

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

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

Ibandronate	Ibandronate sodium, 1 mg, (HCPCS J1740) is reimbursable for the treatment of women with post-menopausal osteoporosis.
Dosage	Dosing frequency is 3 mg every three months administered intravenously over 15 – 30 seconds by a health care provider. Ibandronate is contraindicated in patients with hypocalcemia or those who have a known hypersensitivity to ibandronate sodium.
Required Diagnosis Code	Restricted to ICD-9-CM diagnosis code 733.01.
Billing	Providers must submit the following documentation in the <i>Remarks</i> field (Box 80)/ <i>Additional Claim Information</i> field (Box 19) on the claim or on an attachment: <ul style="list-style-type: none">• A diagnostic T score of -2.5 or more in women who have documented difficulty with the oral bisphosphonates dosing requirement, which includes an inability to sit upright for 30 to 60 minutes and/or difficulty in swallowing a pill; <u>or</u>,• A diagnostic T score of -2.5 or more in women with documented esophagitis, gastritis, gastric or esophageal ulcers which prohibit the use of oral bisphosphonates.

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Ibuprofen	The daily maximum dosage for HCPCS code J1741 (injection, ibuprofen, 100 mg) is 3,200 mg.
Authorization	For doses greater than 3,200 mg per day, an approved <i>Treatment Authorization Request (TAR)</i> is required for reimbursement.
Idursulfase	For detailed billing policy information about idursulfase, refer to the “Enzyme Replacement Drugs” topic in the <i>Injections: Drugs E-H Policy</i> manual section.
Imiglucerase	For detailed billing policy information about imiglucerase, refer to the “Enzyme Replacement Drugs” topic in the <i>Injections: Drugs E-H Policy</i> manual section.
Immune Globulin	Immune globulin preparations contain highly purified (>90 percent) polyvalent IgG. Immune globulin preparations are made from pooled human plasma from several thousand screened volunteer donors. Cold alcohol fractionation is used to isolate the immunoglobulin-containing fraction. This is followed by further purification techniques including several specific treatments to inactivate or remove potentially present blood-borne pathogens. These include low pH treatment, solvent-detergent treatment, pasteurization and/or nanofiltration.

Indications	<p>Immune globulin is indicated for any of the following:</p> <ul style="list-style-type: none"> • Primary congenital hypogammaglobulinemia <ul style="list-style-type: none"> - X-linked hypogammaglobulinemia - Common variable immunodeficiency - Severe combined immune deficiency - Ataxia-telangiectasia - Wiscott-Aldrich syndrome • Secondary acquired antibody deficiency <ul style="list-style-type: none"> - Chronic lymphocytic leukemia (CLL) - HIV infection in children • Autoimmune disorders <ul style="list-style-type: none"> - Idiopathic thrombocytopenic purpura (ITP) - Anti-factor VIII autoantibodies - Kawasaki disease - Polymyositis and dermatomyositis - Guillain-Barre syndrome (GBS) • Other <ul style="list-style-type: none"> - Chronic inflammatory demyelinating polyneuropathy
Authorization	<p>An approved <i>Treatment Authorization Request</i> (TAR) is required for reimbursement. TARs may be approved for any of the indications above. In many instances immune globulin is not considered first line therapy and may be used as second line therapy or in special circumstances. The TAR must not only state the diagnoses but also must contain sufficient clinical information to establish medical necessity.</p>
Routes of Administration	<p>Immune globulin may be administered intravenously, intramuscularly or subcutaneously. In most cases, products are designed for a specific route of administration, although some preparations designed for intravenous administration can also be given subcutaneously. Subcutaneous and intramuscular products are generally more concentrated than intravenous preparations.</p>

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Billing

Intravenous immune globulin injections:

<u>HCPCS Code</u>	<u>Description</u>
J1459	Injection, immune globulin, (Privigen), non-lyophilized (e.g. liquid), 500 mg
J1556	Injection, immune globulin, (Bivigam), 500 mg
J1557	Injection, immune globulin, (Gammaplex), non-lyophilized (e.g. liquid), 500 mg
J1561	Injection, immune globulin, (Gamunex/ Gamunex-C/Gammaked), non-lyophilized (e.g. liquid), 500 mg
J1566	Injection, immune globulin, lyophilized (e.g. powder), not otherwise specified, 500 mg
J1568	Injection, immune globulin, (Octagam), non-lyophilized (e.g. liquid), 500 mg
J1569	Injection, immune globulin, (Gammagard Liquid), non-lyophilized (e.g. liquid), 500 mg
J1572	Injection, immune globulin, (flebogamma/flebogamma DIF), non-lyophilized (e.g. liquid), 500 mg
J1599	Injection, immune globulin, non-lyophilized (e.g. liquid), not otherwise specified, 500 mg

Intramuscular or subcutaneous immune injections:

<u>HCPCS Code</u>	<u>Description</u>
J1460	Injection, gamma globulin, intramuscular 1 cc
J1559	Injection, immune globulin, (Hizentra), 100 mg
J1560	Injection, gamma globulin, intramuscular over 10 cc
J1562	Injection, immune globulin, (Vivaglobin), 100 mg

Providers must use the correct code when submitting claims or the claim will be denied. Claims submitted with codes J1460, J1560, J1566 or J1599 must include an invoice or the claim will be denied.

IncobotulinumtoxinA

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

Infliximab

Infliximab may be reimbursed when used for:

- Crohn’s disease:
 - For reduction in the signs and symptoms of Crohn’s disease in recipients with moderately to severely active Crohn’s disease who have had an inadequate response to conventional therapy.
 - For reduction in the number of draining enterocutaneous fistulae in recipients with fistulizing Crohn’s disease.
- Rheumatoid arthritis:
 - When used in combination with methotrexate, for the reduction in signs and symptoms of rheumatoid arthritis in recipients who have had an inadequate response to methotrexate, or who are refractory to other disease-modifying anti-rheumatic drugs. If the recipient is intolerant to methotrexate, infliximab must be used in conjunction with another disease-modifying agent.
- Refractory ankylosing spondylitis.
- Destructive psoriatic arthropathy.
- Active ulcerative colitis that has had an inadequate response to conventional therapy.
- Plaque psoriasis that covers 10 percent or more of the patient’s body surface area.

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Dosage

For treatment of moderate to severe Crohn's disease, the recommended dose of infliximab is an initial 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg doses given at two and six weeks, then every eight weeks thereafter. The dosage may be increased to 10 mg/kg for patients who have an incomplete response to the 5 mg/kg dose. If patients do not respond to the increased dosage after 14 weeks, providers should consider discontinuing treatment with infliximab.

For treatment of fistulizing Crohn's disease, the recommended dose of infliximab is an initial dose of 5 mg/kg given as an intravenous infusion followed by additional 5 mg/kg doses given at two and six weeks after the initial dose.

For treatment of rheumatoid arthritis, the recommended dose of infliximab is an initial 3 mg/kg given as an intravenous infusion followed by additional 3 mg/kg doses given at two and six weeks, then every eight weeks thereafter. The dosage may be adjusted to 10 mg/kg every eight weeks or 5 mg/kg every four weeks for patients who have an incomplete response to the 3 mg/kg dose. Infliximab should be given in combination with methotrexate or another disease-modifying agent.

TAR Required

Infliximab treatment requires a *Treatment Authorization Request* (TAR). The patient's condition must be entered in the *Medical Justification* area of the TAR. When requesting authorization for plaque psoriasis, documentation stating that the plaque psoriasis covers 10 percent or more of the patient's body surface area must be on or attached to the TAR.

Billing

Infliximab, 10 mg (HCPCS code J1745).

Iron Sucrose

Iron sucrose injection is an aqueous complex of polynuclear iron (III)-hydroxide in sucrose containing 20 mg elemental iron per ml. Iron is essential to the formation of hemoglobin. Untreated depletion of iron stores leads to iron-deficient erythropoiesis and, in turn, to iron deficiency anemia. Administration of iron sucrose replenishes tissue iron stores, reverses iron depletion and iron-deficient erythropoiesis, and corrects or prevents iron deficiency anemia. Following intravenous administration, iron sucrose is dissociated into iron and sucrose by the reticuloendothelial system and iron is transferred from the blood to a pool of iron in the liver and bone marrow. After a series of interactions with storage and transport proteins, iron becomes internalized and intracellular iron becomes hemoglobin in circulating red blood cells.

Indications

Iron sucrose is indicated in the treatment of iron deficiency anemia in the following patients:

- Non-dialysis dependent-chronic kidney disease patients receiving an erythropoietin
- Non-dialysis dependent-chronic kidney disease patients not receiving an erythropoietin
- Hemodialysis dependent-chronic kidney disease patients receiving an erythropoietin
- Peritoneal dialysis dependent-chronic kidney disease patients receiving an erythropoietin

Dosage

Iron sucrose must only be administered intravenously either by slow injection or infusion.

Hemodialysis Dependent Chronic Kidney Disease Patients:
Iron sucrose may be administered undiluted as a 100 mg slow intravenous injection over a period of at least 15 minutes per consecutive hemodialysis session for a total cumulative dose of 1,000 mg.

Non-Dialysis Dependent-Chronic Kidney Disease Patients:
Iron sucrose is administered as a total cumulative dose of 1,000 mg over a 14-day period as a 200 mg slow intravenous injection over a period of at least 15 minutes on five different occasions within the 14-day period.

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Diagnosis Restrictions Two ICD-9-CM codes are required for reimbursement. One code must be for chronic kidney disease (585.1 – 585.6) and the other must be for iron deficiency anemia (280.9).

Billing HCPCS code J1756 (injection, iron sucrose, 1 mg)

Lacosamide Lacosamide injection is indicated for intravenous use as adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy aged 17 years and older when oral administration is temporarily not feasible. The precise mechanism by which lacosamide exerts its antiepileptic effects in humans remains to be fully elucidated.

Dosage The initial dose should be 100 mg intravenously in two divided doses and can be increased at weekly intervals by 100 mg per day in two divided doses up to the recommended maintenance dose of 200 to 400 mg per day.

The maximum daily dose is 400 mg.

Diagnosis Restrictions Restricted to ICD-9-CM diagnosis codes 345.40 – 345.51.

Billing HCPCS code C9254 (injection, lacosamide, 1 mg)

Lanreotide Lanreotide acetate, 1 mg (HCPCS code J1930) is reimbursable for the treatment of acromegaly and gigantism. Claims must be billed with ICD-9-CM diagnosis code 253.0. The maximum daily dosage is 120 mg. Claims billed for quantities exceeding the daily limitation require appropriate documentation for payment.

Laronidase	For detailed billing policy information about laronidase, refer to the “Enzyme Replacement Drugs” topic in the <i>Injections: Drugs E-H Policy</i> section of the manual.						
Leuprolide	<p>Leuprolide acetate injections are reimbursable when billed in conjunction with an appropriate ICD-9-CM diagnosis code. Leuprolide acetate is used to suppress sex hormone production and is available for both adult and pediatric care.</p> <p>Refer to “Leuprolide acetate” in the <i>Chemotherapy: Drugs E-O Policy</i> section of the appropriate Part 2 manual for information on the use of leuprolide in malignant disease.</p>						
Dosage	The various dosage schedules are based upon the disease being treated. The usual dose is between 3.75 and 45 mg and is administered as frequently as monthly and as infrequently as every six months depending on which drug formulation is administered.						
Required Codes	<p>Leuprolide acetate is reimbursable at a frequency of up to once every 30 days when billed with any of the following ICD-9-CM codes:</p> <p>218.0 – 218.9 259.1 <u>302.50 – 302.53</u> <u>302.6</u> 617.0 – 617.9</p>						
Billing	<p>The following HCPCS codes should be billed in conjunction with the appropriate ICD-9-CM diagnosis code.</p> <table border="0"> <thead> <tr> <th style="text-align: left;"><u>HCPCS Code</u></th> <th style="text-align: left;"><u>Description</u></th> </tr> </thead> <tbody> <tr> <td>J1950</td> <td>Injection, leuprolide acetate (for depot suspension), per 3.75 mg</td> </tr> <tr> <td>J9217</td> <td>Injection, leuprolide acetate (for depot suspension), per 7.5 mg (Lupron or Eligard may be used for the 7.5 mg dose)</td> </tr> </tbody> </table>	<u>HCPCS Code</u>	<u>Description</u>	J1950	Injection, leuprolide acetate (for depot suspension), per 3.75 mg	J9217	Injection, leuprolide acetate (for depot suspension), per 7.5 mg (Lupron or Eligard may be used for the 7.5 mg dose)
<u>HCPCS Code</u>	<u>Description</u>						
J1950	Injection, leuprolide acetate (for depot suspension), per 3.75 mg						
J9217	Injection, leuprolide acetate (for depot suspension), per 7.5 mg (Lupron or Eligard may be used for the 7.5 mg dose)						

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Levetiracetam

Levetiracetam, 10 mg (HCPCS code J1953) has a maximum daily dose of 3,000 mg. Claims billed for quantities exceeding the daily limitation require appropriate documentation for payment.

Medroxyprogesterone Acetate

When administered as an injectable contraceptive, refer to the *Family Planning* section in the appropriate Part 2 manual for billing information.

When administered for the treatment of endometrial carcinoma, refer to the *Chemotherapy: Drugs E-O Policy* section in the appropriate Part 2 manual for billing information.

Authorization

An approved *Treatment Authorization Request (TAR)* is required for reimbursement only when the dose exceeds 1,000 mg per day.

Billing

HCPCS injection code J1050 (injection, medroxyprogesterone acetate, 1 mg)

Mesna	Mesna (HCPCS code J9209), is a uroprotective agent in patients who receive oxazaphosphorine alkylating agents including ifosfamide (HCPCS code J9208) and cyclophosphamide (HCPCS code J9070). The active ingredient is a synthetic sulfhydryl compound which is rapidly metabolized to its major metabolite, mesna disulfide. In the kidney, mesna disulfide is reduced to the free thiol compound, mesna which reacts with urotoxic metabolites resulting in their detoxification.
Indications	Mesna is indicated for use as a prophylactic agent in reducing the incidence of drug induced hemorrhagic cystitis in patients receiving ifosfamide or cyclophosphamide.
Dosage	The mesna dosage is 60 percent of the total daily dose of ifosfamide or cyclophosphamide divided into three separate aliquots and administered at the time of, and at four and eight hours after, each dose of chemotherapy. The maximum daily dose of mesna should be 9 gms or 45 units per day. Medical justification is required to allow more if the cyclophosphamide dose is greater than 6.8 gms or the ifosfamide dose is greater than 15 gms.
Billing	HCPCS code J9209 (injection, mesna, 200 mg) Mesna is reimbursable only if billed in conjunction with ifosfamide or cyclophosphamide. CPT-4 code 96375 (therapeutic, prophylactic or diagnostic injection; each additional sequential intravenous push of a new substance/drug) is reimbursable when billed in conjunction with mesna.

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Methotrexate	Injectable methotrexate is reimbursable when used in the treatment of both malignant and non-malignant diseases.
Dosage	Due to the wide variety of diseases and dosages in which methotrexate is used, a usual, recommended or maximum dose cannot be stated.
Billing	HCPCS code J9260 (methotrexate sodium, 50 mg); one (1) unit = 50 mg Note: If less than 50 mg is administered, one unit may be submitted on the claim form.

Micafungin	Micafungin is a semi-synthetic water-soluble lipopeptide of the echinocandin class of antifungal agents. It inhibits the synthesis of 1, 3 beta-D-glucan, an integral component of fungal cell wall synthesis. It exhibits fungicidal activity against <i>Candida</i> species and fungistatic activity against <i>Aspergillus</i> species.
Indications	Micafungin is indicated for: <ul style="list-style-type: none">• Treatment of patients with candidemia, acute disseminated candidiasis, candida peritonitis and abscesses• Treatment of patients with esophageal candidiasis• Prophylaxis of candida infections in patients undergoing hematopoietic stem cell transplantation• Treatment or prophylaxis of other cancer related fungal infections such as but not limited to patients who have received a bone marrow transplant
Authorization	Not required.
Dosage	The usual dose is 50 – 150 mg daily for the duration of treatment or prophylactic therapy.
Billing	HCPCS code J2248 (injection, micafungin sodium, 1 mg)
Mitomycin	HCPCS code J7315 (mitomycin, ophthalmic, 0.2 mg) has a daily maximum of 0.2 mg.
Authorization	An approved <i>Treatment Authorization Request (TAR)</i> is required for reimbursement only when the dose exceeds 0.2 mg per day.

Mitoxantrone

Injectable mitoxantrone is a synthetic antineoplastic anthracenedione that intercalates into deoxyribonucleic acid causing crosslinks and strand breaks. It also interferes with ribonucleic acid (RNA) and is a potent inhibitor of topoisomerase II, an enzyme responsible for uncoiling and repairing damaged DNA. It has a cytotoxic effect on both proliferating and non-proliferating cultured human cells, suggesting lack of cell cycle phase specificity.

Refer to “mitoxantrone” in the *Chemotherapy: Drugs E-O Policy* section of this manual for the use of mitoxantrone in malignant conditions.

Indication

For reducing neurologic disability and/or the frequency of clinical relapses in patients with secondary (chronic) progressive, progressive relapsing, or worsening relapsing-remitting multiple sclerosis (for example, patients whose neurologic status is significantly abnormal between relapses).

Mitoxantrone is not indicated in the treatment of patients with primary progressive multiple sclerosis.

Dose

The recommended dose is 12 mg/m² given as a short (approximately 5 to 15 minutes), intravenous infusion every three months.

The maximum dosage is 38 mg per day.

Billing

HCPCS code J9293 (injection, mitoxantrone HCl, per 5 mg)