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

Abatacept (Orencia®) is a selective T-cell co-stimulation modulator for intravenous (IV) or subcutaneous (SQ) administration.

Indications

Abatacept is used to treat the following conditions:

- Rheumatoid Arthritis (RA)
- Juvenile Idiopathic Arthritis (JIA)
- Psoriatic Arthritis (PsA)

Abatacept should not be given concomitantly with TNF (tumor necrosis factor) antagonists.

Age

2 years and older

Dosage

The recommended dosage varies based on the treatment condition, the patient's body weight, and the route of administration.

Authorization

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

The TAR must include clinical documentation that demonstrates the following:

- The service is medically necessary to treat RA, JIA, or PsA.
- Alternative treatments have been tried or considered, have failed, or are contraindicated, including one or more non-biologic disease-modifying anti-rheumatic drugs (DMARDs) or at least one of the TNF antagonists such as infliximab, etanercept, adalimumab, etc.
- The physician's legible, complete, and signed treatment plan/order for abatacept.

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.

‹‹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

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

Alemtuzumab is indicated for the treatment of relapsing forms of multiple sclerosis. Because of its safety profile, the use of alemtuzumab should be reserved for patients 18 years of age and older who have had an inadequate response to two or more drugs such as, but not restricted to, interferons and glatiramer or other drugs.

Authorization

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

Dosage

The recommended dosing schedule is as follows:

- First treatment course: 12 mg/day on five consecutive days
- Second treatment course: 12 mg/day on three consecutive days administered 12 months after the first treatment course

Billing

HCPCS code J0202 (injection, alemtuzumab, 1 mg)

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.

Alteplase

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

Alteplase is indicated for:

- The management of acute myocardial infarction (AMI) in adults.
- The management of acute ischemic stroke in adults.
- The management of acute massive pulmonary embolism (PE) in adults.
- The restoration of function to central venous access devices as assessed by the inability to withdraw blood.

Dosage

Multiple dosing regimens are available depending upon the condition being treated. The maximum recommended dose is 90 mg for acute ischemic stroke and 100 mg for AMI and PE.

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

Amifostine is indicated for:

- The reduction of cisplatin-induced renal toxicity
- The reduction of xerostomia from head and neck cancer
- The prevention of radiation proctitis in rectal cancer

Dosage

Variable depending upon the condition for which the drug is being used.

Billing

HCPCS code J0207 (injection, amifostine, 500 mg)

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

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 for ESRD on dialysis

Argatroban is a synthetic direct thrombin inhibitor. It is a sterile, non-pyrogenic, clear, colorless to pale yellow isotonic solution. It is supplied in a single-use clear glass vial containing 125 mg of argatroban in 125 ml sodium chloride solution. Each milliliter contains 1 mg argatroban, 9 mg sodium chloride and 3 mg sorbitol, in water for injection.

Argatroban under HCPCS code J0884 (injection, argatroban, 1 mg [for ESRD on dialysis]) is a drug that is used for access management.

Indication

Argatroban is indicated in patients 18 years of age or older for the treatment of End-Stage Renal Disease (ESRD).

Authorization

An approved TAR is required. Supporting documentation must indicate that the patient has ESRD.

Dosage

Before administering argatroban, discontinue heparin therapy and obtain a baseline activated partial thromboplastin time (aPTT). The recommended initial dose of argatroban for patients without hepatic impairment is 2 mcg/kg/min, administered as a continuous infusion.

Required Codes

ICD-10-CM diagnosis codes N17.0 thru N17.9, N18.5, N18.6, N18.9 and N19

Billing

HCPCS code J0884

Page updated: February 2021

Argatroban for non-ESRD use

Argatroban is a synthetic direct thrombin inhibitor. It is a sterile, non-pyrogenic, clear, colorless to pale yellow isotonic solution. It is supplied in a single-use clear glass vial containing 125 mg of argatroban in 125 ml sodium chloride solution. Each milliliter contains 1 mg argatroban, 9 mg sodium chloride and 3 mg sorbitol, in water for injection. The pH of the solution is between 3.2 to 7.5.

Indication

Argatroban is indicated in patients 18 years of age or older for:

- The prophylaxis or treatment of thrombosis in patients with HIT.
- Anticoagulant in patients with or at risk for HIT undergoing PCI.

Dosage

Before administering argatroban, discontinue heparin therapy and obtain a baseline aPTT. The recommended initial dose of argatroban for patients without hepatic impairment is 2 mcg/kg/min, administered as a continuous infusion.

For use in HIT, therapy with argatroban injection is monitored using the aPTT with a target range of 1.5 to 3 times the initial baseline value (not to exceed 100 seconds). Tests of anticoagulant effects (including the aPTT) typically attain steady-state levels within one to three hours following initiation of argatroban injection. Check the aPTT two hours after initiation of therapy and after any dose change to confirm that the patient has attained the desired therapeutic range. After the initiation of argatroban injection, adjust the dose (not to exceed 10 mcg/kg/min) as necessary to obtain a steady-state aPTT in the target range.

For use in PCI, initiate an infusion of argatroban injection at 25 mcg/kg/min and administer a bolus of 350 mcg/kg via a large bore intravenous line over three to five minutes. Check an activated clotting time (ACT) five to 10 minutes after the bolus dose is completed. The PCI procedure may proceed if the ACT is greater than 300 seconds.

If the ACT is less than 300 seconds, an additional intravenous bolus dose of 150 mcg/kg should be administered, the infusion dose increased to 30 mcg/kg/min and the ACT checked five to 10 minutes later. If the ACT is greater than 450 seconds, decrease the infusion rate to 15 mcg/kg/min and check the ACT five to 10 minutes later.

Continue titrating the dose until a therapeutic ACT (between 300 and 450 seconds) has been achieved; continue the same infusion rate for the duration of the PCI procedure.

Required Codes

ICD-10-CM diagnosis code D75.82

Billing

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

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 Extended Release Suspension

Aripiprazole extended release suspension is indicated for the treatment of schizophrenia.

Dosage

The maximum dose is 400 mg every 26 days.

Required Codes

ICD-10-CM codes F20.0 thru F20.9, F25.0 thru F25.9

Billing

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

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

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

Benralizumab injection is an interleukin-5 receptor alpha-directed cytolytic monoclonal antibody (IgG1, kappa) for subcutaneous (SQ) administration.

Indications

Benralizumab is indicated for the add-on maintenance treatment of severe asthma with an eosinophilic phenotype.

Benralizumab is not indicated for the treatment of other eosinophilic conditions or for the relief of acute bronchospasm or status asthmaticus. Benralizumab is not indicated for use in combination with any of the following: mepolizumab, omalizumab, or reslizumab.

Age

12 years or older

Dosage

30 mg SQ given every 4 weeks for the first 3 doses, followed by one dose administered every 8 weeks thereafter.

Authorization

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

The TAR must include clinical documentation that demonstrates the service is medically necessary to treat severe asthma with an eosinophilic type as add-on maintenance therapy:

- Severe asthma as defined by symptoms that are persistent and uncontrolled despite the use of high dose inhaled corticosteroids combined with a long-acting beta2 agonist, leukotriene receptor agonist, or theophylline for greater than or equal to the previous one year or the use of systemic glucocorticoids for greater than or equal to 50% of the previous year*.
- Persistent uncontrolled asthma as defined by <u>at least one</u> of the following*:
  - An ACQ score consistently greater than 1.5 (Asthma Control Questionnaire) or an ACT score less than 20 (Asthma Control Test).
  - Two or more exacerbations in the previous year, each requiring 3 or more days of treatment with systemic glucocorticoids.
  - A history of hospitalization, intensive care unit stay, or mechanical ventilation in the previous year.
  - A FEV1 (Forced Expiratory Volume in 1 second) at less than 80% of predicted after bronchodilator administration measured by pulmonary function testing <u>or</u> spirometry and documented by report and interpretation.

- Eosinophilia as defined by a blood eosinophil count of greater than or equal to 300 cells/microliter at initiation of therapy and documented by laboratory report (in the absence of other causes of eosinophilia such as a documented or suspected parasitic infection, neoplastic disease, or hypereosinophilic syndromes, etc.).
- The physician's legible, complete, and signed treatment plan/order for benralizumab.

Required Codes

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

- J82 (Eosinophilic asthma)

Billing

HCPCS code J0517 (injection, benralizumab, 1 mg)

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

Betamethasone

Betamethasone acetate and betamethasone sodium phosphate is reimbursable up to two units when billed by the same provider, for the same patient and date of service.

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

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

Indications

Bezlotoxumab is indicated to reduce recurrence of Clostridium difficile infection (CDI) in patients 18 years of age or older who are receiving antibacterial drug treatment of CDI and are at a high risk for CDI recurrence.

Dosage

Administer Bezlotoxumab as a single dose of 10 mg/kg administered as an intravenous infusion over 60 minutes.

Required Codes

ICD-10-CM diagnosis code A04.71 and A04.72

Billing

HCPCS code J0565 (injection, bezlotoxumab, 10 mg)

Bimatoprost (Durysta™)

Bimatoprost, a prostaglandin analog, is a synthetic structural analog of prostaglandin with ocular hypotensive activity. Bimatoprost is believed to lower IOP in humans by increasing outflow of aqueous humor through both the trabecular meshwork (conventional) and uveoscleral routes (unconventional). Elevated IOP presents a major risk factor for glaucomatous field loss. The higher the level of IOP, the greater the likelihood of optic nerve damage and visual field loss.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

Durysta is considered medically necessary when the following criteria are met:

- Must be used for FDA-labelled indication and dosages
- Patient must be 18 years of age or older
- Patient must have a diagnosis of Open Angle Glaucoma or Ocular Hypertension
- Must be prescribed by or in consultation with an ophthalmologist
- The affected eye has not received prior treatment with Durysta
- Patient has had a trial of at least one prostaglandin analog (as monotherapy or combination therapy) with insufficient response, intolerance or adverse effects (for example, bimatoprost, latanoprost, travoprost, or tafluprost).
- Patient has had a trial of least two ophthalmic products with different mechanisms of action, such as a prostaglandin analog, beta blocker (e.g. Timolol, Betaxolol, levobunolon), alpha agonist (e.g. Brimonidine, Apraclonidine), carbonic anhydrase inhibitor (e.g. Dorzolamide, Brinzolamide), etc., and had insufficient response, intolerance or adverse effects.
- Patient does not have any of the following contraindications:
  - Ocular or periocular infections
  - Corneal endothelial cell dystrophy
  - Prior corneal transplantation
  - Absent or ruptured posterior lens capsule

Approval duration: one implant per eye per lifetime.

Continued Therapy

Reauthorization is not allowed.

Age Limits

Must be 18 years of age or older

Billing

HCPCS code J7351 (injection, bimatoprost, intracameral implant, 1 microgram)

Prescribing Restrictions

Frequency of billing equals 1 implant (10 mcg) /10 units per eye per lifetime

Maximum billing unit(s) equals 1 implant (10 mcg) /10 units per eye

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 (e.g. 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 2 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 (e.g., 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 = one time per pregnancy.

‹‹Brexucabtagene autoleucel (Tecartus™)

Brexucabtagene autoleucel, a CD19 (Cluster of Differentiation 19)-directed genetically modified autologous T cell immunotherapy, binds to CD19-expressing cancer cells and normal B cells. Studies demonstrated that following anti-CD19 CAR T cell engagement with CD19-expressing target cells, the CD28 and CD3-zeta co-stimulatory domains activate downstream signaling cascades that lead to T cell activation, proliferation, acquisition of effector functions, and secretion of inflammatory cytokines and chemokines. This sequence of events leads to killing of CD19-expressing cells.

Indications

All FDA-approved indications

Dosage

FDA-approved dosages

TAR Requirement

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

TAR Criteria

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

- Must be used for FDA-approved indications and dosages
- Must be administered in a health care facility registered with the Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS Program
- Patient must be 18 years of age or older
- Patient must have a diagnosis of relapsed or refractory mantle cell lymphoma (MCL)
- Patient previously received anthracycline- or bendamustine-containing chemotherapy, an anti-CD20 antibody (e.g rituximab), and a Bruton tyrosine kinase inhibitor (BTKi) e.g acalabrutinib, ibrutinib, zanubrutinib)
- Patient had disease progression after their last regimen or refractory disease to their most recent therapy
- Patient must have adequate bone marrow, cardiac, pulmonary, renal, and organ functions››

- ‹‹Patient does not have the following:
  - Active or serious infections
  - Prior allogeneic hematopoietic stem cell transplant (HSCT)
  - Detectable cerebrospinal fluid malignant cells or brain metastases
  - History of central nervous system (CNS) lymphoma or CNS disorders
- Tecartus is not prescribed concurrently with other CAR T-cell immunotherapy (e.g., Kymriah, Yescarta)

Initial Authorization is for 3 months (1 dose only)

Reauthorization:

Continued therapy is not approvable.

REMS Program:

Tecartus is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Yescarta and Tecartus REMS Program. This is due to Cytokine Release Syndrome and Neurologic Toxicities. Tecartus must be administered in a certified health care facility**.**

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code C9073, Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose.

Providers are to take the following steps when submitting claims for Tecartus:

- Submit and receive back an approved *Treatment Authorization Request* (TAR)/Service Authorization Request (SAR)
- Completion of claim forms:
  - Outpatient claims may be billed by paper claim using *CMS-1500* or electronically using ASC X12N 837P v.5010.
  - Providers must submit one (1) service line on the TAR/SAR request, and enter “4” in the Units box
  - On the 837P or *CMS-1500* claim form, provider must submit one claim line to represent one (1) service.
    - ❖ Claims submitted with more than one claim line will be denied››

- ‹‹Provider must submit an invoice for reimbursement.
- This process will ensure that the total reimbursement paid for the quantity of four (4) is no more than the paid price on the provider submitted invoice
- Tecartus must be billed on its own with no other drug or biological
- For instructions regarding physician claim form completion, refer to the Medi-Cal website, forms section for completion of 837P and *CMS-1500* claim forms.

Suggested ICD-10-CM Diagnosis Codes

C83.10, C83.11, C83.12, C83.13, C83.14, C83.15, C83.16, C83.17, C83.18, C83.19

Prescribing Restrictions

Frequency of billing equals 1 dose only. No repeat authorization››

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 (e.g., 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 (e.g. 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

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).

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).

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)

‹‹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 J0693 (injection, cefiderocol, 5 mg)

Prescribing Restrictions

Frequency of billing equals 2 g/400 units every 6 hours for 7 to 14 days

Maximum billing unit(s) equals 8 g/1600 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

Certolizumab pegol is a tumor necrosis factor blocker. It is a recombinant humanized antibody Fab fragment, with specificity for human tumor necrosis factor alfa conjugated to an approximately 40 kDa polyethylene glycol. It specifically neutralizes tumor necrosis factor alfa.

Indications

Certolizumab pegol is indicated for:

- Reducing the signs and symptoms of Crohn's Disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy
- The treatment of adults with moderately to severely active rheumatoid arthritis
- The treatment of adults with psoriatic arthritis

Certolizumab pegol is not indicated for:

- The treatment of enterocutaneous or rectovaginal fistulas
- Maintaining fistula closure

Authorization

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

Dosage

Crohn's Disease:

- The recommended initial dose is 400 mg subcutaneously and at weeks two and four, and in patients who achieve a clinical response, the recommended maintenance regimen is 400 mg subcutaneously every four weeks.

Rheumatoid Arthritis and Psoriatic Arthritis:

- The recommended dose is 400 mg subcutaneously and at weeks two and four, followed by 200 mg every other week. For maintenance, a dosage of 400 mg every four weeks may be considered.

Billing

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

Page updated: February 2021

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 six months of age or older

Billing

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

Prescribing Restriction(s)

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

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

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 (…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.

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, ≤ 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 duel 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).

Page updated: February 2021

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 (e.g. 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')$_2$

Crotalidae immune F(ab')$_2$ (equine) is an equine-derived antivenin solution of intravenous (I.V.) administration.

Indications

Crotalidae immune F(ab')$_2$ (equine) is reimbursable for the management of patients with North American rattlesnake envenomation.

Age

All ages

Dosage

One vial of Crotalidae immune F(ab')$_2$ (equine) contains up to 120 mg of antivenin protein.

- The recommended dosage is as follows:
- For initial dose: 10 vials administered by I.V. infusion.
- For additional dose(s) to achieve initial control (as needed): 10 vials administered by I.V. infusion.
- For observation and late dosing (as needed): 4 vials administered by I.V. infusion.

Authorization

No *Treatment Authorization Request* (TAR) is generally 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.

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

Delafloxacin injection is a fluoroquinolone antibiotic for intravenous (I.V.) administration.

Indications

Delafloxacin is used to treat acute bacterial skin and skin structure infections caused by susceptible isolates of various gram-positive and gram-negative bacteria, including methicillin-resistant Staphylococcus aureus.

Age

18 years and older

Dosage

300 mg delafloxacin I.V. given every 12 hours for a duration of 5 to 14 days.

Authorization

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

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

- The service is medically necessary to treat an infection caused by bacteria that are sensitive to delafloxacin based on a positive laboratory culture and sensitivity report.
- First and second-line antibiotic alternatives have been tried or considered, have failed, and/or are contra-indicated.
- The patient cannot tolerate or absorb a delafloxacin oral-enteral formulation.
- A doctor's completely written order, prescription, and/or treatment plan for delafloxacin I.V.

Billing

HCPCS code C9462 (injection, delafloxacin, 1 mg)

One (1) unit of C9462 equals 1 mg delafloxacin

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.

Page updated: February 2021

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

Dolasetron

Providers may be reimbursed for dolasetron mesylate when used for the prevention or treatment of postoperative nausea and/or vomiting.

Dosage

Adults:

The recommended intravenous dose is 12.5 mg given as a single dose approximately 15 minutes before the cessation of anesthesia (prevention) or as soon as nausea and vomiting presents (treatment).

Pediatric Patients:

The recommended intravenous dose in pediatric patients 2 years of age and older is 0.35 mg/kg, with a maximum dose of 12.5 mg, given as a single dose approximately 15 minutes before the cessation of anesthesia or as soon as nausea and vomiting presents.

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