Injections: Drugs P-Q Policy

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

- *Immunizations*
- *Injections: Drugs A Policy*
- *Injections: Drugs B Policy*
- *Injections: Drugs 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 R Policy*
- *Injections: Drugs S Policy*
- *Injections: Drugs T Policy*
- *Injections: Drugs U-Z Policy*
- *Injections: Hydration*

Palifermin

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

Paliperidone Palmitate (Invega Sustenna®, Invega Trinza®, Invega Hafyera™)

Paliperidone palmitate is hydrolyzed to paliperidone [see Clinical Pharmacology (12.3)]. Paliperidone is the major active metabolite of risperidone. The mechanism of action of paliperidone is unclear. However, its efficacy in the treatment of schizophrenia could be mediated through a combination of central dopamine D2 and serotonin 5HT2A receptor antagonism.

Invega Sustenna, Invega Trinza and Invega Hafyera are dosed monthly, every three months, or every six months, respectively, per their individual Prescribing Information.

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 codes:

- J2426 (Injection, paliperidone palmitate extended release [Invega Sustenna], 1 mg).
- J2427(Injection, paliperidone palmitate extended release [Invega Hayera, or Invega Trinza], 1 mg).

Suggested ICD-10CM Diagnosis Codes

F20, F20.0, F20.1, F20.2, F20.3, F20.5, F20.8, F20.9

Invega Sustenna only: F25.0, F25.1, F25.9

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® 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 codes 96365 (intraveous infusion for therapy prophylaxis or diagnosis; initial, up to one hour) and 96366 (intraveous infusion for therapy prophylaxis or diagnosis; each additional hour) when billed for outpatient treatment with one of the following ICD-10-CM diagnosis codes:

C50.011 thru C50.929	C90.00 thru C90.02
C61	E83.52
C79.51	M88.0 thru M88.9

Billing

For billing, use HCPCS code J2430 (injection, pamidronate disodium, per 30 mg).

Dosage

The maximum dosage is 90 mg per day.

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 (1) unit equals 1 mcg.

Note: Code J2501 cannot be block billed.

Patisiran (Onpattro®)

Patisiran is a double-stranded small interfering ribonucleic acid (siRNA) that causes degradation of mutant and wild-type transthyretin (TTR) mRNA through RNA interference, which results in a reduction of serum TTR protein and TTR protein deposits in tissues. Serum TTR is a carrier of retinol binding protein, which is involved in the transport of vitamin A in the blood.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria

Must summit clinical documentation to substantiate the following:

- Must be for FDA-approved indications and dosing regimens.
- Must be 18 years of age or older.
- Must be prescribed by or in consultation with a neurologist, hematologist, cardiologist, geneticist, or a physician who specializes in the treatment of amyloidosis.
- Patient has a diagnosis of hereditary transthyretin-mediated (hATTR) amyloidosis with documented mutation in transthyretin (TTR) gene; or tissue biopsy results consistent with amyloid.
- Patient has clinical signs and symptoms of the disease (for example, peripheral sensorimotor neuropathy, autonomic neuropathy, motor disability, etc.).
- Patient had one of the following test results at baseline:
  - Neuropathy Impairment Score of (five to 130)
  - Polyneuropathy disability (PND) score stage 3B or less (equal to or less than IIIb)

- Other causes of peripheral neuropathy have been ruled out.
- Patient has not had a liver transplant and is not planning to undergo one.
- Patient is receiving supplementation with vitamin A at the recommended daily allowance.
- Patient is not currently taking diflunisal, tafamidis, doxycycline, or inotersen.

Initial authorization is for 12 months.

Continued therapy

- Patient continues to meet initial coverage criteria.
- Patient has shown clinical improvement or lack of disease progression from baseline as evidenced by at least one of the following:
  - Improvement in neurologic impairment or motor function
  - Improvement or stability in Neuropathy Impairment score, or Polyneuropathy disability (PND) score

Reauthorization is for 12 months.

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code J0222 (injection, patisiran, 0.1 mg).

Suggested ICD-10-CM Diagnosis Codes

E85.1

Prescribing Restrictions

Frequency of billing equals 30 mg/300 units every 21 days.

Maximum billing units equals 30 mg equals 300 units.

Pegademase Bovine

Claims for pegademase bovine, 25 IU, (HCPCS injection code J2504) must be billed with ICD-10-CM codes D81.3 (adenosine deaminase [ADA] deficiency).

Pegaptanib Sodium

Policy for intravitreal pegaptanib sodium (HCPCS code J2503) is located in the *Ophthalmology* section of the appropriate Part 2 manual.

Pegloticase

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 *Escherichia coli*. 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.

Indications

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.

Pegloticase is not recommended for the treatment of asymptomatic hyperuricemia.

Required Codes

Pegloticase is reimbursable only with ICD-10-CM diagnosis codes M1A.00 thru M10.9.

Dosage

The recommended dose and regimen of pegloticase for adult patients is 8 mg given as an intravenous infusion every two weeks.

Restricted to patients 18 years of age and older.

Billing

HCPCS code J2507 (injection, pegloticase, 1 mg).

Peramivir

Peramivir is an antiviral drug with activity against influenza virus. It is an inhibitor of influenza virus neuraminidase, an enzyme that releases viral particles from the plasma membrane of infected cells.

Indications

For the treatment of acute uncomplicated influenza in patients 18 years of age and older who have been symptomatic for no more than two days.

Dosage

The recommended dose is a single 600 mg dose administered intravenously over 15 to 30 minutes.

Billing

HCPCS code J2547 (injection, peramivir, 1 mg).

Phenobarbital Sodium (Sezaby™)

The precise mechanism of action for phenobarbital for the treatment of neonatal seizures is not fully understood, but it is thought to involve potentiation of synaptic inhibition through an action on the GABAA receptor.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS code J2561 (Injection, phenobarbital sodium [Sezaby], 1 mg).

Phenylephrine Hydrochloride

Potent, direct-acting alpha-adrenergic agonist with virtually no beta-adrenergic activity; produces systemic arterial vasoconstriction. Such increases in systemic vascular resistance may result in dose-dependent increases in systolic and diastolic blood pressure and reductions in heart rate and cardiac output (most noticeable in patients with preexisting cardiac dysfunction).

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS code J2371 (Injection, phenylephrine hydrochloride, 20 mcg).

Phenylephrine Hydrocholoride (Biorphen)

Potent, direct-acting alpha-adrenergic agonist with virtually no beta-adrenergic activity; produces systemic arterial vasoconstriction. Such increases in systemic vascular resistance may result in dose-dependent increases in systolic and diastolic blood pressure and reductions in heart rate and cardiac output (most noticeable in patients with preexisting cardiac dysfunction).

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

Billing

HCPCS code J2372 (Injection, phenylephrine hydrochloride [Biorphen], 20 mcg).

Plasminogen, human-tvmh (Ryplazim®)

Treatment with Ryplazim temporarily increases plasminogen levels in blood.

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 11 months of age or older.
- Must be prescribed by or in consultation with a geneticist, hematologist, or specialist with experience in treating hypoplasminogenemia.
- Patient has a diagnosis of plasminogen deficiency type 1 as evidenced by at least two of the following:
  - Biallelic mutations in the plasminogen (PLG) gene confirmed by genetic testing
  - A baseline plasminogen activity level less than 45 percent of normal
  - A documented history of typical lesions and symptoms (for example, ligneous conjunctivitis, ligneous gingivitis and tonsillar lesions, ligneous airway disease, ligneous lesions of the hands and feet, impaired wound healing, etc.)
- For patients with respiratory tract involvement, spirometry measurements (forced expiratory volume in 1 second (FEV1), forced vital capacity (FVC), peak expiratory flow, and FEV1/FVC ratio) at baseline and every four weeks.

Initial authorization is for 12 months.

Continued therapy

- Patient continues to meet initial approval criteria.
- Patient has shown clinical benefit as evidenced by at least one of the following:
  - Improvement in lesion number or size from baseline
  - Absence of new lesions compared to baseline
  - Improvement in wound healing
  - Improvement in spirometry measurements from baseline if respiratory tract involvement

Reauthorization is for 12 months.

Billing

HCPCS code J2998 (injection, plasminogen, human-tvmh, 1 mg).

Required ICD-10 Diagnosis Codes

E88.02

Prescribing Restriction(s)

Frequency of billing equals 6.6 mg/kg every two to four days.

Plazomicin (Zemdri)

Plazomicin is an aminoglycoside antibacterial which interferes with bacterial protein synthesis by binding to 30S ribosomal subunit resulting in a defective bacterial cell membrane.

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

- Must be for an FDA-approved indication and dosing regimen.
- Must have a diagnosis of complicated urinary tract infection (cUTI) including pyelonephritis caused by Escherichia coli, Klebsiella penumoniae, Proteus mirabilis and Enterobacter cloacae.
- Must be 18 years of age or older.

- Must not be pregnant.
- Must justify why patient cannot use formulary alternatives such as an aminoglycoside, carbapenems, fluoroquinolone or other therapeutic equivalent.
- Must provide the patient's recent weight for dose determination.

Age Limits

Must be 18 years of age or older.

Billing

HCPCS code J0291 (injection, plazomicin, 5 mg).

Prescribing Restrictions

Frequency of billing equals every 24 hours for four to seven days.

Maximum billing units equals 3,400 mg equals 680 units.

Plerixafor

Plerixafor is used to enhance mobilization of stem cells for autologous transplantation in patients with non-Hodgkin lymphoma and multiple myeloma.

Required Codes

Plerixafor is reimbursable when billed in conjunction with an ICD-10-CM diagnosis code in the range C82.00 thru C86.6, C88.4 or C90.00 thru C90.02.

Billing

HCPCS code J2562 (injection, plerixafor, 1 mg) one unit equals1 mg.

‹‹Pozelimab-bbfg Injection (Veopoz™)

Pozelimab-bbfg is a human, monoclonal immunoglobulin G4P (IgG4P) antibody directed against the terminal complement protein C5 that inhibits terminal complement activation by blocking cleavage of C5 into C5a (anaphylatoxin) and C5b, thereby blocking the formation of the membrane-attack complex (C5b-C9, a structure mediating cell lysis).

Indications

All FDA-approved indications.

Dosage

FDA-approved dosages.

TAR Requirement

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

TAR Criteria:

Veopoz will be considered medically necessary if all of the following criteria are met:

1. Used for FDA approved indications and dosages.
2. Patient is one year of age or older.
3. Patient has received meningococcal vaccination at least two weeks prior to treatment with Veopoz unless the risks of delaying Veopoz outweighs the risk of meningococcal infection.
4. Patient is not currently on other complement inhibitors (for example, eculizumab, ravulizumab, pegcetacoplan, etc.).››

5. ‹‹Diagnosis of CD55-deficient protein losing enteropathy (CHAPLE disease) as documented by:
   - Confirmed biallelic CD55 loss of function mutation and
   - Hypoalbuminemia (serum albumin concentration of no more than 3.2 g/dL) and
   - One or more of the following signs and symptoms of CD-55 PLE for at least six months: abdominal pain, diarrhea, peripheral edema, or facial edema)

Initial authorization is for six months.

Re-authorization criteria:

1. Patient continues to meet the initial criteria.
2. Lack of unacceptable toxicities (cardiovascular instability, infections).
3. Documentation of a clinically significant improvement (e.g. improvement in abdominal pain, diarrhea, etc., normalization of serum albumin concentrations, reduced hospitalization).

Re-authorization is for 12 months.

Age Limits

Must be one year of age or older.

Billing

HCPCS code J9376 (injection, pozelimab-bbfg, 1 mg).

Required ICD-10-CM Diagnosis Codes

D84.1

Prescribing Restriction(s)

Frequency of billing equal to once a week.››

Protein C Concentrate

Protein C concentrate, intravenous, human, 10 IU (HCPCS code J2724) is reimbursable when billed with ICD-10-CM diagnosis code D68.59 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 *Treatment Authorization Request* (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.

The maximum recommended dosage is 5,000 units.

Billing

HCPCS code J7168 Prothrombin complex concentrate (human), kcentra per i.u. of factor IX activity.

Prothrombin Complex Concentrate, Human-lans (BALFAXAR)

The administration of BALFAXAR provides a rapid increase in plasma levels of the vitamin K-dependent coagulation factors (FII, FVII, FIX, FX) and antithrombotic proteins C and S. Together they are referred to as the prothrombin complex. BALFAXAR can temporarily correct the coagulation defect of patients with deficiency of one or several of these factors.

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 J7165 (injection, prothrombin complex concentrate [human], balfaxar, per i.u. of factor IX activity).››

Prescribing Restriction(s)

Frequency of billing equals 5000 iu / 5000 units as a single dose.

Maximum billing unit(s) equals 5000 iu / 5000 units.

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.