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.

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.

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.

ARANESP® (darbepoetin alfa), for injection

Product Affected

- *ARANESP® (darbepoetin alfa), for injection*

PA Criteria	Criteria Details
Billing code	J0881 – non-esrd J0882 – esrd
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Uncontrolled hypertension • Pure red cell aplasia (PRCA) that begins after treatment with Aranesp or other erythropoietin protein drugs. • Serious allergic reaction. Limitation of use: • It has not been shown to improve quality of life, fatigue, or patient well-being.
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: Aranesp [package insert]. Thousand Oaks, California: Amgen Inc.; 2011.

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: 01.01.2024
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: 01.01.2024
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

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.

BYOOVIZ® (ranibizumab-nuna), for injection

Product Affected

- *BYOOVIZ® (ranibizumab-nuna), for injection*

PA Criteria	Criteria Details
Billing code	Q5124
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Ocular or periocular infections • 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. **Diagnosis Confirmation** **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 (retina specialist)
Coverage Duration	6 months
Other Criteria	

Reference:

Byooviz [package insert]. Cambridge, MA: Biogen Inc.; 2023.

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.

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.

CIMERLI® (ranibizumab-eqrn), for injection

Product Affected

- *CIMERLI® (ranibizumab-eqrn), for injection*

PA Criteria	Criteria Details
Billing code	Q5128
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients with ocular o 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. **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 (retina specialist)
Coverage Duration	1 months
Other Criteria	

Reference:

Cimerli [package insert]. Redwood City, California: Coherus BioSciences, Inc.; 2022.

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.

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: 01.01.2024
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: 01.01.204
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 (retina specialist)
Coverage Duration	6 months
Other Criteria	

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

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.

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

Products 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 Indication: Active Crohn's Disease (moderate to severe) Active Ulcerative Colitis (moderate to severe)
Exclusion Criteria	Contraindication(s): Hypersensitivity reaction to Entyvio or any of its excipients (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 **One** of the following diagnoses: • Crohn's Disease • Ulcerative Colitis **AND** Select one of the following type of request: **Initial request:** o Documentation of disease severity, activity, and risk o For Crohn's Disease (CD): Crohn's Disease Activity Index (CDAI) • Crohn's disease activity index (CDAI) o Asymptomatic remission < 150 o Mild to moderate 150 – 220 o **Moderate to severe 221 – 450** o Severely active to fulminate 451 – 1100 CDAIcalculator: https://www.mdcalc.com/calc/3318/crohns-disease-activity-index-cdai o For Ulcerative Colitis (UC): Mayo Score / Disease Activity Index (DAI)

PA Criteria	Criteria Details
	▪ 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 request:** o Documentation of change in disease severity: ▪ CD (CDAI, indicators of severe disease) ▪ UC (Mayo Score / DAI) o Concomitant therapy o Absence of contraindications o Negative test for tuberculosis (PPD Test or Chest X-Ray) o 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	Apply
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist
Coverage Duration	Initial: 42 days Continuation of Therapy: 6 months
Other Criteria	

References:

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.

EPOGEN® (epoetin alfa), for injection

Product Affected

- *EPOGEN® (epoetin alfa), for injection*

PA Criteria	Criteria Details
Billing code	Q4081
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Uncontrolled hypertension • Pure red cell aplasia (PRCA) that begins after treatment with Epogen or other erythropoietin protein drugs. • Serious allergic reaction • Use of the multiple-dose vials containing benzyl alcohol in neonates, infants, pregnant women, and lactating women. Limitation of use: • It has not been shown to improve quality of life, fatigue, or patient well-being. • Epogen is not indicated for use: o In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy. o In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure. o In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion. o In patients scheduled for surgery who are willing to donate autologous blood. o In patients undergoing cardiac or vascular surgery. o 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, laboratory results, previous treatments, and other relevant clinical information. **AND**

PA Criteria	Criteria Details
	Provide laboratory results to monitor the iron level before and during treatment. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement
Age Restrictions	Apply
Prescriber Restrictions	
Coverage Duration	3 months
Other Criteria	

Reference: Epogen [package insert]. Thousand Oaks, California: Amgen, Inc.; 2017.

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 Byooviz/Cimerli. **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.

FERRLECIT ® (sodium ferric gluconate complex in sucrose), for injection

Product Affected

- *FERRLECIT ® (sodium ferric gluconate complex in sucrose), for injection*

PA Criteria	Criteria Details
Billing code	J2916
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	
Coverage Duration	6 months
Other Criteria	

Reference: FERRLECIT [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC.; 2022.

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.

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	

Gel-One Hyaluronate

Products Affected

- Gel-One Hyaluronate

PA Criteria	Criteria Details
Billing code	J7326
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 Osteoarthritis (OA) of the knee (Confirmatory Test) **AND** **Documentation** that the patient has failed to respond adequately to non-pharmacologic therapy, non-steroidal anti-inflammatory drugs (NSAIDs) or simple analgesics (e.g. acetaminophen) **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 Durolane and/or Synvisc. **AND** Dosing: 30 mg per 3 mL (contents of prefilled syringe) intra-articularly into the knee
Age Restrictions	Apply
Prescriber Restrictions	
Coverage Duration	One Time per Knee
Other Criteria	

Reference: Product Information: Gel-One(R) intra-articular injection, sodium hyaluronate intra-articular injection. Zimmer (per Manufacturer), Warsaw, IN, 2011.

GRANIX® (tbo-filgrastim), for injection

Product Affected

- *GRANIX® (tbo-filgrastim), for injection*

PA Criteria	Criteria Details
Billing code	J1447
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients with a history of serious allergic reactions to filgrastim products or pegfilgrastim 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. **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	6 months
Other Criteria	

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

Reference: Granix [package insert]. Vilnius, Lithuania: Sicor Biotech.; 2019.

Prior Authorization Criteria for Part B drugs
Effective Date: 01.01.2024
Utilization Management Committee Approval Date: 04.11.2024

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: 01.01.2024
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.

Prior Authorization Criteria for Part B drugs
Effective date: 01.01.204
Utilization Management Committee Approval Date: 04.11.2024

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.

ILUVIEN (fluocinolone acetonide) for injection, for intravitreal use

Products 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.*
Exclusion Criteria	Contraindication(s): Ocular or periocular infections, glaucoma, hypersensitivity (continuous request)
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 • 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:

PA Criteria	Criteria Details
	• 0.19 mg lasting 36 months
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist.
Coverage Duration	36 months
Other Criteria	None

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

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.

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: 01.01.2024
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.

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.

LEQVIO® (inclisiran), for injection

Product Affected

- *LEQVIO® (inclisiran), for injection*

PA Criteria	Criteria Details
Billing code	J1306
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): None Limitation of use: Its effect on cardiovascular morbidity and mortality 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 Confirmation **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 cardiologist or endocrinologist.
Coverage Duration	6 months
Other Criteria	

Reference: Leqvio [package insert]. East Honover, New Jersey: Novartis Pharmaceuticals Corporation.; 2021.

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.

LUCENTIS ® (ranibizumab injection) for intravitreal injection

Products Affected

- LUCENTIS ® (ranibizumab injection) for intravitreal injection

PA Criteria	Criteria Details
J code (HCPCS)	J2778
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) Myopic Choroidal Neovascularization (mCNV)
Exclusion Criteria	Contraindication(s): Ocular or periocular infections **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 **Step Therapy Requirement (Only for New Patients)** 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: Byooviz (*except for Diabetic Macular Edema (DME) and Diabetic Retinopathy) or Cimerli (applies for ALL indications) **AND** **Medical Information Requirements:** 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) e. Myopic Choroidal Neovascularization (mCNV)

PA Criteria	Criteria Details
	AND Dose Verification a. **AMD:** a. 0.5 mg (0.05 mL) is recommended to be administered by intravitreal injection once a month (approximately 28 days). b. patients may be treated with 3 monthly doses followed by less frequent dosing with regular assessment c. patients may also be treated with one dose every 3 months after 4 monthly doses. Patients should be assessed regularly. b. **RVO:** 0.5 mg (0.05 mL) administered by intravitreal injection once a month c. **DME and DR:** 0.3 mg (0.05 mL) administered by intravitreal injection once a month. d. **mCNV:** 0.5 mg (0.05 mL) is recommended to be initially administered by intravitreal injection once a month (approximately 28 days) for up to three months.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist (retina specialist)
Coverage Duration	**Initial and Continuation:** 6 months
Other Criteria	**Continuation Criteria:** Clinical Response- Member is responding positively to therapy and is documented by the prescriber.

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.

MIRCERA® (epoetin beta), for injection

Product Affected

- *MIRCERA® (epoetin beta), for injection*

PA Criteria	Criteria Details
Billing code	J0887 – esrd J0888 – non esrd
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Uncontrolled hypertension • Pure red cell aplasia (PRCA) that begins after treatment with Procrit or other erythropoietin protein drugs. • Serious allergic reaction. Limitation of use: • In the treatment of anemia due to cancer chemotherapy. • As a substitute for RBC transfusions in patients who require immediate correction of anemia. • Has not been shown to improve quality of life, fatigue, or patient well-being.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **AND** Provide laboratory results to monitor the iron level before and during treatment. **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 an oncologist or hematologist.
Coverage Duration	6 months
Other Criteria	

Reference: Mircera [package insert]. St. Galen, Switzerland: Vifor Inc.; 2018.

MONOVISC™ High Molecular Weight Hyaluronan

Products Affected

- MONOVISC™ High Molecular Weight Hyaluronan

PA Criteria	Criteria Details
Billing code	J7327
Covered Uses	*All FDA approved and medically accepted indications.* **FDA Indication:** • Treatment of pain in Osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy or simple analgesics.
Exclusion Criteria	Contraindication(s): • Pre-existing infections of the skin region of the intended injection site **OR** • Known infection of the index joint **OR** • Known systemic bleeding disorders
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. **AND** Dosing Monovisc™ is supplied in a single-use 5 mL syringe containing a 4 mL dose of treatment.
Age Restrictions	Apply
Prescriber Restrictions	
Coverage Duration	One Time per Knee
Other Criteria	

Reference: Monovisc® Package Insert. PENDOPHARM. October 2023.

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.

NEUPOGEN® (filgrastim), for injection

Product Affected

- *NEUPOGEN® (filgrastim), for injection*

PA Criteria	Criteria Details
Billing code	J1442
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: 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 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: Neupogen [package insert]. Thousand Oaks, California: Amgen Inc.; 2013.

Prior Authorization Criteria for Part B drugs
Effective Date: 01.01.2024
Utilization Management Committee Approval Date: 04.11.2024

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	Q5125
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

PA Criteria	Criteria Details
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
	  o Patient has not experienced a relapse of MS
	  o 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.

Oncology Treatments

Product Affected

- *BCG live intravesical instillation, 1 mg*
- *Cyclophosphamide, 100 mg*
- *Dacarbazine, 100 mg*
- *Goserelin acetate implant, per 3.6 mg*
- *Histrelin implant (Supprelin LA), 50 mg*
- *Histrelin implant (Vantas), 50 mg*
- *Injection, ado-trastuzumab emtansine, 1 mg*
- *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*
- *Injection, asparaginase, recombinant, (rylaze), 0.1 mg*
- *Injection, atezolizumab, 10 mg*
- *Injection, avelumab, 10 mg*
- *Injection, azacitidine, 1 mg*
- *Injection, belantamab mafodontin-blmf, 0.5 mg*
- *Injection, belinostat, 10 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*
- *Injection, 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, per 1 mg*
- *Injection, clofarabine, 1 mg*
- *Injection, copanlisib, 1 mg*
- *Injection, cyclophosphamide, (auromedics), 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 hyaluronidase-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 micrograms*
- *Injection, diethylstilbestrol diphosphate, 250 mg*
- *Injection, dinutuximab, 0.1 mg*
- *Injection, docetaxel, 1 mg*
- *Injection, 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-nxki, 1 mg*
- *Injection, floxuridine, 500 mg*
- *Injection, fludarabine phosphate, 50 mg*

- *Injection, fluorouracil, 500 mg*
- *Injection, fulvestrant (fresenius kabi) 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, gemtuzumab ozogamicin, 0.1 mg*
- *Injection, glofitamab gxbm, 2.5 mg*
- *Injection, idarubicin hydrochloride, 5 mg*
- *Injection, ifosfamide, 1 gram*
- *Injection, inotuzumab ozogamicin, 0.1 mg*
- *Injection, interferon alfacon-1, recombinant, 1 microgram*
- *Injection, interferon, alfa-2a, recombinant, 3 million units*
- *Injection, interferon, alfa-2b, recombinant, 1 million units*
- *Injection, interferon, alfa-N3, (human leukocyte derived), 250, 000 IU*
- *Injection, interferon, gamma 1-b, 3 million units*
- *Injection, ipilimumab, 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, (nitrogen mustard), 10 mg*
- *Injection, melphalan (evomela), 1 mg*
- *Injection, melphalan flufenamide, 1mg*
- *Injection, melphalan hydrochloride, not otherwise specified, 50 mg*
- *Injection, mesna, 200 mg*
- *Injection, mirvetuximab soravtansine-gynx, 1 mg*
- *Injection, mitomycin, 5 mg*
- *Injection, mitoxantrone hydrochloride, per 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, 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, 1 mg*
- *Injection, paclitaxel, 1 mg*
- *Injection, panitumumab, 10 mg*
- *Injection, pegaspargase, per single dose vial*
- *Injection, pembrolizumab, 1 mg*
- *Injection, pemetrexed (accord) 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 hyaluronidase-zzxf, per 10 mg*
- *Injection, plicamycin, 2.5 mg*
- *Injection, polatuzumab vedotin-piiq, 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 hyaluronidase*
- *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, lyophilized, 0.1 mg*
- *Injection, romidepsin, non-lyophilized, 0.1 mg*
- *Injection, sacituzumab govitecan-hziy, 2.5 mg*
- *Injection, sirolimus protein-bound particles, 1 mg*
- *Injection, streptozocin, 1 gram*
- *Injection, tafasitamab-cxix, 2 mg*

- *Injection, tagraxofusp-erzs, 10 micrograms*
- *Injection, talimogene laherparepvec, per 1 million plaque forming units*
- *Injection, tebentafusp-tebn, 1 microgram*
- *Injection, teclistamab-cqyv, 0.5 mg*
- *Injection, temozolomide, 1 mg*
- *Injection, temsirolimus, 1 mg*
- *Injection, thiotepa, 15 mg*
- *Injection, tisotumab vedotin-tftv, 1 mg*
- *Injection, topotecan, 0.1 mg*
- *Injection, trabectedin, 0.1 mg*
- *Injection, trastuzumab, 10 mg and Hyaluronidase-oysk*
- *Injection, trastuzumab, excludes biosimilar, 10 mg*
- *Injection, trastuzumab-anns, biosimilar, (kanjinti), 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 (for depot suspension), 7.5 mg*
- *Leuprolide acetate implant, 65 mg*
- *Leuprolide acetate, per 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

PA Criteria	Criteria Details
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): As applicable by each product package insert Limitation of use: As applicable by each product package insert
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: Provide clinical documentation that evidence improvement
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a hematologist and/or oncologist
Coverage Duration	Per chemoregimen protocol and/or medical necessity
Other Criteria	

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

Reference: 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 accepted if supported by any of the following compendia below and not listed as unsupported, not indicated, or not recommended within any compendium below**.**

- NCCN Drugs & Biologics Compendium ®
    - Category 1-2A recommendations are considered medically accepted uses
    - Category 2B recommendations will be considered if 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 not medically accepted uses
    - OA subscribes to the NCCN Flash Updates™, which informs OA when the NCCN Guidelines® and the NCCN Drugs & Biologics Compendium are update
- Clinical Pharmacology

- Medically accepted uses are identified by narrative text that is supportive
- Not medically accepted uses are identified by narrative text that is “not supportive
- American Hospital Formulary Service-Drug Information (AHFS-DI)
    - Medically accepted uses are identified by narrative text that is supportive
    - Not medically accepted uses are identified by narrative text that is “not supportive”

- Thompson Micromedex DrugDex®

    - Class I, IIA, or IIb recommendations are considered medically accepted uses
    - Class III listings are considered not medically accepted uses

- Wolters Kluwer Lexi-Drugs®
    - Medically accepted uses are identified by an indication listed as “Use: Off-Label” and rated as “Evidence Level A”
    - Not medically accepted uses are those indications listed as “Use: Unsupported”
- 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 accepted if supported as safe and effective according to peer-reviewed articles eligible for coverage from 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 abstracts and case reports are excluded from consideration

ORENCIA (abatacept) for injection, for intravenous use

Products Affected

- ORENCIA (abatacept) for injection, for intravenous

PA Criteria	Criteria Details
Billing code	J0129
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. **Step Therapy Requirement (Only for New Patients in Therapy)** Must try/fail, have contraindication to, or intolerance to one of the following: Inflectra, Renflexis or Avsola prior to receiving Orencia Diagnosis of Rheumatoid Arthritis in adults (moderate to severe); Age ≥ 2 years Polyarticular juvenile idiopathic arthritis (pJIA) (moderate to severe); Prophylaxis of acute graft versus host disease (Agvhf), in combination with a calcineurin inhibitor and methotrexate in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor; **AND** The following criteria: Initial request: • Past, current, and concurrent medication trial, failure, contraindication, or intolerance when used to treat the same indication • Tuberculosis test validation • Screening of Hepatitis B virus • Immunization history (live vaccines) Continuation of therapy request: • Tuberculosis test validation • Immunization history (live vaccines) • Tolerance and response to treatment **AND**

<table>
<tr><th>PA Criteria</th><th>Criteria Details</th></tr>
<tr><td></td><td>
Dosing:
IV use for adult RA and PsA
Administer at 0, 2, and 4 weeks thereafter
<table>
<tr><td>Body weight</td><td>Dose</td><td>Number of vials</td></tr>
<tr><td>Less than 60 kg</td><td>500 mg</td><td>2</td></tr>
<tr><td>60 – 100 kg</td><td>750 mg</td><td>3</td></tr>
<tr><td>More than 100 kg</td><td>1,000 mg</td><td>4</td></tr>
</table>
Subcutaneous use for RA
Prior to first dose, may administer an optional loading dose as a single IV as per body with categories above
125 mg once weekly (within a day of the IV infusion
IV for pJIA in pediatric patients ≥ 6 years old
Patients weighing < 75 kg administer 10 mg/kg IV
Patients weighing ≥ 75 kg administer the adult IV regiment
Subsequent administer infusions at 2 and 4 weeks and every 4 weeks thereafter
SC use for pJIA in pediatric patients ≥ 2 years old
Administer SC without an IV loading dose
<table>
<tr><td>Body weight</td><td>Dose (Once weekly)</td></tr>
<tr><td>10 kg to 24 kg</td><td>50 mg</td></tr>
<tr><td>25 kg to 49 kg</td><td>87.5 mg</td></tr>
<tr><td>50 kg or more</td><td>125 mg</td></tr>
</table>
SC use for Adult PsA
Administer 125 mg once weekly without an IV loading dose
IV use for prophylaxis of a GVHD:
For patients Age ≥6 years old, administer at 10 mg/kg dose (maximum dose 1000 mg) on the day before transplantation, followed by a dose on day 5, 14 and 28 after transplant
For patient 2 to 6 years old, administer a 15 mg/kg dose on the day before transplantation, followed by a 12 mg/kg dose on day 5, 14, and 28 after transplant
</td></tr>
<tr><td>Age Restrictions</td><td>Apply</td></tr>
</table>

PA Criteria	Criteria Details
Prescriber Restrictions	Prescribed by or in consultation with: • RA: Rheumatologist • Polyarticular juvenile idiopathic arthritis: Rheumatologist • Prophylaxis of aGVHD): Hematologist/oncologist • Active psoriatic arthritis: rheumatologist or dermatologist
Coverage Duration	Approve medication for 12 months
Other Criteria	

Reference: Product Information: ORENCIA(R) intravenous, subcutaneous injection, abatacept intravenous, subcutaneous injection. Bristol-Myers Squibb Company (per FDA), Princeton, NJ, 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.

ORTHOVISC® (high molecular weight hyaluronan), for injection

Product Affected

- *ORTHOVISC® (high molecular weight hyaluronan), for injection*

PA Criteria	Criteria Details
Billing code	J7324
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • In patients who are allergic to products from birds. • In patients that have an injection into the knee if you have infections or skin diseases around the injection site. 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	6 months
Other Criteria	

Reference:

Orthovisc [package insert]. Woburn, MA: Anika Therapeutics, Inc.; 2022.

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	1 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.

PERFOROMIST (formoterol fumarate) for inhalation, for oral use

Products Affected

- PERFOROMIST (formoterol fumarate) for inhalation, for oral use

PA Criteria	Criteria Details
Billing code	J7606
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Acute deteriorations of COPD • Asthma, acutely deteriorating patients • Acute symptoms
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information Diagnosis of Maintenance treatment of bronchoconstriction in COPD, including bronchitis and emphysema; **AND** The following criteria: Initial request: • Spirometry Results (Confirmed diagnosis) • History of COPD medication use • CAT (COPD Assessment Test) and/or mMRC (Modified British Medical Research Council) score and risk of exacerbations Continuation therapy request 1. Report response to treatment, defined as one or more of the following • Reduction in frequency and severity of exacerbations and improve exercise tolerance and health status. • Reduction in signs and symptoms of asthma. • Improve in pulmonary function tests **AND** Dosing: 20 mcg/2mL vial every 12 hours
Age Restrictions	Apply

PA Criteria	Criteria Details
Prescriber Restrictions	Prescribed by or in consultation with an allergist, immunologist or pneumologist
Coverage Duration	12 months
Other Criteria	Use with a standard jet mobilizer (with a facemask or mouthpiece) connected to an air compressor

Reference: Product Information: PERFOROMIST(R) inhalation solution, formoterol fumarate inhalation solution. Mylan Specialty LP (per FDA), Morgantown, WV, 2019.

PROCRIT® (epoetin alfa non-esrd), for injection

Product Affected

- *PROCRIT® (epoetin alfa non-esrd), for injection*

PA Criteria	Criteria Details
Billing code	J0885
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Uncontrolled hypertension • Pure red cell aplasia (PRCA) that begins after treatment with Procrit or other erythropoietin protein drugs. • Serious allergic reaction. • Use of the multiple-dose vials containing benzyl alcohol in neonates, infants, pregnant women, and lactating women. Limitation of use: • It has not been shown to improve quality of life, fatigue, or patient well-being. • Procrit is not indicated for use: o In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy. o In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure. o In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion. o In patients scheduled for surgery who are willing to donate autologous blood. o In patients undergoing cardiac or vascular surgery. o 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, laboratory results, previous treatments, and other relevant clinical information. **AND** Pretreatment hemoglobin levels of less than 10g/dL.

PA Criteria	Criteria Details
	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) in addition to 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 **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement. 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) in addition to supporting statement of diagnosis from physician.
Age Restrictions	None
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist.
Coverage Duration	3 months
Other Criteria	B vs D determination required per CMS guidance

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

Reference:
Procrit [package insert]. Thousand Oaks, California: Amgen, Inc.; 2023.

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: 01.01.204
Utilization Management Committee Approval Date: 04.11.2024

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

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

RELEUKO® (filgrastim-ayow), for injection

Product Affected

- *RELEUKO® (filgrastim-ayow), for injection*

PA Criteria	Criteria Details
Billing code	Q5125
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: None.
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information. **Provide an approved diagnosis for this medication.** **AND** Provide an absolute neutrophil count (ANC) result to closely monitor neutrophils count. **Continuation of Therapy** Tolerance and response to treatment: describe disease improvement or abatement.
Age Restrictions	Age ≥ 18 years
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months

PA Criteria	Criteria Details
Other Criteria	RELEUKO (filgrastim-ayow) is biosimilar to NEUPOGEN® (filgrastim).

Reference: Releuko [package insert]. Piscataway, New Jersey: Kashiv BioSciences, LLC.; 2022.

REMICADE (infliximab) for injection, for intravenous use

Products Affected

- REMICADE (infliximab) for injection, for intravenous use

PA Criteria	Criteria Details
Billing code	J1745
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): REMICADE doses >5 mg/kg in moderate or severe heart failure. Previous severe hypersensitivity reaction to infliximab or any inactive ingredients of REMICADE or to any murine proteins (Continuation of Therapy)
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 one of the following: Inflectra, Renflexis or Avsola prior to receiving Remicade. **Medical Information Requirements:** 1. Diagnosis Confirmation **AND** 2. Documentation of disease severity, activity, and risk **AND** 3. HBV infection Screening (Hepatitis B Laboratory) **AND** 4. Test for latent TB (PPD Test or Chest X-Ray): a. Expected result: negative b. If positive, the patient has to start treatment for TB prior to starting REMICADE **AND** 5. Past, current, and concurrent medication trial, failure, contraindication, or intolerance when used to treat the same indication. (**Only for Initial Evaluation**) **AND** 6. Appropriate Dosing: • *Crohn's Disease:* 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Some adult Crohn's Disease: 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Some adult patients who initially respond to

PA Criteria	Criteria Details
	treatment may benefit from increasing the dose to 10 mg/kg every 8 weeks if they later lose their response. • *Pediatric Crohn's Disease (≥ 6 years old):* 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. • *Ulcerative Colitis:* 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. • *Pediatric Ulcerative Colitis (≥ 6 years old):* 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. • *Rheumatoid Arthritis:* In conjunction with methotrexate, 3 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Some patients may benefit from increasing the dose up to 10 mg/kg every 8 weeks or treating as often as every 4 weeks. • *Ankylosing Spondylitis:* 5 mg/kg at 0, 2 and 6 weeks, then every 6 weeks. • *Psoriatic Arthritis and Plaque Psoriasis:* 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a rheumatologist, dermatologist, or gastroenterologist depends of the diagnosis.
Coverage Duration	6 months

References:

Product Information: REMICADE(R) intravenous injection, infliximab intravenous injection. Janssen Biotech Inc (per FDA), Horsham, PA, 2020.

Fraenkel, L., Bathon, J. M., England, B. R., St Clair, E. W., Arayssi, T., Carandang, K., Deane, K. D., Genovese, M. C., Huston, K., Kerr, G. S., Kremer, J. M., Nakamura, M. C., Russell, L., Singh, J. A., Smith, B. J., Sparks, J. A., Venkatachalam, S., Weinblatt, M. E., Al-Gibbawi, M., . . . Akl, E. A. (2021). 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care and Research, 73(7), 924–939. https://doi.org/10.1002/acr.24596

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

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

RETACRIT® (epoetin alfa-epbx), for injection

Product Affected

- *RETACRIT® (epoetin alfa-epbx), for injection*

PA Criteria	Criteria Details
Billing code	Q5106
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Uncontrolled hypertension • Pure red cell aplasia (PRCA) that begins after treatment with Retacrit or other erythropoietin protein drugs. • Serious allergic reaction Limitation of use: • It has not been shown to improve quality of life, fatigue, or patient well-being. • Retracrit is not indicated for use: o In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy. o In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure. o In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion. o In patients scheduled for surgery who are willing to donate autologous blood. o In patients undergoing cardiac or vascular surgery. o 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, laboratory results, previous treatments, and other relevant clinical information. **AND**

PA Criteria	Criteria Details
	Provide laboratory results to monitor the iron level before and during 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: Retacrit [package insert]. Lake Forest,IL: Hospira, Inc.; 2018.

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.

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.

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.com/calc/3318/crohns-disease-activity-index-cdai **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: 01.01.2024
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.

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.

SYNOJOYNT® (1% sodium hyaluronate), for injection

Product Affected

- *SYNOJOYNT® (1% sodium hyaluronate), for injection*

PA Criteria	Criteria Details
Billing code	J7331
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Do not use SYNOJOYNT to treat patients who have a known hypersensitivity to hyaluronan preparations. • Do not use to treat patients with knee joint infections or to treat patients with infections or skin disease in the area of the injection site. 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	6 months
Other Criteria	

Reference:

Synojoynt [package insert]. Gyeonggi-do, Korea: Hanmi Pharm Co., Ltd.; 2022.

SYNVISC-ONE® (hylan G-F 20), for injection

Product Affected

- *SYNVISC-ONE® (hylan G-F 20), for injection*

PA Criteria	Criteria Details
Billing code	J7325
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Do not use to treat patients who have a known hypersensitivity to hyaluronan preparations. • Do not use to treat patients with knee joint infections or to treat patients with infections or skin disease in the area of the injection site. 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	6 months
Other Criteria	

Reference: Synvisc-One [package insert]. Ridgefield, New Jersey: Genzyme Biosurgery.; 2022.

TEZSPIRE (tezepelumab-ekko) for injection, for subcutaneous use

Products Affected

- TEZSPIRE (Tezepelumab-ekko) for injection, for subcutaneous use

PA Criteria	Criteria Details
Billing code	J2356
Covered Uses	*All FDA approved and medically accepted indications.* **FDA Indication:** Add-on maintenance treatment of severe asthma
Exclusion Criteria	Contraindication(s): Known hypersensitivity to tezepelumab-ekko or excipients. (Only for Continuation 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 Diagnosis of severe asthma **AND** One of the following type of request: Initial request: • Concurrent medications, when used to treat the same indication • Absence of contraindications • Immunization status: Avoid use of live attenuated vaccines Continuation of therapy request: • Concurrent medications, when used to treat the same indication • Absence of contraindications • Immunization status: Avoid use of live attenuated vaccines • Tolerance and response to treatment: describe disease improvement or abatement, e.g. **AND** Dosing: • 210 mg once every 4 weeks
Age Restrictions	Age ≥ 12 years

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

Reference:

Product Information: TEZSPIRE(R) subcutaneous injection, tezepelumab-ekko subcutaneous injection. Amgen Inc (per FDA), Thousand Oaks, CA, 2023.

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.

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.

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 injection, for intravenous use

Products Affected

- TYSABRI (natalizumab) for injection, for intravenous use

PA Criteria	Criteria Details
Billing code	J2323
Covered Uses	*All FDA approved and medically accepted indications.*
Exclusion Criteria	Contraindication(s): • Patients who have of have had PML • Hypersensitivity reaction to TYSABRI (Continuation therapy)
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments and other relevant clinical information **Step Therapy Requirement (Only New Patients)** 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 Ocrevus. Diagnosis of Multiple Sclerosis (MS), Crohn's Disease (CD); **AND** The following criteria: Initial request • Applicable diagnostic tests or criteria • 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 • Pharmacy is enrolled in Tysabri TOUCH REMS program Continuation of therapy request: • Concurrent medications, when used to treat the same indication • Absence of contraindications • Pharmacy in enrolled in Tysabri TOUCH REMS program • Tolerance and response to treatment **AND** Dosing: 300 mg every 4 weeks

PA Criteria	Criteria Details
Age Restrictions	Apply
Prescriber Restrictions	Prescribed by or in consultation with a neurologist or gastroenterologist.
Coverage Duration	MS: Initial and subsequent approval: 6 months CD: • Initial approval: 12 weeks • Subsequent approval: 6 months
Other Criteria	For CD, should not be used in combination with immunosuppressants or inhibitors of TNF-a.

Reference:

Product Information: TYSABRI(R) intravenous injection, natalizumab intravenous injection. Biogen Inc (per FDA), Cambridge, MA, 2023

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) injection, for intravenous or subcutaneous use

Products Affected

- *ULTOMIRIS® (ravulizumab-cwvz) injection, for intravenous or subcutaneous use*

PA Criteria	Criteria Details
Billing code	J1303
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* aHUS Limitation of Use: ULTOMIRIS is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).
Required Medical Information	Provider must submit supporting documentation such as progress notes, laboratory results, previous treatments, and other relevant clinical information **Diagnosis 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:
<table>
<tr><th>Indication</th><th>Body Weight Rage (kg)</th><th>Loading Dose (mg)**</th><th colspan="2">Maintenace Dose (mg) and Dosing Interval</th></tr>
<tr><td rowspan="4">PNH and aHUS</td><td>5 to less than 10</td><td>600</td><td>300</td><td rowspan="2">Every 4 weeks</td></tr>
<tr><td>10 to less than 20</td><td>600</td><td>600</td></tr>
<tr><td>20 to less than 30</td><td>900</td><td>2,100</td><td rowspan="2">Every 8weeks</td></tr>
<tr><td>30 to less than 10</td><td>1,200</td><td>2,700</td></tr>
</table>
<table>
<tr><th>Indication</th><th>Body Weight Rage (kg)</th><th>Loading Dose (mg)**</th><th colspan="2">Maintenace Dose (mg) and Dosing Interval</th></tr>
<tr><td rowspan="3">PNH,aHUS and gMG</td><td>40 to less than 60</td><td>2,400</td><td>3,000</td><td rowspan="3">Every 8weeks</td></tr>
<tr><td>60 to less than 100</td><td>2,700</td><td>3,300</td></tr>
<tr><td>100 or greater</td><td>3,000</td><td>3,600</td></tr>
</table></td></tr>
<tr><td>Age Restrictions</td><td>None</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</td></tr>
<tr><td>Coverage Duration</td><td>Initial: One month
Continuation of Therapy: 6 months</td></tr>
<tr><td>Other Criteria</td><td></td></tr>
</table>

Reference: Product Information: ULTOMIRIS(R) intravenous injection, ravulizumab-cwvz intravenous injection. Alexion Pharmaceuticals Inc (per FDA), Boston, MA, 2022.

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.

VABYSMO™ (faricimab-svoa) injection, for intravitreal use

Products Affected

- VABYSMO™ (faricimab-svoa) injection, for intravitreal use

PA Criteria	Criteria Details
Billing code	J2777
Covered Uses	*All FDA approved and medically accepted indications.*
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 (nAMD) **OR** b. Diabetic Macular Edema (DME) **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), Cimerli and Eylea. **AND** 3. Vabysmo 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** 4. Dose:

PA Criteria	Criteria Details
	a. **nAMD**: VABYSMO 6 mg administered by intravitreal injection every 4 weeks b. **DME: one** of these two dose regimens i. 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days ± 7 days, monthly) for at least 4 doses. ii. 6 mg dose can be administered every 4 weeks for the first 6 doses, followed by 6 mg dose via intravitreal injection at intervals of every 8 weeks (2 months)
Age Restrictions	Age ≥ 18 years
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist
Coverage Duration	**Initial: nAMD-** 4 months **DME**- 6months **Continuation:** 4 months
Other Criteria	**Continuation Criteria:** **Neovascular (Wet) Age-Related Macular Degeneration (nAMD)** • Optical coherence tomography and visual acuity evaluations 8 and 12 weeks later • Dose: o 6 mg dose via intravitreal injection on **one** of the following three regimens: ▪ Weeks 28 and 44 ▪ Weeks 24, 36 and 48 ▪ Weeks 20, 28, 36 and 44 **Diabetic Macular Edema (DME)** • Evaluation of resolution of edema based on the central subfield thickness (CST) of the macula as measured by optical coherence tomography and visual acuity evaluations • Dose: o 6mg but the interval of dosing may be modified by extensions of up to 4 week interval increments or reductions of up to 8 week interval increments based on CST and visual acuity evaluations

Reference: VABYSMO [package insert]. South San Francisco, CA: Genentech, Inc; 2023.

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.

Prior Authorization Criteria for Part B drugs
Effective Date: 01.01.2024
Utilization Management Committee Approval Date: 04.11.2024

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.

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.