- *Epogen® (epoetin alfa) injection, for intravenous or subcutaneous use*
- *Mircera® (methoxy polyethylene glycol-epoetin beta intravenous or subcutaneous injection – Vifor)*
- *PROCRIT® (epoetin alfa) injection, for intravenous or subcutaneous use*
- *RETACRIT® (epoetin alfa-epbx) injection, for intravenous or subcutaneous use*

PA Criteria	Criteria Details
Preferred Products	Aranesp, Retacrit
Non-Preferred Products	Epogen, Mircera, Procrit
Billing Code	J0881 – Aranesp Non-ESRD J0882 _ Aranesp ESRD Q4081 – Epogen Q5106 - Retacrit J0885 - Procrit J0887 – Mircera ESRD J0888 – Mircera Non-ESRD
Covered Uses	*All FDA approved and medically accepted indications.* **FDA Indications:** **Retacrit, Epogen, Procrit, Aranesp** • Anemia Due to Chronic Kidney Disease • Anemia Due to Chemotherapy in Patients With Cancer **Retacrit, Epogen, Procrit** • Anemia Due to Zidovudine in Patients with HIV-infection • Reduction of Allogeneic Red Blood Cell Transfusions in Patients Undergoing Elective, Noncardiac, Nonvascular Surgery **Mircera**

PA Criteria	Criteria Details
	• Anemia Due to Chronic Kidney Disease
Exclusion Criteria	**<u>Contraindications:</u>** **Retacrit, Epogen, Procrit, Aranesp, Mircera** • Uncontrolled hypertension • Pure red cell aplasia (PRCA) that begins after treatment with RETACRIT or other erythropoietin protein drugs. **<u>Limitation of use:</u>** **Retacrit, Epogen, Procrit, Aranesp** These products have not been shown to improve quality of life, fatigue, or patient well-being in the following scenarios: • In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy. • In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure. • In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion. • In patients scheduled for surgery who are willing to donate autologous blood. • In patients undergoing cardiac or vascular surgery. • As a substitute for RBC transfusions in patients who require immediate correction of anemia. **Mircera** • In the treatment of anemia due to cancer chemotherapy. • As a substitute for RBC transfusions in patients who require immediate correction of anemia.
Required Medical Information	Provider must submit supporting documentation such as progress notes (including weight and height), laboratory results, previous treatments and other relevant clinical information **Step Therapy Requirement (Only for New Patients)** **Medical Information Requirements:** • Hemoglobin Laboratory • Evaluation of Iron Store: Evaluate the iron status in all patients before and during treatment. Requirement of supplemental iron therapy when serum ferritin is less than 100 mcg/L or when serum transferrin saturation is less than 20%. Most patients with CKD will require supplemental iron during the course of ESA therapy.

PA Criteria	Criteria Details
	• Correct or exclude other causes of anemia (e.g., vitamin deficiency, metabolic or chronic inflammatory conditions, bleeding, etc.) before initiating. • Pretreatment hemoglobin levels of less than 10g/dL. " • Dose reduction or interruption if hemoglobin exceeds 10 g/dL (CKD not on dialysis-adult, cancer), 11 g/dL (CKD on dialysis), 12 g/dL (pediatric CKD. • Supporting statement of diagnosis from physician. • Patients with perioperative hemoglobin more than 10 g/dL to 13 g/dL scheduled to undergo elective, noncardiac, nonvascular surgery
Age Restrictions	None
Prescriber Restrictions	Approve if prescribed by or in consultation with a hematologist or nephrologist.
Coverage Duration	3 months
Other Criteria	**Continuation Criteria:** Progress notes
Exception Criteria for Step Therapy	Patient is Currently Receiving an Erythropoiesis-Stimulating Agent. Approve if the patient meets the following: Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit), a darbepoetin alfa product (e.g., Aranesp), or a methoxy polyethylene glycol-epoetin beta product (e.g., Mircera). **i.** Patient has a hemoglobin ≤ 12.0 g/dL; AND **ii.** Patient meets one of the following (a or b): a) Patient is currently receiving iron therapy; OR b) Patient has adequate iron stores according to the prescriber.

References:

1. Procrit® intravenous or subcutaneous injection [prescribing information]. Horsham, PA: Janssen; May 2020.
2. Epogen® intravenous or subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; July 2018.
3. Retacrit™ subcutaneous or intravenous injection [prescribing information]. New York, NY: Pfizer; July 2022.
4. Mircera® intravenous or subcutaneous injection [prescribing information]. Basking Ridge, NJ: Vifor Pharma; August 2019.

5. Aranesp® intravenous or subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; January 2019.
6. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (110.21). [Original effective date: 7/30/2007; Revision effective date: 01/2021]. Accessed October 10, 2023
7. Aranesp® intravenous or subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; January 2019.
8. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. *Kidney Int*. 2012; 2(Suppl):279-335.
9. The NCCN Myelodysplastic Syndromes Clinical Practice Guidelines in Oncology (version 3.2022 – January 13, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 14, 2022.
10. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (version 2.2022 – April 13, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 14, 2022.
11. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (110.21). [Version Number 1, Effective date of version: 7/30/2007. Accessed April 19, 2023].
12. Procrit® intravenous or subcutaneous injection [prescribing information]. Horsham, PA: Janssen; May 2020.
13. Epogen® intravenous or subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; July 2018.
14. Retacrit® subcutaneous or intravenous injection [prescribing information]. New York, NY and Lake Forest, IL: Pfizer and Hospira; June 2021.
15. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. *Kidney Int*. 2012; 2(Suppl):279-335.
16. The NCCN Myelodysplastic Syndromes Clinical Practice Guidelines in Oncology (version 3.2022 – January 13, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 24, 2022.
17. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (version 2.2022 – April 13, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 24, 2022.
18. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (110.21). [Version Number 1, Effective date of version: 7/30/2007. Accessed April 17, 2023].

EVENITY® (romosozumab-aqqg) injection, for subcutaneous use

Products Affected

- EVENITY® (romosozumab-aqqg) injection, for subcutaneous use

PA Criteria	Criteria Details
Billing code	J3111
Covered Uses	All FDA approved and medically accepted indications.
Exclusion Criteria	Contraindication(s): Hypocalcemia Known hypersensitivity to EVENITY Limitations of Use: Limit duration of use to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments and other relevant clinical information **Diagnosis** **AND** **Step Therapy Requirement** a. The patient is considered a new start to the non-preferred product (defined as no use in the previous 365 days) **AND** **b.** Must try/fail, have contraindication to, or intolerance to **two** of the following bisphosphonates (oral or IV), Prolia or Tymlos. Patient has a documented diagnosis of osteoporosis indicated by one or more of the following: • Hip DXA (femoral neck or total hip) or lumbar spine T-score ≤-2.5 and/or forearm DXA 33% (one-third) radius; **OR** • T-score ≤-1 or low bone mass and a history of fragility fracture to the hip or spine; **OR**

PA Criteria	Criteria Details
	• T-score between -1 and -2.5 with a FRAX 10-year probability for major fracture ≥20% or hip fracture ≥3% **AND** The patient is at a very high fracture risk as defined by **ONE** of the following: A. Patient had a recent fracture (within the past 12 months) **OR** B. Patient had fractures while on FDA approved osteoporosis therapy **OR** C. Patient has had multiple fractures **OR** D. Patient had fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids) **OR** E. Patient has a very low T-score (less than -3.0) **OR** F. Patient is at high risk for falls or has a history of injurious falls **OR** G. Patient has a very high fracture probability by FRAX (e.g.,major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or by other validated fracture risk algorithm. **AND** Metabolic Panel Laboratory with normal Calcium Levels (Range: 8.6 to 10.3 mg/dL) **AND** Dosing: • 210 mg subcutaneously once every month for 12 doses
Age Restrictions	Age ≥ 18 years
Prescriber Restrictions	
Coverage Duration	12 months (Medication is limited only for 12 months in a lifetime)
Other Criteria	Medication **Cannot** be renewed if patient have completed 12 months of treatment.

Reference:

Evenity (Package insert) Manufactured by: Amgen Inc., One Amgen Center Drive, Thousand Oaks, CA 91320-1799 US License No. 1080 © 2019, 2020 Amgen Inc

EVKEEZA® (evinacumab-dgnb), for injection

Product Affected

- *EVKEEZA® (evinacumab-dgnb), for injection*

PA Criteria	Criteria Details
Billing code	J1305
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • History of serious hypersensitivity reactions to evinacumab-dgnb or to any of the excipients in EVKEEZA. Limitation of use: • The safety and effectiveness of EVKEEZA have not been established in patients with other causes of hypercholesterolemia, including those with heterozygous familial hypercholesterolemia (HeFH). • The effects of EVKEEZA on cardiovascular morbidity and mortality have not been determined.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. Diagnosis of homozygous familial hypercholesterolemia (HoFH) confirmed by genetic testing or by the presence of the following clinical criteria: • history of an untreated total cholesterol (TC) >500 mg/dL **AND** • either xanthoma before 10 years of age **OR** • evidence of TC >250 mg/dL in both parents **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply
Prescriber Restrictions	
Coverage Duration	6 months

PA Criteria	Criteria Details
Other Criteria	

Reference:

Evkeeza [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; 2021.

EYLEA® (aflibercept) Injection, for intravitreal use

Products Affected

- EYLEA® (aflibercept) Injection, for intravitreal use

PA Criteria	Criteria Details
Billing code	J0178
Covered Uses	*All FDA approved and medically accepted indications.* FDA Indications: • Neovascular (Wet) Age-Related Macular Degeneration (AMD) • Macular Edema Following Retinal Vein Occlusion (RVO) • Diabetic Macular Edema (DME) • Diabetic Retinopathy (DR) • Retinopathy of prematurity
Exclusion Criteria	Contraindication(s): Ocular or periocular infection **OR** Active intraocular inflammation **OR** Hypersensitivity (Only for Continuation of Therapy)
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments and other relevant clinical information 1. Diagnosis Confirmation of **one** of the followings: a. Neovascular (Wet) Age-Related Macular Degeneration (AMD) b. Macular Edema Following Retinal Vein Occlusion (RVO) c. Diabetic Macular Edema (DME) **d.** Diabetic Retinopathy (DR) **AND** **2. Step Therapy Requirement** a. The patient is considered a new start to the non-preferred product (defined as no use in the previous 365 days) **AND** b. Must try/fail, have contraindication to, or intolerance to Avastin-ophthalmic formulation (Compounded Formulation) and Byooviz/Cimerli. **AND**

PA Criteria	Criteria Details
	3. EYLEA will not be used concurrently with other VEGF inhibitors for intraocular use in the absence of documentation indicating that individual products are to be used in different eyes. **AND** 1. Dose a. AMD: 2 mg (1 vial) every 4 weeks for the first 3 months, then every 8 weeks thereafter b. DME and DR: 2 mg (1 vial) every 4 weeks for the first 5 injections, then every 8 weeks thereafter c. RVO: 2 mg (1 vial) every 4 weeks
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist
Coverage Duration	**Initial and Continuation:** 6 months
Other Criteria	**Continuation Criteria:** 1. Currently receiving medication **AND** 2. Member is responding positively to therapy as evidenced by **one** of the following: a. Detained neovascularization **OR** b. Improvement/stabilization in visual acuity **OR** c. Maintenance of corrected visual acuity from prior treatment **OR** d. Supportive findings from optical coherence tomography or fluorescein angiography 3. If request is for a dose increase, new dose does not exceed: a. DME and DR: 2 mg (1 vial) every 8 weeks b. RVO: 2 mg (1 vial) every 4 weeks c. AMD: 2 mg (1 vial) every 8 weeks

References:

Product Information: EYLEA(R) intravitreal injection, aflibercept intravitreal injection. Regeneron Pharmaceuticals Inc (per DailyMed), Tarrytown, NY, 2023.

EYLEA® HD (aflibercept) Injection, for intravitreal use

Products Affected

- EYLEA® HD (aflibercept) Injection, for intravitreal use

PA Criteria	Criteria Details
Billing code	J3590 - Unclassified biologics.
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): Ocular or periocular infections; Active intraocular inflammation; Hypersensitivity
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments and other relevant clinical information. 1. Diagnosis Confirmation of **one** of the followings: a. Neovascular (Wet) Age-Related Macular Degeneration (AMD) b. Diabetic Macular Edema (DME) **c.** Diabetic Retinopathy (DR) **AND** **2. Step Therapy Requirement** a. The patient is considered a new start to the non-preferred product (defined as no use in the previous 365 days) **AND** b. Must try/fail, have contraindication to, or intolerance to Avastin-ophthalmic formulation (Compounded Formulation) **AND** 3. EYLEA will not be used concurrently with other VEGF inhibitors for intraocular use in the absence of documentation indicating that individual products are to be used in different eyes. **AND** 1. Dose a. AMD and DME:8 mg (1 vial) every 4 weeks for the first 3 months, then every 8 to 16 weeks thereafter b. DME and DR: 8 mg (1 vial) every 4 weeks for the first 3 dose months, then every 8 to 12 weeks thereafter

PA Criteria	Criteria Details
3Age Restrictions	Age ≥ 18 years
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist
Coverage Duration	**Initial and Continuation:** 6 months
Other Criteria	**Continuation Criteria:** 1. Currently receiving medication **AND** 2. Member is responding positively to therapy as evidenced by **one** of the following: a. Detained neovascularization **OR** b. Improvement/stabilization in visual acuity **OR** c. Maintenance of corrected visual acuity from prior treatment **OR** d. Supportive findings from optical coherence tomography or fluorescein angiography

References:

Product Information: EYLEA (R) HD intravitreal injection, aflibercept intravitreal injection. Regeneron Pharmaceuticals Inc (per DailyMed), Tarrytown, NY, 2023.

FABRAZYME (agalsidase alfa) for injection, for intravenous use

Products Affected

- FABRAZYME (agalsidase) for injection, for intravenous use

PA Criteria	Criteria Details
Billing code	J0180
Covered Uses	*All FDA approved and medically accepted indications*
Exclusion Criteria	Contraindication(s): None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information Diagnosis Fabry Disease confirmed GLA gene test; **AND** **AND** Dosing: 1 mg/kg body weight given every two weeks.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a nephrologists, geneticists or cardiologists
Coverage Duration	12 months
Other Criteria	None

References:

Product Information: FABRAZYME(R) intravenous injection, agalsidase beta intravenous injection. Genzyme Corporation (per manufacturer), Cambridge, MA, 2021.

FACTOR IX® (recombinant), for injection

Product Affected

- *FACTOR IX® (recombinant), for injection*

Reference:

PA Criteria	Criteria Details
Billing code	J7201 - Alprolix J7202 - Idelvion J7213 - Ixinity
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): Do not use in patients with known hypersensitivity to the medication. Limitation of use: Not indicated for induction of immune tolerance in patients with hemophilia B.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	6 months
Other Criteria	

Reference: Coagulation Factor IX [package insert]. Chicago, IL: Medexus Pharma, Inc.; 2022.

FEIBA® (anti-inhibitor coagulant complex), for injection

Product Affected

- *FEIBA® (anti-inhibitor coagulant complex), for injection*

PA Criteria	Criteria Details
Billing code	J7198
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • History of anaphylactic or severe hypersensitivity reactions to FEIBA or any of its components, including factors of the kinin generating system. • Disseminated intravascular coagulation (DIC). • Acute thrombosis or embolism (including myocardial infarction). Limitation of use: • Not indicated for the treatment of bleeding episodes resulting from coagulation factor deficiencies in the absence of inhibitors to factor VIII or factor IX.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	6 months
Other Criteria	

Reference: Feiba [package insert]. Lexington, MA: Takeda Pharmaceuticals.

FENSOLVI® (leuprolide acetate), for injection

Product Affected

- *FENSOLVI® (leuprolide acetate), for injection*

PA Criteria	Criteria Details
Billing code	J1951
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Hypersensitivity to Fensolvi • Pregnancy Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist
Coverage Duration	6 months
Other Criteria	

Reference: Fensolvi [package insert]. Fort Collins, CO: Tolmar, Inc.; 2020.

FIBRYGA® (fibrogen (human)), for inyection

Product Affected

- *FIBRYGA® (fibrogen (human)), for inyection*

PA Criteria	Criteria Details
Billing code	J7177
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): Anaphylactic or severe reactions to FIBRYGA or its components. Limitation of use: No indicated for dysfibrinogenemia.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement
Age Restrictions	None
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	

Reference: Fibryga [package insert]. Vienna, Austria: Octapharma Pharmazeutika Produktionsges.m.b.H..; 2020.

Filgrastim - Colony Stimulating Factors, for intravenous or subcutaneous use

Products Affected

- *Granix® (tbo-filgrastim subcutaneous injection – Teva)*
- *Neupogen® (filgrastim intravenous or subcutaneous injection – Amgen)*
- *Nivestym™ (filgrastim-aafi intravenous or subcutaneous injection – Hospira/Pfizer)*
- *Releuko® (filgrastim-ayow intravenous or subcutaneous injection – Amneal)*
- *Zarxio® (filgrastim-sndz intravenous or subcutaneous injection – Sandoz)*

PA Criteria	Criteria Details
Preferred Products	Zarxio, Nivestym
Non-Preferred Products	Granix, Neupogen, Releuko
Billing Code	J1447 - Granix J1442 - Neupógeno Q5110 – Nivestym Q5125 - Releuko Q5101 - Zarxio
Covered Uses	*For the FDA-Approved Indications* **Neupogen, Nivestym, Releuko, Zarxio:** **Acute Myeloid Leukemia (AML)**: in a Patient Receiving Chemotherapy. **Bone Marrow Transplant**: in a Patient with Cancer Who Received Chemotherapy. **Peripheral Blood Progenitor Cell Collection and Therapy** **Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome)** **Severe Chronic Neutropenia (e.g., Congenital Neutropenia, Cyclic Neutropenia, Idiopathic Neutropenia)** **Neupogen, Nivestym, Releuko, Zarxio, Granix:**

PA Criteria	Criteria Details
	Cancer in a Patient Receiving Myelosuppressive Chemotherapy: Approve if the patient meets the following A) Patient meets ONE of the following (i, ii, iii, or iv): i. Patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen); OR ii. Patient meets both of the following (a and b): a) Patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia, but the risk is less than 20% based on the chemotherapy regimen; AND b) Patient has at least one risk factor for febrile neutropenia according to the prescriber; OR Note: Examples of risk factors include age ≥ 65 years; prior chemotherapy or radiation therapy; persistent neutropenia; bone marrow involvement by tumor; recent surgery and/or open wounds; liver and/or renal dysfunction; poor performance status; or human immunodeficiency virus (HIV) infection. iii. Patient meets both of the following (a and b): a) Patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor; AND Note: Examples of colony stimulating factors include filgrastim products, pegfilgrastim products, and sargramostim products (e.g., Leukine). b) A reduced dose or frequency of chemotherapy may compromise treatment outcome; OR iv. Patient who has received chemotherapy has febrile neutropenia and has at least one risk factor for poor clinical outcomes or for developing infection-associated complications according to the prescriber; AND Note: Examples of risk factors include sepsis syndrome; age > 65 years; severe neutropenia (absolute neutrophil count [ANC] < 100 cells/mm3); neutropenia expected to be > 10 days in duration; invasive fungal infection; or other clinically documented infections.

PA Criteria	Criteria Details
Exclusion Criteria	**Contraindication(s):** The guidelines state CSFs should be avoided in patients receiving concomitant chemotherapy and radiation therapy, particularly involving the mediastinum.
Required Medical Information	Provider must submit supporting documentation such as progress notes (including weight and height), laboratory results, previous treatments, and other relevant clinical information. **Step Therapy Requirement (Only for New Patients)** **Medical Information Requirements:** **Neupogen**: should be discontinued if the ANC surpasses 10,000/mm^3 after the expected therapy-induced neutrophil nadir.
Age Restrictions	For patients ≥ 18 years of age **Granix** is only indicated for patients ≥ 1 month of age
Prescriber Restrictions	Prescribed by or in consultation with a hematologist & oncologist, or a physician who specializes in transplantation.
Coverage Duration	**New and Continuation:** **Approve for 6 months:** AML Cancer in a Patient Receiving Myelosuppressive Chemotherapy Severe Chronic Neutropenia (e.g., Congenital Neutropenia, Cyclic Neutropenia, Idiopathic Neutropenia **Approve for 1 month:** Bone Marrow Transplant Peripheral Blood Progenitor Cell Collection and Therapy Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome)
Other Criteria	**Continuation Criteria:** Monitor complete blood count (CBC) prior to chemotherapy and twice per week until recovery. Absolute neutrophil count (ANC) and CBC
Exception Criteria for Step Therapy	**Granix, Neupogen, Releuko** **1.** Approve if the patient meets the following (A and B):

PA Criteria	Criteria Details
	A) Patient meets the standard *Colony Stimulating Factors – Granix Neupogen, Releuko, Utilization Management Medical Policy* criteria; AND **B)** Patient meets one of the following (i or ii): **i.** Patient meets both of the following (a and b): **a)** Patient has tried ONE of Nivestym or Zarxio; AND **b)** Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR **ii.** Patient has initiated therapy with Granix and requires further medication to complete the current cycle of chemotherapy

Note: All Oncology Cases must be review first by OncoHealth Team to provide an expert recommendation.

References:

1. Granix® subcutaneous injection [prescribing information]. North Wales, PA: Teva; April 2020.
2. Neupogen® subcutaneous or intravenous injection [prescribing information]. Thousand Oaks, CA: Amgen; April 2023.
3. Zarxio™ subcutaneous or intravenous injection [prescribing information]. Princeton, NJ: Sandoz; March 2021.
4. Nivestym™ subcutaneous or intravenous injection [prescribing information]. Lake Forest, IL and New York, NY: Hospira and Pfizer; March 2023.
5. Releuko® subcutaneous or intravenous injection [prescribing information]. Bridgewater, NJ: Amneal; June 2023.
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13. Mitsuyasu R. Prevention of bacterial infections in patients with advanced HIV infection. *AIDS*. 1999;13(Suppl 2):S19-S23.
14. Tesfa D, Keisu M, Palblad J. Idiosyncratic drug-induced agranulocytosis: Possible mechanism and management. *Am J Hematol*. 2009;84:428-434.
15. Andersohn F, Konzen C, Garbe E. Systematic review: Agranulocytosis induced by nonchemotherapy drugs. *Ann Intern Med*. 2007;146:657-665.
16. Beaushesne MF, Shalansky SJ. Nonchemotherapy drug-induced agranulocytosis: A review of 118 patients treated with colony-stimulating factors. *Pharmacother*. 1999;19(3):299-305.
17. Bhatt V, Saleem A. Review: Drug-induced neutropenia-pathophysiology, clinical features, and management. *Ann Clin Lab Sci*. 2004;34(2):131-136.
18. Curtis BR. Drug-induced immune neutropenia/agranulocytosis. *Immunohematology*. 2014;30(2):95-101.
19. Andres E, Mourot-Cottet R. Non-chemotherapy drug-induced neutropenia – an update. *Expert Opin Drug Saf*. 2017;16(11):1235-1242.
20. Andres E, Mourot-Cottet R, Maloisel F, et al. Idiosyncratic drug-induced neutropenia and agranulocytosis. *QJM*. 2017 May;110(5):299-305.
21. https://www.granixhcp.com/resources
22. https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/125294s0000lbl.pdf
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FULPHILA® (pegfilgrastim-jmdb), for injection

Product Affected

- *FULPHILA® (pegfilgrastim-jmbd), for injection*

PA Criteria	Criteria Details
Billing code	Q5108
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients with a history of serious allergic reactions to human granulocyte colony-stimulating factors such as filgrastim products or pegfilgrastim products. Limitation of use: • Not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **AND** Provide an absolute neutrophil count (ANC) and CBC results. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	None.
Prescriber Restrictions	Prescribed by or in consultation with a hematologist and/or oncologist.
Coverage Duration	According to chemoregimen protocol
Other Criteria	

Note:
All Oncology Cases must be review first by OncoHealth Team to provide an expert recommendation.

Reference:

Lexicomp
Fulphila [package insert]. Zurich, Switzerland: Mylan GmbH.; 2019.

FYARRO® (sirolimus protein-bound particles), for injection

Product Affected

- *FYARRO® (sirolimus protein-bound particles), for injection*

PA Criteria	Criteria Details
Billing code	J9331
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Severe hypersensitivity to sirolimus, other rapamycin derivatives, or albumin. Limitation of use: None.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **AND** Provide CBC results and monitor risk of myelosuppression, hypokalemia, and hyperglycemia. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement
Age Restrictions	Apply
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	

Reference: Fyarro [package insert]. Pacific Palisades, California: Aadi Bioscience, Inc,; 2021.

GAMMA GLOBULIN 1 CC INJ

Products Affected

- Asceniv™
- Bivigam™,
- Carimune NF
- Cutaquig
- Cuvitru™
- Flebogamma
- GamaSTAN S/D
- Gammagard liquid
- Gammagard S/D
- Gammaked
- Gammaplex
- Gamunex-C
- Hizentra®
- HyQvia
- Octagam
- Panzyga
- Privigen
- Xembify

PA Criteria	Criteria Details
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): History of anaphylactic or severe systemic reactions to human immune globulin IgA-deficient patients with antibodies against IgA and a history of hypersensitivity Boxed warning(s): thrombosis, renal dysfunction, and acute renal failure
Required Medical Information	Supporting documentation such as office chart notes, failure of previous treatments, lab results or other clinical information Doses: Refer to full prescribing information for specific dosage instructions. Dosage must be individualized and is highly variable depending on the nature and severity of the disease and on the individual patient response (e.g., serum IgG trough levels). There is no absolute maximum dosage of immune globulin or hyaluronidase. **Step Therapy Requirement** For IV administration (Asceniv, Bivigam, Gammagard Liq, Gammaplex and Panzyga): a. The patient is considered a new start to the non-preferred product (defined as no use in the previous 365 days) **AND**

PA Criteria	Criteria Details
	b. Must try/fail, have contraindication to, or intolerance to Flebogamma, Gammaked, Gamunex-C, Octagam and Privigen. For SC administration (Cutaquig, Cuvitru, HyQvia, Xembify) a. The patient is considered a new start to the non-preferred product (defined as no use in the previous 365 days) **AND** b. Must try/fail, have contraindication to, or intolerance to Hizentra
Age Restrictions	Refer to full prescribing information for specific age restrictions.
Prescriber Restrictions	**B-Cell Chronic Lymphocytic Leukemia Infection Prophylaxis** • Prescribed by or in consultation with a hematologist, oncologist, or immunologist **Inflammatory Demyelinating Polyneuropathy (Acute/Guillain-Barre Syndrome or Chronic) or Multifocal Motor Neuropathy** • Prescribed by or in consultation with a neurologist or neuromuscular specialist **Idiopathic Thrombocytopenic Purpura (Acute or Chronic)** • Prescribed by or in consultation with a hematologist; **Kawasaki Syndrome Aneurysm Prevention** • Prescribed by or in consultation with a cardiologist, allergist, immunologist, infectious disease specialist, or rheumatologist; **Primary Immunodeficiencies** • Prescribed by or in consultation with an immunologist;
Coverage Duration	1 (one) year
Other Criteria	

HEPAGAM® (hepatitis B immune globulin), for injection

Product Affected

- *HEPAGAM® (hepatitis B immune globulin), for injection*

PA Criteria	Criteria Details
Billing code	J1571
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • History of anaphylactic or severe systemic reactions to human globulins. • IgA deficient individuals may have the potential to develop IgA antibodies and have an anaphylactoid reaction. • IM injections may be contraindicated in patients with coagulation disorders. Limitation of use: None.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply.
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	6 months
Other Criteria	

Reference:
LexicompHepaGam [package insert]. Winnipeg, Canada: CangeneCorporation.; 2012.

Prior Authorization Criteria for Part B drugs
Effective Date: 01.01.2025
Utilization Management Committee Approval Date: 04.11.2024

HIZENTRA® (immune globulin), for injection

Product Affected

- *HIZENTRA® (immune globulin), for injection*

PA Criteria	Criteria Details
Billing code	J1559
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Anaphylactic or severe systemic reaction to human immune globulin or inactive ingredients of HIZENTRA, such as polysorbate 80. • Hyperprolinemia Type I or II (HIZENTRA contains stabilizer L-proline). • IgA-deficient patients with antibodies against IgA and a history of hypersensitivity. Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	6 months
Other Criteria	

Reference: Hizentra [package insert]. Kankakee, IL: CSL Behring LLC.; 2021 .

HUMAN-P® (antihemophilic factor/von willebrand factor complex (human)), for injection

Product Affected

- *HUMAN-P® (antihemophilic factor/von willebrand factor complex (human)), for injection*

PA Criteria	Criteria Details
Billing code	J7187
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients with a history of anaphylactic or severe systemic response to antihemophilic factor or von Willebrand factor preparations. • It is also contraindicated in individuals with a known hypersensitivity to any of its components. Limitation of use: • Not indicated for the prophylaxis of spontaneous bleeding episodes in VWD.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	None.
Prescriber Restrictions	Prescribed by or in consultation with an hematologist.

PA Criteria	Criteria Details
Coverage Duration	6 months
Other Criteria	

Reference: Human-P [package insert]. Marburg, Germany: CSL Behring.; 2020.

HYCAMTIN® (topotecan), for oral

Product Affected

- *HYCAMTIN® (topotecan), for oral*

PA Criteria	Criteria Details
Billing code	J8705
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • History of severe hypersensitivity reactions to topotecan. Limitation of use: None.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply.
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	6 months
Other Criteria	

Reference: Hycamtin [package insert]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation.; 2018.

iDose® TR *(travoprost), for intracameral use*

Product Affected

- iDose TR *(travoprost) IMP 75MCG for intracameral use*

PA Criteria	Criteria Details
Billing code	J7355
Covered Uses	*All FDA approved and medically accepted indications.* FDA Indications: • Open-angle glaucoma • Ocular hypertension
Exclusion Criteria	Contraindication(s): • In patients with ocular or periocular infections • In patients with hypersensitivity to this medication Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Diagnosis confirmation**
Age Restrictions	≥ 18 years old.
Prescriber Restrictions	Prescribed by or in consultation with an Ophthalmologist.
Coverage Duration	Approve for only one dose per eye.
Other Criteria	None

Reference:

iDose® TR. [package insert]. Glaukos Corp.; 2001
iDose® TR. In: *Lexi-Drugs*. UpToDate Inc; 2024. Updated April 15, 2024. Accessed May 20, 2024. http://online.lexi.com

ILUVIEN (fluocinolone acetonide) for injection, for intravitreal use

Product Affected

- ILUVIEN *(fluocinolone acetonide) for injection, for intravitreal use*

PA Criteria	Criteria Details
Billing code	J7313
Covered Uses	*All FDA approved and medically accepted indications.* FDA Indications: • Diabetic macular edema (DME) in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure.
Exclusion Criteria	Contraindication(s): • Ocular or periocular infections, glaucoma, hypersensitivity (continuous request) Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. Diagnosis of Diabetic Macular Edema (DME); **AND** The following criteria: • Must not be in combination with other sustained-release intravitreal corticosteroids • Does not have a torn or ruptured posterior lens capsule • Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment • Patient's intraocular pressure is measured at baseline and periodically during treatment **AND** DME

PA Criteria	Criteria Details
	• Patient has had an inadequate response or has a contraindication to treatment with bevacizumab intravitreal injection • Patient will not receive Iluvien concurrently, in the same eye with: o Yutiq, Macugen, Lucentis **AND** Confirm that the patient has been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure. **AND** Dosing: 0.19 mg lasting 36 months
Age Restrictions	Apply.
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist.
Coverage Duration	Approve one implant per affected eye every 36 months
Other Criteria	None

Reference:

Iluvien (fluocinolone) [prescribing information]. Alpharetta, GA: Alimera Sciences Inc; January 2022.

Infliximab - Products, for intravenous use

Products Affected

- *Avsola™ (infliximab-axxq intravenous infusion – Amgen)*
- *Inflectra™ (infliximab-dyyb intravenous infusion – Hospira/Pfizer)*
- *Remicade® (infliximab intravenous infusion – Janssen, authorized generic)*
- *Renflexis® (infliximab-abda intravenous infusion – Samsung Bioepis/Merck)*

PA Criteria	Criteria Details
Preferred Products	Avsola, Inflectra
Non-Preferred Products	Infliximab (authorized generic), Remicade, Renflexis
Billing Code	Q5121 - Avsola Q5103 - Inflectra J1745 - Infliximab (authorized generic) J1745 - Remicade Q5104 - Renflexis
Covered Uses	*All FDA approved and medically accepted indications.* **FDA Indications:** **1. Ankylosing Spondylitis.** Approve for the duration noted if the patient meets ONE of the following (A or B): **A)** Initial Therapy. Approve for 6 months if prescribed by or in consultation with a rheumatologist. **B)** Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii): **i.** Patient has been established on therapy for at least 6 months; AND Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy). **ii.** Patient meets at least one of the following (a or b): **a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); OR

PA Criteria	Criteria Details
	Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondyloarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate). **b)** Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.
	2. Crohn's Disease. Approve for the duration noted if the patient meets ONE of the following (A or B): **A)** Initial Therapy. Approve for 6 months if the patient meets the following (i, ii, and iii): **i.** Patient is ≥ 6 years of age; AND **ii.** Patient meets ONE of the following (a, b, c, or d): **a)** Patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated in this patient; OR Note: Examples of corticosteroids are prednisone and methylprednisolone. **b)** Patient has tried one other conventional systemic therapy for Crohn's disease; OR Note: Examples of conventional systemic therapies for Crohn's disease include azathioprine, 6-mercaptopurine, or methotrexate. An exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried at least one biologic other than the requested medication A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for Crohn's disease. A trial of mesalamine does not count as a systemic therapy for Crohn's disease.

PA Criteria	Criteria Details
	c) Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR **d)** Patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence); AND **iii.** The medication is prescribed by or in consultation with a gastroenterologist. **B)** Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii): **i.** Patient has been established on therapy for at least 6 months; AND Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy). **ii.** Patient meets at least one of the following (a or b): **a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); OR Note: Examples of objective measures include fecal markers (e.g., fecal lactoferrin, fecal calprotectin), serum markers (e.g., C-reactive protein), imaging studies (magnetic resonance enterography [MRE], computed tomography enterography [CTE]), endoscopic assessment, and/or reduced dose of corticosteroids. **b)** Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or blood in stool.
	3. Plaque Psoriasis. Approve for the duration noted if the patient meets ONE of the following (A or B): **A)** Initial Therapy. Approve for 3 months if the patient meets the following (i, ii, and iii): **i.** Patient is ≥ 18 years of age; AND **ii.** Patient meets ONE of the following (a or b): **a)** Patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; OR Note: Examples include methotrexate, cyclosporine, acitretin (Soriatane®, generics), or psoralen plus ultraviolet A light (PUVA). An exception to the

PA Criteria	Criteria Details
	requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient already had a 3-month trial or previous intolerance to at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for psoriasis. A patient who has already tried a biologic for psoriasis is not required to "step back" and try a traditional systemic agent for psoriasis. **b)** Patient has a contraindication to methotrexate, as determined by the prescriber; AND **iii.** The medication is prescribed by or in consultation with a dermatologist. **B)** Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii): **i.** Patient has been established on therapy for at least 90 days; AND Note: A patient who has received < 90 days of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy). **ii.** Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating an infliximab product) in at least one of the following: estimated body surface area affected, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND **iii.** Compared with baseline (prior to receiving an infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.
	4. Psoriatic Arthritis. Approve for the duration noted if the patient meets ONE of the following (A or B): **A)** Initial Therapy. Approve for 6 months if prescribed by or in consultation with a rheumatologist or a dermatologist. **B)** Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii): **i.** Patient has been established on therapy for at least 6 months; AND Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy).

PA Criteria	Criteria Details
	ii. Patient meets at least one of the following (a or b): **a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); OR Note: Examples of objective measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate). **b)** Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; or decreased soft tissue swelling in joints or tendon sheaths.
	5. Rheumatoid Arthritis. Approve for the duration noted if the patient meets ONE of the following (A or B): **A)** Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii): **i.** Patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months; AND Note: Examples include methotrexate (oral or injectable), leflunomide, hydroxychloroquine, and sulfasalazine. An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient already had a 3-month trial of at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for rheumatoid arthritis. A patient who has already tried a biologic is not required to "step back" and try a conventional synthetic DMARD. **ii.** The medication is prescribed by or in consultation with a rheumatologist.

PA Criteria	Criteria Details
	B) Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii): **i.** Patient has been established on therapy for at least 6 months; AND Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy). **ii.** Patient meets at least one of the following (a or b): **a)** Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR Note: Examples of objective measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate or C-reactive protein, Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI). **b)** Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; or decreased soft tissue swelling in joints or tendon sheaths.
	6. Ulcerative Colitis. Approve for the duration noted if the patient meets ONE of the following (A or B): **A)** Initial Therapy. Approve for 6 months if the patient meets the following (i, ii, and iii): **i.** Patient is ≥ 6 years of age; AND **ii.** Patient meets ONE of the following (a or b): **a)** Patient had a trial of one systemic agent or was intolerant to one of these agents for ulcerative colitis; OR Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone. A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis. A previous trial of one biologic other than the requested medication also counts as a trial of one systemic agent for ulcerative colitis. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for ulcerative colitis.

PA Criteria	Criteria Details
	b) Patient meets BOTH of the following [(1) and (2)]: **(1)** Patient has pouchitis; AND **(2)** Patient has tried therapy with an antibiotic, probiotic, corticosteroid enema, or Rowasa® (mesalamine enema); AND Note: Examples of antibiotics include metronidazole and ciprofloxacin. Examples of corticosteroid enemas include hydrocortisone enema (Cortenema, generics). **iii.** The medication is prescribed by or in consultation with a gastroenterologist. **B)** Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii): **i.** Patient has been established on therapy for at least 6 months; AND Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy). **ii.** Patient meets at least one of the following (a or b): **a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); OR Note: Examples of objective measures include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids. **b)** Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or rectal bleeding. **Other Uses with Supportive Evidence:** **7. Behcet's Disease.** Approve for the duration noted if the patient meets ONE of the following (A or B): **A)** Initial Therapy. Approve for 3 months if the patient meets BOTH of the following (i and ii): **i.** Patient meets ONE of the following (a or b): **a)** Patient has tried at least ONE conventional therapy; OR

PA Criteria	Criteria Details
	Note: Examples include systemic corticosteroids (e.g., methylprednisolone), immunosuppressants (azathioprine, methotrexate, mycophenolate mofetil, cyclosporine, tacrolimus, Leukeran® [chlorambucil tablet], cyclophosphamide, interferon alfa). An exception to the requirement for a trial of one conventional therapy can be made if the patient has already had a trial of at least one tumor necrosis factor inhibitor (e.g., an adalimumab product, an etanercept product). A patient who has already tried one biologic other than the requested drug for Behcet's disease is not required to "step back" and try a conventional therapy. A biosimilar of the requested biologic does not count. **b)** Patient has ophthalmic manifestations of Behcet's disease; AND **ii.** The medication is prescribed by or in consultation with a rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist. **A)** Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii): **i.** Patient has been established on therapy for at least 90 days; AND Note: A patient who has received < 90 days of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy). **ii.** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); AND Note: Examples of objective measures are dependent upon organ involvement but may include best-corrected visual acuity (if ophthalmic manifestations); serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate); or ulcer depth, number, and/or lesion size. **iii.** Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain or improved visual acuity (if ophthalmic manifestations).
	8. Graft-Versus-Host Disease. Approve for the duration noted if the patient meets ONE of the following (A or B):

PA Criteria	Criteria Details
	A) Initial Therapy. Approve for 1 month if the patient meets BOTH of the following (i and ii): **i.** Patient has tried at least one conventional systemic treatment for graft-versus-host disease; AND Note: Examples of conventional treatments include corticosteroids (e.g., methylprednisolone), antithymocyte globulin, cyclosporine, tacrolimus, and mycophenolate mofetil. **ii.** The medication is prescribed by or in consultation with an oncologist, hematologist, or a physician affiliated with a transplant center; OR **B)** Patient is Currently Receiving an Infliximab Product. Approve for 3 months if the patient meets BOTH of the following (i and ii): **i.** Patient has been established on an infliximab product for at least 1 month; AND Note: A patient who has received < 1 month of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy). **ii.** Patient meets at least one of the following (a or b): **a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); OR Note: An example of objective measures is normalization of liver function tests, red blood cell count, or platelet count, or resolution of fever or rash. **b)** Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as improvement in skin, oral mucosal, ocular, or gastrointestinal symptoms (e.g., nausea, vomiting, anorexia).
	9. Hidradenitis Suppurativa. Approve for the duration noted if the patient meets ONE of the following (A or B): **A)** Initial Therapy. Approve for 3 months if the patient meets BOTH of the following (i and ii): **i.** Patient has tried one other therapy; AND Note: Examples include intralesional or oral corticosteroids (e.g., triamcinolone, prednisone), systemic antibiotics (e.g., clindamycin, dicloxacillin, erythromycin), and isotretinoin.

PA Criteria	Criteria Details
	ii. The medication is prescribed by or in consultation with a dermatologist. **B)** Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii): **i.** Patient has been established on therapy for at least 90 days; AND Note: A patient who has received < 90 days of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy). **ii.** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); AND Note: Examples of objective measures include Hurley staging, Sartorius score, Physician Global Assessment, and Hidradenitis Suppurativa Severity Index. **iii.** Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain or drainage of lesions, nodules, or cysts.
	10. Immunotherapy-Related Toxicities Associated with Checkpoint Inhibitor Therapy. Approve for the duration noted if the patient meets ONE of the following (A or B): **A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, and iv): **i.** Patient developed an immunotherapy-related toxicity other than hepatitis; AND Note: For example, gastrointestinal system toxicity (e.g., colitis), ocular toxicity (e.g., uveitis/iritis, episcleritis, and blepharitis). myocarditis, pericarditis, inflammatory arthritis, acute kidney injury (e.g., azotemia, creatinine elevation, inability to maintain acid/base or electrolyte balance, urine output change), pneumonitis, myalgia, or myositis. **ii.** Patient developed this immune-related toxicity while receiving a checkpoint inhibitor; AND Note: Examples of checkpoint inhibitors include Keytruda (pembrolizumab intravenous [IV] infusion), Opdivo (nivolumab IV infusion), Yervoy (ipilimumab IV infusion), Tecentriq (atezolizumab IV infusion), Bavencio (avelumab IV infusion), or Imfinzi (durvalumab IV infusion). **iii.** Patient has tried one systemic corticosteroid; AND

PA Criteria	Criteria Details
	Note: Examples include methylprednisone and prednisone. **iv.** The medication is prescribed by or in consultation with an oncologist, gastroenterologist, rheumatologist, or ophthalmologist; OR **B)** Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii): **i.** Patient has been established on therapy for at least 6 months; AND Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy). **ii.** Patient meets at least ONE of the following (a or b): **a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); OR Note: Examples of objective measures are dependent upon organ involvement but may include clinically significant improvement or normalization of serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), fecal markers (e.g., fecal calprotectin), and/or reduced dosage of corticosteroids. **b)** Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as less joint pain/tenderness, stiffness or swelling (if joint symptoms), stool frequency and/or rectal bleeding (if gastrointestinal symptoms), and/or improved function or activities of daily living. **Indeterminate Colitis**. Approve for the duration noted if the patient meets ONE of the following (A or B): Note: Indeterminate colitis is defined as colitis that cannot be classified with certainty as either ulcerative colitis or Crohn's disease. **A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, and v): **i.** Patient is ≥ 6 years of age; AND **ii.** Patient has tried one systemic corticosteroid; AND Note: Examples include prednisone and methylprednisolone.

PA Criteria	Criteria Details
	iii. Patient has tried mesalamine; AND **iv.** Patient has tried either azathioprine or 6-mercaptopurine; AND **v.** The medication is prescribed by or in consultation with a gastroenterologist. **B)** Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii): **ii.** Patient has been established on therapy for at least 6 months; AND Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy). **iii.** Patient meets at least one of the following (a or b): **a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); OR Note: Examples of objective measures include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids. **b)** Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or rectal bleeding.
	11. Juvenile Idiopathic Arthritis (JIA). Approve for the duration noted if the patient meets ONE of the following (A or B): Note: This includes JIA regardless of type of onset, including a patient with juvenile spondyloarthropathy/active sacroiliac arthritis. JIA is also referred to as Juvenile Rheumatoid Arthritis. **A)** Initial Therapy. Approve for 6 months if the patient meets the following (i and ii): **i.** Patient meets ONE of the following (a or b): **a)** Patient has tried one other systemic medication for this condition; OR Note: Examples of other medications for JIA include methotrexate, sulfasalazine, or leflunomide, a nonsteroidal anti-inflammatory drug (NSAID) [e.g., ibuprofen, naproxen]. A previous trial of one biologic other than the requested medication also

PA Criteria	Criteria Details
	counts as a trial of one medication. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for JIA. **b)** Patient has aggressive disease, as determined by the prescriber; AND **ii.** The medication is prescribed by or in consultation with a rheumatologist. **B)** Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii): **i.** Patient has been established on therapy for at least 6 months; AND Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy). **ii.** Patient meets at least one of the following (a or b): **a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); OR Note: Examples of objective measures include Physician Global Assessment (MD global), Parent/Patient Global Assessment of Overall Well-Being (PGA), Parent/Patient Global Assessment of Disease Activity (PDA), Juvenile Arthritis Disease Activity Score (JDAS), Clinical Juvenile Arthritis Disease Activity Score (cJDAS), Juvenile Spondyloarthritis Disease Activity Index (JSpADA), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids. **b)** Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, or improved function or activities of daily living.
	12. Pyoderma Gangrenosum. Approve for the duration noted if the patient meets ONE of the following (A or B): **A)** Initial Therapy. Approve for 4 months if the patient meets BOTH of the following (i and ii): **i.** Patient meets ONE of the following conditions (a or b):

PA Criteria	Criteria Details
	a) Patient has tried one systemic corticosteroid; OR Note: Examples include prednisone and methylprednisolone. **b)** Patient has tried one other immunosuppressant for at least 2 months or was intolerant to one of these medications; AND Note: Examples include mycophenolate mofetil and cyclosporine. **ii.** The medication is prescribed by or in consultation with a dermatologist; OR **B)** Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii): **i.** Patient has been established on therapy for at least 4 months; AND Note: A patient who has received < 4 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy). **ii.** Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating an infliximab product) in at least one of the following: size, depth, and/or number of lesions; AND **iii.** Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain and/or tenderness of affected lesions.
	13. Sarcoidosis. Approve for the duration noted if the patient meets ONE of the following (A or B): **A)** Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, and iii): **i.** Patient has tried at least one corticosteroid; AND Note: Examples include prednisone and methylprednisolone. **ii.** Patient has tried at least one immunosuppressive medication; AND Note: Examples include methotrexate, azathioprine, leflunomide, mycophenolate mofetil, hydroxychloroquine, or chloroquine. **iii.** The medication is prescribed by or in consultation with a pulmonologist, ophthalmologist, cardiologist, neurologist, or dermatologist; OR

PA Criteria	Criteria Details
	B) Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii): **i.** Patient has been established on therapy for at least 90 days; AND Note: A patient who has received < 90 days of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy). **ii.** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); AND Note: Examples of objective measures are dependent upon organ involvement but may include lung function (e.g., predicted forced vital capacity and/or 6-minute walk distance); serum markers (e.g., C-reactive protein, liver enzymes, N-terminal pro-brain natriuretic peptide [NT-proBNP]); improvement in rash or skin manifestations, neurologic symptoms, or rhythm control; or imaging (e.g., if indicated, chest radiograph, magnetic resonance imaging [MRI], or echocardiography). **iii.** Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased cough, fatigue, pain, palpitations, neurologic symptoms, and/or shortness of breath.
	14. Scleritis or Sterile Corneal Ulceration. Approve for the duration noted if the patient meets ONE of the following (A or B): **A)** Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii): **i.** Patient has tried one other therapy for this condition; AND Note: Examples include oral non-steroidal anti-inflammatory drugs (NSAIDs) such as indomethacin; oral, topical (ophthalmic) or intravenous corticosteroids (such as prednisone, prednisolone, methylprednisolone); methotrexate; cyclosporine; or other immunosuppressants. **ii.** The medication is prescribed by or in consultation with an ophthalmologist; OR

PA Criteria	Criteria Details
	B) Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii): **i.** Patient has been established on therapy for at least 6 months; AND Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy). **ii.** Patient meets at least one of the following (a or b): **a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); OR Note: Examples of objective measures are serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate). **b)** Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased eye pain, redness, light sensitivity, tearing, and/or improvement in visual acuity.
	15. Spondyloarthritis, Other Subtypes Approve for the duration noted if the patient meets ONE of the following (A or B): Note: Examples of other subtypes include undifferentiated arthritis, non-radiographic axial spondylitis, Reactive Arthritis [Reiter's disease]. For ankylosing spondylitis or psoriatic arthritis, refer to the respective criteria under FDA-approved indications. **A)** Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii): **i.** Patient meets ONE of the following (a or b): **a)** Patient has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet AND has tried at least ONE conventional synthetic disease-modifying antirheumatic drug (DMARD); OR Note: Examples include methotrexate, leflunomide, and sulfasalazine. **b)** Patient has axial spondyloarthritis with objective signs of inflammation, defined as at least one of the following [(1) or (2)]: **(1)** C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory; OR

PA Criteria	Criteria Details
	(2) Sacroiliitis reported on magnetic resonance imaging; AND **ii.** The medication is prescribed by or in consultation with a rheumatologist; OR **B)** Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii): **i.** Patient has been established on therapy for at least 6 months; AND Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy). **ii.** Patient meets at least one of the following (a or b): **a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); OR Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS) and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate). **b)** Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.
	16. Still's Disease. Approve for the duration noted if the patient meets ONE of the following (A or B): **A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, and iii): **i.** Patient has tried one corticosteroid; AND Note: Examples include prednisone and methylprednisolone. **ii.** Patient has tried one conventional synthetic disease-modifying antirheumatic drug (DMARD) given for at least 2 months or was intolerant; AND Note: An example is methotrexate. A previous trial of one biologic other than the requested drug (e.g., Actemra [tocilizumab intravenous injection, tocilizumab subcutaneous injection], Arcalyst [rilonacept subcutaneous injection], Ilaris [canakinumab subcutaneous injection]) also counts towards this

PA Criteria	Criteria Details
	requirement for previous therapy for Still's disease. A biosimilar of the requested biologic does not count. **iii.** The medication is prescribed by or in consultation with a rheumatologist. **B)** Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii): **i.** Patient has been established on an this medication for at least 6 months; AND Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy). **ii.** Patient meets at least one of the following (a or b): **a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); OR Note: Examples of objective measures include resolution of fever, improvement in rash or skin manifestations, clinically significant improvement or normalization of serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids. **b)** Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as less joint pain/tenderness, stiffness, or swelling; decreased fatigue; improved function or activities of daily living. **Uveitis.** Approve for the duration noted if the patient meets ONE of the following (A or B): Note: This includes other posterior uveitides and panuveitis syndromes. **A)** Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii): **i.** Patient has tried one of the following therapies: periocular, intraocular, or systemic corticosteroids, or immunosuppressives; AND Note: Examples of corticosteroids include prednisolone, triamcinolone, betamethasone, methylprednisolone, prednisone. Examples of immunosuppressives include methotrexate, mycophenolate mofetil, and cyclosporine. An exception to the requirement for a trial of one of these

PA Criteria	Criteria Details
	therapies can be made if the patient has already had a trial of an etanercept product or an adalimumab product for uveitis. A patient who has already tried one biologic other than the requested medication also counts. A biosimilar of the requested biologic does not count. **ii.** The medication is prescribed by or in consultation with an ophthalmologist. **B)** Patient is Currently Receiving an Infliximab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii): **i.** Patient has been established on therapy for at least 6 months; AND Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy). **ii.** Patient meets at least one of the following (a or b): **a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an infliximab product); OR Note: Examples of objective measures include best-corrected visual acuity, assessment of chorioretinal and/or inflammatory retinal vascular lesions, or anterior chamber cell grade or vitreous haze grade. **b)** Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased eye pain, redness, light sensitivity, and/or blurred vision; or improvement in visual acuity.
Exclusion Criteria	Contraindication(s): Concurrent use with a Biologic or with a Targeted Synthetic Disease Modifying Antirheumatic Drug (DMARD)
Required Medical Information	Provider must submit supporting documentation such as progress notes (including weight and height), laboratory results, previous treatments and other relevant clinical information **Step Therapy Requirement (Only for New Patients):** none **Medical Information Requirements:** none
Age Restrictions	Crohn's Disease, Ulcerative Colitis, Intermediate Colitis: Patient is ≥ 6 years of age Plaque Psoriasis: Patient is ≥ 18 years of age

<table>
<tr><th>PA Criteria</th><th>Criteria Details</th></tr>
<tr><td>Prescriber Restrictions</td><td>Prescribed by or consult with a rheumatologist or dermatologist.</td></tr>
<tr><td>Coverage Duration</td><td>New:
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<tr><td>Approve for 1 month</td><td>Graft Versus Host Disease</td></tr>
<tr><td>Approve for 3 months</td><td>Plaque Psoriasis
Behcet’s Disease
Hidradenitis Suppurativa
Sarcoidosis</td></tr>
<tr><td>Approve for 4 months</td><td>Pyoderma Gangrenosum</td></tr>
<tr><td>Approve for 6 months</td><td>Other diagnoses</td></tr>
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Continuation:
<table>
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<tr><td>Approve for 3 months</td><td>Graft versus Host Disease</td></tr>
<tr><td>Approve for 1 year</td><td>Other Diagnoses</td></tr>
</table></td></tr>
<tr><td>Other Criteria</td><td>Continuation Criteria:</td></tr>
<tr><td>Exception Criteria for Step Therapy</td><td>For infliximab (authorized generic), Remicade, Renflexis approve if the patient meets both of the following (A and B):
A) Patient meets the standard Inflammatory Conditions – Infliximab Products Utilization Management Prior Authorization criteria; AND
B) Patient meets ONE of the following conditions (i or ii):
i. Patient meets both of the following (a and b):
a) Patient has tried one of Inflectra or Avsola; AND
b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR
ii. Patient is currently receiving requested agent for a condition other than plaque psoriasis.</td></tr>
</table>

PA Criteria	Criteria Details
	Note: For a patient currently taking for plaque psoriasis, refer to criterion 1Bi. However, if the patient is currently taking for concomitant plaque psoriasis and psoriatic arthritis, 1Bii applies.

References:

1. Remicade injection [prescribing information]. Horsham, PA: Janssen; June 2018.
2. Inflectra injection [prescribing information]. Lake Forest, IL: Hospira/Pfizer; April 2016.
3. Renflexis injection [prescribing information]. Whitehouse Station, NJ: Samsung Bioepis/Merck; April 2017.
4. Avsola injection [prescribing information]. Thousand Oaks, CA: Amgen; December 2019.
5. Infliximab intravenous infusion [prescribing information]. Horsham, PA: Janssen; October 2021.
6. Inflectra injection [prescribing information]. Lake Forest, IL: Hospira/Pfizer; June 2021.
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INVANZ (ertapenem) for injection, for intravenous or intramuscular use

Products Affected

- INVANZ (ertapenem) for injection, for intravenous or intramuscular use

PA Criteria	Criteria Details
Billing code	J1335
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Known hypersensitivity to product components or anaphylactic reactions to B-lactams; • INVANZ IM in patients with a known hypersensitivity to local anesthetics of the amide type (Lidocaine HCL).

Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments and other relevant clinical information
	Diagnosis or prophylaxis of susceptible bacteria; **AND**
	The following criteria:
	• Laboratory tests, periodic assessment of organ system function, including:
	  o Renal
	  o Hepatic
	  o Hematopoietic
	• Laboratory test that confirms bacteria or infection
	Continuation request:
	• Patient have an improvement or resolution of signs and symptoms of infection
	AND
	Dosing:
	• Age ≥ 13 years: 1g/day IV or IM
	• Age ≥ 3 months-12 years: 15 mg/kg twice daily (not to exceed 1g/day IV or IM
	• IV infusions may be administered in pediatrics and adults up to 14 days. IM injections may be administered for up to 7 days

PA Criteria	Criteria Details
	• Prophylaxis regimen in adults: 1 gram sin dose given 1 hour prior to elective colorectal surgery
Age Restrictions	Apply
Prescriber Restrictions	
Coverage Duration	3 to 14 days depending on type of infection
Other Criteria	None

Reference:

Product Information: INVANZ(R) intravenous injection, intramuscular injection, ertapenem intravenous injection, intramuscular injection. Merck Sharp & Dohme Corp (per FDA), Whitehouse Station, NJ, 2020.

Iron Replacement Products, for injection

Products Affected

- *Feraheme® (ferumoxytol intravenous infusion – AMAG)*
- *Ferrlecit® (sodium ferric gluconate complex in sucrose intravenous infusion or injection – sanofi-aventis, generic)*
- *INFeD® (iron dextran intramuscular or intravenous injection – Allergan)*
- *Injectafer® (ferric carboxymaltose intravenous infusion or injection – American Regent)*
- *Monoferric (ferric derisomaltose intravenous infusion – Pharmacosmos)*
- *Venofer® (iron sucrose intravenous infusion or injection – American Regent)*

PA Criteria	Criteria Details
Preferred Products	Ferrlecit, INFeD, Venofer
Non-Preferred Products	Feraheme, Injectafer, Monoferric
Billing Code	J2916 - Ferrlecit J1750 - INFeD J1756 - Venofer Q0138 - Feraheme J1439 - Inyector J1437 - Monoférrico
Covered Uses	*All FDA approved and medically accepted indications.* **Ferlecit, INFeD, Venofer:** FDA-Approved Indication. **1. Iron Deficiency Anemia in Patients with Chronic Kidney Disease who are on Dialysis**. **2. Iron Deficiency Anemia in Patients with Chronic Kidney Disease who are NOT on Dialysis**. **3. Iron Deficiency Anemia, Other.** Patient meets one of the following (i, ii, iii, or iv): **i.** Patient meets both of the following (a and b): **a)** Patient has tried oral iron supplementation; AND **b)** According to the prescriber, oral iron supplementation was ineffective or intolerable, OR

PA Criteria	Criteria Details
	ii. Patient has a condition which, per the prescriber, will interfere with oral iron absorption (e.g., inflammatory bowel disease, Crohn's disease); OR **iii.** Patient is currently receiving an erythroid stimulating agent, OR Note: Examples of erythroid stimulating agents include an epoetin alfa product, a darbepoetin alfa product, or a methoxy polyethylene glycol-epoetin beta product. **iv.** The medication is being requested for cancer- or chemotherapy-related anemia. _____ **Ferlecit, INFeD:** FDA-Approved Indication. _____ **4. Iron Deficiency Associated with Heart Failure.**
Exclusion Criteria	Contraindication(s): Known anaphylaxis to the specific iron product. Iron overload conditions (e.g., hemochromatosis, hemosiderosis, thalassemia major). High-risk patients with serious comorbidities (e.g., moderate to severe failure of the heart, liver, or respiratory organ).
Required Medical Information	**Medical Information Requirements:** Diagnosis Confirmation (Laboratories) **AND** Assess baseline hematologic (hemoglobin and hematocrit) and iron storage parameters (serum iron, total iron binding capacity, and percent saturation of transferrin) to monitor response to therapy. Provider must submit supporting documentation such as progress notes (including weight and height), laboratory results, previous treatments and other relevant clinical information. **Step Therapy Requirement (Only for New Patients)**
Age Restrictions	Patient is ≥ 18 years of age For Ferrlecit: Patient is ≥ 6 years of age
Prescriber Restrictions	To be prescribed by or in consultation with a physician who specializes in the condition being treated. Nephrologist, cardiologist or hematologist.

PA Criteria	Criteria Details
Coverage Duration	**Ferrlecit, Infed:** Approve for 1 year **Venofer:** Approve for 3 years.
Other Criteria	**Continuation Criteria:** Extended approvals are allowed if the patient continues to meet the Criteria and Dosing.
Exception Criteria for Step Therapy	**Feraheme, Injectafer, Monoferric:** 1. **Iron Deficiency Anemia in a Patient with Chronic Kidney Disease who is on Dialysis.** Approve. 2. **Other Conditions**. Patient meets one of the following (A or B): **A)** Patient meets both of the following (i and ii): **i.** Patient meets the standard *Iron Replacement – Feraheme Injectafer or Monoferric -Utilization Management Medical Policy* criteria; AND **ii.** Patient has tried one of Ferrlecit, INFeD, or Venofer; OR **B)** Patient has initiated therapy with Feraheme, Injectafer, or Monoferric and requires further medication to complete the current course of therapy.

References:

Injectafer® intravenous infusion or injection [prescribing information]. Shirley, NY: American Regent; February 2022.

1. Venofer® intravenous infusion or injection [prescribing information]. Shirley, NY: American Regent; July 2022.
2. Feraheme® intravenous infusion [prescribing information]. Waltham, MA: AMAG Pharmaceuticals; June 2022.
3. Ferrlecit® intravenous infusion or injection [prescribing information]. Bridgewater, NJ: sanofi-aventis; March 2022.
4. INFeD® intramuscular or intravenous injection [prescribing information]. Irvine, CA: Allergan; September 2021.
5. Monoferric® intravenous infusion [prescribing information]. Morristown, NJ: Pharmacosmos Therapeutics; August 2022.
6. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Kidney Int. 2012;2(Suppl):279-335.

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IZERVAY (avacincaptad pegol) for injection, for intravitreal use

Products Affected

- IZERVAY (avacincaptad pegol) for injection, for intravitreal use

PA Criteria	Criteria Details
Billing code	J3490
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Ocular or periocular infections • Active intraocular inflammation
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information Diagnosis of Geographic atrophy secondary to age-related macular degeneration; **AND** The following criteria: • Diagnosis has been verified by geographic atrophy of the macula secondary to age-related macular degeneration sensitive tests (optical coherence tomography, fluorescein angiography, fundus photography) **AND** Dosing: • 2 mg (0.1 mL) in each affected aye once monthly (every 21 to 35 days) for up to 12 months
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist (retina specialist)
Coverage Duration	12 months
Other Criteria	Use is limited to 12 months

Reference: Product Information: IZERVAY(TM) intravitreal injection, avacincaptad pegol intravitreal injection. IVERIC bio, Inc (per Manufacturer), Parsippany, NJ, 2023

Prior Authorization Criteria for Part B drugs
Effective Date: 01.01.2025
Utilization Management Committee Approval Date: 04.11.2024

JIVI (factor VIIa recombinant - PEGylated-aucl), for injection

Product Affected

- *JIVI (factor VIIa recombinant - PEGylated-aucl), for injection*

PA Criteria	Criteria Details
Billing code	J7208
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients who have manifested severe hypersensitivity reactions. Limitation of use: • Not indicated for use in children < 12 years of age due to a greater risk for hypersensitivity reactions. • Not indicated for use in previously untreated patients (PUPs). • Not indicated for the treatment of von Willebrand disease.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply.
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	6 months
Other Criteria	

Reference: Jivi [package insert]. Whippany, New Jersey: Bayer HealthCare LLC.; 2021.

KENALOG (triamcinolone acetonide) for injection, for intramuscular or intraarticular use

Products Affected

- KENALOG (triamcinolone acetonide) for injection, for intramuscular or intraarticular use

PA Criteria	Criteria Details
Billing code	J3301
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Concomitant administration of live or live, attenuated vaccines; • Hypersensitivity to triamcinolone acetonide or any other component of the product; • IM injection for idiopathic thrombocytopenic purpura; • Primary treatment for status asthmaticus or acute asthma; • Suprachoroidal injection for active or suspected ocular or periocular infections including most viral diseases of the cornea and conjunctiva, including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal diseases.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments and other relevant clinical information Diagnosis; **AND** The following criteria: • History of previous medication use for patient's diagnosis. • Clinical documentation supporting medication use.
Age Restrictions	Apply
Prescriber Restrictions	None
Coverage Duration	1 year

PA Criteria	Criteria Details
Other Criteria	None

Reference:

Product Information: KENALOG(R)-40 intramuscular, intra-articular injection, triamcinolone acetonide intramuscular, intra-articular injection. Bristol-Myers Squibb Company (per FDA), Princeton, NJ, 2018.

KHAPZORY® (leucovorin), for injection

Product Affected

- *KHAPZORY® (leucovorin), for injection*

PA Criteria	Criteria Details
Billing code	J0642
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients who had severe hypersensitivity reactions to leucovorin products, folic acid, or folinic acid. Limitation of use: • For the treatment of pernicious anemia and megaloblastic anemia secondary to lack of vitamin B12 because of the risk of progression of neurologic manifestations despite hematologic remission.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply.
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist.
Coverage Duration	6 months
Other Criteria	

Reference: Khapzory [package insert]. Irvine, CA: Spectrum Pharmaceuticals, Inc.; 2022.

KISUNLA (donanemab-azbt), for injection, for intravenous use

Products Affected

- *KISUNLA (donanemab-azbt) for injection, for intravenous use*

PA Criteria	Criteria Details
Billing Code	J0175
Covered Uses	*All FDA approved and medically accepted indications.* **FDA Indications:** Alzheimer's disease in patients with mild cognitive impairment or mild dementia stage of disease.
Exclusion Criteria	Contraindication(s): KISUNLA is contraindicated in patients with known serious hypersensitivity to donanemab-azbt or to any of the excipients. Reactions have included anaphylaxis. Black Box Warning • Warning: Amyloid Related Imaging Abnormalities • Monoclonal antibodies directed against aggregated forms of beta amyloid, including donanemab-azbt, can cause amyloid related imaging abnormalities (ARIA), characterized as ARIA with edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H). Incidence and timing of ARIA vary among treatments. ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events rarely can occur. Serious intracerebral hemorrhages greater than 1 cm, some of which have been fatal, have been observed in patients treated with this class of medications. Because ARIA-E can cause focal neurologic deficits that can mimic an ischemic stroke, treating clinicians should consider whether such symptoms could be due to ARIA-E before giving thrombolytic therapy in a patient being treated with donanemab-azbt. • ApoE e4 Homozygotes: Patients who are apolipoprotein E e4 (ApoE e4) homozygotes (approximately 15% of Alzheimer's disease patients) treated with this class of medications, including donanemab-azbt, have a higher incidence of ARIA, including symptomatic, serious, and severe radiographic ARIA, compared to heterozygotes and

PA Criteria	Criteria Details
	noncarriers. Testing for ApoE e4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. Prior to testing, prescribers should discuss with patients the risk ARIA across genotypes and the implications of genetic testing results. Prescribers should inform patients that if genotype testing is not performed they can still be treated with donanemab-azbt; however, it cannot be determined if they are ApoE e4 homozygotes and at higher risk for ARIA. • Consider the benefit of donanemab-azbt for the treatment of Alzheimer's disease and potential risk of serious adverse events associated with ARIA when deciding to initiate treatment with donanemab-azbt
Required Medical Information	Confirm the presence of amyloid beta pathology prior to initiating treatment. The provider must obtain a recent baseline brain magnetic resonance imaging (MRI) prior to initiating treatment with KISUNLA. Obtain an MRI prior to the 2nd, 3rd, 4th, and 7th infusions. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including an MRI if indicated. Discontinuation, may consider stopping dosing based on reduction of amyloid plaques to minimal levels on amyloid PET imaging
Age Restrictions	≥ 18 years of age
Prescriber Restrictions	This medication must be prescribed by or in consultation with a geriatrician, neurologist, psychiatrist, or neuropsychiatrist.
Coverage Duration	12 months
Other Criteria	

References:

1. U.S. Food and Drug Administration. (2024). *Prescribing information: [KISUNLA donanemab-azbt]*. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761248s000lbl.pdf
2. Eli Lilly and Company. (n.d.). *Billing and coding guide*. https://kisunla.lilly.com/assets/pdf/billingandcodingguide.pdf

KOATE (antihemophilic factor VIII (human)), for injection

Product Affected

- *KOATE (antihemophilic factor VIII (human)), for injection*

PA Criteria	Criteria Details
Billing code	J7191
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients who have known hypersensitivity reactions, including anaphylaxis, to KOĀTE or its components. Limitation of use: • Not indicated for the treatment of von Willebrand disease.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	None.
Prescriber Restrictions	Prescribed by or in consultation with an hematologist.
Coverage Duration	6 months
Other Criteria	

Reference: Koate [package insert]. Research Triangle Park, NC: Grifols Therapeutics LLC.; 2018.

KOGENATE FS (antihemophilic factor VIII (recombinant)), for injection

Product Affected

- *KOGENATE (antihemophilic factor VIII (recombinant)), for injection*

PA Criteria	Criteria Details
Billing code	J7192
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients who have life-threatening hypersensitivity reactions, including anaphylaxis to mouse or hamster protein or other constituents of the product. Limitation of use: • Not indicated for the treatment of von Willebrand disease.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	None.
Prescriber Restrictions	Prescribed by or in consultation with an hematologist.
Coverage Duration	6 months
Other Criteria	

Reference: Kogenate FS [package insert]. Tarrytown, NY: Bayer HealthCare LLC.; 2014.

Krystexxa (pegloticase) for injection, for intravenous use

Products Affected

- Krystexxa (pegloticase) for injection, for intravenous use

PA Criteria	Criteria Details
Billing code	J2507
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Glucose-6-phospahte dehydrogenase (G6PD) deficiency, • History of serious hypersensitivity reactions to Krystexxa or any of its components
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments and other relevant clinical information Diagnosis of chronic gout refractory to conventional therapy **AND** The following criteria: Initial request: o Absence of contraindications o Serum uric acid levels o Concomitant therapy Continuation request o Absence of contraindications o Serum uric acid levels o Concomitant therapy o Patient experienced a positive clinical response to therapy **AND** Dosing: 8 mg every two weeks with or without weekly methotrexate 15 mg PO
Age Restrictions	Apply
Prescriber Restrictions	

PA Criteria	Criteria Details
Coverage Duration	Initial approval: 6 months Subsequent approval: 12 months
Other Criteria	

Reference: Product Information: KRYSTEXXA(R) intravenous injection, pegloticase intravenous injection. Horizon Therapeutics USA Inc (per manufacturer), Deerfield, IL, 2022.

LAMZEDE (Velmanase alfa-tycv), for injection, for intravenous use

Products Affected

- LAMZEDE (Velmanase alfa-tycv) for injection, for intravenous use

PA Criteria	Criteria Details
Billing Code	J0217
Covered Uses	*All FDA approved and medically accepted indications.* **FDA Indications:** For the treatment of non-central nervous system manifestations of alpha-mannosidosis in adult and pediatric patients.
Exclusion Criteria	Contraindication(s): Black Box Warning: Hypersensitivity Reactions Including Anaphylaxis
Required Medical Information	• Provider must verify that the patient is not pregnant. • The diagnosis of alpha-mannosidosis is established in a proband by identification of deficiency of lysosomal enzyme acid alpha-mannosidase (typically 5%-10% of normal activity) in leukocytes or other nucleated cells AND/OR by the identification of biallelic pathogenic variants in *MAN2B1* by molecular genetic testing.
Age Restrictions	No age restriction
Prescriber Restrictions	The medication is prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders.
Coverage Duration	12 months
Other Criteria	

References:

1) Ficicioglu C, Stepien KM. Alpha-Mannosidosis. GeneReviews® - NCBI Bookshelf. http://www.ncbi.nlm.nih.gov/books/NBK1396/. Published June 13, 2024.
2) U.S. Food and Drug Administration. Label for [Lamzede]. Silver Spring, MD: U.S. Food and Drug Administration; 2023. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761278s000lbl.pdf.
3) BuyandBill.com. (n.d.). *About Lamzede (J0217)*. https://buyandbill.com/lamzede-j0217/#:~:text=About%20Lamzede%3A&text=The%20J%20Code%3A%20J0217%20is,to%20break%20down%20complex%20sugars.

LEUKINE ® (sargramostim), for injection

Product Affected

- *LEUKINE ® (sargramostim), for injection*

PA Criteria	Criteria Details
Billing code	J2820
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Do not use in patients who have manifested life-threatening, immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including human granulocyte-macrophage colony stimulating factor such as sargramostim, yeast-derived products. Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a hematologist and/or oncologist
Coverage Duration	6 months
Other Criteria	

Reference: LEUKINE [package insert]. Bridgewater, NJ: Sanofi-aventis U.S. LLC.; 2018.

LEVULAN KERASTICK® (aminolevulinic acid hydrochloride gel 20%), for topical

Product Affected

- *LEVULAN KERASTICK® (aminolevulinic acid hydrochloride gel 20%), for topical*

PA Criteria	Criteria Details
Billing code	J7308
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients with cutaneous photosensitivity at wavelengths of 400-450 nm. • Porphyria or known allergies to porphyrins. • Sensitivity to any of the components of the LEVULAN KERASTICK. Limitation of use: None.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement
Age Restrictions	Apply.
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist.
Coverage Duration	6 months
Other Criteria	

Reference: Levulan Kerastick [package insert]. Wilmington, MA: DUSA Pharmaceuticals, Inc.; 2021.

LUMIZYME (alglucosidase alfa) for injection, for intravenous use

Products Affected

- LUMIZYME (alglucosidase alfa) for injection, for intravenous use

PA Criteria	Criteria Details
Billing code	J0221
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments and other relevant clinical information Diagnosis of Late (non-infantile) onset Pompe disease **AND** The following criteria: • Laboratory test that demonstrates deficiency of acid-glucosidase activity in blood, fibroblast, or muscle tissue or molecular genetic test demonstrating biallelic pathogenic or likely pathogenic acid aplpha-glucosidase(GAA) gene variants • **AND** Dosing: 20 mg/kg every 2 weeks
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a geneticist or neurologist
Coverage Duration	12 months
Other Criteria	Physicians are encouraged to enroll breastfeeding females in the Pompe Registry

Reference: Product Information: LUMIZYME(R) intravenous injection, alglucosidase alfa intravenous injection. Genzyme Corporation (per FDA), Cambridge, MA, 2020.

MYCOPHENOLATE MOFETIL HCl, for injection

Product Affected

- *MYCOPHENOLATE MOFETIL HCl, for injection*

PA Criteria	Criteria Details
Billing code	J7519
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Hypersensitivity to mycophenolate mofetil, mycophenolic acid, or any other component of the drug product. • Hypersensitivity to polysorbate 80 (TWEEN)
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a specialist.
Coverage Duration	14 days
Other Criteria	The drug must be administered in combination with other immunosuppressants

Reference:

Lexicomp
MYCOPHENOLATE MOFETIL HCl, for injection [package insert]. Roche Laboratories Inc., Nutley, New Jersey.

NAGLAZYME® (galsulfase), for injection

Product Affected

- *NAGLAZYME® (galsulfase), for injection*

PA Criteria	Criteria Details
Billing code	J1458
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): None Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a geneticist.
Coverage Duration	6 months
Other Criteria	

Reference: Naglazyme [package insert]. Novato: Novartis Pharmaceuticals Corporation.; 2019.

NEULASTA® (pegfilgrastim), for injection

Product Affected

- *NEULASTA® (pegfilgrastim), for injection*

PA Criteria	Criteria Details
Billing code	J2506
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients with a history of serious allergic reactions to human granulocyte colony-stimulating factors. Limitation of use: • Not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **AND** Provide CBC result to closely monitor neutrophils count. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	According to chemoregimen protocol
Other Criteria	

Note:
All Oncology Cases must be review first by OncoHealth Team to provide an expert recommendation.
Reference: Neulasta [package insert]. Thousand Oaks, California: Amgen Inc.; 2019.

NOVOSEVEN RT (coagulation factor VIIa (recombiant), for injection

Product Affected

- *NOVOSEVEN RT (coagulation factor VIIa (recombiant), for injection*

PA Criteria	Criteria Details
Billing code	J7189
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): None Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	None.
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	6 months
Other Criteria	

Reference:

Novoseven RT [package insert]. Bagsvaerd, Denmark: Novo Nordisk A/S.; 2014.

NPLATE (romiplostim) for injection, for subcutaneous use

Products Affected

- NPLATE (romiplostim) for injection, for subcutaneous use

PA Criteria	Criteria Details
Billing code	J2796
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments and other relevant clinical information. Diagnosis of Thrombocytopenia in chronic immune thrombocytopenia (ITP); **AND** The following criteria: o Platelet count o Patient weight o For ITP, previous therapy o For Hematopoietic syndrome of acute radiation syndrome, radiation exposure and dose **AND** Dosing: • Initial dose: 1 mcg/kg once weekly
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	Initial request: • ITP: 3 months • Hematopoietic syndrome of acute radiation syndrome: one time use Continuation Request: • ITP: 3 months

PA Criteria	Criteria Details
Other Criteria	For women, appropriate forms of contraception during and after discontinuation of Nplate should be implemented due to fetal harm

Reference:

Product Information: NPLATE(R) subcutaneous injection, romiplostim subcutaneous injection. Amgen Inc (per FDA), Thousand Oaks, CA, 2022.

NUCALA (mepolizumab) for injection, for subcutaneous use

Products Affected

- NUCALA (mepolizumab) for injection, for subcutaneous use

PA Criteria	Criteria Details
Billing code	J2182
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): History of hypersensitivity to mepolizumab or excipients in the formulation (Continuation of Therapy) Limitations of use: Not for relief of acute bronchospasm or status asthmaticus.

Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information
	One of the following diagnosis:
	• Severe Asthma
	• Chronic Rhinosinusitis with Nasal Polyps
	• Eosinophilic Granulomatosis with Polyangiitis
	• Hypereosinophilic Syndrome
	AND
	One of the following type of request
	Initial request:
	• Absence of contraindication
	• Allergies if applicable
	• For severe asthma:
	  o CBC with differentiation test results (for eosinophils count)
	  o History of exacerbations and/or asthma-related hospitalization, intubation or ICU stay in the past 12 months
	• For eosinophilic granulomatosis with polyangiitis (EGPA)
	  o If the patient has history of one or more relapse or has a refractory disease
	• For hypereosinophilic syndrome (HES):

PA Criteria	Criteria Details
	○ If the patient has presented with hypereosinophilic syndrome for the > 6 months without an identifiable non-hematologic secondary cause • For chronic rhinosinusitis with nasal polyps: ○ If the patient has inadequate response to nasal corticosteroid **Continuation of therapy request:** • Allergies (if applicable) • Absence of contraindications • Tolerance and response to treatment **AND** Dosing: • Severe asthma in patients aged 12 years and older: 100 mg administered subcutaneously once every 4 weeks. • Severe asthma in patients aged 6 to 11 years: 40 mg administered subcutaneously once every 4 weeks. • CRSwNP: 100 mg administered subcutaneously once every 4 weeks • EGPA: 300 mg as 3 separate 100-mg injections administered subcutaneously once every 4 weeks • HES: 300 mg as 3 separate 100-mg injections administered subcutaneously once every 4 weeks.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a pneumologist
Coverage Duration	6 months
Other Criteria	None

Reference:

Product Information: NUCALA(R) subcutaneous injection, mepolizumab subcutaneous injection. GlaxoSmithKline (per FDA), Research Triangle Park, NC, 2022.

NYVEPRIA® (pegfilgrastim-apgf), for injection

Product Affected

- *NYVEPRIA® (pegfilgrastim-apgf), for injection*

PA Criteria	Criteria Details
Billing code	Q5122
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients with a history of serious allergic reactions to human granulocyte colony-stimulating factors such as filgrastim products or pegfilgrastim products. Limitation of use: • Not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **AND** Provide an approved diagnosis for this medication. **AND** Provide an absolute neutrophil count (ANC) and CBC results to closely monitor neutrophils and platelets count. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	According to chemoregimen protocol
Other Criteria	

Note:
All Oncology Cases must be review first by OncoHealth Team to provide an expert recommendation.

Reference: Nyvepria [package insert]. Lake Forest, IL: Hospira, Inc.; 2023.

OBIZUR (antihemophilic factor VIII recombiant), for injection

Product Affected

- *OBIZUR (antihemophilic factor VIII recombiant), for injection*

PA Criteria	Criteria Details
Billing code	J7188
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Patients who have had life-threatening hypersensitivity reactions to OBIZUR or its components, including hamster protein. • Patients with congenital hemophilia A with inhibitors. Limitation of use: • Safety and efficacy of OBIZUR has not been established in patients with a baseline anti-porcine factor VIII inhibitor titer of greater than 20 BU. • OBIZUR is not indicated for the treatment of von Willebrand disease.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a hematologist
Coverage Duration	6 months
Other Criteria	

Reference: Obizur [package insert]. Lexington, MA: Baxalta US Inc.; 2023.

OCREVUS (ocrelizumab) for injection, for intravenous use

Products Affected

- OCREVUS (ocrelizumab) for injection, for intravenous use

PA Criteria	Criteria Details
Billing code	J2350
Covered Uses	All FDA approved and medically accepted indications.
Exclusion Criteria	Contraindication(s): • Active hepatitis B virus infection • History of life-threatening infusion reaction to OCREVUS (continuation therapy)

Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information
	Diagnosis of Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; Primary progressive MS, in adults; **AND**
	The following criteria:
	Initial request:
	• Has the patient been vaccinated with a live attenuated vaccine within the last month
	  o If yes, ask pharmacist
	  o If no, proceed
	• Hepatitis B virus infection test before initiating treatment
	• MRI results
	• Confirm if the patient has experienced a relapse after treatment with another medication indicated for the treatment of MS
	• Will the requested medication be used in combination with another drug indicated for the treatment of MS
	OR
	Continuation of therapy request:
	• Has the patient been vaccinated with a live attenuated vaccine within the last month

PA Criteria	Criteria Details

	• Will the requested medication be used in combination with another drug indicated for the treatment of MS
	• Is the patient tolerating and responding to medication
	  ○ Patient has not experienced a relapse of MS
	  ○ No toxicity related to the requested drug.
	AND
	Dosing:
	• Initial dose: 300 mg followed by 300 mg 2 weeks later
	• Subsequent doses: 600 mg every 6 months

Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	Initial approval: 1 month Subsequent approval: 12 months
Other Criteria	Pre-medicate with methylprednisolone (or an equivalent corticosteroid) and an antihistamine prior to each infusion

Reference: Product Information: OCREVUS(R) intravenous injection, ocrelizumab intravenous injection. Genentech Inc (per FDA), South San Francisco, CA, 2022.

OCTAGAM® (immune globulin), for injection

Product Affected

- *OCTAGAM® (immune globulin), for injection*

PA Criteria	Criteria Details
Billing code	J1568
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Anaphylactic or severe systemic reaction to human immune globulin. • IgA-deficient patients with antibodies against IgA and a history of hypersensitivity. • Patients with acute hypersensitivity reaction to corn. Limitation of use: None.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement,
Age Restrictions	Apply.
Prescriber Restrictions	Prescribed by or in consultation with a pneumologist.
Coverage Duration	6 months
Other Criteria	

Reference: Octagram [package insert]. Vienna, Austria: Octapharma Pharmazeutika Produktionsges.; 2022.

OMVOH® (mirikizumab-mrkz), for injection

Product affected

- *OMVOH® (mirikizumab-mrkz), for injection*

PA Criteria	Criteria Details
Billing Code	J2267
Covered Uses	*All FDA-approved and medically accepted indications.* FDA Indications: Moderate to severe active ulcerative colitis.
Exclusion Criteria	Contraindication(s): • Hypersensitivity • Limitation of Use: None
Required Medical Information	The provider must submit supporting documentation, such as progress notes, lab results, previous treatments, and other relevant clinical information. **Confirmation of diagnosis AND;** **For new patients:** • The patient is considered to have started over with the non-preferred product (defined as not having used in the previous 365 days) **AND** • They must try/fail, have contraindications, or intolerance to treatment with mesalamine and/or glucocorticoids before opting for biologic agents **Continuation of therapy** Tolerance and response to treatment: describe the improvement or decrease of the disease activity. Unaltered liver enzymes panel and bilirubin level.
Age Restrictions	Adults ≥ 18 years old
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist.
Other Criteria	• Negative tuberculosis (TB) test or evidence of treatment • Liver enzymes panel and bilirubin level • The patient should not receive live vaccines during treatment.

References:

1. D'Haens G, Dubinsky M, Kobayashi T, et al; LUCENT Study Group. Mirikizumab as induction and maintenance therapy for ulcerative colitis. N Engl J Med. 2023; 388(26):2444-2455. doi:10.1056/NEJMoa2207940
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Oncology - Bevacizumab IV products

Products Affected

- *Alymsys® (bevacizumab-maly intravenous infusion – Amneal)*
- *Avastin® (bevacizumab intravenous infusion – Genentech)*
- *Mvasi™ (bevacizumab-awwb intravenous infusion – Amgen)*
- *Vegzelma™ (bevacizumab-adcd intravenous infusion – Celltrion)*
- *Zirabev™ (bevacizumab-bvzr intravenous infusion – Pfizer)*

PA Criteria	Criteria Details
Preferred Products	Mvasi, Zirabev
Non-Preferred Products	Alymsys, Avastin, Vegzelma
Billing Code	Q5126 - Alymsys J9035 - Avastin Q5107 - Mvasi Q5129 - Vegzelma Q5118 - Zirabev
Covered Uses	*All FDA approved and medically accepted indications.* **FDA Indications:** • Central Nervous System Tumors • Cervical Cancer • Colon, Rectal, or Appendiceal Cancer • Hepatocellular carcinoma • Non-small Cell Lung Cancer • Ovarian, Fallopian Tube or Primary Peritoneal Cancer • Renal Cell Cancer • Vulvar Cancer
Exclusion Criteria	Contraindication(s): None
Required Medical Information	Provider must submit supporting documentation such as progress notes (including weight and height), laboratory results, previous treatments and other relevant clinical information. **Step Therapy Requirement (Only for New Patients)** Must try/fail, have contraindication to, or intolerance to Mvasi or Zirabev prior to using Avastin, Alymsys or Vegzelma.

PA Criteria	Criteria Details
	Central Nervous System Tumors. Approve if the patient meets the following criteria (A, B, and C): Note: For pediatric patients see Pediatric Central Nervous System Tumors. **A)** Patient has tried at least one previous therapy; AND Note: Examples are temozolomide capsules or injection, etoposide, carmustine, radiotherapy. **B)** Patient has ONE of the following (i, ii, iii, iv, v, vi, or vii): **i.** Anaplastic gliomas; OR **ii.** Astrocytoma; OR **iii.** Glioblastoma; OR **iv.** Intracranial and spinal ependymoma (excluding subependymoma); OR **v.** Meningiomas; OR **vi.** Oligodendroglioma; OR **vii.** Symptoms due to one of the following (a, b, or c): **a)** Radiation necrosis; OR **b)** Poorly controlled vasogenic edema; OR **c)** Mass effect; AND **C)** The medication is prescribed by or in consultation with an oncologist.
	Cervical Cancer. Approve if the patient meets the following criteria (A, and B): **A)** Patient meets ONE of the following (i or ii): a. Patient has recurrent or metastatic cervical cancer; OR b. Patient has persistent, recurrent, or metastatic small cell neuroendocrine carcinoma of the cervix; AND **B)** The medication is prescribed by or in consultation with an oncologist.
	Colon, Rectal, or Appendiceal Cancer. Approve if the patient meets the following criteria (A, B, and C): A) Patient has recurrent, advanced or metastatic colon, rectal, or appendiceal cancer; AND B) The medication is used in combination with a chemotherapy regimen; AND Note: Examples of chemotherapy are 5-fluorouracil with leucovorin, and may include one or both of oxaliplatin, irinotecan; capecitabine with or without oxaliplatin; irinotecan with or without oxaliplatin. C) The medication is prescribed by or in consultation with an oncologist.

PA Criteria	Criteria Details
	Hepatocellular Carcinoma. Approve if the patient meets all of the following criteria: **A)** Patient meets ONE of the following (i or ii): **i.** Patient has unresectable or metastatic hepatocellular carcinoma; OR **ii.** According to the prescriber, the patient is not a surgical candidate; AND **B)** Patient has Child-Pugh Class A disease; AND **C)** The medication is used in combination with Tecentriq (atezolizumab intravenous infusion); AND **D)** Patient has not received prior systemic therapy; AND **E)** The medication is prescribed by or in consultation with an oncologist.
	Non-Small Cell Lung Cancer. Approve if the patient meets all of the following criteria: **A)** Patient does not have a history of recent hemoptysis; AND **B)** Patient has recurrent, advanced, or metastatic non-squamous non-small cell lung cancer (NSCLC) and meets ONE of the following criteria (i, ii, iii, iv, or v): Note: Non-squamous NSCLC includes adenocarcinoma, large cell, or NSCLC not otherwise specified. **i.** The NSCLC tumor is negative or unknown for actionable mutations and the patient meets ONE of the following criteria (a, b, or c): Note: Examples of actionable mutations include sensitizing epidermal growth factor receptor (*EGFR*) mutation, anaplastic lymphoma kinase (*ALK*) fusions, *RET* rearrangement positive, *MET* exon 14 skipping, *NTRK* gene fusion positive, *BRAF V600E* mutation positive, and ROS proto-oncogene 1 (*ROS1*) rearrangement positive. **a)** The medication is used as initial therapy in combination with other systemic therapies; OR Note: Examples of systemic therapies are cisplatin, carboplatin, Tecentriq (atezolizumab intravenous infusion), pemetrexed, paclitaxel. **b)** The medication is used as continuation maintenance therapy and meets ONE of the following [(1), (2), or (3)]: **(1)** The medication is used as a single agent; OR **(2)** The medication is used in combination with Tecentriq, if Tecentriq was used in combination with bevacizumab for first-line therapy; OR

PA Criteria	Criteria Details
	(3) The medication is used in combination with pemetrexed, if pemetrexed was used in combination with bevacizumab for first line therapy; OR **c)** The medication is used as subsequent therapy in combination with other systemic therapies, OR Note: Examples of systemic therapies are cisplatin, carboplatin, pemetrexed, paclitaxel. **ii.** The tumor is positive for (*EGFR*) exon 19 deletion or exon 21 *L858R* mutations and the patient meets ONE of the following (a or b): **a)** The medication is used as first-line or continuation maintenance therapy in combination with erlotinib; OR **b)** The medication is used as subsequent therapy following prior targeted therapy; OR Note: Examples of targeted therapy include Gilotrif (afatinib tablet), Tagrisso (osimertinib tablet), erlotinib, Iressa (gefitinib tablet), Vizimpro (dacomitinib tablet). **iii.** Patient meets all of the following (a, b, and c): **a)** The medication is used first-line; AND **b)** The medication is used in combination with other systemic therapies; AND Note: Examples include carboplatin plus paclitaxel or pemetrexed; cisplatin plus pemetrexed; and Tecentriq plus carboplatin and paclitaxel. **c)** The tumor is positive for ONE of the following mutations [(1), (2), or (3)]: **(1)** *EGFR* exon 20 mutation; OR **(2)** *KRAS G12C* mutation; OR **(3)** *ERBB2* (HER2) mutation; OR **iv.** Patient meets all of the following (a, b, and c): **a)** The medication is used as first-line or subsequent therapy; AND **b)** The medication is used in combination with other systemic therapies; AND Note: Examples include carboplatin plus paclitaxel or pemetrexed; cisplatin plus pemetrexed; and Tecentriq plus carboplatin and paclitaxel. **c)** The tumor is positive for ONE of the following mutations [(1), (2), (3), or (4)]: **a)** *BRAF V600E* mutation; OR

PA Criteria	Criteria Details
	b) *NTRK1/2/3* gene fusion positive; OR **c)** *MET* exon 14 skipping mutation; OR **d)** *RET* rearrangement positive; OR **v.** Patient meets all of the following (a, b, c, and d): **a)** The medication is used as subsequent therapy; AND **b)** The medication is used in combination with other systemic therapies; AND Note: Examples include carboplatin plus paclitaxel or pemetrexed; cisplatin plus pemetrexed; and Tecentriq plus carboplatin and paclitaxel. **c)** The tumor is positive for ONE of the following mutations [(1), (2), or (3)] **a)** *EGFR S768I, L861Q,* and/or *G719X* mutation; OR **b)** *ALK* rearrangement positive; OR **c)** *ROS1* rearrangement positive; AND **d)** Patient has previously received targeted drug therapy for the specific mutation; AND Note: Examples of targeted drug therapy include Gilotrif (afatinib tablet), Tagrisso (osimertinib tablet), erlotinib, Iressa (gefitinib tablet), Vizimpro (dacomitinib tablet), Xalkori (crizotinib capsule), Rozlytrek (entrectinib capsule), or Zykadia (ceritinib tablet). **C)** The medication is prescribed by or in consultation with an oncologist. **Ovarian, Fallopian Tube, or Primary Peritoneal Cancer.** Approve if the patient meets all of the following criteria: **A)** The medication is prescribed by or in consultation with an oncologist. **Renal Cell Cancer.** Approve if the patient meets all of the following criteria: **A)** Patient has relapsed, metastatic, or stage IV renal cell cancer; AND **B)** The medication is prescribed by or in consultation with an oncologist.
Age Restrictions	For all products: Patient is ≥ 18 years of age For Pediatric Central Nervous System Tumors: Patient is < 18 years of age
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	According to chemoregimen protocol

PA Criteria	Criteria Details
Other Criteria	
Exception Criteria for Step Therapy	Alymsys, Avastin, Vegzelma: **Oncology Conditions.** Approve if the patient meets BOTH of the following (A and B): **A)** Patient meets the standard *Oncology (Injectable) – Bevacizumab Products Utilization Management Medical Policy* criteria; AND **B)** Patient meets ONE of the following (i or ii): **i.** Patient meets both of the following (a and b): **a)** Patient has tried one of Mvasi or Zirabev; AND **b)** Patient cannot continue to use the Preferred Product due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR **ii.** Patient is currently receiving the requested bevacizumab product.

Note: All Oncology Cases must be review first by OncoHealth Team to provide an expert recommendation.

References:

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3. Zirabev™ intravenous infusion [prescribing information]. New York, NY: Pfizer; February 2023.
4. Alymsys® intravenous infusion [prescribing information]. Bridgewater, NJ: Amneal; April 2022.
5. Vegzelma™ intravenous infusion [prescribing information]. Incheon, Republic of Korea: Celltrion; September 2022.
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19. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2022 – May 17, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed March 14, 2023.
20. The NCCN Hepatobiliary Cancers Clinical Practice Guidelines in Oncology (version 5.2022 – January 13, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed March 15, 2023.
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35. Rubinstein M, Dickinson S, Narayan P, et al. Bevacizumab in advanced endometrial cancer. *Gynecol Oncol*. 2021;161:720-726.

Oncology Treatments

Affected Products

- *BCG live instilación intravesical, 1 mg*
- *Cyclophosphamide, 100 mg*
- *Dacarbazine, 100 mg*
- *Goserelin acetate implant 3.6 mg each*
- *Implanted Histrelin (Supprelin LA), 50 mg*
- *Histrelin Implant (Vantas), 50 mg*
- *Injection, ado-trastuzumab emtansine, 1 mg*
- *Injection, afamitresgene autoleucel (Tecelra)*
- *Injection, aldesleukin, per single-use vial*
- *Injection, amivantamab-vmjw, 2 mg*
- *Injection, arsenic trioxide, 1 mg*
- *Injection, asparaginase (Erwinaze), 1,000 IU*
- *Injection, asparaginase, not otherwise specified, 10, 000 units*
- *Rylaze Injection Asparaginase Recombinant 0.1 mg*
- *Atezolizumab 10 mg*
- *Injection, avelumab, 10 mg*
- *Injection, azacitidine, 1 mg*
- *Injection, belantab mafodontin-blmf, 0.5 mg*
- *Injection, belinostat, 10 mg*
- *Injection, bendamustine HCL, 1 mg*
- *Injection, bendamustine HCL (bendeka), 1 mg*
- *Injection, bendamustine HCL (treanda), 1 mg*
- *Injection, bendamustine hydrochloride (apotex), 1 mg*
- *Injection, bendamustine hydrochloride (baxter), 1 mg*
- *Injection, bendamustine hydrochloride (vivimusta), 1 mg*
- *Bendamustine hydrochloride (Belrapzo) 1 mg*
- *Injection, bevacizumab, 10 mg*
- *Injection, bevacizumab-adcd (vegzelma), biosimilar, 10 mg*
- *Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg*
- *Injection, bevacizumab-bvzr, biosimilar, (Zirabev), 10 mg*
- *Injection, bevacizumab-maly, biosimilar, (alymsys), 10 mg*
- *Injection, bleomycin sulfate, 15 units*
- *Injection, blinatumomab, 1 microgram*
- *Injection, bortezomib (fresenius kabi), not therapeutically equivalent to j9041, 0.1 mg*
- *Injection, bortezomib (hospira), not therapeutically equivalent to j9041, 0.1 mg*
- *Injection, bortezomib (maia), not therapeutically equivalent to j9041, 0.1 mg*
- *Injection, bortezomib, (Dr. Reddy's), not therapeutically equivalent to j9041, 0.1 mg*
- *Injection, bortezomib, 0.1 mg*
- *Injection, brentuximab vedotin, 1 mg*

- *Injection, busulfan, 1 mg*
- *Injection, cabazitaxel (sandoz not therapeutically equivalent to J9043, 1 mg*
- *Injection, cabazitaxel, 1 mg*
- *Injection, calaspargase pegol-mknl, 10 units*
- *Injection, carboplatin, 50 mg*
- *Injection, carfilzomib, 1 mg*
- *Injection, carmustine, 100 mg*
- *Injection, cemiplimab-rwlc, 1 mg*
- *Injection, cetuximab, 10 mg*
- *Injection, cisplatin, powder or solution, 10 mg*
- *Injection, cladribine, 1 mg*
- *Injection, clofarabine, 1 mg*
- *Injection, copanlisib, 1 mg*
- *Injection, cyclophosphamide, (auromedics), 5 mg*
- *Injection, cyclophosphamide, (avyxa), 5 mg*
- *Injection, cyclophosphamide, (baxter), 5 mg*
- *Injection, cytarabine liposome, 10 mg*
- *Injection, cytarabine, 100 mg*
- *Injection, dactinomycin, 0.5 mg*
- *Injection, daratumumab, 10 mg*
- *Injection, daratumumab, 10 mg and hyaluronidasa-fihj*
- *Injection, daunorubicin citrate, liposomal formulation, 10 mg*
- *Injection, daunorubicin, 10 mg*
- *Injection, decitabine (sun pharma), not therapeutically equivalent to j0894, 1 mg*
- *Injection, decitabine, 1 mg*
- *Injection, degarelix, 1 mg*
- *Injection, denileukin diftitox, 300 mcg*
- *Injection, denileukin diftitox-cxdl (Lymphir)*
- *Injection, diethylstilbestrol diphosphate, 250 mg*
- *Injection, dinutuximab, 0.1 mg*
- *Injection, docetaxel, 1 mg*
- *Injection, docetaxel (avyxa), not therapeutically equivalent to J9171, 1 mg*
- *Dostarlimab-gxly 10 mg*
- *Injection, doxorubicin hydrochloride, 10 mg*
- *Injection, durvalumab, 10 mg*
- *Injection, efgartigimod alfa-fcab, 2mg*
- *Injection, Elliotts' B solution, 1 ml*
- *Injection, elotuzumab, 1 mg*
- *Injection, emapalumab-lzsg, 1 mg*
- *Injection, enfortumab vedotin-ejfv, 0.25 mg*
- *Injection, epcoritamab-bysp 0.16 mg*
- *Injection, epirubicin HCl, 2 mg*
- *Injection, eribulin mesylate, 0.1 mg*

- *Injection, etoposide, 10 mg*
- *Injection, fam-trastuzumab deruxtecan-xki, 1 mg*
- *Injection, floxuridine, 500 mg*
- *Injection, fludarabine phosphate, 50 mg*
- *Injection, fluorouracyl, 500 mg*
- *Fulvestrant (Fresenius Kabi) injection not therapeutically equivalent to J9395, 25 mg*
- *Injection, fulvestrant (teva) not therapeutically equivalent to j9395, 25 mg*
- *Injection, fulvestrant, 25 mg*
- *Injection, gemcitabine hydrochloride (accord), not therapeutically equivalent to j9201, 200 mg*
- *Injection, gemcitabine hydrochloride, (infugem), 100 mg*
- *Injection, gemcitabine hydrochloride, not otherwise specified, 200 mg.*
- *Injection of gemtuzumab ozogamicin 0.1 mg*
- *Injection, glofitamab gxbm, 2.5 mg*
- *Injection, idarubicin hydrochloride, 5 mg*
- *Injection, ifosfamide, 1 gram*
- *Injection, imetelstat, 1 mg*
- *Injection, immunoglobulin (alyglo), 100 mg*
- *Injection, inotuzumab ozogamicin, 0.1 mg*
- *Injection, interferon alfacon-1, recombinant, 1 mcg*
- *Injection, interferon, alpha-2a, recombinant, 3 million units*
- *Injection, interferon, alfa-2b, recombinant, 1 million units*
- *Injection, interferon, alpha-N3, (derived from human leukocyte), 250,000 IU*
- *Injection, interferon, gamma 1-b, 3 million units*
- *Injection, faltaimumab, 1 mg*
- *Injection, irinotecan liposome, 1 mg*
- *Injection, irinotecan, 20 mg*
- *Injection, isatuximab-irfc, 10 mg*
- *Injection, ixabepilone, 1 mg*
- *Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine*
- *Injection, loncastuximab tesirine-lpyl, 0.075 mg*
- *Injection, lurbinectedin, 0.1 mg*
- *Injection, margetuximab-cmkb, 5 mg*
- *Injection, mechlorethamine hydrochloride, (mostaza nitrogenada), 10 mg*
- *Injection, melphalan (evomela), 1 mg*
- *Injection, melphalan flufenamide, 1mg*
- *Injection, melphalan hydrochloride, not otherwise specified, 50 mg*
- *Injection, mesna, 200 mg*
- *Mirvetuximab soravtansine-gynx 1 mg*
- *Injection, mitomycin, 5 mg*
- *Injection, mitoxantrone hydrochloride, 5 mg*
- *Injection, mogamulizumab-kpkc, 1 mg*
- *Injection, mosunetuzumab-axgb, 1 mg*

- *Injection, moxetumomab pasudotox-tdfk, 0.01 mg*
- *Injection, nadofaragene firadenovec-vncg, per therapeutic dose*
- *Injection, naxitamab-gqgk, 1 mg*
- *Injection, necitumumab, 1 mg*
- *Injection, nelarabine, 50 mg*
- *Injection, nivolumab and relatlimab-rmbw, 3 mg/1 mg*
- *Injection, nivolumab, 1 mg*
- *Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 mcg*
- *Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 400 mcg/0.4 mL*
- *Obinutuzumab 10 mg*
- *Injection, ofatumumab, 10 mg*
- *Injection, olaratumab, 10 mg*
- *Injection, omacetaxine mepesuccinate, 0.01 mg*
- *Injection, oxaliplatin, 0.5 mg*
- *Injection, paclitaxel protein-bound particles (American regent) not therapeutically equivalent to J9264, 1 mg*
- *Injection, paclitaxel protein-bound particles (teva) not therapeutically equivalent to J9264, 1 mg*
- *Injection, paclitaxel protein-bound particles, 1 mg*
- *Injection, paclitaxel, 1 mg*
- *Injection, palonosetron hydrochloride (post-cold), 25 mcg*
- *Injection, panitumumab, 10 mg*
- *Injection, pegaspargase, per single-use vial*
- *Injection, pembrolizumab, 1 mg*
- *Injection, pemetrexed (accord) not therapeutically equivalent to J9305, 10 mg*
- *Injection, pemetrexed (avyxa) not therapeutically equivalent to J9305, 10 mg*
- *Injection, pemetrexed (bluepoint) not therapeutically equivalent to J9305, 10 mg*
- *Injection, pemetrexed (hospira) not therapeutically equivalent to J9305, 10 mg*
- *Injection, pemetrexed (pemfexy), 10 mg*
- *Injection, pemetrexed (sandoz), not therapeutically equivalent to J9305, 10 mg*
- *Injection, pemetrexed (teva) not therapeutically equivalent to J9305, 10 mg*
- *Injection, pemetrexed ditromethamine, 10 mg*
- *Injection, pemetrexed, not otherwise specified, 10 mg.*
- *Injection, pentostatin, 10 mg*
- *Injection, pertuzumab, 1 mg*
- *Injection, pertuzumab, trastuzumab, and hialuronidasa-zzxf, 10 mg*
- *Injection, plicamycin, 2.5 mg*
- *Polatuzumab vedotin-piiq injection, 1 mg*
- *Injection, porfimer sodium, 75 mg*
- *Injection, pralatrexate, 1 mg*
- *Injection, ramucirumab, 5 mg*
- *Injection, retifanlimab-dlwr, 1 mg*
- *Injection, rituximab 10 mg and hialuronidasa*

- *Injection, rituximab, 10 mg*
- *Injection, rituximab-abbs, biosimilar, (Truxima), 10 mg*
- *Injection, rituximab-arrx, biosimilar, (riabni), 10 mg*
- *Injection, rituximab-pvvr, biosimilar, (ruxience), 10 mg*
- *Injection, romidepsin, freeze-dried, 0.1 mg*
- *Injection, romidepsin, non-freeze-dried, 0.1 mg*
- *Shot, romiplostim, 1 mcg*
- *Injection, sacituzumab govitecan-hziy, 2.5 mg*
- *Injection, sirolimus protein-bound particles, 1 mg*
- *Injection, streptozocin, 1 g*
- *Injection, tafasitamab-cxix, 2 mg*
- *Injection, tagraxofusp-erzs, 10 mcg*
- *Injection, talimogene laherparepvec, 1 million plaque forming units*
- *Injection, tarlatamab-dlle, 1 mg*
- *Injection, tebentafusp-tebn, 1 mcg*
- *Injection, teclistamab-cqyv, 0.5 mg*
- *Injection, temozolomide, 1 mg*
- *Injection, temsirolimus, 1 mg*
- *Injection, thiotepa, 15 mg*
- *Tislelizumab 1 mg*
- *Injection, tisotumab vedotin-tftv, 1 mg*
- *Injection, topotecan, 0.1 mg*
- *Injection, toripalimab-tpzi (loqtorzi), 1mg*
- *Injection, trabectedin, 0.1 mg*
- *Injection, trastuzumab, 10 mg and Hialuronidasa-oysk*
- *Injection, trastuzumab, excludes biosimilar, 10 mg*
- *Injection, trastuzumab-strf, 150 mg*
- *Injection, trastuzumab-strf (Hercessi), biosimilar, 10 mg*
- *Injection, trastuzumab-anns, biosimilar, (canjinti), 10 mg*
- *Injection, trastuzumab-dkst, biosimilar, (Ogivri), 10 mg*
- *Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg*
- *Injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg*
- *Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg*
- *Injection, tremelimumab-actl, 1 mg*
- *Injection, valrubicin, intravesical, 200 mg*
- *Injection, vinblastine sulfate, 1 mg*
- *Injection, vincristine sulfate liposome, 1 mg*
- *Injection, vinorelbine tartrate, 10 mg*
- *Injection, ziv-aflibercept, 1 mg*
- *Leuprolide acetate (suspended deposition), 7.5 mg*
- *Leuprolide acetate implante, 65 mg*
- *Leuprolide acetate, 1 mg*
- *Methotrexate sodium, 5 mg*

- *Methotrexate sodium, 50 mg*
- *Mitomycin pyelocalyceal instillation, 1 mg*
- *Not otherwise classified, antineoplastic drugs*
- *Vincristine sulfate, 1 mg*

PA Criteria	Criteria details
Billing Code	J0594 J0893-J0894 J9000-J9999, excluding J9381 Q5101 Q5112-Q5120 Q5123, Q5126, Q5129
Covered Uses	*All FDA-approved and medically accepted indications.*
Exclusion Criteria	Contraindications: As appropriate on the label of each product. Limitation of use: As appropriate on the label of each product.
Required Medical Information	Provider must submit supporting documentation such as: progress notes, lab results, previous treatments, and any other relevant clinical information. Confirmation of diagnosis **Continuity of Therapy** Tolerance and response to treatment: Improvement or decrease in the progression of the disease is described.
Restriction of age	Apply.
Prescriber restrictions	Prescribed by or in consultation with a hematologist and/or oncologist
Duration of coverage	According to chemotherapy regimen protocol and/or medical necessity.
Other criteria	

Note: All oncology cases will be reviewed first by the OncoHealth team to provide an expert recommendation.

Referencia: L33394 Drugs and Biologicals, Coverage of, for Label and Off-Label Uses

- Drugs or regimens may be used off-label (without FDA approval) and considered medically acceptable if they are supported by any of the following compendiums below and are not listed as unendorsed, not indicated, or not recommended in any compendium below. NCCN Drugs & Biologics Compendium ®
    - Category 1-2A recommendations are considered medically acceptable uses.
    - Category 2B recommendations will be considered if they are identified as medically accepted in an alternative compendium or supported by peer-reviewed scientific literature eligible for coverage (meeting abstracts and case reports are excluded from consideration).
    - Category 3 listings are considered non-medically accepted uses.
    - OA subscribes to NCCN Flash Updates™ which informs OA when the NCCN® Guidelines and NCCN Compendium of Drugs and Biologics are updated.

- Clinical Pharmacology
- Medically accepted uses are identified by narrative text that supports them.
- Non-medically accepted uses are identified by narrative text that "does not endorse."
- American Hospitals Formulary Service: Drug Information (AHFS-DI)
    - Medically accepted uses are identified by a narrative text that supports them.
    - Non-medically accepted uses are identified by narrative text that "does not endorse."

- Thompson Micromedex DrugDex®
    - Class I, IIA, or IIb recommendations are considered medically acceptable uses.
    - Class III listings are considered non-medically accepted uses.

- Wolters Kluwer Lexi-Drugs®
    - Medically acceptable uses are identified by a statement listed as "Use: Not Indicated on the Label" and is classified as "Level of Evidence A."
      o Uses not medically accepted are those indications listed as "Use: Not admitted"

- American Society for Radiation Oncology (ASTRO)
- Clinical Practice Guidelines and Model Policies; American Radium Society Appropriate Use Criteria; American Brachytherapy Consensus Statement
- American Brachytherapy Consensus Statements
- Pediatric Hematology and Oncology
- Pediatric Blood and Cancer
- Journal of Adolescent and Young Adult Oncology

Off-label use of drugs or regimens may also be considered medically acceptable if it is deemed safe and effective based on peer-reviewed articles eligible for coverage by one of the following journals:

- *American Journal of Medicine;*
- *Annals of Internal Medicine;*
- *Annals of Oncology;*
- *Annals of Surgical Oncology;*
- *Biology of Blood and Marrow Transplantation;*
- *Blood;*
- *Bone Marrow Transplantation;*
- *British Journal of Cancer*
- *British Journal of Hematology;*
- *British Medical Journal;*
- *Cancer;*
- *Clinical Cancer Research;*
- *Drugs;*
- *European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology);*
- *Gynecologic Oncology*
- *International Journal of Radiation, Oncology, Biology, and Physics;*
- *The Journal of the American Medical Association;*
- *Journal of Clinical Oncology;*
- *Journal of the National Cancer Institute;*
- *Journal of the National Comprehensive Cancer Network (NCCN);*
- *Journal of Urology;*
- *Lancet;*
- *Lancet Oncology;*
- *Leukemia;*
- *The New England Journal of Medicine;*
- *Radiation Oncology*
    - Meeting summaries and case reports are excluded from consideration.

Ophthalmology *– Vascular Endothelial Growth Factor Inhibitors Products (**VEGF inhibitors**), **intravitreal injection***

Products Affected

- *Byooviz™ (ranibizumab-nuna intravitreal injection – Biogen)*
- *Cimerli™ (ranibizumab-eqrn intravitreal injection – Coherus)*
- *Vabysmo® (faricimab-svoa intravitreal injection – Genentech)*
- *Lucentis® (ranibizumab intravitreal injection – Genentech)*

PA Criteria	Criteria Details
Preferred Products	Avastin Ophthalmic (only Buy and Bill), Byooviz, Cimerli, Vabysmo
Non-Preferred Products	Lucentis
Billing Code	Q5124 - Byooviz J2777 - Vabysmo Q5128 - Cimerli J2778 - Lucentis
Covered Uses	*All FDA approved and medically accepted indications.* **Byooviz** • Neovascular (Wet) Age-Related Macular Degeneration (AMD) • Macular Edema Following Retinal Vein Occlusion (RVO) • Myopic Choroidal Neovascularization (mCNV) **Cimerli & Lucentis** • Neovascular (Wet) Age-Related Macular Degeneration (AMD) • Macular Edema Following Retinal Vein Occlusion (RVO) • Diabetic Macular Edema (DME) • Diabetic Retinopathy (DR) • Myopic Choroidal Neovascularization (mCNV) **Vabysmo** • Neovascular (Wet) Age-Related Macular Degeneration (nAMD) • Diabetic Macular Edema (DME)

PA Criteria	Criteria Details
	• Macular Edema Following Retinal Vein Occlusion (RVO)
Exclusion Criteria	**Contraindication(s):** Ocular or periocular infections and hypersensitivity.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments and other relevant clinical information **Medical Information Requirements:** Approve if the patient meets **all** the following**:** 1. Diagnosis Confirmation 2. Dose Verification
Age Restrictions	Age ≥ 18 years
Prescriber Restrictions	Medication is prescribed by an ophthalmologist/retina specialist
Coverage Duration	For all products **approve for 1 year**
Other Criteria	
Exception Criteria for Step Therapy	Coverage for Lucentis is provided when any the following criteria are met: 1. Members have received treatment with the targeted product in the past 365 days. 2. The requested product is Lucentis and member meets both of the following criteria: a. Member has had a documented inadequate response or intolerable adverse event with the primary preferred product, Avastin ophthalmic, Byooviz, Cimerli or Vabysmo.

References:

1. Barakat MR, Kaiser PK. VEGF inhibitors for the treatment of neovascular age-related macular degeneration. *Expert Opin Investig Drugs*. 2009;18(5):637-646.
2. Tolentino M. Systemic and ocular safety of intravitreal anti-VEGF therapies for ocular neovascular disease. *Surv Ophthalmol*. 2011;56(2):95-113.
3. Kinnunen K, Ylä-Herttuala S. Vascular endothelial growth factors in retinal and choroidal neovascular diseases. *Ann Med*. 2012;44(1):1-17.
4. Horsley MB, Kahook MY. Anti-VEGF therapy for glaucoma. *Curr Opin Ophthalmol*. 2010;21(2):112-117.

5. Barakat MR, Kaiser PK. VEGF inhibitors for the treatment of neovascular age-related macular degeneration. Expert Opin Investig Drugs. 2009;18(5):637-646.
6. Tolentino M. Systemic and ocular safety of intravitreal anti-VEGF therapies for ocular neovascular disease. Surv Ophthalmol. 2011;56(2):95-113.
7. Kinnunen K, Ylä-Herttuala S. Vascular endothelial growth factors in retinal and choroidal neovascular diseases. Ann Med. 2012;44(1):1-17.
8. Horsley MB, Kahook MY. Anti-VEGF therapy for glaucoma. Curr Opin Ophthalmol. 2010;21(2):112-117.
9. Lucentis® intravitreal injection [prescribing information]. South San Francisco, CA: Genentech; August 2023.
10. Barakat MR, Kaiser PK. VEGF inhibitors for the treatment of neovascular age-related macular degeneration. Expert Opin Investig Drugs. 2009;18(5):637-646.
11. Tolentino M. Systemic and ocular safety of intravitreal anti-VEGF therapies for ocular neovascular disease. Surv Ophthalmol. 2011;56(2):95-113.
12. Kinnunen K, Ylä-Herttuala S. Vascular endothelial growth factors in retinal and choroidal neovascular diseases. Ann Med. 2012;44(1):1-17.
13. Horsley MB, Kahook MY. Anti-VEGF therapy for glaucoma. Curr Opin Ophthalmol. 2010;21(2):112-117.
14. Byooviz™ intravitreal injection [prescribing information]. Cambridge, MA: Biogen; October 2023.
15. Cimerli™ intravitreal injection [prescribing information]. Redwood City, CA: Coherus; August 2022.
16. Vabysmo™ intravitreal injection [prescribing information]. South San Francisco, CA: Genentech; October 2023.

Osteoarthritis, Viscosupplements-Multi Injection

Products Affected

Durolane® (sodium hyaluronate injection – Bioventus)
Euflexxa® (sodium hyaluronate injection – Ferring)
Gel-One® (sodium hyaluronate injection – Seikagaku/Zimmer)
Gelsyn-3™ (sodium hyaluronate injection – Bioventus)
GenVisc® 850 (sodium hyaluronate injection – OrthogenRx)
Hyalganâ (sodium hyaluronate injection - Fidia)
Hymovisâ (high molecular weight viscoelastic hyaluronan injection – Fidia)
Monovisc™ (high molecular weight hyaluronan injection – Anika)
Orthoviscâ (high molecular weight hyaluronan injection –Anika)
Supartz FX™ (sodium hyaluronate injection - Seikagaku/Bioventus)
Sodium hyaluronate 1% injection – Teva
SynoJoynt™ (sodium hyaluronate injection - Arthrex)
Synviscâ (hylan G-F 20 sodium hyaluronate injection – Genzyme)
Synvisc-One® (hylan G-F 20 sodium hyaluronate injection – Genzyme)
Triluron™ (sodium hyaluronate injection – Fidia)
TriVisc™ (sodium hyaluronate injection – OrthogenRx)
Visco-3™ (sodium hyaluronate injection – Seikagaku/Bioventus)

PA Criteria	Criteria Details
Billing code	J7317, J7318, J7320, J7321, J7322, J7323, J7324, J7325, J7326, J7327, J7328, J7329, J7331, J7332
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): None
Required Medical Information	Approve one course of therapy per treated knee if the patient meets **ONE** of the following (A or B): A) **Initial Therapy.** Approve an initial course if the patient meets **ALL** of the following (i and ii): i. Diagnosis of the knee to be treated is confirmed by radiologic evidence of knee osteoarthritis; AND

PA Criteria	Criteria Details
	Note: Examples of radiographic evidence includes x-ray, magnetic resonance imaging (MRI), computed tomography (CT) scan, ultrasound. ii. Patient has tried at least **TWO** of the following three modalities of therapy for osteoarthritis (a, b, c): a. At least one course of physical therapy for knee osteoarthritis; b. At least TWO of the following pharmacologic therapies (1) Oral or topical nonsteroidal anti-inflammatory drug(s) [NSAID(s)] Note: Examples of oral NSAIDs include naproxen, ibuprofen, celecoxib. Examples of topical NSAIDs include diclofenac solution or diclofenac gel. A trial of two or more NSAIDs (oral and/or topical) counts as one pharmacologic therapy. (2) Acetaminophen (3) Tramadol (Ultram/XR, generic) (4) Duloxetine (Cymbalta, generic) c. At least TWO injections of intraarticular corticosteroids to the affected knee; AND B) **Continuation of therapy.** Patient has Already Received One or More Courses of a Hyaluronic Acid Derivative in the Same Knee. Approve one repeat course if the patient meets **ALL** of the following (i and ii) i. At least 6 months have elapsed since the last injection with any hyaluronic acid derivative; **AND** ii. According to the prescriber, the patient had a response to the previous course of hyaluronic acid derivative therapy for osteoarthritis of the knee and now requires additional therapy for osteoarthritis symptoms. **Note:** Examples of a response include reduced joint pain, tenderness, morning stiffness, or improved mobility. **Dosing.** Approve the following dosing regimens: Note: Dose listed is for one knee. If two knees are being treated, then each knee requires a syringe or vial of product. A) Durolane, Gel-One, Monovisc, Synvisc-One: Approve one injection. B) Hymovisc: Approve up to two injections given 1 week apart. C) Euflexxa, Gelsyn-3, sodium hyaluronate 1% injection, SynoJoynt, Synvisc, Triluron, TriVisc, Visco-3: Approve up to three injections given 1 week apart.

<table>
<tr><th>PA Criteria</th><th>Criteria Details</th></tr>
<tr><td></td><td>D) Orthovisc: Approve up to 4 injections given 1 week apart.
E) GenVisc 850, Hyalgan, Supartz FX: Approve up to 5 injections given 1 week apart.</td></tr>
<tr><td>Age Restrictions</td><td>Age ≥ 18 years</td></tr>
<tr><td>Prescriber Restrictions</td><td>The product is administered by or under the supervision of a physician specializing in rheumatology, orthopedic surgery, or physical medicine and rehabilitation (physiatrist).</td></tr>
<tr><td>Coverage Duration</td><td>Dosing. Approve the following dosing regimens:
Note: Dose listed is for one knee. If two knees are being treated, then each knee requires a syringe or vial of product.
<table>
<tr><th>Product</th><th>Number of injections per course</th></tr>
<tr><td>Durolane/ Gel-One/ Monovisc/ Synvisc-One</td><td>One injection given one time</td></tr>
<tr><td>Hymovis</td><td>Two injections given 1 week apart</td></tr>
<tr><td>Euflexxa/ Gelsyn-3/ Sodium Hyaluronate/ SynoJoynt/ Synvisc/ Triluron/ TriVisc/ Visco-3</td><td>Three injections given 1 week apart</td></tr>
<tr><td>Orthovisc</td><td>Three or four injections given 1 week apart</td></tr>
<tr><td>GenVisc 850/ Hyalgan/ Supartz FX</td><td>Five injections given 1 week apart</td></tr>
</table></td></tr>
<tr><td>Other Criteria</td><td></td></tr>
</table>

References:

1. Durolane® intraarticular injection [prescribing information]. Durham, NC: Bioventus; not dated.
2. Euflexxa® intraarticular injection [prescribing information]. Parsippany, NJ: Ferring; July 2016.

3. Gel-One® intraarticular injection [prescribing information]. Warsaw, IN: Zimmer; May 2011.
4. Gelsyn-3® intraarticular injection [prescribing information]. Durham, NC: Bioventus; 2016.
5. GenVisc® 850 intraarticular injection [prescribing information]. Doylestown, PA: OrthogenRx; not dated.
6. Hyalgan® intraarticular injection [prescribing information]. Parsippany, NJ: Fidia Pharma; May 2014.
7. Hymovis® intraarticular injection [prescribing information]. Parsippany, NJ: Fidia Pharma; October 2015.
8. Monovisc® intraarticular injection [prescribing information]. Bedford, MA: Anika; not dated.
9. Orthovisc® intraarticular injection [prescribing information]. Bedford, MA: Anika; September 2014.
10. Sodium hyaluronate 1% intraarticular injection [prescribing information]. North Wales, PA: Teva; March 2019.
11. Supartzâ FX™ intraarticular injection [prescribing information]. Durham, NC: Bioventus; April 2015.
12. Synvisc® intraarticular injection [prescribing information]. Ridgefield, NJ: Genzyme; September 2014.
13. Synvisc-One® intraarticular injection [prescribing information]. Ridgefield, NJ: Genzyme; September 2014.
14. Triluron intraarticular injection [prescribing information]. Florham Park, NJ: Fidia Pharma; March 2019.
15. Trivisc intraarticular injection [prescribing information]. Doylestown, PA: OrthogenRx; not dated.
16. Visco-3 intraarticular injection [prescribing information]. Durhan, NC: Bioventus; not dated.
17. Kolasinski SH, Neogi T, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the management of osteoarthritis of the hand, hip, and knee. Arthritis Care Res. 2019;72(2):149-162.
18. American Academy of Orthopaedic Surgeons Management of Osteoarthritis of the Knee (Non-Arthroplasty) Evidence-Based Clinical Practice Guideline. Published August 31, 2021. Available at: Osteoarthritis of the Knee - Clinical Practice Guideline (CPG) | American Academy of Orthopaedic Surgeons (aaos.org). Accessed on September 21, 2023.

OZURDEX (dexamethasone) for injection, for intravitreal use

Products Affected

- OZURDEX (dexamethasone) for injection, for intravitreal use

PA Criteria	Criteria Details
Billing code	J7312
Covered Uses	All FDA approved and medically accepted indications.
Exclusion Criteria	Contraindication(s): • Ocular or periocular infections • advanced glaucoma; Non-intact posterior lens capsule; Hypersensitivity
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information Diagnosis of BRVO or CRVO, Non-infectious uveitis affecting the posterior segment of the eye, Diabetic macular edema in patients who are pseudophakia or are phakic and scheduled for cataract surgery; **AND** The following universal criteria: • Must not be used in combination with other sustained-release intravitreal corticosteroids • Patient's best corrected visual acuity (BVCA) is measured at baseline and periodically throughout treatment • Patient's intraocular pressure is measured at baseline and periodically throughout therapy DME and BRVO • Patient had an inadequate response or has a contraindication to treatment with bevacizumab intravitreal injection Non-infectious uveitis affecting posterior segment of the eye • Patient has had an inadequate response or has a contraindication to treatment with triamcinolone acetonide intravitreal injection, **OR** • Patient is receiving triamcinolone acetonide injection but requires injections more often than every 12 weeks Renewal Criteria

PA Criteria	Criteria Details
	• Patient continues to meet universal and indication specific criteria • Absence of unacceptable toxicity from the drug BRAVO and DME • Disease response as indicated by stabilization of visual acuity or improvement in best-corrected visual acuity (BVCA) score when compared to baseline Posterior Segment Uveitis • Stabilization of visual acuity or improvement in BVCA score when compared to baseline or improvement in vitreous haze score **AND** Dosing: 0.7 mg once every 4- 6 months
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist.
Coverage Duration	One implant per affected eye every 4 to 6 months
Other Criteria	None

Reference: Ozurdex (dexamethasone) [prescribing information]. Madison, NJ: Allergan USA Inc; December 2022.

PALONOSETRON HCL®, for injection

Product Affected

- *PALONOSETRON HCL®, for injection*

PA Criteria	Criteria Details
Billing code	J2469
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Hypersensitivity to the drug or any of its components. Limitation of use: None.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a hematologist and or oncologist
Coverage Duration	According to treatment protocol
Other Criteria	

Reference: Palonosetron HCl [package insert]. Lake Zurich, IL: Fresenius Kabi.; 2018.

PANHEMATIN® (hemin), for injection

Product Affected

- *PANHEMATIN® (hemin), for injection*

PA Criteria	Criteria Details
Billing code	J1640
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Do not use in patients with known hypersensitivity to PANHEMATIN. Limitation of use: • Before administering PANHEMATIN, consider an appropriate period of carbohydrate loading. • PANHEMATIN is not effective in repairing neuronal damage due to progression of porphyria attacks.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	6 months
Other Criteria	

Reference: Panhemantin [package insert]. Raleigh, NC: Sagent Pharmaceuticals, Inc.; 2019.

POMBILITI® (cipaglucosidase), for injection

Product affected

- *POMBILITI® (cipaglucosidase), for injection*

Criterios de PA	Detalles de los criterios
Billing Code	J1203
Covered Uses	*All FDA-approved and medically accepted indications.* FDA Indications: Used in combination with Opfolda for late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency)
Exclusion Criteria	Contraindication(s): • Pregnancy Limitations of use: None
Required Medical Information	The provider must submit supporting documentation, such as progress notes, lab results, previous treatments, and other relevant clinical information. **Confirmation of diagnosis** **AND** **Step Therapy Requirement (New Patients Only)** • The patient is considered to have started over with the non-preferred product (defined as not having used in the previous 365 days) **AND** • You must try/fail, have contraindications, or intolerance to treatment with enzyme replacement therapy (ERT), such as Lumizyme (alglucosidase alfa) and Nexviazyme (avalglucosidase alfa). **Continuation of therapy** Opfolda is usually administered orally first. One hour later, Pombiliti is given as an infusion over 4 hours as a **single dose**.
Restriction of age	Adults ≥ 18 years old
Prescriber restrictions	Prescribed by or in consultation with a geneticist, cardiologist, pulmonologist, or gastroenterologist
Duration of Coverage	1 month - a single dose

Criterios de PA	Detalles de los criterios
Other criteria	• Weight of ≥40 kg Start 2 weeks after the last previous dose of enzyme replacement (ERT). If premedication with therapy (ERT) was used, pretreatment with antihistamines, antipyretics, and/or corticosteroids should be used prior to administration.

References:

1. POMBILITI In: Lexi-drugs. Uptodate Inc; 2024. Updated September 9, 2024. Accessed September 30, 2024 https://online-lexi-com.

2. POMBILITI In: Package insert. Revised August 2024. Accessed September 27, 2024. https://www.accessdata.fda.gov/

3. Bolano-Diaz C, Diaz-Manera J. Therapeutic Options for the Management of Pompe Disease: Current Challenges and Clinical Evidence in Therapeutics and Clinical Risk Management. Ther Clin Risk Manag. 2022 Dec 13;18:1099-1115. doi: 10.2147/TCRM.S334232. PMID: 36536827; PMCID: PMC9759116.

Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) - Products

Products Affected

- *Leqvio® (inclisiran subcutaneous injection – Novartis)*

PA Criteria	Criteria Details
Billing Code	J1306
Covered Uses	*All FDA approved and medically accepted indications.* LEQVIO® is indicated as an adjunct to diet and statin therapy for the treatment of adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce low-density lipoprotein cholesterol (LDL-C).
Exclusion Criteria	Contraindication(s): • Concurrent use with Repatha or Praluent. • LEQVIO is contraindicated in patients with a prior serious hypersensitivity reaction to inclisiran or any of the excipients in LEQVIO
Required Medical Information	Provider must submit supporting documentation such as progress notes (including weight and height), laboratory results, previous treatments and other relevant clinical information. **Medical Information Requirements:** Diagnosis made by genetic confirmation, met threshold for the Dutch Lipid Network Criteria score, or Simon Broome criteria LDL-C levels before, during and after treatment **FDA Indications:** **1. Heterozygous Familial Hypercholesterolemia (HeFH).** Approve for 1 year if the patient meets ONE of the following (A or B): **A.** Initial Therapy. Approve if the patient meets the following: **i.** Patient meets one of the following (a, b, or c): **a)** Patient has an untreated low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL (prior to treatment with antihyperlipidemic agents); OR **b)** Patient has genetic confirmation of heterozygous familial hypercholesterolemia by mutations in the

PA Criteria	Criteria Details
	low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9, or low-density lipoprotein receptor adaptor protein 1 gene; OR **c)** Patient has been diagnosed with heterozygous familial hypercholesterolemia meeting one of the following diagnostic criteria thresholds [(1) or (2)]: **(1)** Prescribing physician confirms that the Dutch Lipid Network criteria score was > 5; OR **(2)** Prescribing physician confirms that Simone Broome criteria met the threshold for "definite" or "possible (or probable)" familial hypercholesterolemia; AND **ii.** Patient meets one of the following (a or b): **a)** Patient meets all of the following [(1), (2), and (3)]: **(1)** (Patient has tried one high-intensity statin therapy (i.e., atorvastatin ≥ 40 mg daily; rosuvastatin ≥ 20 mg daily [as a single entity or as a combination product]); AND **(2)** Patient has tried one high-intensity statin along with ezetimibe (as a single-entity or as a combination product) for ≥ 8 continuous weeks; AND **(3)** LDL-C level after this treatment regimen remains ≥ 70 mg/dL; OR **b)** Patient has been determined to be statin intolerant by meeting one of the following [(1) or (2)]: **(1)** Patient experienced statin-related rhabdomyolysis; ORNote: Rhabdomyolysis is statin-induced muscle breakdown that is associated with markedly elevated creatine kinase levels (at least 10 times the upper limit of normal), along with evidence of end organ damage which can include signs of acute renal injury (noted by substantial increases in serum creatinine [Scr] levels [a ≥ 0.5 mg/dL increase in Scr or doubling of the Scr] and/or myoglobinuria [myoglobin present in urine]). **(2)** Patient meets all of the following [(a),(b),and(c)]: **a)** Patient experienced skeletal-related muscle symptoms; AND

PA Criteria	Criteria Details
	Note: Examples of skeletal-related muscle symptoms include myopathy (muscle weakness) or myalgia (muscle aches, soreness, stiffness, or tenderness). **b)** The skeletal-muscle related symptoms occurred while receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or combination products); AND **c)** When receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) the skeletal-related muscle symptoms resolved upon discontinuation of each respective statin therapy (atorvastatin and rosuvastatin); ANDNote: Examples of skeletal-related muscle symptoms include myopathy and myalgia. **iii.** Medication is prescribed by or in consultation with a cardiologist, an endocrinologist, or a physician who focuses in the treatment of cardiovascular risk management and/or lipid disorders; OR **B.** Patient Currently Receiving Leqvio. Approve if according to the prescribing physician, the patient has experienced a response to therapy. Note: Examples of a response to therapy include decreasing LDL-C, total cholesterol, non-high-density lipoprotein (non-HDL-C), or apolipoprotein B levels. Also, if the patient is currently receiving the requested therapy but has not previously received approval of Leqvio for this specific indication through the Coverage Review Department, review under criteria for Initial Therapy. If the patient is restarting therapy with Leqvio, Initial Therapy criteria must be met. **2. Primary Hyperlipidemia.** * Approve for 1 year if the patient meets ONE of the following (A or B): Note: This is not associated with atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH) and may be referred to as combined hyperlipidemia,

PA Criteria	Criteria Details
	hypercholesterolemia (pure, primary), dyslipidemia, or increased/elevated low-density lipoprotein cholesterol (LDL-C) levels. **A.** Initial Therapy. Approve if the patient meets all of the following (i, ii, iii, and iv): **i.** Patient is ≥ 18 years of age; AND **ii.** Patient has a coronary artery calcium or calcification score ≥ 300 Agatston units; AND **iii.** Patient meets one of the following (a or b): **a)** Patient meets all of the following [(1]), (2), and (3)]: **(1)** Patient has tried one high-intensity statin therapy (i.e., atorvastatin ≥ 40 mg daily; rosuvastatin ≥ 20 mg daily [as a single-entity or as a combination product]); AND **(2)** Patient has tried the one high-intensity statin therapy above along with ezetimibe (as a single-entity or as a combination product) for ≥ 8 continuous weeks; AND **(3)** LDL-C level after this treatment regimen remains ≥ 100 mg/dL; OR **b)** Patient has been determined to be statin intolerant by meeting one of the following [(1) or (2)]: **(1)** Patient experienced statin-related rhabdomyolysis; OR Note: Rhabdomyolysis is statin-induced muscle breakdown that is associated with markedly elevated creatine kinase levels (at least 10 times the upper limit of normal), along with evidence of end organ damage which can include signs of acute renal injury (noted by substantial increases in serum creatinine [Scr] levels [a ≥ 0.5 mg/dL increase in Scr or doubling of the Scr] and/or myoglobinuria [myoglobin present in urine]). **(2)** Patient meets all of the following [(a), (b), and (c)]: **a)** Patient experienced skeletal-related muscle symptoms; AND

PA Criteria	Criteria Details
	Note: Examples of skeletal-related muscle symptoms include myopathy (muscle weakness) or myalgia (muscle aches, soreness, stiffness, or tenderness). **b)** The skeletal-muscle related symptoms occurred while receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or combination products); AND **c)** When receiving separate trials of both atorvastatin and rosuvastatin (as single-entity or as combination products) the skeletal-related muscle symptoms resolved upon discontinuation of each respective statin therapy (atorvastatin and rosuvastatin); AND Note: Examples of skeletal-related muscle symptoms include myopathy and myalgia. **iv.** Medication is prescribed by or in consultation with a cardiologist, an endocrinologist, or a physician who focuses in the treatment of cardiovascular risk management and/or lipid disorders; OR **B.** Patient Currently Receiving Leqvio. Approve if according to the prescribing physician, the patient has experienced a response to therapy. Note: Examples of a response to therapy include decreasing LDL-C, total cholesterol, non-high-density lipoprotein (non-HDL-C), or apolipoprotein B levels. Also, if the patient is currently receiving the requested therapy but has not previously received approval of Leqvio for this specific indication through the Coverage Review Department, review under criteria for Initial Therapy. If the patient is restarting therapy with Leqvio, Initial Therapy criteria must be met.
Age Restrictions	Patient is ≥ 18 years of age

PA Criteria	Criteria Details
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist, an endocrinologist, or a physician who focuses in the treatment of cardiovascular risk management and/or lipid disorders
Coverage Duration	**New and Continuation:** Approve for 1 year
Other Criteria	

References:

1. Leqvio® subcutaneous injection [prescribing information]. East Hanover, NJ: Novartis; December 2021.
4. Leqvio® subcutaneous injection [prescribing information]. East Hanover, NJ: Novartis; July 2023.
5. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2022 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk. *J Am Coll Cardiol*. 2022;80(14):1366-1418.
6. Stone NJ, Robinson J, Lichtenstein AH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice guidelines. *Circulation*. 2014;129(25 Suppl 2):S1-S45.
7. Grundy SM, Stone NJ, Bailey AL, et al. AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol. A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation*. 2019;139:e1082-e1143.
8. Newman CB, Blaha MJ, Boord JB, et al. Lipid management in patients with endocrine disorders: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2020;105(12):3613-3682.
9. Jacobson TA, Ito MK, Maki KC, et al. National Lipid Association recommendations for patient-centered management of dyslipidemia: Part 1-full report. *J Clin Lipidol*. 2015;9:129-169.
10. Goldberg AC, Hopkins PN, Toth PP, et al. Familial hypercholesterolemia: screening, diagnosis and management of pediatric and adult patients. *J Clin Lipidol*. 2011;5:S1-S8.
11. Gidding SS, Champagne MA, de Ferranti SD, et al. The agenda for familial hypercholesterolemia. A scientific statement from the American Heart Association. *Circulation*. 2015;132(22):2167-2192.
12. Haase A, Goldberg AC. Identification of people with heterozygous familial hypercholesterolemia. *Curr Opin Lipidol*. 2012;23:282-289.
13. Virani SS, Newby LK, Arnold SV, et al. 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA guideline for the management of patients with chronic coronary disease: a report of the

American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2023 July 14. [Online ahead of print].
14. https://www.novartis.com/us-en/sites/novartis_us/files/leqvio.pdf

PROFILNINE SD (antihemophilic factor IX complex), for injection

Product Affected

- *PROFILNINE SD (antihemophilic factor IX complex), for injection*

PA Criteria	Criteria Details
Billing code	J7194
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • None. Limitation of use: • Not indicated for the treatment of von Willebrand disease.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement
Age Restrictions	Apply.
Prescriber Restrictions	Prescribed by or in consultation with an hematologist.
Coverage Duration	6 months
Other Criteria	

Reference:

Prior Authorization Criteria for Part B drugs
Effective date: 01.01.2025
Utilization Management Committee Approval Date: 04.11.2024

Lexicomp
Profilnine SD [package insert]. Los Angeles, CA: Grifols Biologicals INC.; 2010.

QUTENZA® *(capsaicin), for topical use*

Product Affected

- QUTENZA *(capsaicin), topical*

PA Criteria	Criteria Details
Billing code	J7335
Covered Uses	*All FDA approved and medically accepted indications.* FDA Indications: • Neuropathic pain associated with postherpetic neuralgia that has persisted for at least 6 months following healing of herpes zoster rash and had an inadequate response or contraindication to Tricyclic antidepressant (e.g., amitriptyline, nortriptyline, etc.) and gabapentinoids (e.g., gabapentin) • Neuropathic pain associated with diabetic peripheral neuropathy (DPN) of the feet that has persisted for at least 1 year prior to screening and had an inadequate response or contraindication to all of the following: Antidepressants (e.g., venlafaxine, duloxetine, amitriptyline, nortriptyline, etc.) and gabapentinoids.
Exclusion Criteria	Contraindication(s): None Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Note: Do not repeat in 3 months.** **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	≥ 18 years old
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist, rheumatologist, or neurologist.
Coverage Duration	Approve medication for 12 months.

PA Criteria	Criteria Details
Other Criteria	None

Reference:

- Qutenza. [prescribing information]. Averitas Pharma, Inc.; 2023
- Qutenza. In: Lexi-Drugs. UpToDate Inc; 2024. Updated May 13, 2024. Accessed May 17, 2024. http://online.lexi.com
- Bruckenthal P, Barkin RL. Options for treating postherpetic neuralgia in the medically complicated patient. Ther Clin Risk Manag. 2013;9:329-340. doi:10.2147/TCRM.S47138
- Ortega E. Postherpetic Neuralgia. UpToDate. October 25, 2021. Accessed May 17, 2024. https://www.uptodate.com/contents/postherpetic-neuralgia.

RADICAVA (edaravone) for injection, for intravenous use

Products Affected

- RADICAVA (edaravone) for injection, for intravenous use

PA Criteria	Criteria Details
Billing code	J1301
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Hypersensitivity to edaravone or any of the ingredients (continuation therapy)
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments and other relevant clinical information Diagnosis of Amyotrophic lateral sclerosis (ALS); **AND** The following criteria: Initial request: • Patient has independence in activities of daily living • Forced vital capacity (FVC) • Absence of contraindications Continuation of therapy request: • Patient has independence in activities of daily living • Forced vital capacity (FVC) • Absence of contraindications • Tolerance and response to treatment: slowing the decline of functional abilities **AND** Must have failed riluzole: Consider edaravone as an add on therapy to riluzole. Does not tolerate riluzole, consider alone
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	None

Reference:

Product Information: RADICAVA(R) intravenous injection, edaravone intravenous injection. Mitsubishi Tanabe Pharma America Inc (per FDA), Jersey City, NJ, 2022.

REBINYN® (factor IX recombinant - GlycoPEGylated), for injection

Product Affected

- *REBINYN® (factor IX recombinant - GlycoPEGylated), for injection*

PA Criteria	Criteria Details
Billing code	J7203
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Do not use in patients with known hypersensitivity to the medication. Limitation of use: • Not indicated for induction of immune tolerance in patients with hemophilia B. • Not indicated for routine prophylaxis in the treatment of patients with hemophilia B.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	6 months
Other Criteria	

Reference: Rebinyn [package insert]. Novo Alle, Bagsvaerd: Novo Nordisk A/S.; 2017.

REBLOZYL (luspatercept-aamt) for injection, for subcutaneous use

Products Affected

- REBLOZYL (luspatercept-aamt) for injection, for subcutaneous use

PA Criteria	Criteria Details
Billing code	J0896
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): None Limitations of Use: REBLOZYL is not indicated for use as a substitute for red blood cell (RBC) transfusions in patients who require immediate correction of anemia
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments and other relevant clinical information Diagnosis confirmation of **one** of the following: • Beta Thalassemia • Myelodysplastic Syndromes Associated Anemia • Myelodysplastic Syndromes with Ring Sideroblasts or • Myelodysplastic/Myeloproliferative Neoplasm with Ring Sideroblasts and Thrombocytosis Associated Anemia **AND** Hemoglobin (Hgb) results
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist
Coverage Duration	Per cycle. Do not exceed 6 months
Other Criteria	

Reference: Product Information: REBLOZYL(R) subcutaneous injection, luspatercept-aamt subcutaneous injection. Celgene Corporation (per FDA), Summit, NJ, 2023

REMODULIN (teprostinil) for injection, for subcutaneous or intravenous use

Products Affected

- REMODULIN (teprostinil) for injection, for subcutaneous or intravenous use

PA Criteria	Criteria Details
Billing code	J3285
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments and other relevant clinical information Diagnosis Confirmation of pulmonary arterial hypertension (PAH; WHO Group 1 in patients with NYHA Class II-IV symptoms) **Continuation therapy request** • Patient stable in condition or has the patient improved while on therapy evidenced by decrease exercise-associated symptoms, delay disease progression or improve exercise ability
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	12 months
Other Criteria	None

Reference:

Remodulin (treprostinil) [prescribing information]. Research Triangle Park, NC: United Therapeutics Corp; October 2023

RETISERT® (fluocinolone acetonide implant), for intravitreal

Product Affected

- *RETISERT® (fluocinolone acetonide implant), for intravitreal*

PA Criteria	Criteria Details
Billing code	J7311
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Surgical placement of RETISERT is contraindicated in active viral, bacterial, mycobacterial and fungal infections of ocular structures. Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement, e.g., Maintenance or improvement in visual acuity.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist and retina specialist
Coverage Duration	One Time (during plan year)
Other Criteria	RETISERT is designed to release fluocinolone acetonide at a nominal initial rate of 0.6 mcg/day, decreasing over the first month to a steady state between 0.3-0.4 mcg/day over approximately 30 months.

Reference:

Retisert [package insert]. Waterford, Ireland: Bausch & Lomb Inc.; 2011.

REZZAYO® (rezafungin), for injection

Product affected

- *REZZAYO® (rezafungin), for injection*

PA Criteria	Criteria details
Billing Code	J0349
Covered Uses	*All FDA-approved and medically accepted indications.* FDA Indications: • Candinemia • Invasive candidiasis
Exclusion Criteria	Contraindication(s): • Hypersensitivity Limitation of use: • Endocarditis, osteomyelitis, and meningitis caused by candida
Required Medical Information	The provider must submit supporting documentation, such as progress notes, lab results, previous treatments, and other relevant clinical information. **Confirmation of diagnosis** **AND** **Step Therapy Requirement (New Patients Only)** • The patient is considered to have started over with the non-preferred product (defined as not having used in the previous 365 days) **AND** • Patients who have limited or no alternatives for the treatment of candinemia and invasive candidiasis. **Continuation of therapy** Tolerance and response to treatment: describe the improvement or decrease of disease activity
Restriction of age	Adults ≥ 18 years old
Prescriber restrictions	Prescribed by or in consultation with an infectious disease specialist
Duration of Coverage	1 month

PA Criteria	Criteria details
Other criteria	• Culture specimens and other laboratory data (e.g., histopathology, non-cultured diagnoses) should be obtained prior to initiating antifungal therapy.

References:

1. REZZAYO In: Lexi-drugs. Uptodate Inc; 2024. Updated August 22, 2024. Accessed September 27, 2024 https://online-lexi-com
2. REZZAYO In: Package insert. Revised August 2024. Accessed September 30, 2024. https://www.accessdata.fda.gov.

RIASTAP® (fibrogen concentrated (human)), for inyection

Product Affected

- *RIASTAP ®, Fibrinogen Concentrate (Human)Lyophilized Powder for Solution for Intravenous Injection*

PA Criteria	Criteria Details
Billing code	J7178
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): Known anaphylactic or severe systemic reactions to human plasma-derived products. Limitation of use: No indicated for dysfibrinogenemia.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	3 months
Other Criteria	RIASTAP dosing, duration of dosing and frequency of administration should be individualized based on the extent of bleeding, laboratory values, and the clinical condition of the patient.

Reference:

Riastap [package insert]. Marburg, Germany: CSL Behring GmbH.; 2021.

Rituximab - Products, for intravenous use

Products Affected

- *Riabni™ (rituximab-arrx intravenous infusion – Amgen)*
- *Rituxan® (rituximab itravenous infusion Genentech)*
- *Rituxan Hycela™ (rituximab and hyaluronidase human subcutaneous injection – Biogen and Genentech/Roche)*
- *Ruxience™ (rituximab-pvvr intravenous infusion – Pfizer)*
- *Truxima® (rituximab-abbs intravenous infusion – Celltrion/Teva)*

PA Criteria	Criteria Details
Preferred Products	Ruxience, Truxima
Non-Preferred Products	Riabni, Rituxan Hycela, Rituxan
Billing Code	Q5119 Ruxience Q5115 Truxima Q5123 Riabni J9310 Rituxan J9311 Rituxan Hycela
Covered Uses	*All FDA approved and medically accepted indications.* **Riabni, Ruxience, Rituxan, Truxima** • Non–Hodgkin's Lymphoma (NHL) • Chronic Lymphocytic Leukemia (CLL) • Rheumatoid Arthritis (RA) • Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) **Rituxan** • Pemphigus Vulgaris (PV) **Rituxan Hycela** • Follicular Lymphoma (FL) • Diffuse Large B-Cell Lymphoma (DLBCL) • Chronic Lymphocytic Leukemia (CLL)
Exclusion Criteria	Contraindication(s): None

PA Criteria	Criteria Details
Required Medical Information	Provider must submit supporting documentation such as progress notes (including weight and height), laboratory results, previous treatments and other relevant clinical information **Medical Information Requirements:** Diagnosis Confirmation (Pathology Report, Image Result, Laboratories) **AND** HBV infection Screening (Hepatitis B Laboratory) Expected result: non-reactive (Only Initial Therapy) Adult patients with Non-Hodgkin's Lymphoma (NHL) • Relapsed or refractory, low grade or follicular, CD20-positive B-cell NHL as a single agent. • Previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy. • Non-progressing (including stable disease), low-grade, CD20- positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy. • Previously untreated diffuse large B-cell, CD20-positive NHL in combination with (cyclophosphamide, doxorubicin, vincristine, and prednisone) (CHOP) or other anthracycline-based chemotherapy regimens. Pediatric patients aged 6 months and older with mature B-cell NHL and mature B-cell acute leukemia (B-AL) • Previously untreated, advanced stage, CD20-positive, diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy. Adult patients with Chronic Lymphocytic Leukemia (CLL) • Previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC). Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to severely-active RA who have inadequate response to one or more TNF antagonist therapies.

PA Criteria	Criteria Details
	Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult and pediatric patients 2 years of age and older in combination with glucocorticoids. Moderate to severe Pemphigus Vulgaris (PV) in adult patient
Age Restrictions	
Prescriber Restrictions	Prescribed by or in consultation with an hematologist & oncologist and/or rheumatologist
Coverage Duration	**New and Continuation:** **Oncology Diagnosis:** Chemotherapy/Treatment Protocol Period but no greater than 6 months **Other Diagnosis:** 1 Year
Other Criteria	**Continuation Criteria:** Progress Notes and Images Report (Examples: Mammography, PET CT scan, CT X-Ray, etc)
Exception Criteria for Step Therapy	**Rituxan Hycela** Approve if the patient meets BOTH of the following (A and B): A) Patient meets the standard Rituximab Intravenous Products Utilization Management Medical Policy criteria; AND B) Patient meets ONE of the following (i or ii): i. Patient meets both of the following (a and b): a) Patient has tried one of Ruxience or Truxima; AND b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; OR ii. Patient has already been started on or has previously received the requested rituximab intravenous product. **Riabni/Rituxan** Approve if the patient meets BOTH of the following (A and B):

PA Criteria	Criteria Details
	A) Patient meets the standard Rituximab Intravenous Products Utilization Management Medical Policy criteria; AND B) Patient meets ONE of the following (i or ii): i. Patient meets both of the following (a and b): a) Patient has tried one of Ruxience or Truxima; AND b) Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction; **OR** ii. Patient has already been started on or has previously received the requested rituximab intravenous product.

Note: All Oncology Cases must be review first by OncoHealth Team to provide an expert recommendation.

References:

1. Rituxan® [prescribing information]. South San Fransisco, CA: Genentech; December 2021.
2. Ruxience™ [prescribing information]. New York, NY: Pfizer; November 2021.
3. Truxima® [prescribing information]. North Wales, PA: Teva/Celltrion; February 2022.
4. Rituxan Hycela™ injection for SC use [prescribing information]. South San Francisco, CA: Biogen and Genentech/Roche; June 2021.
5. Riabni™ [prescribing information]. Thousand Oaks, CA: Amgen; June 2022.

RIXUBIS® (factor IX recombinant), for injection

Product Affected

- *RIXUBIS® (factor IX recombinant), for injection*

PA Criteria	Criteria Details
Billing code	J7200
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Do not use in patients with known hypersensitivity to the medication. • Disseminated intravascular coagulation (DIC). • Signs of fibrinolysis. Limitation of use: Not indicated for induction of immune tolerance in patients with hemophilia B.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	6 months
Other Criteria	

Reference:

Rixubis [package insert]. Westlake Village, CA: Baxter Healthcare Corporation.; 2014.

Ruconest (recombinant) for injection, for intravenous use

Products Affected

- Ruconest (recombinant) for injection, for intravenous use

<table>
<tr><th>PA Criteria</th><th>Criteria Details</th></tr>
<tr><td>Billing code</td><td>J0596</td></tr>
<tr><td>Covered Uses</td><td>All FDA approved and medically accepted indications.</td></tr>
<tr><td>Exclusion Criteria</td><td><u>Contraindication(s):</u>
Known or suspected allergy to rabbits and rabbit-derived products
History of immediate hypersensitivity reactions, including anaphylaxis to C1 esterase inhibitor preparations.
<u>Limitation of Use:</u> Effectiveness was not established in Hereditary Angioedema Attacks (HAE) patients with laryngeal attacks.</td></tr>
<tr><td>Required Medical Information</td><td>Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments and other relevant clinical information
Diagnosis Hereditary Angioedema Attacks (HAE)
AND
Dosing<table><tr><th>Body weight</th><th>Dose for IV Injection</th><th>Volume (mL) of Reconstituted Solution (150 IU/mL) to be administered</th></tr><tr><td>< 84 kg</td><td>50 IU/kg</td><td>Body weight divided by 3</td></tr><tr><td>≥ 84 kg</td><td>4200 IU (2 vials)</td><td>28 mL</td></tr></table>If the attack symptoms persist, an additional (second) dose can be administered at the recommended dose level. Do not exceed 4200 U per dose. No more than two doses should be administered within a 24-hour
period.</td></tr>
<tr><td>Age Restrictions</td><td>Apply</td></tr>
</table>

PA Criteria	Criteria Details
Prescriber Restrictions	Prescribed by or in consultation with an allergist, hematologist, or immunologist
Coverage Duration	6 months
Other Criteria	

Reference:

Ruconest (C1 esterase inhibitor [recombinant]) [prescribing information]. Warren, NJ: Pharming Healthcare Inc; April 2020.

SANDOSTATIN LAR DEPOT (octreotide acetate) for injection, for gluteal intramuscular use

Products Affected

- SANDOSTATIN LAR DEPOT (octreotide acetate) for injection, for gluteal intramuscular use

PA Criteria	Criteria Details
Billing code	J2353
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): None Limitation of use: In patients with carcinoid syndrome and VIPomas, the effect of Sandostatin Injection and SANDOSTATIN LAR DEPOT on tumor size, rate of growth and development of metastases, has not been determined.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information Diagnosis of **one** of the following: • Acromegaly • Carcinoid Tumors • Vasoactive Intestinal Peptide Tumors (VIPomas) **AND** Dosing: Patients **not** currently receiving Sandostatin Injection subcutaneously: • Acromegaly: 50 mcg TID Sandostatin Injection subcutaneously for 2 weeks by SANDOSTATIN LAR DEPT 20 mg intragluteally every 4 weeks for 3 months • Carcinoid Tumors and VIPomas: Sandostatin Injection subcutaneously 100-600 mcg/day in 2-4 divided doses for 2 weeks followed by SANDOSTATIN LAR DEPOT 20 mg every 4 weeks for 2 months Patients currently **receiving** Sandostatin Injection subcutaneously: • Acromegaly: 20 mg every 4 weeks for 3 months • Carcinoid Tumors and VIPomas: 20 mg every 4 weeks for 2 months Renal Impairment, Patients on Dialysis: 10 mg every 4 weeks

PA Criteria	Criteria Details
	Hepatic Impairment, Patients with Cirrhosis: 10 mg every 4 weeks
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist, gastroenterologist, or oncologist.
Coverage Duration	Approve for 6 months
Other Criteria	None

Reference: Sandostatin (octreotide injection solution) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2022.

SEVENFACT (factor VIIa recombiant), for injection

Product Affected

- *SEVENFACT (factor VIIa recombiant), for injection*

<table>
<tr><th>PA Criteria</th><th>Criteria Details</th></tr>
<tr><td>Billing code</td><td>J7212</td></tr>
<tr><td>Covered Uses</td><td>All FDA approved and medically accepted indications.</td></tr>
<tr><td>Exclusion Criteria</td><td>Contraindication(s): In patients who have manifested severe hypersensitivity reactions.
Limitation of use: Not indicated for treatment of congenital factor VII deficiency.</td></tr>
<tr><td>Required Medical Information</td><td>Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information.
Diagnosis Confirmation of Congenital Hemophilia A or B
AND
Dosing
<table>
<tr><th>Type of Bleeding</th><th>Dosing Regimen Recommendation</th></tr>
<tr><td>For Mild or Moderate bleeds</td><td>75 mcg/kg repeated every 3 hours until hemostasis is achieved
or
Initial dose of 225 mcg/kg. If hemostasis is not achieved withing 9 hour, additional 75 mcg/kg doses may be administered every 3 hours as need to achieve hemostasis</td></tr>
</table>
<table>
<tr><th>Type of Bleeding</th><th>Dosing Regimen Recommendation</th></tr>
<tr><td>For Severe bleeds</td><td>225 mcg/kg, followed if necessary 6 hours later with 75 mcg/kg every 2 hours</td></tr>
</table>
Continuation of Therapy
Tolerance and response to treatment: describe disease improvement or abatement.</td></tr>
</table>

PA Criteria	Criteria Details
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	6 months
Other Criteria	

Reference: Sevenfact [package insert]. Puteaux, France: LFB S.A..; 2022.

SIGNIFOR® LAR (pasireotide) for injectable suspension, for intramuscular use

Products Affected

- SIGNIFOR® LAR (pasireotide) for injectable suspension, for intramuscular use

PA Criteria	Criteria Details
Billing code	J2502
Covered Uses	*All FDA approved and medically accepted indications.* •
Exclusion Criteria	Contraindication(s): None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information **One** of the following diagnoses with specifications: 1. Acromegaly 2. Cushing's Disease **AND** **One** of the following types of request following criteria: Initial request • Fasting plasma glucose (FPG) • Hemoglobin A1c (HbA1c) • Electrocardiogram (ECG), • Complete Metabolic Panel (Magnesium and Potassium levels) • Liver enzyme test (**Expected Result:** Within normal range) • For acromegalia o IGF-1 and growth hormone (GH) levels o Patient has had an inadequate response to surgery/radiation or is not a candidate **OR**

PA Criteria	Criteria Details
	Continuation of therapy request: • Tolerance and response to treatment • Acromegaly: Serum GH and IGF-1 levels are useful markers of the disease and the effectiveness of treatment (Expected Results: Decreasing Levels) **AND** Dosing: **Acromegaly:** 40 mg administered by intramuscular injection once every 4 weeks (every 28 days) **Cushing's Disease:** 10 mg administered by intramuscular injection once every 4 weeks (every 28 days). Maximum recommend dose is 20mg once every 4 weeks (every 28 days)
Age Restrictions	Age ≥ 18 years
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or oncologist.
Coverage Duration	6 months
Other Criteria	Avoid use in patient with severe hepatic impairment (Child Pugh C)

Reference:

Product Information: SIGNIFOR(R) LAR intramuscular injection suspension, pasireotide intramuscular injection suspension. Novartis Pharmaceuticals Corporation (per FDA), East Hanover, NJ, 2023.

SIMULECT® (basiliximab), for injection

Product Affected

- *SIMULECT® (basiliximab), for injection*

PA Criteria	Criteria Details
Billing code	J0480
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): None Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. Simulect® should only be administered once it has been determined that the patient will receive the graft and concomitant immunosuppression. **AND** Simulect® is used as part of an immunosuppressive regimen that includes cyclosporine, USP (MODIFIED) and corticosteroids. **AND** Patients previously administered Simulect® should only be re-exposed to a subsequent course of therapy with extreme caution. **AND** A maximum tolerated dose of Simulect® has not been determined in patients. During the course of clinical studies, Simulect® has been administered to adult renal transplantation patients in single doses of up to 60 mg, or in divided doses over 3-5 days of up to 120 mg, without any associated serious adverse events.
Age Restrictions	None
Prescriber Restrictions	
Coverage Duration	5 days
Other Criteria	

Reference: Simulect [package insert]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation.; 2003.

Skyrizi (Risankizumab) for injection, for intravenous use

Products Affected

- Skyrizi (Risankizumab) for injection, for intravenous use

PA Criteria	Criteria Details
Billing code	J2327
Covered Uses	All FDA approved and medically accepted indications.
Exclusion Criteria	Contraindication(s): Patients with a history of serious hypersensitivity reaction to Risankizumab-rzaa or any of the excipients (continuation of therapy)
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments and other relevant clinical information Initial request: • Diagnosis • Documentation of disease severity, activity and risk • Past, current and concurrent medication trial, failure, contraindication or intolerance when used to treat the same indication • Absence of contraindications • Test for TB (PPD Test or Chest X-Ray) • Recent vaccination history (within the last month; if applicable) Continuation of therapy request: • Diagnosis • Absence of contraindications • Test for TB (PPD Test or Chest X-Ray) • Tolerance and response to treatment: describe disease improvement or abatement **AND** Provide at least one objective measure of disease or condition severity, including: • Crohn's disease activity index (CDAI) ○ Asymptomatic remission < 150

PA Criteria	Criteria Details
	○ Mild to moderate 150 – 220 ○ Moderate to severe 221 – 450 ○ Severely active to fulminate 451 – 1100 **CDAI calculator: https://www.mdcalc/calc/3318/crohns-disease-activity-indexcdai** **AND** Dosing: • Initial (IV): 600 mg at week 0, week 4, and week 8 • Maintenance (SC): 180-360 mg at week 12 and every 8 weeks thereafter. Use lowest effective dosage to maintain therapeutic response
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterology
Coverage Duration	Validity of the tuberculin test, up to one year
Other Criteria	Avoid use of live vaccines

References: Package insert of Abbvie: Dosing and Administration | SKYRIZI® (risankizumab-rzaa) (skyrizihcp.com)

SOLIRIS (eculizumab) for injection, for intravenous use

Products Affected

- SOLIRIS (eculizumab) for injection, for intravenous use

PA Criteria	Criteria Details
Billing code	J1300
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): Unresolved serious *Neisseria meningitidis* infection Patients who are not currently vaccinated against *Neisseria meningitidis*
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information **One** of the following diagnosis and specification: • Paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis • Atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy • Generalized myasthenia gravis (gMG) in adults who are anti-acetylcholine receptor (AchR) antibody positive • Neuromyelitis optica spectrum disorder (NMOSD) in adults who are anti-aquaporin-4 antibody positive **AND** **One** of the following types of request: Initial request: • Absence of contraindications • Evidence of compliance with REMS program requirements • Previous therapy (if applicable) **OR** Continuation of therapy request: • Absence of contraindications • Evidence of compliance with REMS program requirements • Tolerance and response to treatment **AND**

<table>
<tr><th>PA Criteria</th><th>Criteria Details</th></tr>
<tr><td></td><td>Dosing:
PNH
600 mg every 7 days for the first 4 weeks, followed by
900 mg for the 5th dose 7 days later, then
900 mg every 14 days thereafter
aHUS
900 mg weekly for the first 4 weeks, followed by
1200 mg for the fifth dose 1 week later, then
1200 mg every 14 days thereafter
Dosing recommendations in aHUS patients less than 18 years of age
<table><tr><th>Patient body weight</th><th>Induction</th><th>Maintenance</th></tr><tr><td>40 kg and over</td><td>900 mg weekly x 4 doses</td><td>1200 mg at week 5; then 1200 mg every 2 weeks</td></tr><tr><td>30 kg to less than 40 kg</td><td>600 mg weekly x 2 doses</td><td>900 mg at week 3; then 900 mg every 2 weeks</td></tr><tr><td>20 kg to less than 30 kg</td><td>600 mg weekly x 2 doses</td><td>600 mg at week 3; then 600 mg every 2 weeks</td></tr><tr><td>10 kg to less than 20 kg</td><td>600 mg weekly x 1 dose</td><td>300 mg at week 2; then 300 mg every 2 weeks</td></tr><tr><td>5 kg to less than 10 kg</td><td>300 mg weekly x 1 dose</td><td>300 mg at week 2; then 300 mg every 3 weeks</td></tr></table>gMG and NMOSD:
900 mg weekly for the first 4 weeks, followed by
1200 mg for the fifth dose 1 week later, then
1200 mg every 14 days thereafter</td></tr>
<tr><td>Age Restrictions</td><td>Apply</td></tr>
<tr><td>Prescriber Restrictions</td><td>Prescribed by or in consultation with
PNH: hematologist and/or oncologist
aHUS: hematologist/oncologist or geneticist
gMG: neurologist
NMOSD: ophthalmologist or neurologist</td></tr>
<tr><td>Coverage Duration</td><td>Initial: One month
Continuation of Therapy: 6 months</td></tr>
</table>

PA Criteria	Criteria Details
Other Criteria	**How supplied:** Soliris (eculizumab) injection is a sterile, clear, colorless, preservative-free 10 mg/mL solution for intravenous infusion and is supplied in 30-mL **single-dose vials**.

Reference: Product Information: SOLIRIS(R) intravenous injection, eculizumab intravenous injection. Alexion Pharmaceuticals Inc (per manufacturer), Boston, MA, 2019.

SOMATULINE® DEPOT (lanreotide) injection, for subcutaneous use

Products Affected

- SOMATULINE® DEPOT (lanreotide) injection, for subcutaneous use

PA Criteria	Criteria Details
Billing code	J1930
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): Hypersensitivity to lanreotide. (Continuation of Therapy)
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information One of the following diagnoses with specifications: 1. Acromegaly 2. Gastroenteropancreatic Neuroendocrine Tumors 3. Carcinoid Syndrome **AND** **Step Therapy Requirement** a. The patient is considered a new start to the non-preferred product (defined as no use in the previous 365 days) **AND** **b.** Must try/fail, have contraindication to, or intolerance to Lanreotide Acetate and/or Sandostatin LAR Depot. **AND** **One** of the following types of request following criteria: Initial request • For acromegalia o IGF-1 and growth hormone (GH) levels o Patient has had an inadequate response to surgery/radiation or is not a candidate **OR** Continuation of therapy request: • Tolerance and response to treatment

PA Criteria	Criteria Details
	• Acromegaly: Serum GH and IGF-1 levels are useful markers of the disease and the effectiveness of treatment (Expected Results: Decreasing Levels) **AND** Dosing: Acromegaly • Initial dose may range from 60 mg to 120 mg every 4 weeks. Recommended starting dose is 90 mg every 4 weeks for 3 months o Moderate and severe renal and hepatic impairment: Initial dose is 60 mg every 4 weeks for 3 months GEP-NET • Recommended dose is 120 mg every 4 weeks Carcinoid Syndrome • Recommended dose is 120 mg every 4 weeks
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with an endocrinologist or oncologist.
Coverage Duration	6 months
Other Criteria	Adjustment in dose is based on growth hormone (GH) and/or IGF-1 levels.

Note: All Oncology Cases must be review first by OncoHealth Team to provide an expert recommendation.

Reference:

Product Information: SOMATULINE(R) DEPOT subcutaneous injection, lanreotide subcutaneous injection. Ipsen Biopharmaceuticals Inc (per FDA), Basking Ridge, NJ, 2023.

SPEVIGO® (spesolimab-sbzo), for injection

Product Affected

- *SPEVIGO® (spesolimab-sbzo), for injection*

PA Criteria	Criteria Details
Billing code	J1747
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): Severe or life-threatening hypersensitivity to spesolimab-sbzo or to any of the excipients in SPEVIGO. Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. Generalized Pustular Psoriasis (GPP) flares **AND** Negative test for Tuberculosis (TB) (PPD Test or Chest X-Ray) **AND** Dosing: Administer SPEVIGO as a single 900 mg dose by intravenous infusion over 90 minutes. If GPP flare symptoms persist, an additional intravenous 900 mg dose (over 90 minutes) may be administered one week after the initial dose.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist and or dermatologist
Coverage Duration	2 weeks
Other Criteria	

Reference:

Spevigo [package insert]. Ridgefield, Connecticut: Boehringer Ingelheim Pharmaceuticals, Inc.; 2022.

Prior Authorization Criteria for Part B drugs
Effective Date: 01.01.2025
Utilization Management Committee Approval Date: 04.11.2024

SPINRAZA (nusinersen) for injection, for intrathecal use

Products Affected

- SPINRAZA (nusinersen) for injection, for intrathecal use

PA Criteria	Criteria Details
Billing code	J2326
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): None

Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments and other relevant clinical information
	Diagnosis of Spinal muscular atrophy (SMA); **AND**
	The following criteria:
	Initiation Request:
	• Documentation confirming genetic diagnosis (At lest **ONE)**
	  o Homozygous gene deletion or mutation
	  o Compound heterozygous mutation
	• Baseline results of at least **ONE** of the following exams of motor ability
	  o Hammersmith Infant Neurological 9HINE) (infant to early childhood)
	  o Hammersmith Functional Motor Scale Expanded (HFMSE)
	  o Upper Limb Module (ULM) TEST (Non ambulatory)
	  o Children's Hospital of Philadelphia Infant Test of Neuromuscular disorders (CHOP INTEND)
	• Documentation of patient history (mechanical ventilation, bacterial meningitis, brain or spinal cord disease
	• Previous therapy
	• Concurrent therapy
	• Monitoring parameters:
	  o Platelet count
	  o Prothrombin time; activated partial thromboplastin time
	  o Quantitative spot urine protein
	Continuation of therapy request:
	• Previous therapy

PA Criteria	Criteria Details

	• Concurrent therapy
	• Recent (< 1 month prior to request) post-treatment results of at least one of the following exams of motor ability
	  o Hammersmith Infant Neurological 9HINE) (infant to early childhood)
	  o Hammersmith Functional Motor Scale Expanded (HFMSE)
	  o Upper Limb Module (ULM) TEST (Non ambulatory)
	  o Children's Hospital of Philadelphia Infant Test of Neuromuscular disorders (CHOP INTEND)
	• Tolerance and response to treatment: describe disease improvement or abatement (e.g., in motor ability, in motor milestones)
	AND
	Laboratory tests should be obtained within several days prior to administration.
	AND
	Dosing:
	• 12 mg (5 mL)
	• Initial dose: 4 loading doses. The first 3 doses should be administered at 14-day intervals; the 4th dose should be administered 30 days after the 3rd dose
	• Maintenance Dose: Once every 4 months thereafter

Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a neurologist
Coverage Duration	Initiation request: 1 year (No more than 6 intrathecal injections) Continuation request: 1 year (After the first 12 months of treatment, no more that 3 intrathecal injections)
Other Criteria	None

Reference:

Product Information: SPINRAZA(R) intrathecal injection, nusinersen intrathecal injection. Biogen Inc (per manufacturer), Cambridge, MA, 2018.

STELARA ® *(ustekinuma), for intravenous use*

Product Affected

- STELARA® *(ustekinumab), for intravenous use*

PA Criteria	Criteria Details
Billing code	J3358
Covered Uses	*All FDA approved and medically accepted indications.* FDA Indications: • Moderate to severe active Crohn's disease • Moderate to severe active ulcerative colitis
Exclusion Criteria	Contraindication(s): • In patients with hypersensitivity to this medication. Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Diagnosis confirmation** **AND** **Step Therapy Requirement (Only for New Patients in Therapy)** a. The patient is considered a new start to the non-preferred product (defined as no use in the previous 365 days) **AND** b. Must try/fail, have contraindication to, or intolerance to one of the following: Inflectra, Renflexis or Avsola prior to receiving STELARA. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	≥ 18 years old.
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist.

PA Criteria	Criteria Details
Coverage Duration	Approve medication for 12 months.
Other Criteria	• Screening for TB latent infection is required before starting treatment. • Discard live vaccines in previous month. These criteria only apply for the intravenous administration. The subcutaneous formulation must be evaluated according to the Article (A52571) Self-Administered Drug exclusion list.

Reference:

1.STELARA [package insert]. Janssen Biotech, Inc., Horsham, PA, 2024
2.STELARA. Micromedex (electronic version). IBM Watson Health; 2019. Accessed June 3, 2024. https://www.micromedexsolutions.com

SUSVIMO™ (ranibizumab injection) for intravitreal use via SUSVIMO ocular implant

Products Affected

- SUSVIMO™ (ranibizumab injection) for intravitreal use via SUSVIMO ocular implant

PA Criteria	Criteria Details
Billing code	J2779
Covered Uses	*All FDA approved and medically accepted indications.* **FDA Indication:** Neovascular (Wet) Age-Related Macular Degeneration (AMD) who have previously responded to at least two intravitreal injections of a VEGF inhibitor
Exclusion Criteria	Contraindication(s): Ocular or Periocular Infections **OR** Active Intraocular Inflammation **OR** Hypersensitivity (Continuation therapy)
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information Diagnosis Confirmation of **one** of the followings: a. Neovascular (Wet) Age-Related Macular Degeneration (nAMD) who have previously responded to at least two intravitreal injections of a VEGF inhibitor **AND** Dosing: AMD: 2 mg (0.02 mL of 100 mg/mL solution) continuously delivered via the SUSVIMO implant with refills every 24 weeks (approximately 6 months). **AND (If applicable)** **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement, e.g., Maintenance or improvement in visual acuity
Age Restrictions	Apply

PA Criteria	Criteria Details
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist and/or retina specialist
Coverage Duration	6 months
Other Criteria	**How supplied:** SUSVIMO 100 mg/mL **single-dose glass vial** **Note:** Supplemental treatment with 0.5 mg (0.05 mL of 10 mg/mL) intravitreal ranibizumab injection may be administered in the affected eye while the SUSVIMO implant is in place and if clinically necessary

Reference:

Product Information: SUSVIMO(TM) intravitreal injection implant, ranibizumab intravitreal injection implant. Genentech Inc (per FDA), South San Francisco, CA, 2022.

SYFOVRE (pegcetacoplan) for injection, for intravenous use

Products Affected

- SYFROVRE (pegcetacoplan) for injection, for intravenous use

PA Criteria	Criteria Details
Billing code	J2781
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Ocular or periocular infections • Active intraocular inflammation
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information Diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) **AND** Confirm that the macular atrophy is not secondary to any conditions other than AMD. **AND** Dosing: 15 mg (0.1 mL) into affected eye once every 25 to 60 days **Continuation Request** o Physician attestation that patient would benefit from continued administration o Documentation of titration to the minimum dosing frequency to achieve maximum benefit
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist (retina specialist)
Coverage Duration	12 months
Other Criteria	

Reference: Product Information: SYFOVRE(TM) intravitreal injection, pegcetacoplan intravitreal injection. Apellis Pharmaceuticals Inc (per manufacturer), Waltham, MA, 2023.

Tezspire® (tezepelumab-ekko), injection, for subcutaneous use

Products Affected

- *Tezspire® (tezepelumab-ekko subcutaneous injection – AstraZeneca/Amgen)*

PA Criteria	Criteria Details
Billing Code	Tezspire J2356
Covered Uses	*All FDA approved and medically accepted indications.* **Severe Asthma**
Exclusion Criteria	Contraindication(s): Conditions not recommended for approval: 1. Atopic Dermatitis 2. Chronic Obstructive Pulmonary Disease (COPD) 3. Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP) 4. Chronic Spontaneous Urticaria 5. Concurrent use of Tezspire with another Monoclonal Antibody Therapy (i.e., Cinqair, Fasenra, Nucala, Dupixent, Xolair, or Adbry)
Required Medical Information	Provider must submit supporting documentation such as progress notes (including weight and height), laboratory results, previous treatments and other relevant clinical information Tezspire is listed as an option for add-on therapy in patients ≥ 12 years of age with difficult-to-treat, severe asthma (i.e., asthma that cannot be managed by therapy with an ICS/LABA combination with or without an additional controller Uncontrolled asthma is defined as asthma that worsens upon tapering of high-dose ICS or systemic corticosteroids or asthma that meets one of the following four criteria: 1) Poor symptom control: Asthma Control Questionnaire consistently ≥ 1.5 or Asthma Control Test < 20; 2) Frequent severe exacerbations: two or more bursts of systemic corticosteroids in the previous year; 3) Serious exacerbations: at least one hospitalization, intensive care unit stay, or mechanical ventilation in the previous year; 4) Airflow limitation: forced expiratory volume in 1 second (FEV_1) < 80% predicted after appropriate bronchodilator withholding.

PA Criteria	Criteria Details
	1)Asthma. Approve Tezspire for the duration noted if the patient meets one of the following conditions (A or B): **A)** Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, iii, and iv): **i.** Patient is ≥ 12 years of age; AND **ii.** Patient has received at least 3 consecutive months of combination therapy with BOTH of the following (a and b): **a)** An inhaled corticosteroid; AND **b)** At least one additional asthma controller or asthma maintenance medication; AND Note: Examples of additional asthma controller or asthma maintenance medications are inhaled long-acting beta$_2$-agonists, inhaled long-acting muscarinic antagonists, leukotriene receptor antagonists, and monoclonal antibody therapies for asthma (e.g., Tezspire, Cinqair [reslizumab intravenous infusion], Fasenra [benralizumab subcutaneous injection], Nucala [mepolizumab subcutaneous injection]), Dupixent [dupilumab subcutaneous injection], Xolair [omalizumab subcutaneous injection]). Use of a combination inhaler containing both an inhaled corticosteroid and additional asthma controller/maintenance medication(s) would fulfill the requirement for both criteria a and b. **iii.** Patient has asthma that is uncontrolled or was uncontrolled at baseline as defined by ONE of the following (a, b, c, d, or e): Note:"Baseline" is defined as prior to receiving Tezspire or another monoclonal antibody therapy for asthma. Examples of monoclonal antibody therapies for asthma include Cinqair, Dupixent, Fasenra, Nucala, Tezspire, and Xolair. **a)** Patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR **b)** Patient experienced one or more asthma exacerbation(s) requiring a hospitalization, an emergency department visit, or an urgent care visit in the previous year; OR

PA Criteria	Criteria Details
	c) Patient has a forced expiratory volume in 1 second (FEV_1) < 80% predicted; OR **d)** Patient has an FEV_1/forced vital capacity (FVC) < 0.80; OR **e)** Patient has asthma that worsens upon tapering of oral (systemic) corticosteroid therapy; AND **iv.** The medication is prescribed by or in consultation with an allergist, immunologist, or pulmonologist. **B)** Patient is Currently Receiving Tezspire. Approve for 1 year if the patient meets the following criteria (i, ii, and iii): **i.** Patient has already received at least 6 months of therapy with Tezspire; AND Note: A patient who has received < 6 months of therapy or who is restarting therapy with Tezspire should be considered under criterion 1A (Asthma, Initial Therapy). **ii.** Patient continues to receive therapy with one inhaled corticosteroid or one inhaled corticosteroid-containing combination inhaler; AND **iii.** Patient has responded to therapy as determined by the prescriber. Note: Examples of a response to Tezspire therapy are decreased asthma exacerbations; decreased asthma symptoms; decreased hospitalizations, emergency department, urgent care, or medical clinic visits due to asthma; improved lung function parameters; and/or a decreased requirement for oral corticosteroid therapy.
Age Restrictions	Patient is ≥ 12 years of age
Prescriber Restrictions	Prescribed by or in consultation with an allergist, immunologist, or pulmonologist.
Coverage Duration	**New:** Approve for 6 months **Continuation:** Approve for 1 year
Other Criteria	

References:

1. Tezspire® subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; December 2021.
2. Menzies-Gow A, Corren J, Bourdin A, et al. Tezepelumab in adults and adolescents with severe, uncontrolled asthma. *N Engl J Med*. 2021;384(19):1800-1809.
3. Corren J, Parnes JR, Wang L, et al. Tezepelumab in adults with uncontrolled asthma. *N Engl J Med*. 2017;377(10):936-946.
4. Global Initiative for Asthma. Global strategy for asthma management and prevention. Updated 2022. Available at: http://www.ginasthma.org. Accessed on: January 17, 2023.
5. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. *Eur Respir J*. 2014;43:343-373.
6. Holguin F, Cardet JC, Chung KF, *et al*. Management of severe asthma: a European Respiratory Society/American Thoracic Society Guideline. *Eur Respir J*. 2020;55:1900588.
7. Simpson EL, Parnes JR, She D, et al. Tezepelumab, an anti-thymic stromal lymphopoietin monoclonal antibody, in the treatment of moderate to severe atopic dermatitis: a randomized phase 2A clinical trial. *J Am Acad Dermatol*. 2019;80(4):1013-1021.
8. US National Institutes of Health. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2023 Jan 17]. Available from: https://www.clinicaltrials.gov/ct2/results?cond=&term=tezepelumab&cntry=&state=&city=&dist=. Search term: tezepelumab.

THROMBATE III® (antithrombian III (human)), for injection

Product Affected

- *THROMBATE III® (antithrombian III (human)), for injection*

PA Criteria	Criteria Details
Billing code	J7197
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): None Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. Diagnosis of hereditary antithrombin deficiency **AND** **One** of the following uses: • Treatment and prevention of thromboembolism • Prevention of peri-operative and peri-partum thromboembolism **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	6 months
Other Criteria	

Reference: Thrombate III [package insert]. Research Triangle Pack, NC: Grifols Therapeutics LLC.; 2019.

Prior Authorization Criteria for Part B drugs
Effective Date: 01.01.2025
Utilization Management Committee Approval Date: 04.11.2024

TOBI® (tobramycin), for oral inhalation

Product Affected

- *TOBI® (tobramycin), for oral inhalation*

PA Criteria	Criteria Details
Billing code	J7682
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): In patients with known hypersensitivity to any aminoglycoside. Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a pneumologist.
Coverage Duration	6 months
Other Criteria	

Reference: Tobi [package insert] East Hanover, New Jersey: Novartis Pharmaceutical Corporation.; 2018.

Trastuzumab, for subcutaneous and intravenous use

Products Affected

- *Herceptin Hylecta™ (trastuzumab and hyaluronidase-oysk for subcutaneous use – Genentech)*
- *Herceptin® (trastuzumab injection for intravenous use – Genentech)*
- *Herzuma® (trastuzumab-pkrb injection for intravenous use – Celltrion)*
- *Kanjinti™ (trastuzumab-anns injection for intravenous use – Amgen)*
- *Ogivri™ (trastuzumab-dkst injection for intravenous use – Mylan)*
- *Ontruzant® (trastuzumab-dttb injection for intravenous use – Merck)*
- *Trazimera™ (trastuzumab-qyyp injection for intravenous use – Pfizer)*

PA Criteria	Criteria Details
Preferred Products	Kanjinti, Trazimera
Non-Preferred Products	Herceptin, Herceptin Hylecta, Herzuma, Ogivri, Ontruzant
Billing Code	J9356 - Herceptin Hylecta J9355 - Herceptin: Q5113 - Herzuma Q5117 - Kanjinti Q5114 - Ogivri Q5112 - Ontruzant Q5116 - Trazimera
Covered Uses	*All FDA approved and medically accepted indications.* **Adjuvant Breast Cancer** **Metastatic Breast Cancer** **Metastatic Gastric Cancer**
Exclusion Criteria	Contraindication(s): None
Required Medical Information	Provider must submit supporting documentation such as progress notes (including weight and height), laboratory results, previous treatments and other relevant clinical information **HER2- positive Breast Cancer and Metastatic HER2-positive breast cancer** Approve if the patient meets the following criteria (A, B and C):

PA Criteria	Criteria Details
	A. Patient is ≥ 18 years of age; AND B. The patient has human epidermal growth factor receptor 2 (HER2)-positive disease; AND C. Patient meets ONE of the following criteria (i or ii): **i.** Approve for 1 year (total) if trastuzumab is used for neoadjuvant (preoperative)/adjuvant therapy; OR **ii.** Approve for 1 year if trastuzumab is used for recurrent or metastatic disease. **Gastric, Esophageal, or Gastroesophageal (GE) Junction Cancer** Approve for 1 year if the patient meets the following criteria (A, B, C and D): A. Patient is ≥ 18 years of age; AND B. Patient has locally advanced or metastatic disease; AND C. Patient has human epidermal growth factor receptor 2 (HER2)-positive disease; AND D. Patient meets the following criteria (i and ii): o Trastuzumab will be used as first-line therapy; AND o Trastuzumab will be used in combination with chemotherapy; AND Note: Examples of chemotherapy are cisplatin, oxaliplatin, capecitabine, 5-fluorouracil [5-FU].
Age Restrictions	Patient is ≥ 18 years of age
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	**New and Continuation:** Chemotherapy Protocol Period but no greater than 6 months.
Other Criteria	
Exception Criteria for Step Therapy	**Herceptin, Herzuma, Ogivri, Ontruzant**: **1.** Approve if the patient meets BOTH of the following (A and B): **A)** The patient meets the standard *Oncology – Trastuzumab Products* ***Medicare Advantage*** *Utilization Review (Medical) Policy* criteria; AND **B)** The patient meets ONE of the following (i or ii): **i.** Patient meets both of the following (a and b): **a)** Patient has tried one of Kanjinti or Trazimera; AND **b)** Patient cannot continue to use the Preferred Product due to a formulation difference in the inactive ingredient(s) [e.g., differences in

PA Criteria	Criteria Details
	stabilizing agent, buffering agent, and/or surfactant], which according to the prescriber, would result in a significant allergy or serious adverse reaction]; OR **ii.** The patient is currently taking the requested agent or has previously taken the requested agent within the past 365 days. **Herceptin, Hylecta:** **1.** Approve if the patient meets BOTH of the following (A and B): **A)** The patient meets the standard *Oncology – Herceptin Hylecta* ***Medicare Advantage*** *Utilization Review (Medical) Policy* criteria; AND **B)** The patient meets ONE of the following (i, ii, or iii): **i.** Patient has tried one of Kanjinti or Trazimera, but according to the prescriber, cannot continue to use this product; OR **ii.** The patient cannot continue on trastuzumab intravenous products due to an inability to obtain or maintain intravenous access; OR **iii.** The patient is currently taking Herceptin Hylecta or has previously taken Herceptin Hylecta within the past 365 days.

Note: All Oncology Cases must be review first by OncoHealth Team to provide an expert recommendation.

References:

1. Herceptin® injection for intravenous use [prescribing information]. South San Francisco, CA: Genentech, Inc.; November 2018.
2. Herzuma® injection for intravenous use [prescribing information]. North Wales, PA: Teva Pharmaceuticals; May 2019.
3. Kanjinti™ injection for intravenous use [prescribing information]. Thousand Oaks, CA: Amgen; June 2019.
4. Ogivri™ injection for intravenous use [prescribing information]. Steinhausen, Switzerland: Mylan; April 2019.
5. Trazimera™ injection for intravenous use [prescribing information]. New York, NY: Pfizer; March 2019.
6. Herceptin Hylecta™ for subcutaneous use [prescribing information]. South San Francisco, CA: Genentech, Inc.; February 2019.
7. Centers for Medicare and Medicaid Services. First Coast Service Options, Inc. Local Coverage Determination (LCD): Trastuzumab – Trastuzumab Biologics (L34026) [Original effective date: 10/01/2015; Revision effective date: 10/01/2019]. Accessed on July 10, 2020.

8. Centers for Medicare and Medicaid Services. First Coast Service Options, Inc. Local Coverage Article: Billing and Coding: Trastuzumab – Trastuzumab Biologics (A56660) [Original effective date: 10/03/2018]. Accessed on July 10, 2020.
9. Herceptin® intravenous infusion [prescribing information]. South San Francisco, CA: Genentech; February 2021.
10. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 4.2023 – March 23, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 21, 2023.
11. The NCCN Colon Clinical Practice Guidelines in Oncology (version 2.2023 – April 25, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 21, 2023.
12. The NCCN Rectal Clinical Practice Guidelines in Oncology (version 3.2023 – May 26, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 21, 2023.
13. The NCCN Gastric Clinical Practice Guidelines in Oncology (version 1.2023 – March 10, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 21, 2023.
14. The NCCN Esophageal and Esophagogastric Junction Cancers Clinical Practice Guidelines in Oncology (version 2.2023 – March 10, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 21, 2023.
15. The NCCN Head and Neck Cancers Clinical Practice Guidelines in Oncology (version 2.2023 – May 15, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 21, 2023.
16. The NCCN Biliary Tract Cancers Clinical Practice Guidelines in Oncology (version 2.2023– May 10, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 21, 2023.
17. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 2.2023 – April 28, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 21, 2023.
18. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 21, 2023. Search term: trastuzumab.
19. Centers for Medicare and Medicaid Services. First Coast Service Options, Inc. Local Coverage Determination (LCD): Trastuzumab – Trastuzumab Biologics (L34026) [Original effective date: 10/01/2015; Revision effective date: 10/01/2019]. Accessed on July 28, 2023.
20. Centers for Medicare and Medicaid Services. First Coast Service Options, Inc. Local Coverage Article: Billing and Coding: Trastuzumab – Trastuzumab Biologics (A56660) [Original effective date: 10/03/2018; Revision effective date: 10/1/2021]. Accessed on July 28, 2023.

TRELSTAR® (triptorelin pamoate), for injection

Product Affected

- *TRELSTAR® (triptorelin pamoate), for injection*

PA Criteria	Criteria Details
Billing code	J3315
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Hypersensitivity to triptorelin or any other component of the product, or other GnRH agonists or GnRH. Limitation of use: None.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply.
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	6 months
Other Criteria	

Reference:

Lexicomp
Trelstar [package insert]. Ra'anana, Israel: Mixject.; 2018.

TRETTEN® (factor XIIIa-subunit recombinant), for injection

Product Affected

- *TRETTEN® (factor XIIIa-subunit recombinant), for injection*

PA Criteria	Criteria Details
Billing code	J7181
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Hypersensitivity to the active substance or to any of the excipients. Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	None.
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	6 months
Other Criteria	

Reference: Tretten [package insert]. Bagsvaerd, Denmark: Novo Nordisk Inc.; 2020.

TROGARZO® (ibalizumab-uiyk), for injection

Product Affected

- *TROGARZO® (ibalizumab-uiyk), for injection*

PA Criteria	Criteria Details
Billing code	J1746
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): None Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply.
Prescriber Restrictions	
Coverage Duration	12 months
Other Criteria	

Reference: Trogarzo [package insert]. Irvine, California: TaiMed Biologics USA Corp.; 2022.

Tysabri® (natalizumab), for intravenous use

Products Affected

- *Tysabri® (natalizumab– Biogen), for intravenous use, infusion*

PA Criteria	Criteria Details
Billing Code	J2323
Covered Uses	*All FDA approved and medically accepted indications.* • **Multiple Sclerosis (MS)** • **Crohn's Disease (CD)**
Exclusion Criteria	Contraindication(s): Patients who have or have had Progressive Multifocal Leukoencephalopathy (PML). Limitations of Use: In Chron's Disease, should not be used in combination with immunosuppressants or inhibitors of TNF-α.
Required Medical Information	Provider must submit supporting documentation such as progress notes (including weight and height), laboratory results, previous treatments, and other relevant clinical information. **Medical Information Requirements:**
Age Restrictions	Patient is ≥ 18 years of age
Prescriber Restrictions	To be prescribed by or in consultation with a physician who specializes in the condition being treated.
Coverage Duration	**Multiple Sclerosis- Initial and Continuation**: Approve for 1 year. **Crohn's Disease** **Initial Therapy:** Approve for 6 months. **Continuation**: Approve for 1 year.
Other Criteria	**Continuation Criteria:** Extended approvals are allowed if the patient continues to meet the Criteria and Dosing.

References:

1. Tysabri® intravenous infusion [prescribing information]. Cambridge, MA: Biogen; October 2023.
2. A Consensus Paper by the Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis. Updated September 2019. Available at: https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf. Accessed on November 10, 2023.
3. McGinley MP, Goldschmidt C, Rae-Grant AD. Diagnosis and treatment of multiple sclerosis. A review. *JAMA*. 2021;325(8):765-779.
4. No authors listed. Drugs for multiple sclerosis. *Med Lett Drugs Ther*. 2021;63(1620):42-48.
5. Lublin FD, Reingold SC, Cohen JA, et al. Defining the clinical course of multiple sclerosis: the 2013 revisions. *Neurology*. 2014;83:278-286.
6. Thompson AJ, Banwell BL, Barkhof F, et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *Lancet Neurol*. 2018;17(2):162-173.
7. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: disease-modifying therapies for adults with multiple sclerosis. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. *Neurology*. 2018;90:777-788.
8. Torres J, Mehandru S, Solombel JF, Peyrin-Biroulet L. Crohn's disease. *Lancet*. 2017;389(10080):1741-1755.
9. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's Disease in Adults. *Am J Gastroenterol*. 2018;113;481-517.
10. Gordon FH, Hamilton MI, Donoghue S, et al. A pilot study of treatment of active ulcerative colitis with natalizumab, a humanized monoclonal antibody to alpha-4 integrin. *Aliment Pharmacol Ther*. 2002;16:699-705.

TYVASO (teprostinil) for injection, for subcutaneous or intravenous use

Products Affected

- TYVASO (teprostinil) for injection, for subcutaneous or intravenous use

PA Criteria	Criteria Details
Billing code	J3285
Covered Uses	All FDA approved and medically accepted indications.
Exclusion Criteria	Contraindication(s): None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information Diagnosis of PAH, Intestitial lung disease- pulmonary hypertension; **AND** The following criteria: Initial request: • History of previous medication use for patient's diagnosis (for example Epoprostenol, Ambrisentan and Tadalafil). • Clinical documentation supporting medication use (patients with rapid or progressive disease). • RHC (Right Heart Catheterization) and Acute Vasoreactivity Testing Negative. Continuation of therapy request: • Patient stable in condition or has the patient improved while on therapy evidenced by decrease exercise associated symptoms, delay disease progression or improve exercise ability. **AND** Dosing: **PAH in patients with WHO Group 1 or NYHA Functional Class II:** • Initial dose for patients new to prostacyclin infusion therapy: 1.25 ng/kg/min (or 0.625 ng/kg/min if not tolerated) • Mild to moderate hepatic insufficiency: Initial dose should be decreased to 0.625 ng/kg/min ideal body weight
Age Restrictions	Apply

PA Criteria	Criteria Details
Prescriber Restrictions	Prescribed by or in consultation with a cardiologist or pulmonologist
Coverage Duration	2 months
Other Criteria	None

Reference:

Nnenna L. Iheagwara, P. (2010, August 19). *Pharmacologic treatment of pulmonary hypertension*. U.S. Pharmacist – The Leading Journal in Pharmacy. https://www.uspharmacist.com/article/pharmacologic-treatment-of-pulmonary-hypertension

Reference ID: 3014913 - Food and Drug Administration. (n.d.). https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021344s015lbl.pdf

TYVASO® (treprostinil), for oral inhalation

Product Affected

- *TYVASO® (treprostinil), for oral inhalation*

PA Criteria	Criteria Details
Billing code	J7686
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): None. Limitation of use: None.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply.
Prescriber Restrictions	Prescribed by or in consultation with a pneumologist.
Coverage Duration	6 months
Other Criteria	

Reference:

Lexicomp
Tyvaso [package insert]. Research Triangle Park, North Carolina: United Therapeutics Corp.; 2022.

Ultomiris® (ravulizumab-cwvz) for intravenous use

Products Affected

- *Ultomiris® (ravulizumab-cwvz– Alexion) for intravenous use, infusion*

PA Criteria	Criteria Details
Billing Code	J1303
Covered Uses	*All FDA approved and medically accepted indications.* • Atypical Hemolytic Uremic Syndrome • Generalized Myasthenia Gravis • Neuromyelitis Optica Spectrum Disorder • Paroxysmal Nocturnal Hemoglobinuria
Exclusion Criteria	Contraindication(s): Initiation in patients with unresolved serious *Neisseria meningitidis* infection. Limitation of use: Not indicated for the treatment of patients with Shiga toxin *Escherichia coli*-related hemolytic uremic syndrome.
Required Medical Information	Provider must submit supporting documentation such as progress notes (including weight and height), laboratory results, previous treatments and other relevant clinical information. **Medical Information Requirements:** **1. Atypical Hemolytic Uremic Syndrome.** Patient meets the following (A): **A)** Patient does not have Shiga toxin *Escherichia coli*-related hemolytic uremic syndrome **2. Generalized Myasthenia Gravis.** Patient meets ONE of the following (A or B): **A)** Initial Therapy. Patient meets the following (i, ii, iii, and iv): **i.** Patient is ≥ 18 years of age; AND **ii.** Patient has confirmed anti-acetylcholine receptor antibody-positive generalized myasthenia gravis; AND **iii.** Patient meets both of the following (a and b):

PA Criteria	Criteria Details
	a) Myasthenia Gravis Foundation of America classification of II to IV; AND **b)** Myasthenia Gravis Activities of Daily Living (MG-ADL) score of ≥ 6; AND **iv.** Patient has evidence of unresolved symptoms of generalized myasthenia gravis. Note: Evidence of unresolved symptoms of generalized myasthenia gravis includes difficulty swallowing, difficulty breathing, and a functional disability resulting in the discontinuation of physical activity (e.g., double vision, talking, impairment of mobility). **B)** Patient is Currently Receiving Ultomiris. Patient meets the following (i, and ii): **i.** Patient is ≥ 18 years of age; AND **ii.** Patient is continuing to derive benefit from Ultomiris, according to the prescriber. Note: Examples of derived benefit include reductions in exacerbations of myasthenia gravis, improvements in speech, swallowing, mobility, and respiratory function. **3. Paroxysmal Nocturnal Hemoglobinuria.** Patient meets ONE of the following (A or B): **A)** Initial Therapy. Patient meets the following (i): **i.** Diagnosis was confirmed by peripheral blood flow cytometry results showing the absence or deficiency of glycosylphosphatidylinositol (GPI)-anchored proteins on at least two cell lineages; OR **B)** Patient is Currently Receiving Soliris. Patient meets the following (i): **i.** Patient is continuing to derive benefit from Soliris, according to the prescriber. Note: Examples of derived benefit include stabilization

PA Criteria	Criteria Details
	of hemoglobin levels, decreased transfusion requirements or transfusion independence, reductions in hemolysis.
Age Restrictions	**Atypical Hemolytic Uremic Syndrome or Paroxysmal Nocturnal Hemoglobinuria:** Patients is ≥ 1 month of age. **Generalized Myasthenia Gravis:** Patient is ≥ 18 years of age.
Prescriber Restrictions	To be prescribed by or in consultation with a physician who specializes in the condition being treated. **1. Atypical Hemolytic Uremic Syndrome:** Nephrologist. **2. Generalized Myasthenia Gravis:** Neurologist. **3. Paroxysmal Nocturnal Hemoglobinuria:** Hematologist.
Coverage Duration	**Atypical Hemolytic Uremic Syndrome:** 1 year **Generalized Myasthenia Gravis**: **a. Initial Therapy**: 6 months **b. Patient is Currently Receiving Ultomiris**: 1 year **Paroxysmal Nocturnal Hemoglobinuria:** **a. Initial Therapy:** 6 months **b. Patient is Currently Receiving Ultomiris**: 1 year
Other Criteria	**Continuation Criteria:** Extended approvals are allowed if the patient continues to meet the Criteria and Dosing.

References:

1. Ultomiris® intravenous infusion and subcutaneous injection [prescribing information]. New Haven, CT: Alexion; July 2022.
2. Campistol JM, Arias M, Ariceta G, et al. An update for atypical haemolytic uraemic syndrome: diagnosis and treatment. A consensus document. *Nefrologia*. 2015;35:421–447.
3. Genetics Home Reference. Atypical hemolytic-uremic syndrome. National Institutes of Health (NIH). Available at: https://ghr.nlm.nih.gov/condition/atypical-hemolytic-uremic-syndrome#sourcesforpage. Accessed on September 18, 2023.
4. National Institute of Neurological Disorders and Stroke (NINDS). Myasthenia Gravis. Updated March 2020. Available at: https://www.ninds.nih.gov/sites/default/files/migrate-documents/myasthenia_gravis_e_march_2020_508c.pdf. Accessed on September 18, 2023.
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7. Shah N, Bhatt H. Paroxysmal nocturnal hemoglobinuria. Stat Pearls [Internet]. Treasure Island (FL): StatPearls Published; 2021 Jan. 2020 Dec 1.
8. Roth A, Maciejewski J, Nishinura JI, et al. Screening and diagnostic clinical algorithm for paroxysmal nocturnal hemoglobinuria: Expert consensus. *Eur J Haematol*. 2018;101(1):3-11.
9. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. *Neurology*. 2021 Jan 19;96(3):114-122.

UPLIZNA (inebilizumab-cdon) for injection, for intravenous use

Products Affected

- UPLIZNA (inebilizumab-cdon) for injection, for intravenous use

PA Criteria	Criteria Details
Billing code	J1823
Covered Uses	*All FDA approved and medically accepted indications.* **FDA Indication:** Neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.
Exclusion Criteria	Contraindication(s): Previous life-threatening reaction to infusion of UPLIZNA (Continuous Therapy) Active hepatitis B infection Active or untreated latent tuberculosis
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments and other relevant clinical information **Diagnosis** of Neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive [including documentation supporting a confirmed diagnosis (e.g. clinical notes, laboratory reports, testing)]; **AND** **One** of the following type of request: Initial request: • Hepatitis B virus: Expected result: Nonreactive • Quantitative serum immunoglobulins: patients with low serum immunoglobulins cannot start treatment until the case have been consult with an immunology expert. 1. Tuberculosis Screening (PPD Test or Chest X-Ray): a. Expected result: negative b. If positive, the patient must start treatment for TB prior to starting UPLIZNA **OR** Continuation of therapy request:

PA Criteria	Criteria Details
	• Confirm place of administration • Tolerance and response to treatment **AND** Dosing: • Initial dose 300 mg followed two weeks later by a second 300 mg • Maintenance Dose: (starting 6 months from the first infusion) single 300 mg infusion every 6 months.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or ophthalmologist.
Coverage Duration	**Initial:** 6 months **Maintenance:** 12 months
Other Criteria	How supplied: Injection: 100 mg/10 mL (10 mg/mL) clear to slightly opalescent, colorless to slightly yellow solution in a **single-dose vial.**

Reference:

Product Information: UPLIZNA(TM) intravenous injection, inebilizumab-cdon intravenous injection. Viela Bio Inc (per FDA), Gaithersburg, MD, 2020.

VENOFER® (iron sucrose), for injection

Product Affected

- *VENOFER® (iron sucrose), for injection*

PA Criteria	Criteria Details
Billing code	J1756
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): In patients with known hypersensitivity to Venofer. Limitation of use: None.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. Diagnosis Confirmation of Iron deficiency anemia (IDA) in patients with chronic kidney disease (CKD). **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply
Prescriber Restrictions	
Coverage Duration	6 months
Other Criteria	

Reference:

Venofer [package insert]. Shirley, New York: American Regent, Inc.; 2017.

VENTAVIS® (iloprost), for inhalation

Product Affected

- *VENTAVIS® (iloprost), for inhalation*

PA Criteria	Criteria Details
Billing code	Q4074
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): None Limitation of use: None.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. Diagnosis pulmonary arterial hypertension (PAH) (WHO Group 1) **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply.
Prescriber Restrictions	Prescribed by or in consultation with a pneumologist.
Coverage Duration	6 months
Other Criteria	VENTAVIS is intended to be inhaled using the I-neb® AAD® System

Reference:

Ventavis [package insert]. South San Francisco, California: Actelion Pharmaceuticals US, Inc.; 2013.

VIMIZIM (elosulfase alfa) for injection, for intravenous use

Products Affected

- VIMIZIM (elosulfase alfa) for injection, for intravenous use

PA Criteria	Criteria Details
Billing code	J1322
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information Diagnosis of Mucopolysaccharidosis type IVA (Morquio A syndrome); **AND** The following criteria: • Laboratory test demonstrating deficiency on N-acetylgalactosamine 6-sulfatase (GALNS) or molecular test demonstrating biallelic pathogenic or likely pathogenic N-acetylgalactosamine 6-sulfase (GALNS) gene variants **AND** Dosing: 2 mg/kg once weekly
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a geneticist or endocrinologist
Coverage Duration	12 months
Other Criteria	

Reference

Product Information: VIMIZIM intravenous injection, elosulfase alfa intravenous injection. BioMarin Pharmaceutical Inc (per FDA), Novato, CA, 2019.

VISUDYNE® (verteporfin), for injection

Product Affected

- *VISUDYNE® (verteporfin), for injection*

PA Criteria	Criteria Details
Billing code	J3396
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients with porphyria. • In patients with known hypersensitivity to any component. Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist (retina specialist)
Coverage Duration	3 months
Other Criteria	

Reference:

Visudyne [package insert] Charleston, South Carolina: Alcami Carolinas Corporation.; 2023.

VONVENDI® (von Willebrand factor (recombinant)), for injection

Product Affected

- *VONVENDI® (von Willebrand factor (recombinant)), for injection*

PA Criteria	Criteria Details
Billing code	J7179
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Do not use in patients who have had life-threatening hypersensitivity reactions to VONVENDI or its components. Limitation of use: None.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with an hematologist.
Coverage Duration	6 months
Other Criteria	

Reference: Vonvendi [package insert]. Lexington, MA: Baxalta US Inc.; 2022.

VPRIV® (velaglucerase alfa) for injection, for intravenous use

Products Affected

- VPRIV® (velaglucerase alfa) for injection, for intravenous use

PA Criteria	Criteria Details
Billing code	J3385
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information **Diagnosis** **AND** Dosing: • naïve adults and naïve pediatric patients 4 years of age and older is 60 Units/kg administered every other week as a 60-minute intravenous infusion. • The dosage can be adjusted based on achievement and maintenance of each patient's therapeutic goals. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement
Age Restrictions	Age ≥ 4 years
Prescriber Restrictions	Prescribed by or in consultation with a geneticist or endocrinologist

PA Criteria	Criteria Details
Coverage Duration	6 months
Other Criteria	**How supplied:** VPRIV is available as: 400 units/vial (**Single-dose vial**)

Reference: VPRIV(R) intravenous injection, velaglucerase alfa intravenous injection. Shire Human Genetic Therapies, Inc. (per FDA), Lexington, MA, 2023.

WILATE® (von Willebrand Factor/Coagulation Factor VIII Complex (Human)), for injection

Product Affected

- *WILATE® (von Willebrand Factor/Coagulation Factor VIII Complex (Human)), for injection*

PA Criteria	Criteria Details
Billing code	J7183
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients with known hypersensitivity reactions, including anaphylactic or severe systemic reactions, to human plasma-derived products, any ingredient in the formulation Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	6 months
Other Criteria	

Reference:

Wilate [package insert]. Vienna, Austria: Octapharma Pharmazeutika Produktionsges.m.b.H.; 2023.

XGEVA (denosumab) for injection, for subcutaneous use

Products Affected

- XGEVA (denosumab) for injection, for subcutaneous use

PA Criteria	Criteria Details
Billing code	J0897
Covered Uses	All FDA approved and medically accepted indications.
Exclusion Criteria	Contraindication(s): Hypocalcemia; Known clinically significant hypersensitivity to Xgeva (continuation therapy)
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information Diagnosis of Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors; Adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity; Hypercalcemia of malignancy refractory to bisphosphonate therapy; **AND** The following criteria: For all request: • Patient Age • Absence of contraindications • Request the patient calcium lab level and date measured Initial request: • Giant Cell tumor of Bone: is the giant cell tumor of bone unresectable or surgical resection is likely to result in severe morbidity • Hypercalcemia of Malignancy: Has the patient tried and failed bisphosphonate therapy, or has a contraindication of intolerance to bisphosphonate therapy Continuation of therapy request: • Is the patient tolerating and responding to the medication

PA Criteria	Criteria Details
	○ Prevention of skeletal-related events (pathological fracture, radiation therapy to bone, surgery to bone, or spinal cord compression) ○ Tumor response ○ Reduction in serum calcium concentration ○ Clinical improvement in disease symptoms ○ No disease progression **AND** Dosing: • Multiple Myeloma and Bone Metastasis form solid tumors: 120 mg every 4 weeks • Giant cell Tumor of Bone: 120 mg every 4 weeks with additional 120 mg doses on days 8 and 15 of the first months of therapy • Administer calcium and vitamin D as necessary to treat hypocalcemia • Hypercalcemia of Malignancy: 120 mg every 4 weeks with additional 120 mg doses on days 8 and 15 of the first month of therapy.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist
Coverage Duration	Initial approval: 6 months Subsequent approval: 6 months
Other Criteria	Females of Reproductive Potential (15-49 years old): Appropriate forms of contraception should be implemented during treatment and for at least 5 months following the last dose of XGEVA

Reference: Highlights of prescribing information - amgen. (n.d.-c). https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/xgeva/xgeva_pi.pdf

XIAFLEX® (collagenase clostridium histolyticum), for injection

Product Affected

- *XIAFLEX® (collagenase clostridium histolyticum), for injection*

PA Criteria	Criteria Details
Billing code	J0775
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Peyronie's plaques that involve the penile urethra. • History of hypersensitivity to XIAFLEX or to collagenase used in other therapeutic applications. Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. One of the following diagnosis: • Diagnosis of Dupuytren's contracture • Diagnosis of Peyronie's Disease **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a dermatologist.
Coverage Duration	6 months
Other Criteria	XIAFLEX is available for the treatment of Peyronie's disease only through a restricted program called the XIAFLEX REMS Program.

Reference:
Xiaflex [package insert]. Malvern, PA: Endo Pharmaceuticals Inc.; 2018.

XIPERE® (triamcinolone acetonide injectable suspension), for injection

Product Affected

- *XIPERE® (triamcinolone acetonide injectable suspension), for injection*

PA Criteria	Criteria Details
Billing code	J3299
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Ocular or periocular infections • Hypersensitivity to triamcinolone or any component of this product Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. Diagnosis Confirmation of Macular Edema associated with uveitis. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist.
Coverage Duration	6 months
Other Criteria	

Reference:

XIPERE [package insert]. Alpharetta, GA: Clearside Biomedical, Inc.; 2021.

XOLAIR® (omalizumab), for injection

Product Affected

- *XOLAIR® (omalizumab), for injection*

PA Criteria	Criteria Details
Billing code	J2357
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients with severe hypersensitivity reaction to Xolair or any ingredient of Xolair. Limitation of use: • Not indicated for other allergic conditions or other forms of urticaria. • Not indicated for acute bronchospasm or status asthmaticus.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **AND** Diagnosis of **one** of the following a. Chronic idiopathic urticaria in patients who remain symptomatic despite H1 antihistamine therapy, b. Moderate to severe persistent asthma in patients with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms are inadequately controlled with inhaled corticosteroids or Dupixent, **OR** c. Nasal polyps in patients with inadequate response to nasal corticosteroids **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with an allergist, dermatologist, immunologist, otolaryngologist, or pulmonologist.

PA Criteria	Criteria Details
Coverage Duration	Initial: 6 months Renewal: Plan Year
Other Criteria	B vs D coverage determination per CMS guidelines

Reference:

Xolair [package insert]. South San Francisco, California: Genentech, Inc.; 2016.

XOPENEX HFA (levalbuterol tartrate) for inhalation, for oral use

Products Affected

- XOPENEX HFA (levalbuterol tartrate) for inhalation, for oral use

PA Criteria	Criteria Details
Billing code	J7614
Covered Uses	All FDA approved and medically accepted indications.
Exclusion Criteria	Contraindication(s): Hypersensitivity to levalbuterol, racemic albuterol or any component of XOPENEX HFA; Use of this medication alone for the treatment of asthma in adults and adolescents without inhaled corticosteroids (ICS).
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments. and other relevant clinical information Diagnosis of Asthma; **AND** The following criteria: Initial request • Classification of Asthma Severity (NAEPP) • History of asthma medication use • Specific allergy testing (blood or skin test) Continuation therapy request: • Response to treatment, defined as one or more of the following o Reduction in the number of asthma exacerbations from baseline (i.e., asthma exacerbation requiring systemic corticosteroid therapy or doubling of ICS dose from baseline). o Reduction in signs and symptoms of bronchospasm. o Decrease in rescue medication use from baseline. **AND** Dosing: • Age ≥ 4 years: 2 inhalations every 4 to 6 hour or 1 inhalation every 4 hours
Age Restrictions	Apply

PA Criteria	Criteria Details
Prescriber Restrictions	Prescribed by or in consultation with an allergist or immunologist
Coverage Duration	6 months
Other Criteria	None

Reference: Xopenex HFA (levalbuterol tartrate) inhalation aerosol, for oral ... (n.d.-f). https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021730s039lbl.pdf

XYNTHA® (antihemophilic factor [recombinant]), for injection

Product Affected

- *XYNTHA® (antihemophilic factor [recombinant]), for injection*

PA Criteria	Criteria Details
Billing code	J7185
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Do not use in patients who have manifested life-threatening, immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including hamster protein. Limitation of use: • Not indicated in patients with von Willebrand's disease.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with a hematologist.
Coverage Duration	6 months
Other Criteria	

Reference: Xyntha [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals LLC.; 2020.

YUPELRI (revefenacin) for inhalation, for oral use

Products Affected

- YUPERLRI (revefenacin) for inhalation, for oral use

PA Criteria	Criteria Details
Billing code	J7677
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): Hypersensitivity to revefenacin or any component of this product (continuation therapy)
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments and other relevant clinical information Diagnosis of COPD The following criteria: Initial request: • Documentation of patient's inability to use alternative long-acting muscarinic antagonist (LAMA) inhalers (tiotropium, umeclidinium, aclidinium) • Absence of contraindications Continuation of therapy request: • Absence of contraindications • Tolerance and response to treatment: describe disease improvement or abatement (e.g., COPD symptoms, improvement in quality of life, reduction in urgent care or hospitalization) **AND** Dosing: • One 175 mcg vial (3 mL) once daily • Use with a standard jet nebulizer with a mouthpiece connected to an air compressor
Age Restrictions	Apply
Prescriber Restrictions	None

PA Criteria	Criteria Details
Coverage Duration	12 months
Other Criteria	None

Reference:

Product Information: YUPELRI(TM) inhalation solution, revefenacin inhalation solution. Mylan Specialty LP (per FDA), Morgantown, WV, 2018.

YUTIQ (fluocinolone acetonide) for injection, for intravitreal use

Products Affected

- YUTIQ (fluocinolone acetonide) for injection, for intravitreal use

PA Criteria	Criteria Details
Billing code	J7314
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): Ocular or periocular infections; Hypersensitivity (continuation therapy)
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information Diagnosis of Chronic non-infectious uveitis; **AND** The following universal criteria: • Must not be used in combination with other sustained-release intravitreal corticosteroids • Patient does not have a torn or ruptured posterior lens capsule • Patient's best corrected visual acuity (BCVA) is measured at baseline and periodically during treatment • Patient's intraocular pressure is measured at baseline and periodically throughout therapy **AND** Initial request Chronic non-infectious uveitis • Patient has had a chronic disease for at least one year Continuation therapy request • Patients meet universal criteria • Absence of toxicity and contraindication • Disease response indicated by: o Stabilization of visual acuity or improvement in BCVA score when compared to baseline, **OR** o Decrease in inflammation **AND**

PA Criteria	Criteria Details
	Dosing: One implant (0.18 mg) for 36 months
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a ophthalmologist (retina specialist)
Coverage Duration	36 months
Other Criteria	None

Reference:

Product Information: YUTIQ(TM) intravitreal implant, fluocinolone acetonide intravitreal implant. EyePoint Pharmaceuticals US Inc (per manufacturer), Watertown, MA, 2018.

ZILRETTA® *(triamcinolone acetonide ER), for intra-articular use*

Product Affected

- ZILRETTA *(triamcinolone acetonide ER), for intra-articular use*

PA Criteria	Criteria Details
Billing code	J3304
Covered Uses	*All FDA approved and medically accepted indications.* FDA Indications: • Osteoarthritis pain of the knee.
Exclusion Criteria	Contraindication(s): • In patients with hypersensitivity to triamcinolone acetonide or corticosteroids. Limitation of use: • The efficacy and safety of repeat administration of ZILRETTA have not been demonstrated.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Diagnosis confirmation** **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	≥ 18 years old.
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist or orthopedist.
Coverage Duration	Approve only one dose per knee.
Other Criteria	None

Reference:

Zilretta. Package insert. Pacira Pharmaceuticals, Inc.; 2022
Zilretta. In: Lexi-Drugs. UpToDate Inc; 2024. Updated May 17, 2024. Accessed May 17, 2024. http://online.lexi.com

ZINECARD® (dexrazoxane), for injection

Product Affected

- *ZINECARD® (dexrazoxane), for injection*

PA Criteria	Criteria Details
Billing code	J1190
Covered Uses	*All FDA approved and medically accepted indications*
Exclusion Criteria	Contraindication(s): • Should not be used with non-anthracycline chemotherapy regimens. Limitation of use: None
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist.
Coverage Duration	6 months
Other Criteria	

Reference:

Zinecard [package insert]. New York, New York: Pharmacia & Upjohn Co.; 2014.