Injections: Drugs A Policy

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

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

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 Limit

Must be two 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.

Acetaminophen and Ibuprofen (Combogesic IV)

COMBOGESIC IV contains acetaminophen and ibuprofen as active drug substances. Acetaminophen is a non-opiate, non-salicylate analgesic. The precise mechanism of the analgesic properties of acetaminophen is not established but is thought to primarily involve central actions. Ibuprofen is a nonsteroidal anti-inflammatory drug (NSAID). Its mechanism of action for analgesia, like that of other NSAIDs, is not completely understood, but involves inhibition of cyclooxygenase (COX-1 and COX-2). Ibuprofen is a potent inhibitor of prostaglandin synthesis in vitro. Prostaglandins sensitize afferent nerves and potentiate the action of bradykinin in inducing pain in animal models. Prostaglandins are mediators of inflammation. Because ibuprofen is an inhibitor of prostaglandin synthesis, its mode of action may be due to a decrease of prostaglandins in peripheral tissues.

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 J0138 (injection, acetaminophen 10 mg and ibuprofen 3 mg).

Prescribing Restriction(s)

Frequency of billing is equal to every six hours for up to five days.
Maximum billing unit(s) is equal to 4000 mg acetaminophen/1200 mg ibuprofen equal to 400/400 units per 24 hours.

‹‹Adalimumab (HUMIRA), Adalimumab-fkjp

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.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS codes:

J0139 (injection, adalimumab, 1 mg).

Q5140 (injection, adalimumab-fkjp, biosimilar, 1 mg).

Prescribing Restriction(s)

Maximum billing unit(s) is equal to 160 mg / 160 units.

Adalimumab-aacf (IDACIO), Adalimumab-aaty (YUFLYMA), Adalimumab-adbm (CYLTEZO), Adalimumab-afzb (ABRILADA), Adalimumab-ryvk (SIMLANDI)

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.››

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

- Must be used for FDA-approved indications and dosages.
- ‹‹Inadequate response, intolerance or contraindication to adalimumab or adalimumab-fkjp

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.

Reauthorization is for 12 months.

Billing

HCPCS codes:

‹‹Q5141 (Injection, adalimumab-aaty, biosimilar, 1 mg).

Q5142 (Injection, adalimumab-ryvk biosimilar, 1 mg).

Q5143 (Injection, adalimumab-adbm, biosimilar, 1 mg).

Q5144 (Injection, adalimumab-aacf [idacio], biosimilar, 1 mg).

Q5145 (Injection, adalimumab-afzb ([brilada], biosimilar, 1 mg).››

ADAMTS13, recombinant-krhn (ADZYNMA®)

ADZYNMA is a recombinant form of the endogenous ADAMTS13. ADAMTS13 is a plasma zinc metalloprotease that regulates the activity of von Willebrand factor (VWF) by cleaving large and ultra large VWF multimers to smaller units and thereby reducing the platelet binding properties of VWF and its propensity to form microthrombi.

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 years of age or older.

Billing

HCPCS code J7171 (injection, adamts13, recombinant-krhn, 10 IU)

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 seven 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 one 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 12 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 Limit

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 Limit

Must be 18 years of age 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 six 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 zero to three)
  - 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 zero thru 30, or the Erthropoietic protoporphyria quality of life measure (EPP-QoL) score zero thru 100

Reauthorization is for six 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.

‹‹Aflibercept-ayyh (PAVBLU)

Policy for intravitreal Aflibercept-ayyh (HCPCS code Q5147) is located in the *Ophthalmology* section of the Part 2 provider manual.

Aflibercept-abzv (ENZEEVU)

Policy for intravitreal Aflibercept-abzv (HCPCS code Q5149) is located in the *Ophthalmology* section of the Part 2 provider manual.››

Aflibercept-mrbb (AHZANTIVE)

Policy for intravitreal Aflibercept-mrbb (HCPCS code Q5150) is located in the *Ophthalmology* section of the Part 2 provider manual.

‹‹Aflibercept-yszy (Opuviz)

Policy for aflibercept-ysyz (Opuviz) (HCPCS code Q5153) 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 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 six months (five doses on five 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 three 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 Limit

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 Limit

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 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).

Aminocaproic acid (AMICAR)

Indications, Dosages and Age

Refer to the FDA-approved labeling.

Must be 18 years of age or older.

TAR Requirement

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

Billing

HCPCS code J0281 (injection, aminocaproic acid, 1 gram).

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 Limit

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 Limit

Must be 18 years of age or older.

Billing

HCPCS code J0184 (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 four 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 12 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 12 months.

Age Limit

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.

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 Limit

Must be 18 years of age or older.

Billing

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

Prescribing Restriction(s)

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

Maximum billing unit(s) equals 32 mg/32 units.

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

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 six 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 Limit

Must be 18 years of age or older.

Billing

HCPCS code J0402 (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 Limit

Must be 18 years of age or older.

Billing

HCPCS code J0401 (injection, aripiprazole, (abilify maintena) 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 Limit

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 Limit

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 six weeks.

Maximum billing units equals 675 mg equals 675 units.

Artesunate for injection

Artesunate is an antimalarial drug.

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.
- Malaria confirmation by microscopy.
- Severe malaria based on at least one of the following:
  - High percent parasitemia (more than or equal to five percent
  - Impaired consciousness
  - Seizures
  - Circulatory collapse/shock
  - Pulmonary edema or acute respiratory distress syndrome (ARDS)
  - Acidosis
  - Acute kidney injury
  - Abnormal bleeding or disseminated intravascular coagulation (DIC)
  - Jaundice (must be accompanied by at least one other sign)
  - Severe anemia (Hb less than seven g/dL) OR
  - Inability to take oral medications despite attempt after an oral antiemetic

Initial authorization is for three months.

Continued therapy:

- Patient continues to meet initial approval criteria.
- Patient has absence of unacceptable toxicity from the drug (for example, acute renal failure, jaundice, etc.).

Reauthorization is for three months.

Billing

HCPCS code J0391 (injection, artesunate, 1 mg).

Suggested ICD-10-CM Diagnosis Codes

B52.9, B52.0, B52.8, B53.0, B53.1, B53.8, B54, B50.9, B50.8, B50.0, B51.9, B51.8, B51.0

‹‹Atropine Sulfate Injection for Intravenous Use

Clinical Use Parameters

Use in accordance with FDA-approved labeling, including indication, dosage, frequency, age and any prescribing limitation.

TAR Requirement

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

Billing

HCPCS code J0462 (injection, atropine sulfate, not therapeutically equivalent to J0461, 0.01 mg).››

Axatilimab-csfr (NIKTIMVO)

Indications, Dosages and Age

Refer to the FDA-approved labeling.

TAR Requirement

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

Billing

HCPCS code J9038 (injection, axatilimab-csfr, 0.1 mg).

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.

‹‹Aztreonam and Avibactam

Clinical Use Parameters

Use in accordance with FDA-approved labeling, including indication, dosage, frequency, age and any prescribing limitation.

TAR Requirement

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

Billing

HCPCS code J0458 (injection, aztreonam/avibactam, 7.5 mg/2.5 mg [10 mg]).››

Legend

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

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