Injections: Drugs A-D Policy

Page updated: September 2020

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:

- *Injections: Drugs E–H Policy*
- *Injections: Drugs I–M Policy*
- *Injections: Drugs N–R Policy*
- *Injections: Drugs S–Z Policy*
- *Injections: Hydration*
- *Immunizations*

‹‹Abatacept (Orencia)

Abatacept, a selective costimulation modulator, inhibits T-cell (T lymphocyte) activation by binding to CD80 and CD86, thereby blocking interaction with CD28. This interaction provides a costimulatory signal necessary for full activation of T lymphocytes. Activated T lymphocytes are implicated in the pathogenesis of RA, pJIA and PsA and are found in the synovium of patients with RA, pJIA and PsA. In vitro, abatacept decreases T-cell proliferation and inhibits the production of the cytokines TNF alpha (TNFD), interferon-J, and interleukin-2. In a rat collagen-induced arthritis model, abatacept suppresses inflammation, decreases anti-collagen antibody production and reduces antigen specific production of interferon-J. The relationship of these biological response markers to the mechanisms by which Orencia® exerts its clinical effects is unknown.››

Indications

‹‹All FDA-approved indications››

Dosage

‹‹FDA-approved dosages››

‹‹TAR Requirements

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

‹‹Age Limits››

‹‹Must be 2 years of age and older ››

Billing

HCPCS code J0129 (injection, abatacept, 10 mg)

One (1) unit of J0129 equals 10 mg of abatacept

AbobotulinumtoxinA

For detailed clinical and billing policy information about abobotulinumtoxinA, refer to the “Botulinum Toxins A and B” topic in this manual section.

Acetaminophen

Although not fully elucidated, the analgesic effects are believed to be due to activation of descending serotonergic inhibitory pathways in the CNS. Interactions with other nociceptive systems may be involved as well (Smith 2009). Antipyresis is produced from inhibition of the hypothalamic heat-regulating center.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Age Limits

Must be two years of age or older (HPCS codes J0131 and J0134). ‹‹All ages (HCPCS code J0136 and J0137)››

Billing

HCPCS codes:

J0131, (injection, acetaminophen, 10 mg).

J0134, (injection, acetaminophen [fresenius kabi] not therapeutically equivalent to J0131, 10 mg).

J0136, (injection, acetaminophen [B. Braun] not therapeutically equivalent to J0131, 10 mg).

‹‹J0137 (injection, acetaminophen [Hikma] not therapeutically equivalent to J0131, 10 mg).››

Prescribing Restriction(s)

Frequency of billing equals 4,000 mg/400 units.

Maximum billing unit(s) equals 4,000 mg/400 units per day.

‹‹Adalimumab-aacf (Idacio®)

Adalimumab is a recombinant monoclonal antibody that binds to human tumor necrosis factor alpha (TNF-alpha), thereby interfering with binding to TNFα receptor sites and subsequent cytokine-driven inflammatory processes. Elevated TNF levels in the synovial fluid are involved in the pathologic pain and joint destruction in immune-mediated arthritis. Adalimumab decreases signs and symptoms of psoriatic arthritis, rheumatoid arthritis, and ankylosing spondylitis. It inhibits progression of structural damage of rheumatoid and psoriatic arthritis. Reduces signs and symptoms and maintains clinical remission in Crohn disease and ulcerative colitis; reduces epidermal thickness and inflammatory cell infiltration in plaque psoriasis.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

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

Universal criteria:

- Must be used for FDA-approved indications and dosages
- Patient does not have active infection (including tuberculosis and hepatitis B virus [HBV]) or other serious active infection
- Patient will not be taking Idacio 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])

Patient must have one of the following diagnoses:

Rheumatoid Arthritis

- Documented diagnosis of Rheumatoid Arthritis (RA)
- Patient must be 18 years of age or older››

- ‹‹Patient must have a history of failure of 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; OR
  - For use as an alternative to methotrexate in DMARD–naive patients with moderate to high disease activity, or as adjunctive therapy in patients who have not met treatment goals despite maximally tolerated methotrexate therapy
- Idacio may be used alone or in combination with other non-biologic DMARDs, glucocorticoids, non-steroidal anti-inflammatory drugs (NSAIDs), and/or analgesics

Juvenile Idiopathic Arthritis

- Documented diagnosis of moderate to severely active polyarticular juvenile idiopathic arthritis
- Patient mut be 2 years of age or older
- Inadequate response, intolerance, or contraindication to one or more of the following conventional therapies: NSAID plus a glucocorticoid with or without methotrexate, etc., unless clinically inappropriate
- Idacio may be used alone or in combination with methotrexate

Psoriatic Arthritis

- Documented diagnosis of active psoriatic arthritis
- Patient must be 18 years of age or older
- Patient must have a history of failure of a three-month trial of at least one conventional Disease-Modifying Antirheumatic Drugs (DMARDS) such as methotrexate at maximally indicated doses within the last six months unless intolerant, contraindicated or clinically inappropriate
- Idacio can be used alone or in combination with non-biologic DMARDS, for example methotrexate, leflunomide, sulfasalazine, hydroxychloroquine, azathioprine, etc.
- May continue methotrexate, other non-biologic DMARDs, corticosteroids, NSAIDs, and/or analgesics with Idacio

Ankylosing Spondylitis

- Documented diagnosis of active ankylosing spondylitis
- Patient must be 18 years of age or older
- Patient must have a history of inadequate response, intolerance or contraindication to at least two NSAIDs, for example, Ibuprofen, Naproxen, etc., unless clinically inappropriate››

‹‹Crohn's Disease

- Documented diagnosis of moderately to severely active Crohn's disease
- Patient must be 6 years of age or older
- Patient must have a history of inadequate response, intolerance, or contraindication to one or more of the following conventional therapies: Oral 5-aminosalicylates (eg, sulfasalazine, mesalamine), glucocorticoids (e.g., prednisone, budesonide), immunomodulators (e.g., azathioprine, 6-mercaptopurine, methotrexate); unless clinically inappropriate
- Idacio therapy may be combined with an immunomodulator (i.e., thiopurine or methotrexate)

Ulcerative Colitis, Moderate-To-Severe

- Documented diagnosis of moderately to severely active ulcerative colitis
- Patient must be 18 years of age or older
- Patient must have a history of inadequate response, intolerance, or contraindication to one or more of the following conventional therapies: Oral 5-aminosalicylates (e.g., sulfasalazine, mesalamine), glucocorticoids (e.g., prednisone, budesonide), immunomodulators (e.g., azathioprine, 6-mercaptopurine, methotrexate), unless clinically inappropriate

Plaque Psoriasis

- Documented diagnosis of chronic moderate to severe plaque psoriasis
- Patient must be 18 years of age or older
- Patient is a candidate for systemic therapy or phototherapy
- Patient must have 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
- Idacio is generally used as systemic monotherapy; may continue adjuvant topical therapies (e.g., emollients, corticosteroids) as needed

Initial authorization is for 12 months

Continued Therapy

- Patient continues to meet initial approval criteria
- Positive clinical response as evidence by disease improvement or stabilization compared to baseline

Reauthorization is for 12 months››

‹‹Billing

HCPCS code Q5131 (Injection, adalimumab-aacf [Idacio], biosimilar, 20 mg)››

Aducanumab–avwa (Aduhelm)

Aducanumab-avwa is a human, immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta. The accumulation of amyloid beta plaques in the brain is a defining pathophysiological feature of Alzheimer's disease.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must include clinical documentation that demonstrates all of the following:

- Must be used for FDA-approved indications and dosages
- Patient is a Medi-Cal only beneficiary and is not a Medicare and Medi-Cal (dually eligible) enrollee (see below for additional information regarding dually eligible enrollees).
- Patient must be 50 to 85 years old.
  - Or patient is 50 years old or younger and has early onset Alzheimer's disease (AD) and meets eligibility criteria.
- Must be prescribed by or in consultation with a neurologist, geriatrician or psychiatrist.
- Patient must have a diagnosis of mild cognitive impairment (MCI) due to AD or mild AD and must have:
  - A global Clinical Dementia Rating (CDR) score of 0.5
  - A Mini-Mental State Examination (MMSE) score of 24 to 30
  - A positive amyloid Positron Emission Tomography (PET) scan or cerebrospinal fluid (CSF) testing for tau proteins.
  - An objective evidence of cognitive impairment at screening

- Patient must have an MRI at baseline and at 7 and 12 months to monitor for amyloid-related imaging abnormalities (ARIA).
  - Patients should be evaluated for brain hemorrhage, bleeding disorders, or cerebral abnormalities to assess potential risk for ARIA.
- If on drugs to treat symptoms related to AD, must be stable for at least 8 weeks prior to treatment initiation.
- Patient does not have any of the following:
  - A stroke or Transient Ischemic Attack (TIA) or unexplained loss of consciousness in the past 1 year
  - Relevant brain hemorrhage, bleeding disorder and cerebrovascular abnormalities
- All other causes of cognitive impairment have been excluded such as the following:
  - Vascular Dementia (for example, stroke, transient ischemic attack)
  - Lewy body dementia
  - Frontotemporal dementia
- Patient is not taking blood thinners (except for aspirin at a prophylactic dose or less)

Initial approval is for twelve months.

Continued therapy

- Patient has shown clinical benefit as evidenced by at least one of the following or by other standard assessment scales:
  - A reduction in amyloid beta plaque from baseline in PET imaging of brain.
  - An improvement from baseline in Clinical Dementia Rating Scale-Sum of Boxes (CDR-SB) score.
  - An improvement from baseline in MMSE score.
- Patient does not have hypersensitivity reactions such as angioedema and urticaria.

Reauthorization is for twelve months.

Age Limits

Must be 50 to 85 years of age

Billing

HCPCS code J0172 (injection, aducanumab-avwa, 2 mg)

Required ICD-10-CM Diagnosis Codes

Primary diagnosis codes: G30.0, G30.1, G30.8, G30.9, G31.84.

Secondary diagnosis codes: F03.90, F03.91.

Prescribing Restriction

Frequency of billing is every three weeks

Guidance for Dually Eligible/Medi-Medi Enrollees

For enrollees that qualify for both Medicare and Medicaid, under the terms of the National Coverage Determination (NCD), Medicare limits Aduhelm coverage to Medicare Part B enrollees who are participating in a clinical trial for the drug. Enrollees must obtain this benefit directly from Medicare. Additional information can be found on the CMS webpage "Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease"

Beneficiaries/caregivers may go to the National Institutes of Health's' clinical trials webpage to search for a particular study of interest. A search using the terms "**Alzheimer's disease**," "**Biogen**," and "**recruiting**" may help yield results.

Note: If study locations and contacts are listed on clinicaltrials.gov, beneficiaries can contact the site directly for more information on how to enroll. If study locations and contacts are NOT listed, contact Biogen (the manufacturer of Aduhelm) directly for more information: 1-833-425-9360.

Below are Enrolling/Upcoming Studies in the United States (US).

Phase 4 ENVISION Confirmatory Study

As part of the post-marketing requirement, in June 2021, the US Food and Drug Administration (FDA) announced that a confirmatory trial of Aduhelm was required as part of the accelerated approval. The initiation of patient screening for ENVISION is planned for May 2022. The ENVISION study will be a global, placebo-controlled trial, aiming to enroll 1,500 patients with early Alzheimer's disease. Once the study begins recruiting, information will be posted on: clinicaltrials.gov. Beneficiaries can check that website for the most up-to-date information.

ICARE AD Trial in the US

Biogen is conducting an ongoing International Collaboration for Real-World Evidence in Alzheimer's Disease (ICARE AD) trial (NCT05097131) in the US. The ICARE AD trial is only enrolling patients who will be prescribed aducanumab-avwa by their treating physician, independently of their participation in the study. The study is taking place at sites in the US and patients can participate at an approved site if they meet study criteria. Further information about the study can be found on the ICARE AD trial webpage, also known as Observational Study of Aducanumab-avwa in Participants with Alzheimer's Disease in the US, on the clinicaltrials.gov website.

2 Ways of Obtaining Aduhelm

Aduhelm can be obtained through either via a specialty distributor (SD) or a specialty pharmacy (SP):

Specialty Distributor (SD) Contacts

SD Name	Phone	Fax
Besse Medical	800-543-2111	800-543-8695
ASD Healthcare	800-746-6273	800-547-9413
Oncology Supply	800-633-755	800-248-8205
Cardinal SPD	866-476-1340	NA
Metro Medical	800-768-2002	NA
CuraScript SD	877-599-7748	800-862-6208
McKesson Plasma and Biologics	877-625-2566	888-752-7626
McKesson Specialty Health	855-477-9800	800-800-5673

Specialty Pharmacy (SP) Contacts

SD Name	Phone	Fax
Accredo	844-412-4764	877-327-4157
Amber Pharmacy	833-448-7322	833-448-7318
CVS Speciality	866-526-4984	855-592-6890
Optum Specialty Pharmacy	855-427-4682	877-342-4596
Orsini	800-264-5899	877-848-8617
Soleo Health	844-960-9090	844-276-1706
Special Care	888-727-1727	855-230-9963

Note: SD and SP names and contact information are subject to change.

Afamelanotide Implant

Afamelanotide is a synthetic tridecapeptide and a structural analog of α-melanocyte stimulating hormone (α-MSH). Afamelanotide is a melanocortin receptor agonist and binds predominantly to MC1-R.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

Age

18 years and older

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. 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 has the characteristic symptoms of erythropoietic protoporphyria (EPP) phototoxicity and a biochemically-confirmed diagnosis of EPP
- Must be prescribed by or in consultation with a dermatologist or other physician with expertise in treating EPP
- Patient must not be a pregnant or lactating female
- Patient does not have any of the following:
  - Significant EPP-associated hepatic involvement
  - Personal history of melanoma or dysplastic nevus syndrome
  - Current Bowen's disease, basal cell carcinoma, squamous cell carcinoma, or other malignant or premalignant skin lesions
  - Any other photodermatosis such as polymorphic light eruption, actinic prurigo, discoid lupus erythematosus, chronic actinic dermatitis or solar urticaria

Initial authorization is for 6 months

Continued therapy:

- Patient continues to meet initial approval criteria
- Patient has experienced clinical improvement as evidenced by improvement in at least one of the following:
  - Combined Sun Exposure and Phototoxic Pain. Time in direct sunlight exposure between 10 am and 6 pm on days when no or mild pain was experienced (Likert scores of 0 to 3)
  - Sun Exposure. Duration of direct sunlight exposure between 10 am and 6 pm while on medication
  - Number of hours spent outdoors between 10 am and 3 pm, mostly in direct sunlight, shade, or a combination of both, and if any phototoxic pain was experienced that day

- Quality of life measure measured with the Dermatology Life Quality Index (DLQI) score 0 thru 30, or the Erthropoietic protoporphyria quality of life measure (EPP-QoL) score 0 thru 100

Reauthorization is for 6 months

Billing

HCPCS code J7352 (afamelanotide implant, 1 mg)

Prescribing Restrictions

Frequency of billing equals 16 mg/ 16 units every two months

Maximum billing unit(s) equals 16 mg/ 16 units

Aflibercept

Policy for intravitreal Aflibercept (HCPCS code J0178) is located in the *Ophthalmology* section of the part 2 provider manual.

Agalsidase Beta

For detailed billing policy information about agalsidase beta, refer to the “Enzyme Replacement Drugs” topic in *the Injections: Drugs E-H Policy* section of this manual.

Alemtuzumab (Lemtrada)

Alemtuzumab is a recombinant humanized IgG1 kappa monoclonal antibody directed against the cell surface glycoprotein, CD52. The precise mechanism by which alemtuzumab exerts its therapeutic effects in multiple sclerosis is unknown but is presumed to involve binding to CD52, a cell surface antigen present on T and B lymphocytes, and on natural killer cells, monocytes and macrophages. Cell surface binding to T and B lymphocytes results in antibody-dependent cellular cytolysis and complement-mediated lysis.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirements

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

TAR Criteria

Patient must meet **all** of the following requirements:

- Patient must be 18 years of age or older
- Patient must have Relapsing Multiple Sclerosis (MS) diagnosis confirmed by laboratory report
- Patient must have tried and failed two or more drugs indicated for the treatment of MS
- Patient must have received a baseline skin exam for melanoma
- Patient must be evaluated and screened for the presence of varicella zoster virus (VZV) and vaccinated, if required, prior to initiating treatment
- All vaccinations must be completed at least 6 weeks prior to starting treatment
- Patient should be screened for the presence of tuberculosis
- Administered with anti-viral prophylaxis for herpetic viral infections initiated on the first day of treatment and continued for two months following treatment (or until the CD4+ lymphocyte count is greater than or equal to 200 cells/mcL
- Patient has a baseline urine protein to creatinine ration measured prior to initiation of treatment
- Patient has a baseline thyroid-stimulation hormone (TSH) level prior to initiation of treatment
- Prescriber and patient must be enrolled in and meet the conditions of the Lemtrada REMS program
- Patient must not have human immunodeficiency virus (HIV) infection
- Alemtuzumab may not be used in combination with another MS disease modifying agent

Initial authorization is for 6 months (5 doses on 5 consecutive days).

Continued therapy

- Patient continues to meet the criteria for initial authorization
- Patient is receiving ongoing monitoring for presence of TB or other active infections
- Patient is receiving yearly skin exam for melanoma
- Patient is receiving ongoing laboratory monitoring (e.g., urine protein to creatinine ration, TSH levels, etc.) and physical examinations.
- Continuous monitoring of response to therapy
- Absence of unacceptable toxicity from the drug

- Patient has not received a dose of alemtuzumab within in the past 12 months

Reauthorizations is for 12 months

Lemtrada REMS

The purpose of the Lemtrada REMS (Risk Evaluation and Mitigation Strategy) is to inform prescribers, pharmacies, healthcare facilities, and patients about the risks of:

Autoimmune Conditions

Lemtrada causes serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia and anti-glomerular basement membrane disease. Monitor complete blood counts with differential, serum creatinine levels, and urinalysis with urine cell counts at periodic intervals for 48 months after the last dose of Lemtrada.

Infusion Reactions

Lemtrada causes serious and life threatening infusion reactions. Lemtrada must be administered in a setting with appropriate equipment and personnel to manage anaphylaxis or serious infusion reactions.

Stroke

Serious and life-threatening stroke (including ischemic and hemorrhagic stroke) has been reported within 3 days of Lemtrada administration. Instruct patients to seek immediate medical attention if symptoms of stroke occur.

Malignancies

Lemtrada may cause an increased risk of malignancy including thyroid cancer, melanoma, and lymphoproliferative disorders. Perform baseline and yearly skin exams.

Age Limits

Must be 18 years of age or older

Billing

HCPCS code J0202 (injection, alemtuzumab, 1 mg)

Prescribing Restrictions

Frequency of billing equals 12 mg/ 12 units for five consecutive doses on five consecutive days followed by 12mg / 12 units on 3 consecutive days every 12 months.

Maximum billing unit(s) equals 12 mg/ 12 units

‹‹Alfentanil Hydrochloride (Alfenta®)

Alfentanil injection is an opioid agonist. The principal actions of therapeutic value are analgesia and sedation.

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 for FDA-approved indications and dosing regimens
- Must be prescribed by or in consultation with a pain specialist in accordance with the Clinical Practice Guidelines for Prescribing Opioids
- Must be administered only by persons specifically trained in the use of intravenous anesthetics and management of the respiratory effects of potent opioids in accordance with Infusion Dosage Guidelines for Continuous Infusion
- Patient must be 12 years of age or older
- Patient does not have:
  - Severe sleep apnea syndrome (apnea-hypopnea index is more than 40) or baseline hypoxia with measured peripheral capillary oxygen saturation (SpO_2) is less than 90 percent in room air
  - A history of alcohol abuse or current use of any psychiatric medication
  - Neurologic disorders or other conditions contributing to difficulty in assessing a conscious response

Approval is for 30 days (one procedure)

Age Limits

Must be 12 years of age or older

Billing

HCPCS Code J0216 (Injection, alfentanil hydrochloride, 500 micrograms)››

Algucosidase Alfa

For detailed billing policy information about algucosidase alfa, refer to the “Enzyme Replacement Drugs” topic in the *Injections: Drugs E-H Policy* section of this manual.

‹‹Allopurinol Sodium for Injection (Aloprim®)

Allopurinol inhibits xanthine oxidase, the enzyme responsible for the conversion of hypoxanthine to xanthine to uric acid. Allopurinol is metabolized to oxypurinol which is also an inhibitor of xanthine oxidase; allopurinol acts on purine catabolism, reducing the production of uric acid without disrupting the biosynthesis of vital purines

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:

- Prescribed for FDA-approved indications and dosing regimens
- Prescribed by or in consultation with an oncologist
- Patient is receiving cancer therapy which causes elevations of serum and urinary uric acid levels
- Patient cannot tolerate oral allopurinol
- Patient is not known to be at risk of allopurinol hypersensitivity syndrome (AHS) or is not a carrier of HLA-B*58:01 allele

Authorization is for six months

Billing

HCPCS code J0206 (Injection, allopurinol sodium, 1 mg)››

Alteplase (Activase; Cathflo Activase)

Alteplase is a tissue plasminogen activator produced by recombinant DNA technology. It is synthesized using the complementary DNA for natural human tissue-type plasminogen activator obtained from an established human cell line. It is an enzyme (serine protease) that has the property of fibrin-enhanced conversion of plasminogen to plasmin and produces limited conversion of plasminogen in the absence of fibrin. Alteplase binds to fibrin in a thrombus and converts the entrapped plasminogen to plasmin, thereby initiating local fibrinolysis.

Refer to “Alteplase” in the *Dialysis: Chronic Dialysis Services* section of the appropriate Part 2 manual for the use of alteplase in chronic dialysis.

Indications

All FDA-approved indications

Dosage

FDA-Approved dosages

TAR Requirement

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

Billing

HCPCS code J2997 (injection, alteplase recombinant, 1 mg)

Note: Treatment initiated in a hospital emergency room is not separately reimbursable as it is included in the hospital reimbursement.

Amifostine

Amifostine is a prodrug that is dephosphorylated by alkaline phosphatase in tissues to a pharmacologically active free thiol metabolite. This metabolite is believed to be responsible for the reduction of the cumulative renal toxicity of cisplatin and for the reduction of the toxic effects of radiation on normal oral tissues.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS code J0207 (injection, amifostine, 500 mg)

Amiodarone HCL (Nexterone)

Amiodarone is a Class III antiarrhythmic agent which inhibits adrenergic stimulation (alpha- and beta-blocking properties), affects sodium, potassium, and calcium channels, prolongs the action potential and refractory period in myocardial tissue; decreases Atrioventricular (AV) conduction and sinus node function.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code: J0283, (Injection, amiodarone hydrochloride [Nexterone], 30 mg).

‹‹Amisulpride (BARHEMSYS®)

Amisulpride is a selective dopamine-2 (D2) and dopamine-3 (D3) receptor antagonist. D2 receptors are located in the chemoreceptor trigger zone (CTZ) and respond to the dopamine released from the nerve endings. Activation of CTZ relays stimuli to the vomiting center which is involved in emesis. Studies in multiple species indicate that D3 receptors in the area postrema also play a role in emesis. Studies conducted in ferrets have shown that amisulpride inhibits emesis caused by apomorphine, with an estimated ED50 of less than 1 mcg/kg, subcutaneously; and inhibits cisplatin-induced emesis at 2 mg/kg and morphine-induced emesis at 3 to 6 mg/kg, when given intravenously.

Amisulpride has no appreciable affinity for any other receptor types apart from low affinities for 5-HT2B and 5-HT7 receptors.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

Must submit clinical documentation to substantiate the following:

- Must be used for FDA-approved indications and dosages.
- Patient must be 18 years of age or older.
- Drug is being used under one of the following conditions:
  - Prevention of postoperative nausea and vomiting (PONV) and will be used alone or in combination with an antiemetic of a different class.
  - Treatment of PONV in patients who have received antiemetic prophylaxis with an agent of a different class or have not received prophylaxis.
- Patient has not received a preoperative dopamine-2 (D_2) antagonist (for example, metoclopramide).
- Prescriber will monitor electrocardiogram (ECG) for QTc prolongation, as clinically indicated.
- Must provide documentation justifying why other formulary alternatives for the prevention or treatment of PONV (for example, ondansetron, dexamethasone, etc.) are not an option.››

‹‹**Authorization is for one month.**

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code C9153 (injection, amisulpride, 1 mg)

Prescribing Restrictions

Frequency of billing equals 10 mg/10 units for one dose

Maximum billing units equals 10 mg/10 units››

Anidulafungin

Anidulafungin, 1 mg injection (HCPCS code J0348) must be billed with ICD-10-CM codes B37.0 thru B37.9. The daily maximum dosage is 200 mg

Anifrolumab-fnia (Saphnelo)

Anifrolumab is an IgG1-kappa monoclonal antibody that blocks the biologic activity of type 1 interferon receptors (IFNAR); elevated IFNAR plays a role in the pathogenesis of systemic lupus erythematosus. This reduces inflammatory and immunological processes.

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 all of the following:

- Must be used for FDA-approved indications and dosages
- Patient must be eighteen years of age or older
- Must be prescribed by or in consultation with a rheumatologist, dermatologist, nephrologist, pulmonologist, or other SLE treatment specialist

- Patient has a diagnosis of moderate to severe SLE
- Patient has fulfilled at least 4 of the 11 American College of Rheumatology (ACR) classification criteria for SLE
- Patient was seropositive for antinuclear antibodies, anti-double-stranded DNA (anti-dsDNA) antibodies, or anti-Smith antibodies
- Patient is receiving stable treatment with at least one of the following:
  - Glucocorticoids (for example, Prednisone, Methylprednisone, etc.)
  - An Antimalarial Agent (hydroxychloroquine or chloroquine)
  - Immunosuppresants (Azathioprine, Mycophenolate MofetilMycophenolic Acid, Methotrexate, etc.)
- Patient does not have active severe lupus nephritis or neuropsychiatric SLE
- Patient does not have any of the following:
  - Serious or active infection
  - Concurrent therapy with a biologic medication such as belimumab or intravenous cyclophosphamide

Initial approval is for twelve months.

Continued therapy

- Patient continues to meet initial approval criteria.
- Patient has shown positive clinical response as evidenced by one or more of the following:
  - Improvement in all organs with disease activity at baseline with no new flares.
  - Reduction in the dosages of oral corticosteroids from baseline.
  - Decrease in symptoms or stabilization in at least one SLE related disease manifestation from baseline.

Reauthorization is for twelve months.

Age Limits

Must be 18 years of age or older

Billing

HCPCS code J0491 (injection, anifrolumab-fnia, 1 mg)

Suggested ICD-10-CM Diagnosis Codes

M32.10, M32.11, M32.12, M32.13, M32.14, M32.15, M32.19, M32.8, M32.9

Prescribing Restrictions

Frequency of billing is 300 mg/300 units every twenty-eight days.

Maximum billing unit(s) equal 300 mg/300 units.

Antigens for Allergy Desensitization

CPT® code 95115 (professional services for allergen immunotherapy not including provision of allergenic extracts; single injection), 95117 (professional services for allergen immunotherapy not including provision of allergenic extracts; 2 or more injections) or 95199 (unlisted allergy/clinical immunologic service or procedure) must be used for allergy desensitization.

Antigens must be billed with CPT code 95144 (professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single dose vial[s]); antigens billed with CPT code 99070 (unlisted medical supplies) will be denied.

Claims for whole body extract of biting insect or other arthropod must be billed with CPT code 95170.

Argatroban

Argatroban is a direct thrombin inhibitor that reversibly binds to the thrombin active site. Argatroban does not require the co-factor antithrombin III for antithrombotic activity. Argatroban exerts its anticoagulant effects by inhibiting thrombin-catalyzed or -induced reactions, including fibrin formation; activation of coagulation factors V, VIII, and XIII; activation of protein C; and platelet aggregation.

Argatroban inhibits thrombin with an inhibition constant (Ki) of 0.04 μM. At therapeutic concentrations, argatroban has little or no effect on related serine proteases (trypsin, factor Xa, plasmin, and kallikrein).

Indication

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Monitoring Parameters

Monitor hemoglobin, hematocrit, signs and symptoms of bleeding.

Heparin-induced thrombocytopenia: Obtain baseline aPTT prior to start of therapy. Check aPTT 2 hours after start of therapy (in critically ill patients, consider monitoring 2 hours after initiation then every 4 hours to allow for steady state to be achieved) to adjust dose, keeping the steady-state aPTT 1.5 to three times the initial baseline value (not exceeding 100 seconds).

Percutaneous coronary intervention: Monitor ACT before dosing, five to 10 minutes after bolus dosing, and after any change in infusion rate and at the end of the procedure. Additional ACT assessments should be made every 20 to 30 minutes during extended percutaneous coronary intervention procedures.

Dosing in Patients with Hepatic Impairment

For adult patients with HIT and moderate or severe hepatic impairment (based on Child-Pugh classification), an initial dose of 0.5 mcg/kg/min is recommended, based on the approximately 4-fold decrease in argatroban clearance relative to those with normal hepatic function. Monitor the aPTT closely, and adjust the dosage as clinically indicated.

Monitoring Therapy:

Achievement of steady state aPTT levels may take longer and require more dose adjustments in patients with hepatic impairment compared to patients with normal hepatic function.

For patients with hepatic impairment undergoing PCI and who have HIT or are at risk for HIT, carefully titrate Argatroban in sodium chloride injection until the desired level of anticoagulation is achieved. Use of Argatroban in sodium chloride injection in PCI patients with clinically significant hepatic disease or AST/ALT levels equal to or greater than three times the upper limit of normal should be avoided.

Billing

Argatroban for ESRD on dialysis

HCPCS codes:
J0884, (injection, argatroban, 1 mg [for esrd on dialysis]).

J0892, (injection, argatroban [accord], not therapeutically equivalent to J0884, 1 mg [for esrd on dialysis]).

J0899, (injection, argatroban [auromedics], not therapeutically equivalent to J0884, 1 mg [for esrd on dialysis]).

Required ICD-10 Diagnosis Codes

N17.0 thru N17.9, N18.5, N18.6, N18.9 and N19.

Argatroban for non-ESRD use

HCPCS codes
J0883 (injection, argatroban, 1 mg [for non-ESRD use])

J0891 (injection, argatroban [accord], not therapeutically equivalent to J0883, 1 mg [for non-esrd use]).

J0898 (injection, argatroban [auromedics], not therapeutically equivalent to J0883, 1 mg [for non-esrd use]).

Required ICD-10 Diagnosis Codes

D75.82

Aprepitant (Aponvie™)

Aprepitant is a selective high-affinity antagonist of human substance P/neurokinin 1 (NK1) receptors. Aprepitant has little or no affinity for serotonin (5-HT3), dopamine, and corticosteroid receptors, the targets of existing therapies for postoperative nausea and vomiting (PONV). Aprepitant has been shown in animal models to inhibit emesis via central actions. Animal and human Positron Emission Tomography (PET) studies with aprepitant have shown that it crosses the blood brain barrier and occupies brain NK1 receptors.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

TAR Criteria

Aponvie 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

- Aponvie is being used for the prevention of postoperative nausea and vomiting (PONV)
- Patient must not be a pregnant female
- Patient will not be taking Aponvie with Pimozide

Authorization: one month (one treatment course)

Age Limits

Must be 18 years of age or older

Billing

HCPCS code: C9145, Injection, aprepitant, (aponvie), 1 mg

Prescribing Restriction(s)

Frequency of billing= 32 mg/32 units prior to induction of anesthesia.

Maximum billing unit(s)= 32 mg/32 units

Aripiprazole

HCPCS code J0400 (aripiprazole, intramuscular, 0.25 mg) is covered for the treatment of schizophrenia/episodic mood disorders. An ICD-10-CM diagnosis code within the range of F20.0 thru F21, F25.0 thru F25.9 or F30.10 thru F39 is required. The maximum daily dosage is 30 mg. Claims billed for quantities exceeding the above daily limitation require appropriate documentation for payment

‹‹Aripiprazole (ABILIFY ASIMTUFII®)

Aripiprazole is a quinolinone antipsychotic which exhibits high affinity for D_2, D_3, 5-HT_{1A}, and 5-HT_{2A} receptors; moderate affinity for D_4, 5-HT_{2C}, 5-HT_7, alpha$_1$ adrenergic, and H_1 receptors. It also possesses moderate affinity for the serotonin reuptake transporter; has no affinity for muscarinic (cholinergic) receptors. Aripiprazole functions as a partial agonist at the D_2 and 5-HT_{1A} receptors, and as an antagonist at the 5-HT_{2A} receptor.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.››

‹‹TAR Requirement

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

TAR Criteria

Must submit clinical documentation to substantiate the following:

- Must be used for FDA-approved indications and dosages.
- Patient must be 18 years of age or older.
- Must be prescribed by or in consultation with a psychiatrist.
- Patient's diagnosis is based on one of the following:
  - Met the DSM criteria for a diagnosis of schizophrenia.
  - Met the DSM criteria for a diagnosis of bipolar I disorder and the drug is being used as maintenance monotherapy.
- Patient has established tolerability with oral aripiprazole in aripiprazole-naïve patients (may require up to a two-week trial of oral aripiprazole).
- Patient meets one of the following conditions:
  - Has a history of non-adherence, refuses to take oral medication, or oral medication is clinically inappropriate.
  - Treatment was initiated in inpatient during a recent hospitalization, within the last 60 days.
- Patient has no known hypersensitivity to aripiprazole or any of its excipients.

Initial authorization is for 6 months.

Continued Therapy

- Patient continues to meet initial approval criteria.
- Patient has experienced documented positive clinical response from baseline.

Reauthorization is for 12 months.

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code C9152 (injection, aripiprazole, [abilify asimtufii], 1 mg)››

‹‹Suggested ICD-10-CM Diagnosis Codes

F20.0 thru F20.9, F25.0 thru F25.9 (Schizophrenia)

F31.0 through F31.31 (Bipolar Disorder)

Prescribing Restrictions

Frequency of billing equals 960 mg/960 units every two months

Maximum billing units equals 960 mg/960 units

Drug Procurement/Distribution:

There are 2 authorized specialty distributors:

Besse Medical
Phone: 1-800-543-2111
Fax: 1-800-543-8695

McKesson
Phone: 1-855-477-9800
Fax: 1-800-371-3963››

Aripiprazole Extended Release Suspension (ABILIFY MAINTENA®)

Aripiprazole is a quinolinone antipsychotic which exhibits high affinity for D2, D3, 5-HT1A, and 5-HT2A receptors; moderate affinity for D4, 5-HT2C, 5-HT7, alpha1 adrenergic, and H1receptors. It also possesses moderate affinity for the serotonin reuptake transporter; has no affinity for muscarinic (cholinergic) receptors. Aripiprazole functions as a partial agonist at the D2 and 5-HT1A receptors, and as an antagonist at the 5-HT2A receptor (de Bartolomeis 2015).

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code J0401 (injection, aripiprazole, extended release, 1 mg)

Required ICD-10 Diagnosis Codes

F20.0 thru F20.9, F25.0 thru F25.9

Prescribing Restriction(s)

Frequency of billing: 400 mg/400 units every 26 days

Maximum billing units: 400 mg/400 units

Aripiprazole Lauroxil (Aristada®)

Aripiprazole lauroxil is an atypical antipsychotic and a prodrug of aripiprazole. Following intramuscular injection, aripiprazole lauroxil is likely converted by enzyme-mediated hydrolysis to N-hydroxymethyl aripiprazole, which is then hydrolyzed to aripiprazole. The mechanism of action of aripiprazole in schizophrenia is unclear. However, efficacy could be mediated through a combination of partial agonist activity at dopamine D2 and serotonin 5-HT1A receptors and antagonist activity at 5-HT2A receptors.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

Age Limits

Must be 18 to 65 years of age

Billing

HCPCS code J1944 (injection, aripiprazole lauroxil, [Aristada], 1 mg)

Prescribing Restrictions

Frequency of billing equals Every month

Maximum billing units equals 882 mg equals 882 units

Aripiprazole Lauroxil (Aristada Initio®)

Aripiprazole lauroxil is an atypical antipsychotic and a prodrug of aripiprazole. Following intramuscular injection, aripiprazole lauroxil is likely converted by enzyme-mediated hydrolysis to N-hydroxymethyl aripiprazole, which is then hydrolyzed to aripiprazole. The mechanism of action of aripiprazole in schizophrenia is unclear. However, efficacy could be mediated through a combination of partial agonist activity at dopamine D2 and serotonin 5-HT1A receptors and antagonist activity at 5-HT2A receptors.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must include clinical documentation that demonstrates the following:

- Prescribed for FDA-approved indications and dosing regimens
- Must be 18 to 65 years of age
- Must have established tolerability with oral aripiprazole if naïve to aripiprazole; may take up to two weeks
- Must show documentation of clinical rationale for avoiding 21-day oral aripiprazole loading dose due to history of patient non-compliance or hospitalization risk
- Must be initiating or re-initiating therapy with Aristada (aripiprazole lauroxil)
- Must be used as a single dose and not for repeated dosing
- Must use in conjunction with the first Aristada injection

  Note: The first Aristada injection may be administered on the same day as Aristada Initio or up to 10 days thereafter

- Must use in conjunction with a single 30 mg dose of oral aripiprazole for the following regimens:
  - Patient is initiating therapy with Aristada, or
  - Patient is reinitiating therapy with Aristada after greater than seven weeks since last Aristada 441 mg dose injection or greater than 12 weeks after all other strengths of Aristada.

Age Limits

Must be 18 to 65 years of age

Billing

HCPCS code J1943 (injection, aripiprazole lauroxil, [Aristada Initio], 1 mg)

Prescribing Restrictions

Frequency of billing equals 6 weeks

Maximum billing units equals 675 mg equals 675 units

Aztreonam

Aztreonam is a bactericidal agent that 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. Monobactam structure makes cross-allergenicity with beta-lactams unlikely.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS code: J0457, Injection, aztreonam, 100 mg

Baclofen (Intrathecal)

Baclofen is a chemical analog of the inhibitory neurotransmitter gamma-aminobutyric acid and may exert its effects by stimulation of the GABAβ receptor subtype. The precise mechanism of action of baclofen as a muscle relaxant and antispasticity agent is not fully understood. Baclofen inhibits both monosynaptic and polysynaptic reflexes at the spinal level, possibly by decreasing excitatory neurotransmitter release from primary afferent terminals, although actions at supraspinal sites may also occur and contribute to its clinical effect.

Indications

For the treatment of severe spasticity or dystonia of cerebral or spinal origin resulting from diseases or conditions such as but not limited to cerebral palsy, multiple sclerosis, hypoxic/anoxic brain injury, traumatic brain injury, or spinal cord injury.

When treating spasticity due to head injury, it is recommended that a waiting period of one year after injury should elapse before considering intrathecal baclofen therapy.

Not for use in patients younger than 4 years of age.

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement for HCPCS code J0475 (injection, baclofen, 10 mg).

The TAR should document all of the following:

- The patient suffers from one of the indications listed previously
- The rationale for using intrathecal baclofen over other medication or treatment modalities, including an inadequate response to oral baclofen
- Failure of physical therapy to relieve spasticity symptoms
- The patient demonstrates a positive clinical response to a baclofen bolus dose administered intrathecally in a screening trial

Patients with spasticity due to a cerebral origin need not receive an oral baclofen trial prior to receiving intrathecal baclofen.

Dosage

Establishment of the optimum dose schedule requires that each patient undergoes an initial screening phase with test doses by intrathecal bolus, followed by a very careful individual dose titration prior to maintenance therapy. This is due to the great variability in the effective individual therapeutic dose.

Pump Implantation Maintenance and Filling

Authorization is not required for 1) implantation of the infusion pump and catheter, 2) outpatient refilling and maintenance of the pump or 3) analysis and reprogramming of the pump.

Billing Codes

The following HCPCS codes are used to bill baclofen:

HCPCS Code	Description
J0475	injection, baclofen, 10 mg
J0476	injection, baclofen, 50 mcg for intrathecal trial

Belatacept

Belatacept is a soluble fusion protein consisting of the modified extracellular domain of CTLA-4 fused to a portion (hinge-CH2-CH3 domains) of the Fc domain of a human immunoglobulin G1 antibody. Belatacept is produced by recombinant DNA technology in a mammalian cell expression system.

Belatacept, a selective T-cell (lymphocyte) costimulation blocker, binds to CD80 and CD86 on antigen-presenting cells thereby blocking CD28 mediated costimulation of T lymphocytes. *In vitro*, belatacept inhibits T lymphocyte proliferation and the production of the cytokines interleukin-2, interferon-γ, interleukin-4, and TNF-α. Activated T lymphocytes are the predominant mediators of immunologic rejection.

Indications

Belatacept is indicated for prophylaxis of organ rejection in adult patients receiving a kidney transplant. It is to be used in combination with basiliximab induction, mycophenolate mofetil and corticosteroids.

Dosage

Belatacept is restricted to patients 18 years of age and older. The maximum daily dosage is 1,300 mg. The recommended dosing schedule is as follows:

Initial Phase Table

Dosage for Initial Phase	Dose
Day 1 (day of transplantation, prior to implantation) and Day 5 (approximately 96 hours after Day 1 dose)	10 mg per kg
End of Week 2 and Week 4 after transplantation	10 mg per kg
End of Week 8 and Week 12 after transplantation	10 mg per kg

Maintenance Phase Table

Dosage for Maintenance Phase	Dose
End of Week 16 after transplantation and every 4 weeks (plus or minus 3 days) thereafter	510 mg per kg

Required Diagnosis Code

Restricted to ICD-10-CM diagnosis code Z94.0.

Authorization

For doses greater than 1,300 mg per day, an approved *Treatment Authorization Request* (TAR) is required for reimbursement.

Billing

HCPCS code J0485 (injection, belatacept, 1 mg).

Belimumab (Benlysta)

Benlysta is a BLyS-specific inhibitor that blocks the binding of soluble BLyS, a B-cell survival factor, to its receptors on B cells. Benlysta does not bind B cells directly, but by binding BLyS, benlysta inhibits the survival of B cells, including autoreactive B cells and reduces the differentiation of B cells into immunoglobulin-producing plasma cells

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Age

5 years of age or older

Billing

HCPCS code J0490 (injection, belimumab, 10 mg).

Prescribing Restrictions

Frequency of billing equals 10 mg/kg every two weeks for three doses, then every four weeks thereafter.

Benralizumab (Fasenra)

Benralizumab is a humanized afucosylated, monoclonal antibody (IgG1, kappa) that directly binds to the alpha subunit of the human interleukin-5 receptor (IL-5Rα) with a dissociation constant of 11 pM. The IL-5 receptor is expressed on the surface of eosinophils and basophils. In an in vitro setting, the absence of fucose in the Fc domain of benralizumab facilitates binding (45.5 nM) to FcγRIII receptors on immune effector cells, such as natural killer (NK) cells, leading to apoptosis of eosinophils and basophils through antibody-dependent cell-mediated cytotoxicity (ADCC). Inflammation is an important component in the pathogenesis of asthma. Multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, cytokines) are involved in inflammation. Benralizumab, by binding to the IL-5Rα chain, reduces eosinophils through ADCC; however, the mechanism of benralizumab action in asthma has not been definitively established.

Indications

All FDA-approved indications.

Dosage

All FDA-approved dosages.

TAR Requirement

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

TAR Criteria

Must submit clinical documentation to substantiate the following:

- Must be used for FDA approved indications and dosages
- Patient must be 12 years of age or older
- Patient has a diagnosis of severe asthma with an eosinophilic phenotype and has a blood eosinophil counts equal to or greater than 150 cells/µL

- Patient has persistent uncontrolled asthma as defined by at least one of the following:
  - An Asthma Control Questionnaire (ACQ6) score of 1.5 or more, or an Asthma Control Test (ACT) score less than 20 at baseline
  - At least two exacerbations while on high-dosage inhaled corticosteroids and long-acting β2-agonists (LABA) (ICS plus LABA) in the previous year
  - A history of Emergency Department (ED) visits requiring use of oral/systemic corticosteroids and/or hospitalization in the past year
  - Reduced lung function at baseline [pre-bronchodilator FEV1 below 80% in adults, and below 90% in adolescents] despite regular treatment with high dose inhaled corticosteroid (ICS) or with medium or high dose ICS plus a LABA with or without oral corticosteroids (OCS) and additional asthma controller medications such as antileukotriene agent, tiotropium, or sustained-release theophylline
- Patient will not use Benralizumab as monotherapy
- Benralizumab will not be used concurrently with mepolizumab, omalizumab, or reslizumab

Initial approval is for 12 months

Continued therapy

Patient has experienced improvement in asthma control as evidenced by at least one of the following:

- A significant reduction in OCS dose compared with baseline while maintaining asthma control
- Reductions in asthma exacerbation rate as shown by any of the following:
  - Improvement in patient's Forced Expiratory Volume in 1 Second (FEV1), peak expiratory flow, nighttime awakenings, short-acting bronchodilator rescue medication use, or any other symptoms that would require an increase in OCS dose
  - Reduction in ED visits requiring use of oral/systemic corticosteroids and/or hospitalization
- Change From baseline in pre-bronchodilator Forced Expiratory Volume in 1 Second (FEV1)
- Improvement in Asthma Control Questionnaire (ACQ6) or Asthma Control Test (ACT) score from baseline

Reauthorization is for 12 months.

Age Limits

Must be 12 years of age or older.

Billing

HCPCS code J0517 (injection, benralizumab, 1 mg)

One (1) unit of J0517 equals 1 mg of benralizumab

Prescribing Restrictions

Frequency of billing equals 30 mg/30 units every 4 weeks for the first 3 doses, then once every 8 weeks thereafter.

Maximum billing unit(s) equals 30 mg/30 units

Required ICD-10-CM Diagnosis Code

J45.50, J45.51, J82.81, J82.82, J82.83, J82.89

Betamethasone Sodium Phosphate and Betamethasone Acetate (Celestone Soluspan)

Betamethasone controls the rate of protein synthesis; depresses the migration of polymorphonuclear leukocytes, fibroblasts; reverses capillary permeability and lysosomal stabilization at the cellular level to prevent or control inflammation.

Indications

All FDA-approved indications

Dosage

All FDA-approved dosages

TAR Requirement

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

Billing

HCPCS code J0702 (injection, betamethasone acetate 3 mg and betamethasone sodium phosphate 3 mg)

One (1) unit equals 6 mg of betamethasone (3 mg each of the acetate and sodium phosphate salts)

Bevacizumab

Policy for intravitreal bevacizumab (HCPCS code J9035) is located in the *Ophthalmology* section of the appropriate Part 2 manual.

Bezlotoxumab (Zinplava™)

Bezlotoxumab is a human monoclonal antibody that binds to Clostridium difficile toxin B and neutralizes its effects.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code J0565 (injection, bezlotoxumab, 10 mg).

Required ICD-10 Diagnosis Codes

A04.71 and A04.72.

Bimatoprost (Durysta™)

See *Ophthalmology* in the appropriate Part 2 manual for policy pertaining to bimatoprost and its corresponding procedure code.

Botulinum Toxins A and B

The botulinum toxins are a family of neurotoxins produced by various toxigenic strains of the gram-positive anaerobic bacterium *Clostridium botulinum* and are comprised of seven antigenically distinct serotypes (A to G). All botulinum neurotoxin serotypes produce their clinical effect of flaccid paralysis by blocking the release of acetylcholine from nerve endings.

Four botulinum toxin products have been approved by the U.S. Food and Drug Administration (FDA).

Three botulinum toxin serotype A products:

I. AbobotulinumtoxinA (Dysport)

II. IncobotulinumtoxinA (Xeomin)

III. OnabotulinumtoxinA (Botox, Botox Cosmetic)

One botulinum toxin serotype B product:

IV. RimabotulinumtoxinB (Myobloc)

A significant difference within botulinum toxin type A serotypes is that the units are not interchangeable between the two FDA-approved products, as there is no common international standard methodology for assaying units within the botulinum toxin serotypes. Therefore, one unit of abobotulinumtoxinA is not equivalent to one unit of onabotulinumtoxinA or incobotulinumtoxinA. Similarly, the units of one botulinum toxin serotype cannot be converted into units of any other botulinum toxin serotype as there is no common international standard methodology for assaying units among the different botulinum toxin serotypes. Consequently, neither the units of abobotulinumtoxinA, onabotulinumtoxinA are interchangeable with rimabotulinumtoxinB. The dosage of any botulinum toxin product must be individualized to each specific patient based upon many factors including, but not limited to, size of the muscles to be injected, the number of muscles to be injected, body weight, the condition being treated, expected patient response, and general health of the patient. Standard doses do not exist.

Authorization

Medical necessity must be established and an approved *Treatment Authorization Request* (TAR) is required for the reimbursement of any of the four botulinum toxins.

Note: The use of botulinum toxins for cosmetics indications is not considered medically necessary and is therefore not a benefit. The least expensive medically necessary option must be used unless supplemental documentation strongly supports the use of the higher cost product.

Billing

Due to the short half-life of the botulinum toxins, Medi-Cal will reimburse the unused portion of the drug only when vials are not split between patients. Scheduling of more than one patient is encouraged to prevent wastage of drug. If a vial is split between two or more patients, the billing must be for the exact amount of drug administered to each individual patient.

AbobotulinumtoxinA (Dysport)

AbobotulinumtoxinA is an acetylcholine release inhibitor and a neuromuscular blocking agent for intramuscular (IM) injection.

Indication

All FDA-approved non-cosmetic indications

Dosage

FDA-approved dosages

Authorization

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

- The TAR must include clinical documentation of the following:
- The service is medically necessary.
- Alternative treatments (for example, physical therapy, oral medication[s], etc.) have been tried or considered, have failed and/or are contra-indicated.
- The physician's legible, complete and signed order, treatment plan and/or procedure note for abobotulinumtoxinA.

Billing

HCPCS code J0586 (injection, abobotulinumtoxinA, 5 units).

One (1) unit of J0586 equals 5 units of abobotulinumtoxinA.

Age Limits

Must be two years of age or older.

Prescribing Restrictions

Frequency of billing equals every 12 weeks.

Maximum billing unit(s) equals 1500 units.

IncobotulinumtoxinA (Xeomin)

IncobotulinumtoxinA is an acetylcholine release inhibitor and neuromuscular blocking agent for intramuscular intraglandular administration.

Indications

All FDA-approved non-cosmetic indications

Dosage

FDA-approved dosages

Authorization

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

The TAR must include clinical documentation of the following:

- The service is medically necessary;
- Conservative treatment (for example, physical therapy, oral medication[s], etc.) have been tried or considered, have failed, or are contra-indicated;
- A doctor's written order, prescription, treatment plan and/or procedure note for the service requested.

Billing

HCPCS code J0588 (injection, incobotulinumtoxinA, 1 unit)

One (1) unit of J0588 equals 1 Unit of incobotulinumtoxinA

Age Limits

Must be 18 years of age or older

Prescribing Restrictions

Frequency of billing equals every 12 weeks

Maximum billing unit(s) equals 400 units

OnabotulinumtoxinA (Botox)

OnabotulinumtoxinA is an acetylcholine release inhibitor and a neuromuscular blocking agent for intramuscular, intradetrusor or intradermal administration.

Indication

All FDA-approved non-cosmetic indications

Dosage

FDA-approved dosages

Authorization

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

The TAR must establish medical necessity and should clearly state that the patient had been unresponsive to conventional methods of treatments such as medication, physical therapy and other appropriate methods used to control or treat this condition.

Age Limits

Must be 2 years of age or older

Billing

HCPCS code J0585 (injection, onabotulinumtoxinA, 1 unit)

One (1) unit equals 1 unit of onabotulinumtoxinA

Prescribing Restrictions

Frequency of billing equals every 12 weeks

Maximum billing unit(s) equals 400 units

RimabotulinumtoxinB (Myobloc)

RimabotulinumtoxinB is an active acetylcholine release inhibitor and neuromuscular blocking agent for intramuscular and intraglandular administration.

Indication

All FDA-approved indications

Dosage

FDA-approved dosages

Authorization

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

The TAR must establish medical necessity and it should be made clear that the patient has been unresponsive to conventional methods of treatments such as medication, physical therapy and other appropriate methods used to control or treat this condition.

Age Limits

Must be 18 years of age or older

Billing

HCPCS code J0587 (injection, rimabotulinumtoxinB, 100 units)

One (1) unit equals 100 units of rimabotulinumtoxinB

Prescribing Restriction

Frequency of billing equals every 12 weeks

Maximum billing unit(s) equals 5000 units

Brexanolone (Zulresso™)

Zulresso contains brexanolone, a neuroactive steroid gamma-aminobutyric acid (GABA), a receptor positive modulator that is chemically identical to endogenous allopregnanolone. The mechanism of action of brexanolone in the treatment of Postpartum Depression (PPD) in adults is not fully understood but is thought to be related to its positive allosteric modulation of GABAA receptors.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

TAR Criteria

A TAR may be approved with a diagnosis of postpartum depression and clinical documentation that shows the following:

- For FDA-approved indications and treatment regimens
- Must be 18 years of age or older
- Must be equal to or less than 6 months postpartum
- Onset of symptoms was in the third trimester or within 4 weeks of delivery
- Must be diagnosed with moderate to severe postpartum depression confirmed by Hamilton Rating Scale for Depression (HAM-D) equal to or greater than 20, or other comparable standardized rating scale
- An adequate trial of at least two anti-depressants from two separate drug classes at an adequate dose and treatment duration was shown to be ineffective or produced untoward effects when used by the patient; or
- Must document why other alternatives are not adequate, effective or have been deemed to be clinically contraindicated for the individual patient.
  - Alternatives indicated for PPD include selective serotonin reuptake inhibitor (SSRI), serotonin-norepinephrine reuptake inhibitor (SNRI), tricyclic antidepressant (TCA), bupropion, or mirtazapine
- Must not have active psychosis

Duration of Approval is for 30 days. Limited to one time use per pregnancy.

REMS Program

Zulresso is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Zulresso REMS because excessive sedation or sudden loss of consciousness can result in serious harm.

Requirements of the Zulresso REMS include the following:

- Healthcare facilities must enroll in the program and ensure that Zulresso is only administered to patients who are enrolled in the Zulresso REMS.
- Pharmacies must be certified with the program and must only dispense Zulresso to healthcare facilities who are certified in the Zulresso REMS.
- Patients must be enrolled in the Zulresso REMS prior to administration of Zulresso.
- Wholesalers and distributors must be registered with the program and must only distribute to certified healthcare facilities and pharmacies.

Further information, including a list of certified healthcare facilities, is available at *www.zulressorems.com* or 1-844-472-4379.

Age Limits

Must be 18 years of age or older

Billing

HCPCS code J1632 (injection, brexanolone,1 mg)

Prescribing Restrictions

Frequency of billing equals one time per pregnancy.

Bupivacaine Hydrochloride

Bupivacaine 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.

Epinephrine is a vasoconstrictor added to bupivacaine to slow absorption into the general circulation and thus prolong maintenance of an active tissue concentration.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS code: J0665 (Injection, bupivicaine, not otherwise specified, 0.5 mg)

Bupivacaine Solution (Posimir)

Bupivacaine blocks both the initiation and conduction of nerve impulses by decreasing the neuronal membrane's permeability to sodium ions, which results in inhibition of depolarization with resultant blockade of conduction.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

Must submit clinical documentation to substantiate the following:

- Must be used for FDA-approved indications and dosages.
- Patient must be 18 years or older.
- Patient is scheduled for elective outpatient procedure.
- Patient is not undergoing a soft tissue procedure.
- Patient is not undergoing obstetrical paracervical block anesthesia.
- Patient is not a pregnant or lactating female.
- Patient is not on a long-term opioid or other analgesic therapy.
- Patient does not have a known hypersensitivity to local anesthetic agents (e.g., lidocaine, bupivacaine, etc.).

Authorization is for three months.

Age Limits

Must be 18 years of age or older.

Billing

HCPCS Code: C9144, (injection, bupivacaine (posimir), 1 mg)

Prescribing Restriction(s)

Frequency of billing equals 660 mg/660 units as a single dose.

Maximum billing unit(s) equals 660 mg/660 units.

Buprenorphine Extended Release

Buprenorphine extended-release injection is a partial opioid agonist for subcutaneous (SQ) administration. The extended-release formulation delivers buprenorphine at a controlled rate over a one-month period.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

Authorization

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

Note: Sublocade is available only through a restricted distribution program called the Sublocade Risk Evaluation and Mitigation Strategy (REMS) Program because of the risk of serious harm or death that could result from intravenous self-administration. This requires that all healthcare settings and pharmacies that dispense it must be certified in the REMS program. Healthcare providers, healthcare settings, and pharmacies must obtain Sublocade through a restricted distribution program and the medication should never be dispensed directly to a patient.

Required ICD-10-CM Code

F11.20 (opioid dependence, uncomplicated)

F11.21 (opioid dependence, in remission)

Billing

HCPCS code Q9991 (injection, buprenorphine extended-release (sublocade), less than or equal to 100 mg)

One (1) unit of Q9991 equals 100 mg or less of buprenorphine extended-release solution

HCPCS code Q9992 (injection, buprenorphine extended-release (sublocade), greater than 100 mg)

One (1) unit of Q9992 equals greater than 100 mg of buprenorphine extended-release solution

Burosumab-twza (Crysvita®)

Burosumab-twza is a fibroblast growth factor 23 (FGF23) blocking antibody. X-linked hypophosphatemia is caused by excess fibroblast growth factor 23 (FGF23) which suppresses renal tubular phosphate reabsorption and the renal production of 1,25 dihydroxy vitamin D. Burosumab-twza binds to and inhibits the biological activity of FGF23 restoring renal phosphate reabsorption and increasing the serum concentration of 1,25 dihydroxy vitamin D.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages

TAR Requirement

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

TAR Criteria

Crysvita will be considered medically necessary if the following criteria are met:

- Must be prescribed for FDA-approved indications and dosing regimens
- Patient must be 6 months of age or older for XLH or 2 years and older for TIO
- Patient must have a diagnosis of X-linked hypophosphatemia (XLH) confirmed by:
  - Genetic testing (PHEX mutation) of patient or family member with X-linked inheritance; or
  - Serum fibroblast growth factor 23 (FGF23) level greater than 30 pg/mL; or
- Patient must have a diagnosis of tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized.
- Must confirm baseline fasting serum phosphorus level is below the reference range for patient age before initiating burosumab.
- Must not be given in combination with oral phosphate and calcitriol or other activated vitamin D metabolites (paricalcitol, doxercalciferol, calcifediol, or alfacalcidol).
- Patient must not have severe renal impairment (defined as glomerular filtration rate (GFR) of less than 30 mL/min
- Patient must discontinue oral phosphate and/or active vitamin D analogs (for example., calcitriol, paricalcitol, doxercalciferol, calcifediol) at least 1 week prior to treatment.
- Provider to monitor serum 25-hydroxy vitamin D levels; and supplement with cholecalciferol or ergocalciferol to maintain levels in the normal range for age as necessary.

Initial approval is for 12 months.

<u>Continued therapy:</u>

- Patient continues to meet the initial approval criteria
- Patient has shown a clinically significant improvement in serum phosphate level
- Patient’s serum phosphorus level is not above the upper limit of the laboratory normal reference range
- Patient has shown a positive clinical response or stabilization of disease

Reauthorization is for 12 months.

Age

Must be 6 months of age or older for XLH or 2 years and older for TIO

Billing

HCPCS code J0584 (injection, burosumab-twza, 1 mg)

Suggested ICD-10-CM Diagnosis Codes

E83.31

Prescribing Restriction(s)

Frequency of billing equals 180 mg/180 units every 2 weeks

Maximum billing unit(s) equals 180 mg/180 units

C1 Esterase Inhibitor (Haegarda®)

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

Indications

C1-INH is used for routine, long-term prophylaxis to prevent hereditary angioedema (HAE or inherited C1 inhibitor (C1-INH) deficiency) attacks.

C1-INH deficiency is a rare genetic disorder that results in deficiency or dysfunction of C1 esterase inhibitor. Affected individuals develop recurrent episodes of angioedema that usually involve the skin or the mucosa of the respiratory and gastrointestinal tracts. Without treatment, swelling resolves spontaneously within days, but symptoms can range in frequency and severity.

C1 esterase inhibitor is not indicated for the treatment of acute angioedema attacks.

Age

12 years and older

Dosage

The recommended dose is 60 International Units (IU)/kg SQ administered twice weekly (or every 3 or 4 days).

Authorization

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

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

- Either:
  - A confirmed diagnosis of HAE as documented by a monoallelic mutation known to cause HAE in either the SERPING1 or F12 gene or
  - A C4 level below the lower limit of the normal reference range as defined by the laboratory performing the test and any one of the following:
    - ❖ A C1 INH antigenic level below the lower limit of the normal reference range as defined by the laboratory performing the test.
    - ❖ A C1 INH functional level below the lower limit of the normal reference range as defined by the laboratory performing the test.
- 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.
- 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.

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)

C1 esterase inhibitor is indicated for the routine prophylaxis against angioedema attacks in patients with hereditary angioedema.

Dosage

Maximum dosage is 3000 units (quantity of 300). Claims billed for greater quantities require documentation that patient's weight exceeds 150 kg. Limited to patients 12 years of age and older.

Diagnosis Restrictions

Restricted to ICD-10-CM diagnosis code D84.1.

Billing

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

One unit billed equals 10 units of drug

C1 Esterase Inhibitor (Treatment)

C1 esterase inhibitor is a normal constituent of human blood and is one of the serine protease inhibitors. The primary function of C1 esterase inhibitor is to regulate the activation of the complement and contact system pathways.

Dosage

Berinert: The usual dose is 20 IU per kg body weight by intravenous injection. Maximum dosage is 2000 units (quantity of 200). Claims billed for greater quantities require documentation that patient's weight exceeds 100 kg.

Ruconest: The recommended dose, if the patient's weight is less than 84 kg, is 50 IU per kg of body weight. If the patient's weight is greater than or equal to 84 kg, the recommended dose is 4200 IU.

Diagnosis Restrictions

Restricted to ICD-10-CM diagnosis code D84.1.

Billing

J0596 (injection, C1 esterase inhibitor [recombinant], ruconest, 10 units)

J0597 (injection, C1 esterase inhibitor [human], Berinert, 10 units)

One billing unit equals 10 units of drug

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 Limits

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

Billing

HCPCS code J0739 (injection, cabotegravir, 1 mg)

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 2 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 Limits

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 4 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 2 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 Limits

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
  - 6-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% predicted or the Brooke score is less than or equal to 5
- 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 6 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.

TAR Requirement

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

Billing

HCPCS codes:

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 Limits

Must be 2 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-2g/4 units every 8-12 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

18 years 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 6 hours for 7 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 Limits

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 Limits

Must be 6 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 Limits

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 Limits

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 4 weeks.››

‹‹Billing

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

Prescribing Restriction(s)

Frequency of billing equals 120 USP units/3 units daily.

Maximum billing unit(s) equals 120 USP units/3 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 4 weeks.

Billing

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

Prescribing Restriction(s)

Frequency of billing equals 120 USP units/3 units daily.

Maximum billing unit(s) equals 120 USP units/3 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 Limits

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

Dalbavancin

The use of HCPCS code J0875 (dalbavancin, 5mg) is restricted to patients 18 years of age and older.

Daptomycin

Daptomycin binds to bacterial cell membranes and causes a rapid depolarization of membrane potential. This loss of membrane potential causes inhibition of DNA, RNA, and protein synthesis, which results in bacterial cell death.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Age Limits

‹‹Must be 1 year of age or older (Baxter only).››

Must be 18 years of age or older (Hospira only).

Billing

HCPCS codes:

‹‹J0874 (injection, daptomycin [baxter], not therapeutically equivalent to J0878, 1mg).››

J0877 (injection, daptomycin [hospira], not therapeutically equivalent to J0878, 1 mg).

J0878 (injection, daptomycin, 1 mg).

Darbepoetin Alfa

Darbepoetin alfa is an erythropoiesis-stimulating protein that is produced in Chinese hamster ovary cells by recombinant DNA technology. It is a 165-amino acid protein that differs from recombinant human erythropoietin in containing five N-linked oligosaccharide chains, whereas recombinant human erythropoietin contains three chains. The two additional N-glycosylation sites result from amino acids substitutions in the erythropoietin peptide backbone. Darbepoetin alfa stimulates erythropoiesis by the same mechanism as endogenous erythropoietin. Increased hemoglobin levels are not generally observed until two to six weeks after initiating treatment with darbepoetin alfa.

Indications

For the treatment of anemia due to:

- Chronic kidney disease (CKD) in patients on dialysis and not on dialysis
- The effects of myelosuppressive chemotherapy in patients with non-myeloid malignancies and upon initiation, there is a minimum of two additional months of planned chemotherapy

Limitations of Use

Darbepoetin alfa has not been shown to improve quality of life, fatigue or patient well-being.

Darbepoetin alfa is not indicated for use:

- In patients with cancer receiving hormonal agents, biologic products or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy

- In patients with cancer receiving myelosuppressive chemotherapy, when the anticipated outcome is cure
- As a substitute for red blood cell (RBC) transfusions in patients who require immediate correction of anemia

In the appropriate circumstances, darbepoetin alfa may be self-administered.

CKD Patients on Hemodialysis

Darbepoetin alfa treatment may be initiated when the hemoglobin (Hgb) level is less than 10 g/dL, taking into consideration specific patient characteristics such as functional and cognitive status, life expectancy and other factors. For continuing and ongoing treatment, the current Hgb level must be less than 11.5 g/dL. If the Hgb level approaches or exceeds 11 g/dL, it is recommended that the dose of darbepoetin alfa should be reduced or interrupted. Darbepoetin alfa treatment will be denied if the Hgb level is greater than 11.5 g/dL at the time of darbepoetin alfa administration.

CKD Patients Not on Hemodialysis

These patients may have darbepoetin alfa initiated when the Hgb level is less than 10 g/dL and the following conditions apply:

- The rate of Hgb decline indicates the likelihood of requiring an RBC transfusion, and
- Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal.

If the Hgb level exceeds 10 g/dL, it is recommended that the dose of darbepoetin alfa be reduced or interrupted.

Myelosuppressive Chemotherapy-Associated Anemia

Darbepoetin alfa is recommended as a treatment option when the Hgb level has decreased below 10 g/dL and there is a minimum of two additional months of planned chemotherapy.

Required Codes

ICD-10-CM diagnosis codes are required on the claim form in the *Diagnosis or Nature Illness or Injury* field (Box 21 or Box 67) of the *CMS-1500* form or in the *Diagnosis Codes* field (Box 66-67) of the UB-04 form.

- CKD patients with anemia on dialysis require ICD-10-CM code N18.6 for HCPCS code J0882.
- CKD patients with anemia not on dialysis require ICD-10-CM codes N18.1 thru N18.5 or N18.9 for HCPCS code J0881.
- Chemotherapy-associated anemia in non-myeloid malignancies requires ICD-10-CM code D63.0 or D64.81 for HCPCS code J0881.

Dosage

Evaluate the iron status in all patients before and during treatment and maintain iron repletion. Correct or exclude other causes of anemia (for example, vitamin deficiency, metabolic or chronic inflammatory conditions, bleeding, etc.) before initiating darbepoetin alfa.

The dose of darbepoetin alfa varies according to the condition being treated. Please refer to appropriate medical literature for specific dosage recommendations.

Billing

The following HCPCS codes are used to bill darbepoetin alfa:

HCPCS Code	Description
J0881	Injection, darbepoetin alfa, 1 microgram (non-ESRD use)
J0882	Injection, darbepoetin alfa, 1 microgram (for ESRD on dialysis)

If darbepoetin alfa is administered by the provider, the claim must include current and previous:

- Darbepoetin alfa dose
- Patient weight in kilograms
- Hemoglobin levels

If darbepoetin alfa is self-administered, the provider must submit the following information:

- A statement that the drug was provided to the patient for self-administration.
- The date and quantity of drug given to the patient, darbepoetin alfa doses, patient weight in kilograms and Hbg levels for the previous three months.

Documentation may be included in the *Remarks* field (Box 80) on the *UB-04* or the *Additional Claim Information* field (Box 19) on the *CMS-1500*, or on an attachment to the claim.

If darbepoetin alfa is administered outside of the general guidelines above or dosage is more than 800 mcg per month, documentation must be submitted in order to establish medical necessity.

Delafloxacin (Baxdela®)

Delafloxacin belongs to the fluoroquinolone class of antibacterial drugs and is anionic in nature. The antibacterial activity of delafloxacin is due to the inhibition of both bacterial topoisomerase IV and DNA gyrase (topoisomerase II) enzymes which are required for bacterial DNA replication, transcription, repair, and recombination.

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 all of the following:

- Must be used for all FDA-approved indications and dosages
- Patient must be 18 years of age or older
- Patient must have a diagnosis of Acute Bacterial Skin and Skin Structure Infection (ABSSSI) or Community-Acquired Bacterial Pneumonia (CABP)
- Documentation of an inadequate response or intolerance or not a candidate for a clinically appropriate first-line therapy based on the current treatment guidelines for the specified indication (for example Amoxicillin, Amoxicillin-Calvulanate, Azithromycin, Levofloxacin, Moxifloxacin, Trimethoprim-Sulfamethoxazole, Doxycycline, Clindamycin, Vancomycin, Aztreonam, Linezolid, etc.)
- Culture and sensitivity report shows isolated pathogen is susceptible to Delafloxacin, or documentation to show obtaining a culture and sensitivity report is not feasible
- Dose does not exceed IV: 600 mg (2 vials) per day
- The duration of treatment does not exceed the following: for ABSSSI: five to 14 days, for CABP: five to 10 days.

Approval: treatment course (up to 14 days)

Age

Must be 18 years and older

Billing

HCPCS code C9462 (injection, delafloxacin, 1 mg)

One (1) unit of C9462 equals 1 mg delafloxacin

Prescribing Restrictions

Frequency of billing equals 600 mg/600 units per day for up to 14 days

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

Denosumab

Denosumab is a human IgG2 monoclonal antibody that binds to RANKL (receptor activator of nuclear factor kappa-B ligand), a transmembrane or soluble protein essential for the formation, function and survival of osteoclasts, the cells responsible for bone resorption. Denosumab prevents RANKL from activating its receptor, RANK, which is expressed on the surface of osteoclasts and their precursors. Prevention of the RANKL/RANK interaction inhibits osteoclast formation, function and survival, thereby decreasing bone resorption and increasing bone mass and strength in both cortical and trabecular bone. In addition, increased osteoclast activity, stimulated by RANKL, is a mediator of bone pathology in solid tumors with osseous metastases.

Indications

Denosumab (Prolia) is indicated:

- For the treatment of postmenopausal women with osteoporosis at high risk for fracture
- To increase bone mass in men with osteoporosis at high risk for fracture
- To increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
- To increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer

Denosumab (XGEVA) is indicated:

- For the prevention of skeletal related events in patients with bone metastases from solid tumors
- For the treatment of 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
- For the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy

Authorization

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

Dosage

The recommended dose of denosumab (Prolia) for the following four conditions is 60 mg subcutaneously every six months. Patients should receive 1,000 mg of calcium daily and at least 400 IU of vitamin D daily.

- Postmenopausal women with osteoporosis at high risk of fracture
- To increase bone mass in men with osteoporosis at high risk for fracture
- To increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
- To increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer

The recommended dose of denosumab (XGEVA):

- For the prevention of skeletal related events in patients with bone metastases from solid tumors is 120 mg subcutaneously every four weeks in the upper arm, upper thigh or abdomen
- For giant cell tumor of bone that is 120 mg subcutaneously every four weeks with additional 120 mg doses on days eight and 15 of the first month of therapy administered in the upper arm, upper thigh, or abdomen
- For hypercalcemia of malignancy is 120 mg administered every four weeks with additional 120 mg doses on days eight and 15 of the first month of therapy

Billing

HCPCS code J0897 (injection, denosumab, 1 mg).

The correct National Drug Code (NDC) must be included on the claim(s) to correctly price the drug.

Diclofenac Sodium Injection

Diclofenac sodium injection is a nonsteroidal anti-inflammatory drug (NSAID) for intravenous (I.V.) administration.

Indications

Diclofenac sodium injection is reimbursable for use in patients 18 years of age or older for:

- The management of mild to moderate pain; or
- The management of moderate to severe pain alone or in combination with opioid analgesics.

Dosage

37.5 mg administered I.V. every six hours as needed (maximum dose is not to exceed 150 mg/day).

Authorization

An approved *Treatment Authorization Request* (TAR) is required for reimbursement. The TAR must document the following:

- The service is medically necessary.
- Alternative drugs (for example, ibuprofen, ketorolac, etc.) have been tried or considered, have failed or are contra-indicated.
- A doctor’s order, prescription, and/or treatment plan written for the service requested.

Billing

HCPCS code J1130 (injection, diclofenac sodium, 0.5 mg)

One (1) unit equals 0.5 mg of diclofenac sodium injection solution

Difelikefalin (Korsuva™)

Korsuva is a kappa opioid receptor (KOR) agonist. The relevance of KOR activation to therapeutic effectiveness is not known;

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

TAR Criteria

Korsuva 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 has end-stage renal disease (ESRD) and has been on hemodialysis three times per week for at least three months.
- Patient has at least two single-pool Kt/V measurements equal to or greater than 1.2, or at least two urea reduction ratio measurements equal to or greater than 65 percent, or one single pool Kt/V measurement equal to or greater than 1.2 and one urea reduction ratio measurement equal to or greater than 65 percent on different dialysis days during the prior three-month period.
- Patient has completed the following assessments at baseline:
  - Mean baseline Worst Itching Intensity NRS indicative of moderate to severe uremic pruritus
- Patient has tried and failed the following unless contraindicated or clinically inappropriate:
  - Emollients and/or topical analgesics (if dry skin)
  - Oral antihistamines (for example diphenhydramine, hydroxyzine, loratadine, etc.)
  - Gabapentin or pregabalin

- Patient cannot undergo or does not respond to UVB therapy
- Patient is not scheduled to receive kidney transplant
- Patient does not have pruritus only during the dialysis session (by patient report)
- Patient is not receiving ongoing ultraviolet B

Initial approval is for six months

Continued treatment:

- Patient has experienced reduction of itch intensity as evidenced by one of the following:
  - Improvement from baseline in intensity of itch measured using Numerical Rating Scale (WI-NRS) or other standard scale
  - Improvement from baseline in itch-related quality of life as assessed by standard scale
- Patient does not have adverse events from prior treatments

Reauthorization is for 12 months

Age Limit

Must be 18 years of age or older

Billing

HCPCS code J0879 (injection, difelikefalin, 0.1 microgram)

Prescribing Restriction(s)

Frequency of billing equals 0.5 mcg/kg at the end of each HD treatment

Dolasetron Mesylate Injection (ANZEMET® Injection)

Dolasetron is a selective serotonin receptor (5-HT3) antagonist which blocks serotonin both peripherally (primary site of action) and centrally at the chemoreceptor trigger zone.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosage.

TAR Requirement

No TAR is required for reimbursement.

Age Limit

Must be two years of age or older.

Billing

HCPCS code J1260 (injection, dolasetron mesylate, 10 mg).

One (1) unit equals 10 mg.

Doripenem

Doripenem, 10 mg (HCPCS code J1267) has a usual dosage of 500 mg every eight hours with a maximum daily dosage of 1,500 mg. For quantities exceeding the daily limitation, appropriate documentation is required.

Doxercalciferol

Doxercalciferol is reimbursable for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease on dialysis.

Dosage

The recommended initial dose of doxercalciferol is 4 mcg administered intravenously as a bolus dose three times weekly at the end of dialysis. The maximum dosage should not exceed 18 mcg weekly.

Billing

HCPCS code J1270 (injection, doxercalciferol, 1 mcg)

One (1) unit equals 1 mcg

Note: Code J1270 cannot be block billed.

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.