Injections: Drugs C Policy

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This section outlines policy related to billing for injection services, listed in alphabetical order by generic drug name or drug type. For general billing policy information regarding injections services, refer to the *Injections: An Overview* section in this manual. Additional policy information for injection services can be found in the following sections of this manual:

- *Immunizations*
- *Injections: Drugs A Policy*
- *Injections: Drugs B Policy*
- *Injections: Drugs D Policy*
- *Injections: Drugs E Policy*
- *Injections: Drugs F Policy*
- *Injections: Drugs G Policy*
- *Injections: Drugs H Policy*
- *Injections: Drugs I Policy*
- *Injections: Drugs J-L Policy*
- *Injections: Drugs M Policy*
- *Injections: Drugs N-O Policy*
- *Injections: Drugs P-Q Policy*
- *Injections: Drugs R Policy*
- *Injections: Drugs S Policy*
- *Injections: Drugs T Policy*
- *Injections: Drugs U-Z Policy*
- *Injections: Hydration*

C1 Esterase Inhibitor (Haegarda®)

C1 Esterase Inhibitor (Human) (C1-INH) is a human plasma-derived concentrate reconstituted solution for subcutaneous (SQ) administration.

Indications

‹‹All FDA-approved indications.

Dosage

FDA-approved dosages.››

TAR Requirements

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

‹‹TAR Criteria

The TAR must include clinical documentation that demonstrates all of the following:

- Must be use for all FDA approved indications and dosages.
- Prescribed by or in consultation with a specialist (immunologist, hematologist or allergist).
- Confirmed diagnosis of HAE as documented by at least one of the following:
  - C4 level below the lower limit of normal defined by a lab performing test
  - C1-INH antigenic level below the lower limit of normal defined by a lab performing test
  - C1-INH functional level/percentage below the lower limit of normal as defined by a lab performing test
  - Genetic test confirming known C1-INH mutation››

- There is a history of at least one moderate or severe angioedema attack per month (for example airway swelling, facial edema or painful distortion, abdominal pain, etc.).
- Medications known to trigger angioedema attacks have been evaluated and discontinued when appropriate.
- ‹‹C1 esterase inhibitor (human) (Haegarda) will not be administered in conjunction with other approved treatments for acute HAE attacks (Cinryze, Takhzyro, etc.).››
- Alternative long-term prophylaxis treatments have been tried or considered, have failed, or are contraindicated.
- The physician’s legible, complete, and signed treatment plan/order for C1 esterase inhibitor (human) as a routine prophylaxis against HAE attacks or as a short-term prophylaxis prior to surgery, dental procedures, or intubation.

‹‹Authorization is for 12 months.

Reauthorization Criteria

- Meets the initial criteria as described under TAR Criteria.
- Documentation of reduction in utilization of on-demand medications used for acute attacks (e.g., Ruconest, Berinert, etc.).
- Requires documentation of at least one of the following:
  - Achieve and maintain at least a 50 percent reduction in the number of HAE attacks
  - Achieve and maintain at least a 30 percent reduction in the duration of HAE attacks
  - Achieve and maintain at least a 60 percent reduction in days of swelling

Reauthorization is for 12 months.››

Age Limit

Must be six years of age or older.››

Required Codes

The following ICD-10-CM diagnosis code is required for reimbursement:

- D84.1 (defects in the complement system [C1 esterase inhibitor (C1-INH) deficiency]).

Billing

HCPCS code J0599 (C1 esterase inhibitor [human] haegarda, 10 units).

One (1) unit of J0599 equals 10 units of C1 esterase inhibitor (human).

C1 Esterase Inhibitor (Prophylaxis) (CINRYZE®)

C1 esterase inhibitor is a normal constituent of human blood and is one of the serine proteinase inhibitors (serpins). The primary function of C1 esterase inhibitor is to regulate the activation of the complement and intrinsic coagulation (contact system) pathways. C1 inhibitor also regulates the fibrinolytic system. Regulation of these systems is performed through the formation of complexes between the proteinases and the inhibitor, resulting in inactivation of both and consumption of the C1 inhibitor.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

Age Limit

Must be six years of age or older.

Billing

HCPCS code J0598 (injection, C1 esterase inhibitor [human], 10 units).

Required ICD-10-CM Diagnosis Code

D84.1

Prescribing Restriction(s)

Frequency of billing equals every three or four days.

Maximum billing unit(s) equals 200 units for adults and adolescents (12 years old and above) and 100 units to children (six to 11 years old).

C1 Esterase Inhibitor [recombinant]) (Treatment) RUCONEST®

C1 inhibitor, a serine protease inhibitor (serpin), regulates the activation of the complement and contact system pathways by irreversibly binding target proteases. Suppression of contact system activation by C1 inhibitor through the inactivation of plasma kallikrein and factor XIIa is thought to modulate vascular permeability that leads to clinical manifestations of hereditary angioedema (HAE) attacks by preventing the generation of bradykinin.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

Age Limit

Must be 13 years of age or older.

Required ICD-10-CM Diagnosis Codes

D84.1

Prescribing Restriction(s)

Maximum billing unit(s) equals 420 units/dose.

Billing

HCPCS code J0596 (injection, C1 esterase inhibitor [recombinant], Ruconest, 10 units).

Cabotegravir Extended-Release (Apretude)

Apretude (cabotegravir) inhibits Human Immunodeficiency Virus (HIV) integrase by binding to the integrase active site and blocking the strand transfer step of retroviral deoxyribonucleic acid (DNA) integration that is essential for the HIV replication cycle.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

Age Limit

Must be 12 years of age or older (weighing at least 35 kg).

Billing

HCPCS code J0739 (injection, cabotegravir, 1 mg, FDA approved prescription, only for use as HIV pre-exposure prophylaxis [not for use as treatment for HIV]).

Prescribing Restriction(s)

Frequency of billing equals 600 mg/600 units one month apart for two consecutive months on the last day of an oral lead-in if used or within three days and continue every two months thereafter.

Maximum billing unit(s) equals 600 mg/600 units.

Note:

- HIV-1 Screening: Screen all individuals for HIV-1 infection immediately prior to initiating Apretude for HIV-1 PrEP and prior to each injection while taking Apretude.
- Prior to initiating Apretude, an oral lead-in dosing may be used for approximately one month to assess the tolerability of Apretude.

Cabotegravir Extended-Release Injectable Suspension; Rilpivirine Extended-Release Injectable Suspension (Cabenuva)

Cabenuva contains two long-acting HIV-1 antiretroviral drugs, cabotegravir and rilpivirine. Cabotegravir inhibits HIV integrase by binding to the integrase active site and blocking the strand transfer step of retroviral DNA integration.

Rilpivirine is a non-nucleoside reverse transcriptase inhibitor; activity is mediated by noncompetitive inhibition of HIV-1 reverse transcriptase.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

Age Limit

Must be 12 years of age or older.

Billing

HCPCS code J0741 (injection, cabotegravir and rilpvirine, 2 mg/3 mg).

Prescribing Restriction(s)

Frequency of billing equals initiate Cabenuva (600 mg of cabotegravir and 900 mg of rilpivirine)/300 units on the last day of oral lead-in and continue with Cabenuva (400 mg of cabotegravir and 600 mg of rilpivirine)/200 units every month thereafter.

Specialty Pharmacy Network for Cabenuva

The following specialty pharmacies currently participate in the specialty pharmacy network for Cabenuva. Fulfillment may vary based on individual health insurance plans.

Accredo

Phone: (877) 222-7336
Fax: (888) 302-1028

AHF Pharmacy

Phone: (877) 429-0708
Fax: (833) 814-1322

Avita

Phone: (469) 592-2000
Fax: (877) 234-0067

Coordinated Care Network

Phone: (877) 349-6330
Fax: (877) 770-4107

Curant Health

Phone: (866) 437-8040
Fax: (866) 437-8411

CVS Specialty

Phone: (800) 237-2767
Fax: (800) 323-2445

Fairview

Phone: (612) 672-7516
Fax: (612) 672-5330

Humana Specialty Pharmacy

Phone: (800) 486-2668
Fax: (877) 405-7940

Kroger Specialty Pharmacy

Phone: (800) 228-3643
Fax: (866) 539-1092

Mail-Meds Clinical Pharmacy

Phone: (800) 939-2022
Fax: (855) 523-0910

Meijer

Phone: (855) 263-4537
Fax: (877) 222-5036

Optum

Phone: (855) 427-4682
Fax: (877) 342-4596

Walgreens/Alliance Rx Walgreens + Prime

Phone: (888) 347-3416
Fax: (877) 231-8302

Specialty Distributor Network for Cabenuva ∞

ASD Healthcare

Phone: (800) 746-6273

Besse Medical

Phone: (800) 543-2111

Cardinal Health Specialty

Phone: (866) 476-1340

CuraScript Specialty Distribution

Phone: (800) 942-5999

McKesson Plasma and Biologics

Phone: (877) 625-2566

McKesson Specialty Health

Phone: (800) 482-6700

Oncology Supply

Phone: (800) 633-7555

Wholesaler Network for Cabenuva ∞

AmerisourceBergen Corporation

Phone: (844) 222-2273

Anda Pharmaceuticals

Phone: (800) 331-2632

Cardinal Health, Inc.

Phone: (888) 999-8031

DMS Pharmaceutical Group, Inc.

Phone: (847) 518-1100

McKesson Corporation

Phone: (855) 625-6285

Morris & Dickson Company, LLC

Phone: (800) 388-3833

Smith Drug Company

Phone: (800) 542-1216

Calcitriol

Calcitriol is indicated in the management of hypocalcemia in patients undergoing chronic renal dialysis. It has been shown to significantly reduce elevated parathyroid hormone levels. The reduction of parathyroid hormone has been shown to result in an improvement in renal osteodystrophy.

Billing

HCPCS code J0636 (injection, calcitriol, 0.1 mcg).

Calcium Gluconate

Intravenous administration of calcium gluconate increases serum ionized calcium level. Calcium gluconate dissociates into ionized calcium in plasma. Ionized calcium and gluconate are constituents of body fluids.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

Billing

HCPCS codes:

- J0613, (injection, calcium gluconate [wg critical care], per 10 mg).
- J0612, (injection, calcium gluconate [fresnius kabi], per 10 mg).

Canakinumab

Canakinumab is a recombinant, human anti-human-interleukin 1 beta (IL-1B) monoclonal antibody. Cryopyrin-Associated Periodic Syndromes (CAPS) refer to rare genetic syndromes generally caused by mutations in the NLRP-3 gene. The NLRP-3 gene encodes the protein cryopyrin which controls the activation of IL-1B. Mutations in NLRP-3 result in excessive release of activated IL-1B that drives inflammation. Canakinumab binds to human IL-1B and neutralizes its activity by blocking its interaction with IL-1 receptors.

Indications

For the treatment of CAPS in adults and children four years of age and older including:

- Familial Cold Autoinflammatory Syndrome
- Muckle-Wells Syndrome

Authorization

An approved TAR is required for reimbursement.

Dosage

The recommended dose is 150 mg for patients with a body weight greater than 40 kg. For patients between 15 and 40 kg, the recommended dose is 2 mg/kg. For children 15 to 40 kg with an inadequate response, the dose can be increased to 3 mg/kg.

Billing

HCPCS code J0638 (injection, canakinumab, 1 mg). One billing unit equals 1 mg.

Cangrelor

Cangrelor is a direct-acting P2Y12 platelet receptor inhibitor that blocks adenosine diphosphate-induced platelet activation and aggregation. Cangrelor binds selectively and reversibly to the P2Y12 receptor to prevent further signaling and platelet activation.

Indications

As an adjunct to percutaneous coronary intervention to reduce the risk of periprocedural myocardial infarction, repeat coronary revascularization and stent thrombosis in patients who have not been treated with a P2Y12 platelet inhibitor and are not receiving a glycoprotein IIb-IIIa inhibitor.

Dosage

The recommended dose is 30 mcg/kg intravenous bolus followed immediately by a 4 mcg/kg/min infusion.

Required Codes

ICD-10-CM diagnosis codes I20 thru I22.9, I24.0, I25.110 thru I25.119 and I25.700 thru I25.799

Billing

HCPCS code C9460 (injection, cangrelor, 1 mg).

Caplacizumab-yhdp (Cablivi®)

Caplacizumab-yhdp targets the A1-domain of von Willebrand factor (vWF), and inhibits the interaction between vWF and platelets, thereby reducing both vWF-mediated platelet adhesion and platelet consumption.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

TAR Criteria

The TAR must include clinical documentation that demonstrates the following:

- Must be used for FDA-approved indications and dosages.
- Patient must be at least 18 years of age or older.
- Must be prescribed by or in consultation with a hematologist.
- Patient must have a diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) (initial or recurrent), which included thrombocytopenia and microscopic evidence of red blood cell fragmentation (for example: schistocytes)
- Patient requires initiation of plasma exchange and Cablivi will be used in combination with immunosuppressive therapy (for example: systemic corticosteroids, rituximab)
- Patient does not have any of the following:
  - Known other causes of thrombocytopenia
  - Congenital TTP.

Initial authorization is for two months.

Treatment continuation (up to 28 additional days if needed):

- Patient has sign(s) of persistent underlying disease such as suppressed ADAMTS13 (A Disintegrin And Metalloproteinase with ThromboSpondin type 1 motif member 13A) activity levels.
- Patient has not experienced more than two recurrences of aTTP while on therapy.
- Patient has not received more than 58 days of Cablivi therapy after completion of the plasma exchange therapy.

Reauthorization is for two months.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code C9047 (injection, caplacizumab-yhdp, 1 mg).

Suggested ICD-10-CM Diagnosis Code

M31.1

Prescribing Restrictions

Frequency of billing:

- First day of treatment: 11 mg/11 units prior to plasma exchange, then 11 mg/11 units after plasma exchange.
- Subsequent treatment during plasma exchange: 11 mg/11 units daily following plasma exchange.
- Treatment after plasma exchange period: 11 mg/11 units daily for 30 days.
- Treatment extension if persistent underlying disease: 11 mg/11 units daily for a maximum of 28 days.

Carbidopa and Levodopa Enteral Suspension

Carbidopa and levodopa enteral suspension is a combination of carbidopa, an aromatic amino acid decarboxylation inhibitor, and levodopa, an aromatic amino acid, indicated for the treatment of motor fluctuations in patients with advanced Parkinson’s disease.

Levodopa is the metabolic precursor of dopamine, crosses the blood-brain barrier and presumably is converted to dopamine in the brain. This is thought to be the mechanism whereby levodopa treats the symptoms of Parkinson's disease.

When levodopa is administered orally, it is rapidly decarboxylated to dopamine in extracerebral tissues so that only a small portion of a given dose is transported unchanged to the central nervous system. Carbidopa inhibits the decarboxylation of peripheral levodopa, making more levodopa available for delivery to the brain. The addition of carbidopa to levodopa reduces the peripheral effects (for example, nausea and vomiting) due to decarboxylation of levodopa; however, carbidopa does not decrease the adverse reactions due to the central effects of levodopa.

Indications

Carbidopa and levodopa enteral suspension is indicated in combination with lenalidomide and dexamethasone for the treatment of motor fluctuations in patients with advanced Parkinson’s disease 18 years of age and older.

Authorization

An approved TAR is required for reimbursement.

Dosage

The maximum recommended daily dose is 2,000 mg of levodopa administered over 16 hours. Administer into the jejunum through a percutaneous endoscopic gastrostomy with jejunal tube (PEG-J) with a portable infusion pump.

Required Codes

ICD-10-CM diagnosis code G20

Billing

HCPCS code J7340 (carbidopa 5mg/ levodopa 20 mg enteral suspension, 100 ml).

Casimersen (Amondys 45)

Casimersen is designed to bind to exon 45 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 45 skipping. Exon 45 skipping is intended to allow for production of an internally truncated dystrophin protein in patients with genetic mutations that are amenable to exon 45 skipping.

Indications

All FDA-approved indications.

Dosage

All FDA-approved dosages.

TAR/SAR Requirement

An approved *Treatment Authorization Request* (TAR) or California Children's Services (CCS) Program Service Authorization Request (SAR) is required for reimbursement.

TAR/SAR Criteria

Casimersen is considered medically necessary when all of the following criteria are met:

- Must be used for FDA-approved indications and dosages.
- Patient must have a genotypically confirmed Duchenne Muscular Dystrophy (DMD), with genetic deletion amenable to exon 45 skipping.
- Care is under the supervision and monitoring of a neurologist, or for CCS patients, a CCS-paneled neurologist or physical medicine and rehabilitation specialist at a CCS Neuromuscular Medicine Special Care Center (SCC).
- The following are completed as part of the assessment for antisense oligonucleotide therapy:
  - Forced Vital Capacity (FVC)
  - Brooke score
  - Six-minute walk test (6MWT), if ambulatory, and
  - Renal toxicity screening with urinalysis, creatinine/protein ratio or serum cystatin C

- The FVC is greater than 30 percent predicted or the Brooke score is less than or equal to five.
- Only one antisense oligonucleotide treatment shall be authorized at a time.
- Patient is on a corticosteroid or has documented medical reason not to be on this medication.

Initial authorization is for 12 months.

Reauthorization

Patient has finished the initial course of treatment and all of the following apply:

- Patient has not had significant decline in FVC beyond the pre-treatment disease trajectory while on the antisense oligonucleotide treatment.
- Motor function has improved or has not declined beyond pretreatment trajectory, evidenced by improved or maintained score in 6MWT, timed function tests, Performance of Upper Limb (PUL), Brooke score, other standardized assessment of motor function, or quantifiable description of improvement by the physician or physical therapist in the medical record.
- Patient has not experienced significant adverse effects attributable to the antisense oligonucleotide treatment.
- Patients with a FVC score of less than or equal to 30 percent and Brooke score of six will not be granted authorizations because, at the time of this policy, there is insufficient evidence of efficacy in that population.

Reauthorization is for 12 months.

Additional Consideration for Medical Necessity Determination

- For CCS patients who do not meet the criteria described above, SCCs may also submit other clinical documentation and/or evidence that would support the medical necessity for initial or reauthorization of the patient’s antisense oligonucleotide treatments. SCCs should submit this documentation to the Integrated Systems of Care Division (ISCD) Medical Director or designee.

Policy Implementation for CCS Patients

A. Submissions of authorization requests for eteplirsen, golodirsen, viltolarsen, or casimersen are not included in Service Code Groupings. Providers should submit a separate SAR with the following documentation: a copy of the prescription, genetic laboratory test result with specific mutation, and clinical progress notes from a visit within the past six months.
    1. For patients residing in an independent county, SARs should be submitted to the CCS independent county office, which shall review and authorize according to the policy above.
    2. For patients residing in a dependent county, SARs should be submitted to the CCS dependent county office. The dependent county program office shall pend and submit the SAR and supporting documentation to the Department of Health Care Services (DHCS) ISCD Special Populations Authorization Unit e-mail at *CCSExpeditedReview@dhcs.ca.gov* or via secure RightFax (916) 440-5306
B. All antisense oligonucleotide requests shall be reviewed by a CCS Program Medical Director or designee before authorization.

If you have any questions regarding the policy for CCS patients, please contact the ISCD Medical Director or designee, via e-mail at ISCD-MedicalPolicy@dhcs.ca.gov.

Billing

HCPCS code J1426 (injection, casimersen, 10 mg).

Required ICD-10-CM Diagnosis Code

G71.01

Prescribing Restrictions

Frequency of billing equals 30 mg/kg once weekly.

Cefazolin

Cefazolin is a bactericidal agent. It inhibits bacterial cell wall synthesis by binding to one or more of the penicillin-binding proteins (PBPs) which in turn inhibits the final transpeptidation step of peptidoglycan synthesis in bacterial cell walls, thus inhibiting cell wall biosynthesis. Bacteria eventually lyse due to ongoing activity of cell wall autolytic enzymes (autolysins and murein hydrolases) while cell wall assembly is arrested.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

‹‹Age Limit

18 years and older (wg critical care only)››

TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

Billing

HCPCS codes:

‹‹J0687 (injection, cefazolin sodium (wg critical care), not therapeutically equivalent to J0690, 500 mg)››

J0688 (injection, cefazolin sodium [hikma], not therapeutically equivalent to J0690, 500 mg).

J0689 (injection, cefazolin sodium [baxter], not therapeutically equivalent to J0690, 500 mg).

J0690 (injection, cefazolin sodium, 500 mg).

Cefepime (Baster and B.braun)

Cefepime is a bactericidal agent that acts by inhibition of bacterial cell wall synthesis. Cefepime has a broad spectrum of in vitro activity that encompasses a wide range of Gram-positive and Gram-negative bacteria. Cefepime has a low affinity for chromosomally-encoded beta-lactamases. Cefepime is highly resistant to hydrolysis by most beta-lactamases and exhibits rapid penetration into Gram-negative bacterial cells. Within bacterial cells, the molecular targets of cefepime are the penicillin binding proteins (PBP).

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

Age Limit

Must be two months of age or older.

Billing

HCPCS codes:

J0701 (injection, cefepime hydrochloride [baxter], not therapeutically equivalent to maxipime, 500 mg).

J0703 (injection, cefepime hydrochloride [b braun], not therapeutically equivalent to maxipime, 500 mg).

Prescribing Restriction(s)

Frequency of billing equals 1g/2 units to 2g/4 units every eight to12 hours.

Maximum billing unit(s) equals 2g/4 units.

Cefiderocol (Fetroja®)

Cefiderocol is a cephalosporin antibacterial with activity against gram-negative aerobic bacteria. Cefiderocol functions as a siderophore and binds to extracellular free (ferric) iron. In addition to passive diffusion via porin channels, cefiderocol is actively transported across the outer cell membrane of bacteria into the periplasmic space using the bacterial siderophore iron uptake mechanism. Cefiderocol exerts bactericidal action by inhibiting cell wall biosynthesis through binding to penicillin-binding proteins (PBPs). Cefiderocol has no clinically relevant in vitro activity against most gram-positive bacteria and anaerobic bacteria.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

Age Limit

Must be 18 years of age and older.

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

TAR Criteria

The TAR must include clinical documentation that demonstrates all of the following:

- Must be used for FDA-approved indications and dosages.
- Patient must be 18 years of age or older.
- Patient must have a diagnosis of the following infections caused by susceptible gram-negative microorganisms:

  A. Clinical diagnosis of either complicated urinary tract infections (cUTI) with or without pyelonephritis or acute uncomplicated pyelonephritis.

  ❖ The infection is caused by the following susceptible gram-negative microorganisms: E. coli, K. pneumoniae, Proteus mirabilis, P. aeruginosa, and E. cloacae complex

- ❖ Patients who were treated previously with an empiric antibiotic but failed treatment, both clinically and microbiologically.
- ❖ Patient had an identified Gram-negative uropathogen that was not susceptible to the previously used empiric treatment and likely to be susceptible to Fetroja.
- ❖ Patient was receiving antibiotic prophylaxis for UTI but presents with signs and symptoms consistent with an active new UTI.

B. Patient has a diagnosis of hospital-acquired bacterial pneumonia (HABP), ventilator-associated bacterial pneumonia (VABP), or healthcare-associated bacterial pneumonia (HCABP)

- ❖ Patient must have a suspected Gram-negative infection involving the lower respiratory tract.
- ❖ Infection was caused by the following susceptible gram-negative microorganisms: Acinetobacter baumannii complex, Escherichia coli, Enterobacter cloacae complex, Klebsiella pneumoniae, Pseudomonas aeruginosa, and Serratia marcescens.
- ❖ Patient does not have known or suspected community-acquired bacterial pneumonia (CABP), atypical pneumonia, viral pneumonia, or chemical pneumonia (including aspiration of gastric contents, inhalation injury).

Must meet the following criteria for both diagnoses:

- The prescriber must verify that limited or no alternative treatment options are available and
- The prescriber to clinically document why the patient cannot use other clinically appropriate and cost-effective therapeutic equivalent alternatives such as imipenem/cilastatin, meropenem, fluoroquinolones, etc.

Authorization is for 14 days treatment duration.

Billing

HCPCS code J0699 (injection, cefiderocol, 10 mg).

Billing Instructions

Since the same injection will be administered more than once on the same day, each injection must be listed on a separate claim line. For additional details, refer to the *Injections: An Overview* section of the appropriate Part 2 provider manual.

Providers must use modifier XE (separate encounter) for each subsequent claim line to ensure appropriate reimbursement.

Prescribing Restrictions

Frequency of billing equals 2 g/200 units every six hours for seven to 14 days.

Maximum billing unit(s) equals 8 g/800 units.

Cefotaxime

Cefotaxime sodium, injection, per gram (HCPCS code J0698) is a broad spectrum cephalosporin antibiotic for treating serious infections caused by susceptible organisms.

Drug Limitations

Claims for cefotaxime sodium are reimbursable up to a maximum dosage of 12 grams daily. Claims in excess of 12 grams will be reimbursed at this limit. To receive additional reimbursement when billing for a quantity in excess of 12 grams, resubmit the claim with a Claims Inquiry Form (CIF) and justification for the additional dosage.

Ceftazidime and Avibactam

The use of HCPCS code J0714 (injection, ceftazidime and avibactam,0.5 g/0.125 g) is restricted to patients 18 years of age and older.

Ceftriaxone Sodium

Ceftriaxone sodium, injection, per 250 mg (HCPCS code J0696), is a parenteral cephalosporin antibiotic and is particularly effective in the treatment of penicillin-resistant gonorrhea and severe multiple-resistant gram-negative rod infections. Its long half-life (six to nine hours) permits non-institutional treatment of severe infections that would otherwise require prolonged inpatient care.

Certolizumab Pegol (Cimzia®)

Certolizumab is a pegylated humanized antibody Fab' fragment of tumor necrosis factor alpha (TNF-alpha) monoclonal antibody. Certolizumab binds to and selectively neutralizes human TNF-alpha activity. (Elevated levels of TNF-alpha have a role in the inflammatory process associated with Crohn's Disease and in joint destruction associated with rheumatoid arthritis.) Since it is not a complete antibody (lacks Fc region), it does not induce complement activation, antibody-dependent cell-mediated cytotoxicity, or apoptosis. Pegylation of certolizumab allows for delayed elimination and therefore an extended half-life.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

TAR Criteria

Cimzia is considered medically necessary when all of the following criteria are met:

- Must be used for FDA-approved indications and dosages.
- Patient must be 18 years of age or older.

- Patient must have one of the following diagnoses:
  - Moderate to severe Crohn's Disease (CD)
    - ❖ Inadequate response, intolerance or contraindication to at least one conventional therapy option such as corticosteroids (for example, prednisone, methylprednisolone, budesonide), mercaptopurine (Purinethol), azathioprine (Imuran) or methotrexate (Rheumatrex, Trexall).
    - ❖ Patient must have tried and failed one of the preferred products (Remicade [infliximab], or Humira [adalimumab]), unless intolerant, inadequate response or contraindication.
  - Moderate to severely active rheumatoid arthritis (RA)
    - ❖ Patient must have a history of failure to a three-month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD), (for example, methotrexate, leflunomide, sulfasalazine, hydroxychloroquine), at maximally indicated doses within the last six months, unless intolerant, contraindicated or clinically inappropriate.
    - ❖ Patient must have tried and failed one of the preferred products (Remicade, Enbrel or Humira) unless intolerant, inadequate response or contraindication.
  - Active psoriatic arthritis (PsA)
    - ❖ Patient must have a history of failure of a three-month trial of at least one conventional DMARD such as methotrexate at maximally indicated doses within the last six months unless intolerant, contraindicated or clinically inappropriate.
    - ❖ Patient must have tried and failed one of the preferred products (Remicade, Enbrel or Humira) unless intolerant, inadequate response or contraindication.
  - Active ankylosing spondylitis (AS)
    - ❖ Patient has inadequate response, intolerance or contraindication to at least two non-steroidal anti-inflammatory drugs (NSAIDs), for example, Ibuprofen, Naproxen, etc.
    - ❖ Patient must have tried and failed one of the preferred products (Remicade, Enbrel or Humira) unless intolerant, inadequate response or contraindication.

- Active Non-radiographic Axial Spondyloarthritis (nr-axSpA)
  - ❖ Patient has inadequate response, intolerance or contraindication to at least two NSAIDs such as ibuprofen, naproxen, etc.
  - ❖ Patient must have tried and failed one of the preferred products (Remicade, Enbrel or Humira) unless intolerant, inadequate response or contraindication.
- Moderate to severe Plaque Psoriasis (Ps)
  - ❖ Patient has a history of failure of one of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced. Corticosteroids (for example, betamethasone, clobetasol, desonide), Vitamin D analogs (for example, calcitriol, calcipotriene), Tazarotene, Calcineurin inhibitors (for example, tacrolimus, pimecrolimus), Anthralin, coal tar or phototherapy.
  - ❖ Patient must have tried and failed one of the preferred products (Remicade, Enbrel or Humira) unless intolerant, inadequate response or contraindication.

For all diagnoses, must meet the following criteria:

- Patient does not have active infection (including tuberculosis and hepatitis B virus [HBV]) or other serious active infection.
- Patient will not be taking Cimzia concurrently with any of the following:
  - Biologic DMARDs (Remicade, Enbrel or Humira), Consentyx (secukinumab), Simponi (golimumab)
  - Janus kinase inhibitor (for example, Xeljanz [tofacitinib])
  - Phosphodiesterase 4 (PDE4) inhibitor (for example, Otezla [apremilast])

Initial authorization is for 12 months.

Continued therapy:

- Patient continues to meet initial approval criteria.
- Positive clinical response as evidenced by disease improvement or stabilization compared to baseline from Cimzia use.

Reauthorization is for 12 months.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J0717 (injection, certolizumab pegol, 1 mg).

Prescribing Restriction(s)

Frequency of billing equals 400 mg/400 units every two weeks.

Maximum billing unit(s) equals 400 mg/400 units.

Cetirizine Hydrochloride (Quzyttir)

Cetirizine hydrochloride, a human metabolite of hydroxyzine, is an antihistamine; its principal effects are mediated via selective inhibition of peripheral H1-receptors. The antihistaminic activity of cetirizine hydrochloride has been clearly documented in a variety of animal and human models. In vivo and ex vivo animal models have shown negligible anticholinergic and antiserotonergic activity. In clinical studies, however, dry mouth was more common with cetirizine hydrochloride than with placebo. In vitro receptor-binding studies have shown no measurable affinity for receptors other than H1-receptors.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

Authorization

No *Treatment Authorization Request* (TAR) is required for reimbursement.

Age Limit

Must be six months of age or older.

Billing

HCPCS code J1201 (injection, cetirizine hydrochloride, 0.5 mg).

Prescribing Restriction(s)

Frequency of billing equals 10 mg/20 units every 24 hours.

Maximum billing unit(s) equals 10 mg/20 units.

Chloroprocaine (Clorotekal®)

Chloroprocaine, like other local anesthetics, blocks the generation and the conduction of nerve impulses, presumably by increasing the threshold for electrical excitation in the nerve, by slowing the propagation of the nerve impulse and by reducing the rate of rise of the action potential. In general, the progression of anesthesia is related to the diameter, myelination and conduction velocity of affected nerve fibers. Clinically, the order of loss of nerve function is as follows: (1) pain, (2) temperature, (3) touch, (4) proprioception, and (5) skeletal muscle tone.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J2402, (injection, chloroprocaine hydrochloride [clorotekal], per 1 mg).

Prescribing Restriction(s)

Frequency of billing equals 50 mg/50 units as a single dose.

Maximum billing unit(s) equals 50 mg/50 units.

Chloroprocaine (Nesacaine®, Nesacaine®-MPF)

Chloroprocaine, like other local anesthetics, blocks the generation and the conduction of nerve impulses, presumably by increasing the threshold for electrical excitation in the nerve, by slowing the propagation of the nerve impulse and by reducing the rate of rise of the action potential. In general, the progression of anesthesia is related to the diameter, myelination and conduction velocity of affected nerve fibers. Clinically, the order of loss of nerve function is as follows: (1) pain, (2) temperature, (3) touch, (4) proprioception, and (5) skeletal muscle tone.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

Billing

HCPCS code: J2401, (injection, chloroprocaine hydrochloride, per 1 mg).

Cidofovir

Cidofovir is an anti-viral agent that suppresses cytomegalovirus (CMV) replication by selective inhibition of CMV DNA polymerase. Cidofovir is reimbursable for the treatment of CMV retinitis in patients with AIDS and when billed with HCPCS code J0740 (injection, cidofovir, 375 mg).

Dosage

Cidofovir must be diluted in 100 ml of 0.9 percent (normal) saline prior to administration. The drug is administered at an induction dose of 5 mg/kg body weight as an intravenous infusion at a constant rate over one hour, given once weekly for two consecutive weeks. The recommended maintenance dose is 5 mg/kg body weight administered once every two weeks.

The maximum dosage is 680 mg every two weeks.

Infusion Administration

CPT codes 96365 (intravenous infusion, for therapy, prophylaxis, or diagnosis; initial, up to 1 hour) and 96366 (intravenous infusion, for therapy, prophylaxis, or diagnosis; each additional hour) are reimbursable in conjunction with cidofovir, as well as up to two liters of 0.9 percent (normal) saline, for the pre- and post-hydration needed with this drug.

Clindamycin Phosphate

Clindamycin exerts its antibacterial effect by binding to the 50 S ribosomal subunit of susceptible bacteria, causing a reduction in the rate of synthesis of nucleic acid, and cessation of protein synthesis.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

Billing

HCPCS codes:

- J0736 (injection, clindamycin phosphate 300 mg).
- J0737 (injection, clindamycin phosphate [Baxter], not therapeutically equivalent to J0736, 300 mg).

Coagulation factor Xa (recombinant), Inactivated-rhzo (Andexxa®)

Andexxa is a recombinant modified human Factor XA (FXa) protein Coagulation factor Xa (recombinant), inactivated-rhzo that exerts its procoagulant effect by binding and sequestering the FXa inhibitors, rivaroxaban and apixaban. It also exerts a procoagulant effect by binding to and inhibiting the activity of Tissue Factor Pathway Inhibitor (TFPI). Inhibition of TFPI activity can increase tissue factor-initiated thrombin generation.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

TAR Criteria

Andexxa (andexanet alfa) will be considered medically necessary when all of the following criteria are met:

- Must be prescribed for FDA-approved indications and dosing regimens.
- Patient must be 18 years of age or older.
- Must show clinical documentation that Andexxa is being used for reversal of anticoagulation due to life-threatening or uncontrolled bleeding in patients treated with rivaroxaban or apixaban.

- Patient must have received the last dose of apixaban or rivaroxaban, less than or equal to 18 hours prior to the start of the Andexxa bolus.
- Patient must not be a pregnant or lactating female.
- Patient is not scheduled to undergo surgery in less than 12 hours with the exception of minimally invasive surgeries or procedures.
- Patient has no recent history (within two weeks) of a diagnosed thrombotic event prior to the bleeding event.

Approval is limited to one course of treatment.

Age Limit

Must be 18 years of age or older.

Billing

HCPCS code J7169 (injection, coagulation factor xa [recombinant], inactivated-rhzo [andexxa], 10 mg).

Prescribing Restriction

Maximum billing units equals 1,800 mg/180 units.

Collagenase Clostridium Histolyticum

Collagenases are proteinases that hydrolyze collagen in its native helical conformation under physiological conditions, resulting in lysis of collagen deposits. Injection of collagenase clostridium histolyticum into a Dupuytren's cord, which is comprised mostly of collagen, may result in enzymatic disruption of the cord. Purified collagenase clostridium histolyticum consists of collagenase AUX-I and collagenase AUX-II both of which are isolated and purified from the fermentation of *Clostridium histolyticum* bacteria.

Indications

Collagenase clostridium histolyticum is indicated for the treatment of adult patients aged 18 years and older with Dupuytren's contracture with a palpable cord.

Collagenase clostridium histolyticum should be administered by a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytren's contracture.

Dosage

The usual dose is 0.58 mg, injected into a palpable Dupuytren's cord with a contracture followed 24 hours later by a finger extension procedure if a contracture persists.

Injections and finger extension procedures may be administered up to three times per cord at approximately four-week intervals.

Billing

HCPCS code J0775 (injection, collagenase, clostridium histolyticum, 0.01 mg).

Conivaptan Hydrochloride

Conivaptan HCL is a dual arginine vasopressin (AVP) antagonist with nanomolar affinity for human V1A and V2 receptors in vitro. The level of AVP in circulating blood is critical for the regulation of water and electrolyte balance and is usually elevated in both euvolemic and hypervolemic hyponatremia. The AVP effect is mediated through V2 receptors, which are functionally coupled to aquaporin channels in the apical membrane of the collecting ducts of the kidney. These receptors help to maintain plasma osmolality within the normal range. The predominant pharmacodynamic effect of conivaptan hydrochloride in the treatment of hyponatremia is through its V2 antagonism of AVP in the renal collecting ducts, an effect that results in aquaresis, or excretion of free water.

Indications

Conivaptan HCL is indicated for patients 18 years of age and older, to raise serum sodium in the treatment of hospitalized patients with euvolemic and hypervolemic hyponatremia.

Dosage

Administer conivaptan HCL accordingly:

- Loading dose: 20 mg I.V. administered over 30 minutes, followed by:
  - Continuous infusion: 20 mg per day over 24 hours, for two to four days
  - Following initial day of treatment, dosage may be increased to 40 mg/day continuous infusion as needed to raise serum sodium
  - Monitor volume status and serum sodium frequently and discontinue if patient develops hypovolemia, hypotension or an undesirably rapid rate of rise of serum sodium
  - Hepatic impairment: decrease the dose in patients with moderate hepatic impairment

Authorization

An approved TAR is required for reimbursement. The TAR must state that the adult patient is hospitalized with euvolemic and hypervolemic hyponatremia.

Billing

HCPCS code C9488 (injection, conivaptan hydrochloride, 1 mg).

Repository Corticotropin Injection (ACTHAR GEL)

Acthar Gel is a naturally sourced complex mixture of adrenocorticotropic hormone analogs and other pituitary peptides. The Acthar Gel manufacturing process converts the initial porcine pituitary extract with low ACTH content into a mixture having modified porcine ACTH and other related peptide analogs solubilized in gelatin. Acthar Gel and endogenous ACTH stimulate the adrenal cortex to secrete cortisol, corticosterone, aldosterone, and a number of weakly androgenic substances.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

TAR Criteria

The TAR must include clinical documentation that demonstrates the following:

- Must be used for an FDA-approved indication and dosage.
- Not for use in patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction, or sensitivity to proteins of porcine origin.
- For infantile spasms:
  - Patient had inadequate response, intolerance, or contraindication to corticosteroid or vigabatrin.
  - Not suspected of congenital infections.
- For multiple sclerosis:
  - Documentation of concurrent multiple sclerosis agent.
  - Patient had inadequate response, intolerance, or contraindication to IV methylprednisolone or high dose oral prednisone.

Duration of approval is for four weeks.

Billing

HCPCS code J0801 (Injection, corticotropin [acthar gel], up to 40 units).

Prescribing Restriction(s)

Frequency of billing equals 120 USP units/three units daily.

Maximum billing unit(s) equals 120 USP units/three units.

Repository Corticotropin Injection (Purified Cortrophin Gel)

Purified Cortrophin Gel is a porcine derived purified corticotropin (ACTH) in a sterile solution of gelatin. It is made up of a complex mixture of ACTH, ACTH related peptides and other porcine pituitary derived peptides. Purified Cortrophin Gel is the anterior pituitary hormone which stimulates the functioning adrenal cortex to produce and secrete adrenocortical hormones.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

TAR Criteria

The TAR must include clinical documentation that demonstrates the following:

- For FDA-approved indications and treatment regimens.
- TARs may be approved for any of the FDA-approved indications. In many instances, corticotropin is not considered first line therapy and may be used in special circumstances. The TAR must not only state the diagnoses but also must contain sufficient clinical information to establish medical necessity.
- Must document why other alternatives are not adequate, effective or have been deemed to be clinically contraindicated for the individual patient.
  - **Rheumatic disorders:** As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in psoriatic arthritis, rheumatoid arthritis, ankylosing spondylitis, and/or acute gouty arthritis.

  - **Collagen diseases:** During an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus or systemic dermatomyositis (polymyositis).
  - **Dermatologic diseases:** Treatment of severe erythema multiforme (Stevens-Johnson syndrome) or severe psoriasis.
  - **Allergic states:** Treatment of atopic dermatitis or serum sickness.
  - **Ophthalmic diseases:** Treatment of severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as allergic conjunctivitis, keratitis, iritis, iridocyclitis, diffuse posterior uveitis, choroiditis, optic neuritis, chorioretinitis, and anterior segment inflammation.
  - **Respiratory diseases: s**ymptomatic sarcoidosis
  - **Edematous states:** To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.
  - **Nervous system:** Acute exacerbations of multiple sclerosis.
- Patient does not have scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, hypertension, or sensitivity to proteins derived from porcine sources.

Duration of approval is for four weeks.

Billing

HCPCS code J0802 (injection, corticotropin [ani], up to 40 units.).

Prescribing Restriction(s)

Frequency of billing equals 120 USP units/three units daily.

Maximum billing unit(s) equals 120 USP units/three units.

Crizanlizumab-tmca (Adakveo)

Crizanlizumabtmca is a selectin blocker humanized IgG2 kappa monoclonal antibody that binds to P-selectin. Crizanlizumab-tmca is produced using recombinant DNA technology in Chinese hamster ovary (CHO) cells. Crizanlizumab-tmca binds to P-selectin and blocks interactions with its ligands including P-selectin glycoprotein ligand 1. Binding P-selectin on the surface of the activated endothelium and platelets blocks interaction between endothelial cells, platelets, red blood cells and leukocytes.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

An approved TAR is required for reimbursement.

TAR Criteria

The TAR must include clinical documentation that demonstrates the following:

- Prescribed for FDA-approved indications and dosing regimens.
- Patient must be 16 years of age or older.
- Patient must have a diagnosis of sickle cell disease, identified by any genotype (for example, HbSS, HbSC, HbS/Beta0 Thalassemia or HbS/Beta+ Thalassemia).
- Patient has experienced at least two vaso-occlusive crises (VOCs) in the previous 12 months or
- Patient has a history of other VOCs such as acute chest syndrome, hepatic sequestration, splenic sequestration and priapism (requiring a medical facility visit).

Initial approval: 12 months

Reauthorization: 12 months

Approvable for lifetime if patient shows continued clinical benefits such as reduction in the annual rate of VOCs leading to a healthcare visit.

Age Limit

Must be 16 years of age or older.

Billing

HCPCS code J0791 (injection, crizanlizumab-tmca, 5 mg).

Suggested ICD-10 Diagnosis Codes

D57.00, D57.01, D57.02, D57.20, D57.211, D57.212, D57.219, D57.3, D57.40, D57.411, D57.412, D57.419, D57.811, D57.812, D57.819

Prescribing Restriction

Frequency of billing equals 5 mg/kg on week zero, week two and every four weeks thereafter.

Crotalidae Immune F(ab')$_2$ (equine) (ANAVIP®)

Anavip contains venom-specific F(ab')2 fragments of immunoglobulin G (IgG) that bind and neutralize venom toxins of North American pit vipers (genera Crotalus and Sistrurus and genus Agkistrodon), facilitating redistribution away from target tissues and elimination from the body.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

No *Treatment Authorization Request* (TAR) is required for reimbursement.

Required Codes

One of following ICD-10-CM diagnosis codes is required for reimbursement:

- T63.011A thru T63.014S (toxic effect of rattlesnake venom).

Billing

HCPCS code J0841 (injection, crotalidae immune F(ab') $_2$ [equine], 120 mg).

One (1) unit of J0841 equals 120 mg of crotalidae immune F(ab') $_2$ (equine) injection solution.

‹‹Crovalimab-akkz (PIASKY)

Crovalimab-akkz is a monoclonal antibody that specifically binds with high affinity to the complement protein C5, inhibiting its cleavage into C5a and C5b, preventing the formation of the membrane attack complex (MAC). Crovalimab-akkz inhibits terminal complement-mediated intravascular hemolysis in patients with PNH.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement.

TAR Criteria

Crovalimab-akkz is considered medically necessary in appropriate patients when the following criteria are met:

- Must be used for FDA-approved indications and dosages.
- Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients with complement deficiencies.››

- ‹‹Patient must be vaccinated against meningococcal infections within three years prior to, or at the time of initiating Crovalimab-akkz (at least two weeks prior to treatment, if not previously vaccinated). In emergent situations, antibiotics may be appropriate with vaccination less than two weeks prior to treatment.
- Patient must be 13 years of age or older.
- Prescriber is enrolled in the PIASKY REMS program.
- Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) is established by flow cytometry that demonstrates a population of granulocytes and red blood cells (RBCs) that are deficient in glycosylphosphatidylinositol (GPI)-linked proteins (e.g., CD55, CD59) in an appropriate clinical setting, such as direct antiglobulin testing (DAT)-negative hemolytic anemia, thrombosis, unexplained abdominal pain, aplastic anemia (AA), or myelodysplastic syndrome (MDS).

For Treatment Naive Patients:

- Lactate dehydrogenase (LDH) level greater than or equal to two times the upper limit of normal (ULN) at the screening and at least one or more of PNH-related signs or symptoms in the past three months of screening (for example, fatigue, dyspnea, transfusion dependence, episodic hemoglobinuria, thrombosis, abdominal pain, bone marrow suppression and/or organ dysfunction). (Documentation is required).

For Eculizumab or Ravulizumab Conversion Patients:

- Lactate dehydrogenase (LDH) level less than or equal to one and a half times the upper limit of normal (ULN) and patient has received approved eculizumab doses for at least six months. (Documentation is required).

Initial authorization for up to six months.

Continued Therapy

Continuation of therapy in appropriate patients is considered medically necessary for the treatment of a patient with documented PNH who is currently receiving treatment with Crovalimab-akkz and one of the following:

- Improvement in hemolysis (LDH level less than or equal to one and a half times the ULN)
- Hemoglobin stabilization
- Transfusion avoidance
- improvement in FACIT

Reauthorization for up to 12 months.››

‹‹REMS

Due to the risk of meningococcal infections, PIASKY is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS).

Prescribers must enroll in the program. Enrollment and additional information are available by telephone: 1-866-4My-Skyy (469-7599) or on the PIASKY website.

Age Limits

Must be 13 years of age or older.

Billing

HCPCS code J1307 (injection, crovalimab-akkz, 10 mg).››

Legend

Symbols used in the document above are explained in the following table.

Symbol	Description
‹‹	This is a change mark symbol. It is used to indicate where on the page the most recent change begins.
››	This is a change mark symbol. It is used to indicate where on the page the most recent change ends.
*	References: 1) The 2014 ERS/ATS (European Respiratory Society/ American Thoracic Society) Task Force Report Guidelines on Severe Asthma and 2) The 2007 NAEPP (National Asthma Education and Prevention Program) Expert Panel Report 3, U.S. Department of Health and Human Services National Institutes of Health
∞	Represents a majority of authorized networks of full-line wholesalers that are eligible to inventory Cabenuva provided they service eligible class of trade.