

CAUTION: Read the [ICD-9 Policy Holding Library](#) page about policy in this document.

Injections: Drugs N-R Policy

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 A–D Policy*
- *Injections: Drugs E–H Policy*
- *Injections: Drugs I–M Policy*
- *Injections: Drugs S–Z Policy*
- *Injections: Hydration*
- *Immunizations*

Naltrexone

Naltrexone is an opioid antagonist with highest affinity for the mu opioid receptor and has little or no opioid agonist activity.

Indications

In the treatment of alcohol dependence, the injectable form of naltrexone is used in professionally supervised treatment that includes medical examination and supervision, indicated laboratory tests, psychosocial support, urinalyses, drug-use monitoring and other appropriate support such as that provided through the Drug/Medi-Cal program. Prior to initiation of treatment with naltrexone, patients must be able to abstain from alcohol in an outpatient setting, and patients should not be actively drinking at the time of initial naltrexone administration.

Naltrexone is also indicated for the prevention of relapse to opioid dependence following opioid detoxification.

Authorization

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

The treating physician administering naltrexone should be experienced in treating addiction or certified by the American Society of Addiction Medicine or should be a psychiatrist through the Drug/Medi-Cal program.

The TAR must document that the patient is being treated for alcohol dependence or for the prevention of relapse to opioid dependence.

inject drug n-r
2

Dosage	The recommended dose is 380 mg as an intramuscular gluteal injection every four weeks or once a month.
Billing	HCPCS code J2315 (injection, naltrexone, depot form, 1 mg)
Natalizumab	Natalizumab, 1 mg injection (HCPCS code J2323), is reimbursable for the treatment of multiple sclerosis (ICD-9-CM diagnosis code 340) or regional enteritis (ICD-9-CM diagnosis code range 555.0 – 555.9). The maximum daily dosage is 300 mg. Claims billed for quantities exceeding the daily limitation require appropriate documentation for payment.
Ocriplasmin	Policy for ocriplasmin (HCPCS code J7316) is located in the <i>Ophthalmology</i> section of the Part 2 manual.
Omalizumab	Omalizumab is a recombinant DNA-derived humanized IgG1κ monoclonal antibody that selectively binds to human immunoglobulin E (IgE). Omalizumab inhibits the binding of IgE to the high-affinity IgE receptor (FcεRI) on the surface of mast cells and basophils. Reduction in surface-bound IgE on FcεRI- bearing cells limits the degree of release of mediators of the allergic response. Omalizumab also binds to IgE and lowers free IgE levels. Subsequently, IgE receptors (FcεRI) on cells down-regulate. The mechanism by which these effects of omalizumab result in an improvement of chronic idiopathic urticaria (CIU) symptoms is unknown.

Indications	<p>For the treatment of adults and adolescents 12 years of age and older with:</p> <ul style="list-style-type: none">• Moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids• CIU who remain symptomatic despite H1 antihistamine treatment
Authorization	<p>An approved <i>Treatment Authorization Request</i> (TAR) is required for reimbursement.</p> <p><u>Moderate to severe persistent asthma</u></p> <p>The TAR must satisfy all of the following:</p> <ul style="list-style-type: none">• A positive skin test or in vitro reactivity to a perennial aeroallergen• Symptoms are inadequately controlled with inhaled corticosteroids• Pre-treatment serum IgE level between 30 and 700 IU/ml• Re-authorization beyond an initial three to six months trial requires documentation of clinical improvement after the administration of omalizumab (required only for re-authorization TARs) <p><u>CIU</u></p> <p>The TAR must document that the patient has received an adequate trial of H1 antihistamines and remains symptomatic</p>

inject drug n-r
4

Dosage Recommended subcutaneous administration for:

- Moderate to severe persistent asthma: frequency and dosing is based on body weight and pretreatment serum total IgE serum levels
- CIU is 150 or 300 mg every four weeks

Billing HCPCS code J2357 (injection, omalizumab, 5 mg)

OnabotulinumtoxinA For detailed clinical and billing policy information about onabotulinumtoxinA, refer to the “Botulinum Toxins A and B” topic in the *Injections: Drugs A-D Policy* section of the manual.

Ondansetron HCl Ondansetron HCl is a selective 5-HT₃ receptor antagonist.

Indications For the prevention of nausea and vomiting associated with the initial and repeated courses of cancer chemotherapy and the prevention of postoperative nausea and/or vomiting.

Dosage Prevention of chemotherapy-induced nausea and vomiting:

- Adults: The recommended adult intravenous dosage is three 0.15-mg/kg doses up to a maximum of 16 mg per dose. The first dose is infused over 15 minutes beginning 30 minutes before the start of emetogenic chemotherapy. Subsequent doses (0.15 mg/kg up to a maximum of 16 mg per dose) are administered 4 and 8 hours after the first dose.
- Pediatrics: For pediatric patients 6 months through 18 years of age, the intravenous dosage is three 0.15-mg/kg doses up to a maximum of 16 mg per dose. The first dose is to be administered 30 minutes before the start of moderately to highly emetogenic chemotherapy. Subsequent doses (0.15 mg/kg up to a maximum of 16 mg per dose) are administered 4 and 8 hours after the first dose.

Prevention of postoperative nausea and vomiting:

- Adults: The recommended adult intravenous dosage is 4 mg *undiluted* administered intravenously in not less than 30 seconds, preferably over 2 to 5 minutes, immediately before induction of anesthesia, or postoperatively if the patient did not receive prophylactic antiemetics and experiences nausea and/or vomiting occurring within 2 hours after surgery. Alternatively, 4 mg *undiluted* may be administered intramuscularly as a single injection for adults.
- Pediatrics: For pediatric patients 1 month through 12 years of age, the dosage is a single 0.1-mg/kg dose for patients weighing 40 kg or less, or a single 4-mg dose for patients weighing more than 40 kg. The rate of administration should not be less than 30 seconds, preferably over 2 to 5 minutes immediately prior to or following anesthesia induction, or postoperatively if the patient did not receive prophylactic antiemetics and experiences nausea and/or vomiting occurring shortly after surgery.

Administration of a second I.V. dose of 4 mg ondansetron postoperatively does not provide additional control of nausea and vomiting.

Billing

HCPCS code J2405 (ondansetron hydrochloride, per 1 mg)

Palifermin

Reimbursement for palifermin, 50 mcg injection (HCPCS code J2425) is allowed up to a maximum of 140 units.

inject drug n-r
6

Paliperidone Palmitate

Injectable paliperidone palmitate is a long-acting drug used for the treatment of schizophrenia in patients 18 years of age and older.

Dosage

The maximum dosage is 350 mg.

Billing

HCPCS code J2426 (injection, paliperidone palmitate, 1 mg)
One unit = 1 mg

Palonosetron

Palonosetron, 25 mcg (HCPCS code J2469) is reimbursable for acute and delayed emesis due to emetogenic chemotherapy. Palonosetron may be combined with aprepitant and dexamethasone for maximal patient benefit for both acute and delayed emesis due to highly emetogenic chemotherapy.

Dosage

A single intravenous dose of 0.25 mg delivered over 30 seconds is given 30 minutes before chemotherapy. CPT-4 code 96375 (therapeutic, prophylactic or diagnostic injection; each additional sequential intravenous push of a new substance/drug) may be reimbursed when billed in conjunction with palonosetron.

Pamidronate	Pamidronate, 30 mg, an aminohydroxypropylidene biphosphonate, is reimbursable for the outpatient treatment of hypercalcemia of malignancy with or without bone metastases, Paget's disease and osteolytic bone lesions of breast and prostate cancer and osteolytic bone lesions of multiple myeloma.
Required Codes	Pamidronate must be billed in conjunction with CPT-4 codes 96365 (intravenous infusion for therapy prophylaxis or diagnosis; initial, up to one hour) and 96366 (...each additional hour) when billed for outpatient treatment with one of the following ICD-9-CM diagnosis codes: 174.0 – 175.9 203.12 185 275.42 198.5 731.0 203.00 – 203.02
Billing	For billing, use HCPCS code J2430 (injection, pamidronate disodium, per 30 mg).
Dosage	The maximum dosage is 90 mg per day.

inject drug m-z

8

Paricalcitol	Paricalcitol is reimbursable for the prevention and treatment of secondary hyperparathyroidism in patients with chronic kidney disease on dialysis.
Dosage	The recommended initial dose of paricalciferol is 0.04 mcg/kg to 0.1 mcg/kg administered intravenously as a bolus dose no more frequently than every other day at any time during dialysis. The maximum dose should not exceed 30 mcg weekly.
Billing	HCPCS code J2501 Injection, paricalcitol, 1 mcg; one unit = 1 mcg Note: Code J2501 cannot be block billed.
Pegademase Bovine	Claims for pegademase bovine, 25 IU, (HCPCS injection code J2504) must be billed with ICD-9-CM codes 277.2 (other disorders of purine and pyrimidine metabolism) or 279.2 (combined immunity deficiency).
Pegaptanib Sodium	Policy for intravitreal pegaptanib sodium (HCPCS code J2503) is located in the <i>Ophthalmology</i> section of the appropriate Part 2 manual.
Pegfilgrastim	Pegfilgrastim is reimbursable for the management of neutropenia associated with chemotherapy in patients who have non-myeloid malignancies and are at high risk for infection.
Dosage	The recommended dosage of pegfilgrastim is a single 6 mg subcutaneous injection. Pegfilgrastim should not be given to recipients who weigh less than 45 kg.
Required Codes	Pegfilgrastim is reimbursable when billed with ICD-9-CM codes 288.03, V07.8, V58.11 or V66.2.
Billing	HCPCS code J2505 (pegfilgrastim, 6 mg); one (1) unit = 6 mg.

Pegloticase	<p>Pegloticase is a uric acid specific enzyme which is a PEGylated product that consists of recombinant modified mammalian urate oxidase (uricase) produced by a genetically modified strain of <i>Escherichia coli</i>. It is a uric acid specific enzyme which is a recombinant uricase and achieves its therapeutic effect by catalyzing the oxidation of uric acid to allantoin, thereby lowering serum uric acid.</p>
Indications	<p>For the treatment of chronic gout in adult patients refractory to conventional therapy who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these drugs are contraindicated.</p> <p>Pegloticase is not recommended for the treatment of asymptomatic hyperuricemia.</p>
Required Codes	<p>Pegloticase is reimbursable only with ICD-9-CM codes 274.00 – 274.9.</p>
Dosing	<p>The recommended dose and regimen of pegloticase for adult patients is 8 mg given as an intravenous infusion every two weeks.</p> <p>Restricted to recipients 18 years of age and older.</p>
Billing	<p>HCPCS code J2507 (injection, pegloticase, 1 mg).</p>

inject drug n-r
10

Plerixafor Plerixafor is used to enhance mobilization of stem cells for autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM).

Required Codes Plerixafor is reimbursable when billed in conjunction with an ICD-9-CM diagnosis code in the range 200.00 – 200.88 or 202.00 – 203.02.

Billing HCPCS code J2562 (injection, plerixafor, 1 mg)
One unit = 1 mg

Protein C Concentrate Protein C concentrate, intravenous, human, 10 IU (HCPCS code J2724) is reimbursable when billed with ICD-9-CM diagnosis code 289.81 and has a maximum daily dosage of 16,360 IU.

Prothrombin Complex Concentrate (Human) Prothrombin complex concentrate is a purified, heat-treated, nanofiltered and lyophilized non-activated, four-factor drug prepared from human plasma. It contains the vitamin K-dependent coagulation Factors II, VII, IX, X and the antithrombotic proteins C and S. A dose-dependent acquired deficiency of the vitamin K dependent coagulation factors occurs during vitamin K antagonist treatment. The administration of prothrombin complex rapidly increases plasma levels of these factors as well as anti-thrombotic proteins C and S.

Indications For the urgent reversal of acquired coagulation factor deficiency induced by vitamin K antagonist therapy in adult patients with acute major bleeding.

It is not indicated for urgent reversal of vitamin K antagonist anticoagulation in patients without acute major bleeding.

The safety and efficacy of prothrombin complex concentrate has not been studied in the pediatric population.

Authorization	An approved <i>Treatment Authorization Request</i> (TAR) is required for reimbursement.
Dosage	The recommended dosage should be individualized based on the patient's baseline international normalized ratio (INR) value and body weight.
Billing	HCPCS code C9132 (prothrombin complex concentrate [human], Kcentra per i.u. of Factor IX activity).
Ranibizumab	Policy for intravitreal ranibizumab (HCPCS code J2778) is located in the <i>Ophthalmology</i> section of the provider manual.
Rilonacept	Rilonacept is an interleukin-1 blocker and is used in the treatment of Cryopyrin-Associated Periodic Syndrome, including Familial Cold Auto-inflammatory Syndrome and Muckle-Wells Syndrome in adults and children 12 years of age and older.
Authorization	An approved TAR is required for reimbursement.
Dosage	In adult patients 18 years of age and older, treatment is initiated with a loading dose of 320 mg, delivered as two subcutaneous injections of 160 mg on the same day at two different sites, then once-weekly injections of 160 mg. In pediatric patients 12 to 17 years of age, treatment is initiated with a loading dose of 4.4 mg/kg, up to a maximum of 320 mg in either one or two subcutaneous injections on the same day (at two different sites if two injections), then once-weekly injections up to a maximum of 160 mg.
Billing	HCPCS code J2793 (injection, rilonacept, 1 mg) One unit = 1 mg

RimabotulinumtoxinB

For detailed billing policy information about rimabotulinumtoxinB, refer to the “Botulinum Toxins A and B” topic in the *Injections: Drugs A-D Policy* section of the manual.

Rituximab

Rituximab is a genetically engineered chimeric murine/human monoclonal IgG, kappa antibody directed against the CD20 antigen and is produced by mammalian cell (Chinese Hamster Ovary) suspension culture. Rituximab binds specifically to the antigen CD20 (human B-lymphocyte-restricted differentiation antigen, Bp35) located on pre-B and mature B lymphocytes. The antigen is expressed on >90% of B-cell non-Hodgkin’s lymphomas, but the antigen is not found on hematopoietic stem cells, pro-B-cells, normal plasma cells or other normal tissues. CD20 regulates an early step(s) in the activation process for cell cycle initiation and differentiation, and possibly functions as a calcium ion channel. B-cells are believed to play a role in the pathogenesis of rheumatoid arthritis (RA) and associated chronic synovitis. In this setting, B-cells may be acting at multiple sites in the autoimmune/inflammatory process, including through production of rheumatoid factor and other autoantibodies, antigen presentation, T-cell activation and/or proinflammatory cytokine production.

Refer to “Rituximab” in the *Chemotherapy: Drugs P-Z Policy* section of the appropriate Part 2 manual for the use of rituximab in malignant disease.

Indications

For patients with either of the following conditions:

RA:

- In combination with methotrexate for the treatment of adult patients with moderately- to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor antagonist therapies.

Wegener’s Granulomatosis (WG) and Microscopic Polyangiitis (MPA):

- In combination with glucocorticoids for the treatment of adult patients with Wegener’s granulomatosis and microscopic polyangiitis.

Dosage

Recommended dose for RA:

- Administer rituximab as two-1000 mg intravenous infusions separated by two weeks.
- Glucocorticoids administered as methylprednisolone 100 mg intravenous or its equivalent 30 minutes prior to each infusion are recommended to reduce the incidence and severity of infusion reactions.
- Subsequent courses should be administered every 24 weeks or based on clinical evaluation, but not sooner than every 16 weeks.
- Rituximab is given in combination with methotrexate.

Recommended dose for WG and MPA:

- Administer rituximab as a 375 mg/m² intravenous infusion once weekly for four weeks.
- Glucocorticoids administered as methylprednisolone 1000 mg intravenously per day for one to three days followed by oral prednisone 1 mg/kg/day (not to exceed 80 mg/day and tapered per clinical need) are recommended to treat severe vasculitis symptoms. This regimen should begin within 14 days prior to, or with the initiation of rituximab and may continue during and after the four-week course of rituximab treatment.
- Safety and efficacy of treatment with subsequent courses of rituximab have not been established.

inject drug n-r
14

Required Codes

Rituximab is reimbursable when billed in conjunction with one of the following ICD-9-CM diagnosis codes:

- 446.0 Polyarteritis nodosa (microscopic polyangiitis*)
- 446.4 Wegener's granulomatosis
- 714.0 – 714.9 Rheumatoid arthritis

* The ICD-9-CM manual states code 446.0 as polyarteritis nodosa; however this code and descriptor is currently the closest available descriptor for microscopic polyangiitis that is the medical condition indicated for rituximab therapy. A more specific code for microscopic polyangiitis will be available when ICD-10-CM implements.

Billing

HCPCS code J9310 (rituximab, 100 mg)
One (1) unit = 100 mg