

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

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

Abatacept

Abatacept (HCPCS code J0129) is used for the treatment of moderately to severely active rheumatoid arthritis for individuals 6 years of age or older.

TAR Required

Abatacept treatments require a *Treatment Authorization Request* (TAR) and the request may be for up to six months of treatment. There must be documentation that the patient has had an inadequate response after treatment with the following:

- One or more non-biologic Disease-Modifying Anti-Rheumatic Drugs (DMARDs) or
- At least one of the tumor necrosis factor (TNF) antagonists (infliximab, etanercept or adalimumab) or the interleukin-1 receptor antagonist anakinra.

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Dosage Abatacept is initially administered as a 30-minute intravenous infusion. Following the first infusion, abatacept should be given at two and four weeks, then every four weeks thereafter. Either of the following dosing schedules may be used:

- Abatacept, 10 mg/kg with a maximum dose of 1,000 mg, or
- According to body weight:

<u>Body Weight of Patient</u>	<u>Dose</u>
<60 kg	500 mg
60 to 100 kg	750 mg
>100 kg	1,000 mg

Dose = 750 mg per administration on days 0, 14, 28 and every 28 days thereafter for a total of six months. This is eight (8) doses for six months.

8 doses X 750 mg = 6,000 mg.

6,000 mg/10 mg/unit = 600 units requested on the TAR.

Diagnosis Restrictions Restricted to ICD-9-CM diagnosis codes 714.0, 714.1 and 714.2.

Medical Considerations Providers should consider the following when administering abatacept:

- It should not be used concurrently with TNF antagonists (infliximab, etanercept, adalimumab), the interleukin-1 receptor antagonist anakinra or rituximab.
- It may be given as a monotherapy or with a non-biologic DMARD.
- It is a pregnancy category C drug.
- A minimum of three months should occur between the administration of abatacept and the patient receiving a live virus vaccine.
- Patients with chronic obstructive pulmonary disease (COPD) may develop adverse reactions to abatacept, including COPD exacerbation.

Billing HCPCS code J0129 (injection, abatacept, 10 mg);
one (1) unit = 10 mg

AbobotulinumtoxinA For detailed clinical and billing policy information about abobotulinumtoxinA, refer to the “Botulinum Toxins A and B” topic in this manual section.

Acyclovir	Acyclovir 5 mg injection (HCPCS code J0133) is reimbursable up to a maximum of 300 units.
Aflibercept	Policy for intravitreal Aflibercept (HCPCS code J0178) is located in the <i>Ophthalmology</i> 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 <i>Injections: Drugs E-H Policy</i> section of this manual.
Alemtuzumab	Alemtuzumab is a recombinant humanized IgG1 kappa monoclonal antibody directed against the cell surface glycoprotein, CD52. The precise mechanism by which alemtuzumab exerts its therapeutic effects in multiple sclerosis is unknown but is presumed to involve binding to CD52, a cell surface antigen present on T and B lymphocytes, and on natural killer cells, monocytes and macrophages. Cell surface binding to T and B lymphocytes results in antibody-dependent cellular cytotoxicity and complement-mediated lysis.
Indications	Alemtuzumab is indicated for the treatment of relapsing forms of multiple sclerosis. Because of its safety profile, the use of alemtuzumab should be reserved for recipients 18 years of age and older who have had an inadequate response to two or more drugs such as, but not restricted to, interferons and glatiramer or other drugs.
Authorization	An approved <i>Treatment Authorization Request</i> (TAR) is required for reimbursement. Refer to the <i>Injections: An Overview</i> section in this manual to review specific TAR requirements for HCPCS code J3590 (unclassified biologics).
Dosage	The recommended dosing schedule is as follows: <ul style="list-style-type: none"> • First treatment course: 12 mg/day on five (5) consecutive days • Second treatment course: 12 mg/day on three (3) consecutive days administered 12 months after the first treatment course
Billing	HCPCS code J3590 (unclassified biologics) Refer to the <i>Injections: An Overview</i> section in this manual to review specific billing requirements for HCPCS code J3590.

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**Alglucosidase Alfa
(Lumizyme, Myozyme)**

For detailed billing policy information about alglucosidase alfa, refer to the “Enzyme Replacement Drugs” topic in the *Injections: Drugs E-H Policy* section of this manual.

Alteplase

Alteplase is a tissue plasminogen activator produced by recombinant DNA technology. It is synthesized using the complementary DNA for natural human tissue-type plasminogen activator obtained from an established human cell line. It is an enzyme (serine protease) that has the property of fibrin-enhanced conversion of plasminogen to plasmin and produces limited conversion of plasminogen in the absence of fibrin. Alteplase binds to fibrin in a thrombus and converts the entrapped plasminogen to plasmin, thereby initiating local fibrinolysis.

Refer to “Alteplase” in the *Dialysis: Chronic Dialysis Services* section of the appropriate Part 2 manual for the use of alteplase in chronic dialysis.

Indications

Alteplase is indicated for:

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

Dosage

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

Billing

HCPCS code J2997 (injection, alteplase recombinant, 1 mg)

Note: Treatment initiated in a hospital emergency room is not separately reimbursable as it is included in the hospital reimbursement.

Amifostine	Amifostine is a prodrug that is dephosphorylated by alkaline phosphatase in tissues to a pharmacologically active free thiol metabolite. This metabolite is believed to be responsible for the reduction of the cumulative renal toxicity of cisplatin and for the reduction of the toxic effects of radiation on normal oral tissues.
Indications	Amifostine is indicated for: <ul style="list-style-type: none"> • The reduction of cisplatin-induced renal toxicity • The reduction of xerostomia from head and neck cancer • The prevention of radiation proctitis in rectal cancer
Dosage	Variable depending upon the condition for which the drug is being used.
Required Codes	Amifostine is reimbursable when billed in conjunction with one of the following ICD-9-CM codes: 527.7 V58.0 V58.11
Billing	HCPCS code J0207, (injection, amifostine, 500 mg)
Anidulafungin	Anidulafungin, 1 mg injection (HCPCS code J0348) must be billed with ICD-9-CM codes 112 – 112.9. The daily maximum dosage is 200 mg.
Antigens for Allergy Desensitization	CPT-4 code 95115 or 95199 must be used for allergy desensitization. Antigens must be billed with HCPCS code X7708; antigens billed with CPT-4 code 99070 (unlisted medical supplies) will be denied. Claims for hymenoptera venom antigen must be billed with code X7710 and must be accompanied by a copy of the invoice.
Aripiprazole	HCPCS code J0400 (aripiprazole, intramuscular, 0.25 mg) is covered for the treatment of schizophrenia/episodic mood disorders. An ICD-9-CM diagnosis code within the range of 295.0 – 296.99 is required. The maximum daily dosage is 30 mg. Claims billed for quantities exceeding the above daily limitation require appropriate documentation for payment.

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Aripiprazole Extended Release Suspension

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

Dosage

The maximum dose is 400 mg every 26 days.

Required Codes

ICD-9-CM 295.0 – 295.95

Billing

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

Baclofen (Intrathecal)

Baclofen is a chemical analog of the inhibitory neurotransmitter gamma-aminobutyric acid and may exert its effects by stimulation of the GABA β receptor subtype. The precise mechanism of action of baclofen as a muscle relaxant and antispasticity agent is not fully understood. Baclofen inhibits both monosynaptic and polysynaptic reflexes at the spinal level, possibly by decreasing excitatory neurotransmitter release from primary afferent terminals, although actions at supraspinal sites may also occur and contribute to its clinical effect.

Indications

For the treatment of severe spasticity or dystonia of cerebral or spinal origin resulting from diseases or conditions such as but not limited to cerebral palsy, multiple sclerosis, hypoxic/anoxic brain injury, traumatic brain injury, or spinal cord injury.

When treating spasticity due to head injury, it is recommended that a waiting period of one year after injury should elapse before considering intrathecal baclofen therapy.

Not for use in patients younger than 4 years of age.

Authorization	<p>An approved <i>Treatment Authorization Request</i> (TAR) is required for reimbursement for HCPCS code J0475 (injection, baclofen, 10 mg).</p> <p>The TAR should document all of the following:</p> <ul style="list-style-type: none"> • The patient suffers from one of the indications listed previously • The rationale for using intrathecal baclofen over other medication or treatment modalities, including an inadequate response to oral baclofen • Failure of physical therapy to relieve spasticity symptoms • The patient demonstrates a positive clinical response to a baclofen bolus dose administered intrathecally in a screening trial <p>Patients with spasticity due to a cerebral origin need not receive an oral baclofen trial prior to receiving intrathecal baclofen.</p>						
Dosage	<p>Establishment of the optimum dose schedule requires that each patient undergoes an initial screening phase with test doses by intrathecal bolus, followed by a very careful individual dose titration prior to maintenance therapy. This is due to the great variability in the effective individual therapeutic dose.</p>						
Pump Implantation, Maintenance and Filling	<p>Authorization is not required for 1) implantation of the infusion pump and catheter, 2) outpatient refilling and maintenance of the pump or 3) analysis and reprogramming of the pump.</p>						
Billing Codes	<p>The following HCPCS codes are used to bill baclofen:</p> <table border="0" style="margin-left: 20px;"> <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>J0475</td> <td>injection, baclofen, 10 mg</td> </tr> <tr> <td>J0476</td> <td>injection, baclofen, 50 mcg for intrathecal trial</td> </tr> </tbody> </table>	<u>HCPCS Code</u>	<u>Description</u>	J0475	injection, baclofen, 10 mg	J0476	injection, baclofen, 50 mcg for intrathecal trial
<u>HCPCS Code</u>	<u>Description</u>						
J0475	injection, baclofen, 10 mg						
J0476	injection, baclofen, 50 mcg for intrathecal trial						

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Belatacept

Belatacept is a soluble fusion protein consisting of the modified extracellular domain of CTLA-4 fused to a portion (hinge-CH2-CH3 domains) of the Fc domain of a human immunoglobulin G1 antibody. Belatacept is produced by recombinant DNA technology in a mammalian cell expression system.

Belatacept, a selective T-cell (lymphocyte) costimulation blocker, binds to CD80 and CD86 on antigen-presenting cells thereby blocking CD28 mediated costimulation of T lymphocytes. *In vitro*, belatacept inhibits T lymphocyte proliferation and the production of the cytokines interleukin-2, interferon- γ , interleukin-4, and TNF- α . Activated T lymphocytes are the predominant mediators of immunologic rejection.

Indications

Belatacept is indicated for prophylaxis of organ rejection in adult recipients receiving a kidney transplant. It is to be used in combination with basiliximab induction, mycophenolate mofetil and corticosteroids.

Dosage

Belatacept is restricted to recipients 18 years of age and older. The maximum daily dosage is 1,300 mg. The recommended dosing schedule is as follows:

<u>Dosage for Initial Phase</u>	<u>Dose</u>
Day 1 (day of transplantation, prior to implantation) and Day 5 (approximately 96 hours after Day 1 dose)	10 mg per kg
End of Week 2 and Week 4 after transplantation	10 mg per kg
End of Week 8 and Week 12 after transplantation	10 mg per kg
<u>Dosage for Maintenance Phase</u>	<u>Dose</u>
End of Week 16 after transplantation and every 4 weeks (plus or minus 3 days) thereafter	5 mg per kg

Required Diagnosis Code

Restricted to ICD-9-CM diagnosis code V42.0.

Authorization

For doses greater than 1,300 mg per day, an approved *Treatment Authorization Request (TAR)* is required for reimbursement.

Billing

HCPCS code J0485 (injection, belatacept, 1 mg).

Belimumab	<p>Belimumab is a human IgG1λ monoclonal antibody specific for soluble human B lymphocyte stimulator protein (BLyS) and is produced by recombinant DNA technology in a mammalian cell expression system. Belimumab is a BLyS-specific inhibitor that blocks the binding of soluble BLyS, a B-cell survival factor, to its receptors on B cells. It does not bind B cells directly, but by binding BLyS, belimumab inhibits the survival of B cells, including autoreactive B cells, and reduces the differentiation of B cells into immunoglobulin-producing plasma cells.</p>
Indications	<p>Belimumab is indicated for the treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus (SLE) who are receiving standard therapy.</p> <p>The efficacy of belimumab has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus and has not been studied in combination with other biologics or intravenous cyclophosphamide. The use of belimumab is not recommended in these situations.</p>
Dosage	<p>The recommended dosage regimen is 10 mg/kg at two-week intervals for the first 3 doses and at four-week intervals thereafter.</p>
Required Codes	<p>ICD-9-CM code 710.0</p>
Billing	<p>HCPCS code J0490 (injection, belimumab, 10 mg).</p>
Betamethasone	<p>Betamethasone acetate and betamethasone sodium phosphate is reimbursable up to two units when billed by the same provider, for the same recipient and date of service.</p>
Billing	<p>HCPCS code J0702 (injection, betamethasone acetate 3 mg and betamethasone sodium phosphate 3 mg).</p> <p>One (1) unit = 6 mg of betamethasone (3 mg each of the acetate and sodium phosphate salts)</p>

Bevacizumab

Policy for intravitreal bevacizumab (HCPCS code J9035) is located in the *Ophthalmology* section of the appropriate Part 2 manual.

Botulinum Toxins A and B

The botulinum toxins are a family of neurotoxins produced by various toxigenic strains of the gram-positive anaerobic bacterium *Clostridium botulinum* and are comprised of seven antigenically distinct serotypes (A to G). All botulinum neurotoxin serotypes produce their clinical effect of flaccid paralysis by blocking the release of acetylcholine from nerve endings.

Four botulinum toxin products have been approved by the U.S. Food and Drug Administration (FDA).

Three botulinum toxin serotype A products:

- AbobotulinumtoxinA
- IncobotulinumtoxinA
- OnabotulinumtoxinA

One botulinum toxin serotype B product:

- RimabotulinumtoxinB

A significant difference within botulinum toxin type A serotypes is that the units are not interchangeable between the two FDA-approved products as there is no common international standard methodology for assaying units within the botulinum toxin serotypes. Therefore one unit of abobotulinumtoxinA is not equivalent to one unit of onabotulinumtoxinA or incobotulinumtoxinA. Similarly the units of one botulinum toxin serotype cannot be converted into units of any other botulinum toxin serotype as there is no common international standard methodology for assaying units among the different botulinum toxin serotypes. Consequently neither the units of abobotulinumtoxinA, onabotulinumtoxinA are interchangeable with rimabotulinumtoxinB. The dosage of any botulinum toxin product must be individualized to each specific patient based upon many factors including, but not limited to, size of the muscles to be injected, the number of muscles to be injected, body weight, the condition being treated, expected patient response, and general health of the patient. Standard doses do not exist.

Authorization	Medical necessity must be established and an approved <i>Treatment Authorization Request</i> (TAR) is required for the reimbursement of any of the four botulinum toxins.
Billing	Due to the short half life of the botulinum toxins, Medi-Cal will reimburse the unused portion of the drug only when vials are not split between patients. Scheduling of more than one patient is encouraged to prevent wastage of drug. If a vial is split between two or more patients, the billing must be for the exact amount of drug administered to each individual patient.
AbobotulinumtoxinA	<p>AbobotulinumtoxinA is reimbursable for the treatment of any of the following:</p> <ul style="list-style-type: none">• Adults with cervical dystonia• Achalasia (see following “Authorization” information) <p><u>Authorization</u> If the request is for the treatment of achalasia, the TAR must document any of the following:</p> <ul style="list-style-type: none">• Failed pneumatic dilation or myotomy• Poor surgical candidate• High risk for complications such as perforation• History of hiatal hernia or epiphrenic diverticulum• History of perforation <p><u>Dosage</u> The initial dose of abobotulinumtoxinA is 500 units given intramuscularly as a divided dose among the affected muscles. Re-treatment is based on return of clinical symptoms with doses administered between 250 and 1,000 units to optimize clinical benefit. Re-treatment should not occur in intervals of less than 12 weeks.</p> <p><u>Billing</u> HCPCS code J0586 (injection, abobotulinumtoxinA, 5 units) One (1) unit = 5 units of abobotulinumtoxinA</p>

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IncobotulinumtoxinA

IncobotulinumtoxinA is reimbursable for the treatment of either of the following:

- Adults with cervical dystonia
- Blepharospasm in adults previously treated with onabotulinumtoxinA

Dosage

Cervical dystonia:

The recommended total dose is 120 units per treatment session.

Blepharospasm:

The dose, number and location of injections should be based on the previous dosage of onabotulinumtoxinA. If the previous dose of onabotulinumtoxinA is unknown, the recommended starting dose is 1.25 – 2.5 units per injection site.

Billing

HCPCS code J0588 (injection, incobotulinumtoxinA, 1 unit)

One (1) unit = 1 unit of incobotulinumtoxinA

OnabotulinumtoxinA

OnabotulinumtoxinA is reimbursable for the treatment of any of the following:

- Adults with cervical dystonia
- Achalasia
- Anal fissure *
- Detrusor sphincter dyssynergia *
- Frey's Syndrome *
- Hemifacial spasm
- Neurogenic overactive bladder muscle dysfunction *
- Overactive bladder with symptoms of urge urinary incontinence, urgency and frequency in adults who have an inadequate response to, or are intolerant of, an anticholinergic medication
- Prophylaxis of headaches in adult patients with chronic migraine (15 or more days per month with headache lasting four hours a day or longer)
- Severe primary axillary hyperhidrosis that is inadequately managed with topical agents *
- Spasticity
- Spasmodic dysphonia
- Sialorrhea *
- Strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and older

Note: The efficacy of onabotulinumtoxinA treatment in deviations over 50 prism diopters, in restrictive strabismus, in Duane's syndrome with lateral rectus weakness, and in secondary strabismus caused by prior surgical over-recession of the antagonist has not been established. OnabotulinumtoxinA is ineffective in chronic paralytic strabismus except when used in conjunction with surgical repair to reduce antagonist contracture.

* Establishing medical necessity is critical and the TAR should clearly state that the patient has been unresponsive to conventional methods of treatments such as medication, physical therapy and other appropriate methods used to control or treat this condition.

Dosage

The dose of onabotulinumtoxinA is highly variable dependent upon which condition is being treated and individual patient response.

Billing

HCPCS code J0585 (injection, onabotulinumtoxinA, 1 unit)
One (1) unit = 1 unit of onabotulinumtoxinA.

RimabotulinumtoxinB

RimabotulinumtoxinB is reimbursable for the treatment of any of the following:

- Adults with cervical dystonia
- Overactive bladder muscle dysfunction *
- Sialorrhea *
- Spasticity

* Establishing medical necessity is critical and it should be made clear that the patient has been unresponsive to conventional methods of treatments such as medication, physical therapy and other appropriate methods used to control or treat this condition.

Dosage

The recommended initial dose of rimabotulinumtoxinB is 2,500 to 5,000 units divided among affected muscles. Subsequent dosage should be optimized according to the patient's individual response.

Billing

HCPCS Code J0587 (injection, rimabotulinumtoxinB, 100 units)
One (1) unit = 100 units of rimabotulinumtoxinB

C1 Esterase Inhibitor (Treatment)	C1 esterase inhibitor is indicated for the treatment of acute abdominal or facial attacks of hereditary angioedema (HAE) in adults.
Dosage	The usual dose is 20 units per kg body weight by intravenous injection. Maximum dosage is 2000 units (quantity of 200). Claims billed for greater quantities require documentation that patient's weight exceeds 100 kg.
Diagnosis Restrictions	Restricted to ICD-9-CM diagnosis code 277.6.
Billing	HCPCS code J0597 (injection, C1 esterase inhibitor [human], Berinert, 10 units) One billing unit = 10 units of drug
C1 Esterase Inhibitor (Prophylaxis)	C1 esterase inhibitor is indicated for the routine prophylaxis against angioedema attacks in patients with hereditary angioedema.
Dosage	Maximum dosage is 3000 units (quantity of 300). Claims billed for greater quantities require documentation that patient's weight exceeds 150 kg. Limited to patients 12 years of age and older.
Diagnosis Restrictions	Restricted to ICD-9-CM diagnosis code 277.6.
Billing	HCPCS code J0598 (injection, C1 esterase inhibitor [human], 10 units). One unit billed = 10 units of drug
Calcitriol	Calcitriol is indicated in the management of hypocalcemia in patients undergoing chronic renal dialysis. It has been shown to significantly reduce elevated parathyroid hormone levels. The reduction of parathyroid hormone has been shown to result in an improvement in renal osteodystrophy.
Billing	HCPCS code J0636 (injection, calcitriol, 0.1 mcg).

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Canakinumab	Canakinumab is a recombinant, human anti-human-interleukin 1 beta (IL-1B) monoclonal antibody. Cryopyrin-Associated Periodic Syndromes (CAPS) refer to rare genetic syndromes generally caused by mutations in the NLRP-3 gene. The NLRP-3 gene encodes the protein cryopyrin which controls the activation of IL-1B. Mutations in NLRP-3 result in excessive release of activated IL-1B that drives inflammation. Canakinumab binds to human IL-1B and neutralizes its activity by blocking its interaction with IL-1 receptors.
Indications	For the treatment of CAPS in adults and children 4 years of age and older including: <ul style="list-style-type: none">• Familial Cold Autoinflammatory Syndrome• Muckle-Wells Syndrome
Authorization	An approved TAR is required for reimbursement.
Dosage	The recommended dose is 150 mg for patients with a body weight greater than 40 kg. For patients between 15 and 40 kg, the recommended dose is 2 mg/kg. For children 15 to 40 kg with an inadequate response, the dose can be increased to 3 mg/kg.
Billing	HCPCS code J0638 (injection, canakinumab, 1 mg) One billing unit = 1 mg
Cefotaxime	Cefotaxime sodium, injection, per gram (HCPCS code J0698) is a broad spectrum cephalosporin antibiotic for treating serious infections caused by susceptible organisms.
Drug Limitations	Claims for cefotaxime sodium are reimbursable up to a maximum dosage of 12 grams daily. Claims in excess of 12 grams will be reimbursed at this limit. To receive additional reimbursement when billing for a quantity in excess of 12 grams, resubmit the claim with a <i>Claims Inquiry Form (CIF)</i> and justification for the additional dosage.

Ceftriaxone Sodium	Ceftriaxone sodium, injection, per 250 mg (HCPCS code J0696), is a parenteral cephalosporin antibiotic and is particularly effective in the treatment of penicillin-resistant gonorrhea and severe multiple-resistant gram-negative rod infections. Its long half-life (six to nine hours) permits non-institutional treatment of severe infections that would otherwise require prolonged inpatient care.
Certolizumab Pegol	Certolizumab pegol is a tumor necrosis factor blocker. It is a recombinant humanized antibody Fab fragment, with specificity for human tumor necrosis factor alfa conjugated to an approximately 40 kDa polyethylene glycol. It specifically neutralizes tumor necrosis factor alfa.
Indications	<p>Certolizumab pegol is indicated for:</p> <ul style="list-style-type: none">• Reducing the signs and symptoms of Crohn's Disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy• The treatment of adults with moderately to severely active rheumatoid arthritis• The treatment of adults with psoriatic arthritis <p>Certolizumab pegol is not indicated for:</p> <ul style="list-style-type: none">• The treatment of enterocutaneous or rectovaginal fistulas• Maintaining fistula closure
Authorization	An approved <i>Treatment Authorization Request (TAR)</i> is required for reimbursement.

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Dosage	<p>Crohn's Disease:</p> <ul style="list-style-type: none">• The recommended initial dose is 400 mg subcutaneously and at weeks two and four, and in patients who achieve a clinical response, the recommended maintenance regimen is 400 mg subcutaneously every four weeks. <p>Rheumatoid Arthritis and Psoriatic Arthritis:</p> <ul style="list-style-type: none">• The recommended dose is 400 mg subcutaneously and at weeks two and four, followed by 200 mg every other week. For maintenance, a dosage of 400 mg every four weeks may be considered.
Billing	<p>HCPCS code J0717 (injection, certolizumab pegol, 1 mg).</p>
Cidofovir	<p>Cidofovir is an anti-viral agent that suppresses cytomegalovirus (CMV) replication by selective inhibition of CMV DNA polymerase. Cidofovir is reimbursable for the treatment of CMV retinitis in patients with AIDS and when billed with HCPCS code J0740 (injection, cidofovir, 375 mg).</p>
Dosage	<p>Cidofovir must be diluted in 100 ml of 0.9 percent (normal) saline prior to administration. The drug is administered at an induction dose of 5 mg/kg body weight as an intravenous infusion at a constant rate over one hour, given once weekly for two consecutive weeks. The recommended maintenance dose is 5 mg/kg body weight administered once every two weeks.</p> <p>The maximum dosage is 680 mg every two weeks.</p>
Required Codes	<p>HCPCS code J0740 must be billed with chorioretinitis (ICD-9-CM codes 363.00 – 363.35) as the primary or secondary diagnosis.</p>
Infusion Administration	<p>CPT-4 codes 96365 and 96366 (intravenous infusion, for therapy, prophylaxis, or diagnosis) are reimbursable in conjunction with cidofovir, as well as up to two liters of 0.9 percent (normal) saline, for the pre- and post-hydration needed with this drug.</p>

Collagenase Clostridium Histolyticum	Collagenases are proteinases that hydrolyze collagen in its native helical conformation under physiological conditions, resulting in lysis of collagen deposits. Injection of collagenase clostridium histolyticum into a Dupuytren’s cord, which is comprised mostly of collagen, may result in enzymatic disruption of the cord. Purified collagenase clostridium histolyticum consists of collagenase AUX-I and collagenase AUX-II both of which are isolated and purified from the fermentation of <i>Clostridium histolyticum</i> bacteria.
Indications	<p>Collagenase clostridium histolyticum is indicated for the treatment of adult patients aged 18 years and older with Dupuytren’s contracture with a palpable cord.</p> <p>Collagenase clostridium histolyticum should be administered by a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytren’s contracture.</p>
Required Codes	ICD-9-CM code 728.6
Dosage	<p>The usual dose is 0.58 mg, injected into a palpable Dupuytren’s cord with a contracture followed 24 hours later by a finger extension procedure if a contracture persists.</p> <p>Injections and finger extension procedures may be administered up to three times per cord at approximately four-week intervals.</p>
Billing	HCPCS code J0775 (injection, collagenase, clostridium histolyticum, 0.01 mg).
Corticoreslin Ovine Triflutate	Corticoreslin Ovine Triflutate, 1 mg injection, (HCPCS code J0795) is reimbursable, with authorization, for patients with ACTH dependent Cushing’s Syndrome. ICD-9-CM diagnosis code 255.0 must be included on the <i>Treatment Authorization Request</i> (TAR).

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Cosyntropin

Cosyntropin is intended for use as a diagnostic agent in the screening of patients presumed to have adrenocortical insufficiency.

Billing Codes

The following HCPCS codes are used to bill cosyntropin:

<u>HCPCS Code</u>	<u>Description</u>
J0833	Injection, cosyntropin, not otherwise specified, 0.25 mg One unit = 0.25 mg
J0834	Injection, cosyntropin (Cortrosyn), 0.25 mg One unit = 0.25 mg

Codes J0833 and J0834 cannot be reported on the same claim.

Darbepoetin Alfa	<p>Darbepoetin alfa (DA) is an erythropoiesis-stimulating protein that is produced in Chinese hamster ovary (CHO) cells by recombinant DNA technology. It is a 165-amino-acid protein that differs from recombinant human erythropoietin in containing five N-linked oligosaccharide chains, whereas recombinant human erythropoietin contains three chains. The two additional N-glycosylation sites result from amino acid substitutions in the erythropoietin peptide backbone. DA stimulates erythropoiesis by the same mechanism as endogenous erythropoietin. Increased hemoglobin levels are not generally observed until two to six weeks after initiating treatment with DA.</p>
Indications	<p>For the treatment of anemia due to:</p> <ul style="list-style-type: none">• Chronic kidney disease (CKD) in patients on dialysis and not on dialysis• The effects of myelosuppressive chemotherapy in patients with non-myeloid malignancies and upon initiation, there is a minimum of two additional months of planned chemotherapy
Limitations of Use	<p>DA has not been shown to improve quality of life, fatigue or patient well-being.</p> <p>DA is not indicated for use:</p> <ul style="list-style-type: none">• In patients with cancer receiving hormonal agents, biologic products or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy• In patients with cancer receiving myelosuppressive chemotherapy, when the anticipated outcome is cure• As a substitute for red blood cell (RBC) transfusions in patients who require immediate correction of anemia <p>In the appropriate circumstances, darbepoetin alfa may be self-administered.</p>
CKD Patients on Hemodialysis	<p>DA treatment may be initiated when the hemoglobin (Hgb) level is less than 10 g/dL, taking into consideration specific patient characteristics such as functional and cognitive status, life expectancy and other factors. If the Hgb level approaches or exceeds 11 g/dL, it is recommended that the dose of DA should be reduced or interrupted.</p>

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CKD Patients not on Hemodialysis

These patients may have DA initiated when the Hgb level is less than 10 g/dL and the following conditions apply:

- The rate of Hgb decline indicates the likelihood of requiring an RBC transfusion, and
- Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal.

If the Hgb level exceeds 10 g/dL, it is recommended that the dose of DA be reduced or interrupted.

Myelosuppressive Chemotherapy-Associated Anemia

DA is recommended as a treatment option when the Hgb level has decreased below 10 g/dL and there is a minimum of two additional months of planned chemotherapy.

Required Codes

ICD-9-CM diagnosis codes are required on the claim form in the *Diagnosis or Nature Illness or Injury* field (Box 21 or Box 67) of the CMS-1500 form or in the *Diagnosis Codes* field (Box 66-67) of the UB-04 form.

- CKD patients with anemia on dialysis require ICD-9-CM code 585.6 for HCPCS code J0882.
- CKD patients with anemia not on dialysis require ICD-9-CM codes 585.1-585.5 or 585.9 for HCPCS code J0881.
- Chemotherapy-associated anemia in non-myeloid malignancies requires ICD-9-CM code 285.3 for HCPCS code J0881.

Dosage

Evaluate the iron status in all patients before and during treatment and maintain iron repletion. Correct or exclude other causes of anemia (for example, vitamin deficiency, metabolic or chronic inflammatory conditions, bleeding, etc.) before initiating DA.

The dose of DA varies according to the condition being treated. Please refer to appropriate medical literature for specific dosage recommendations.

Billing

The following HCPCS codes are used to bill darbepoetin alfa:

<u>HCPCS Code</u>	<u>Description</u>
J0881	Injection, darbepoetin alfa, 1 microgram (non-ESRD use)
J0882	Injection, darbepoetin alfa, 1 microgram (for ESRD on dialysis)

If darbepoetin alfa is administered by the provider, the claim must include current and previous:

- DA dose
- Patient weight in kilograms
- Hemoglobin levels

If DA is self-administered, the provider must submit the following information:

- A statement that the drug was provided to the recipient for self-administration.
- The date and quantity of drug given to the recipient DA doses, patient weight in kilograms and Hbg levels for the previous three months.

Documentation may be included in the *Remarks* field (Box 80) on the *UB-04* or the *Additional Claim Information* field (Box 19) on the *CMS-1500*, or on an attachment to the claim.

If DA is administered outside of the general guidelines above or dosage is more than 800 mcg per month, documentation must be submitted in order to establish medical necessity.

Denosumab (Prolia, XGEVA)

Denosumab is a human IgG2 monoclonal antibody that binds to RANKL (receptor activator of nuclear factor kappa-B ligand), a transmembrane or soluble protein essential for the formation, function and survival of osteoclasts, the cells responsible for bone resorption. Denosumab prevents RANKL from activating its receptor, RANK, which is expressed on the surface of osteoclasts and their precursors. Prevention of the RANKL/RANK interaction inhibits osteoclast formation, function and survival, thereby decreasing bone resorption and increasing bone mass and strength in both cortical and trabecular bone. In addition, increased osteoclast activity, stimulated by RANKL, is a mediator of bone pathology in solid tumors with osseous metastases.

Indications

Denosumab (Prolia) is indicated:

- For the treatment of postmenopausal women with osteoporosis at high risk for fracture
- To increase bone mass in men with osteoporosis at high risk for fracture
- To increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
- To increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer

Denosumab (XGEVA) is indicated:

- For the prevention of skeletal related events in patients with bone metastases from solid tumors
- For the treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity
- For the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy

Dosage

The recommended dose of denosumab (Prolia) for the following four conditions is 60 mg subcutaneously every six months. Recipients should receive 1,000 mg of calcium daily and at least 400 IU of vitamin D daily.

- Postmenopausal women with osteoporosis at high risk of fracture
- To increase bone mass in men with osteoporosis at high risk for fracture
- To increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
- To increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer

The recommended dose of denosumab (XGEVA):

- For the prevention of skeletal related events in patients with bone metastases from solid tumors is 120 mg subcutaneously every four weeks in the upper arm, upper thigh or abdomen
- For giant cell tumor of bone that is 120 mg subcutaneously every four weeks with additional 120 mg doses on days eight and 15 of the first month of therapy administered in the upper arm, upper thigh, or abdomen
- For hypercalcemia of malignancy is 120 mg administered every four weeks with additional 120 mg doses on days eight and 15 of the first month of therapy

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Diagnosis Restrictions

When using denosumab (Prolia) for the treatment of postmenopausal women with osteoporosis at high risk for fracture or to increase bone mass in men with osteoporosis at high risk for fracture, providers must document one ICD-9- CM diagnosis code within the range of 733.0 – 733.09.

When using denosumab (Prolia) to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer, providers must document ICD-9-CM diagnosis code 185.

When using denosumab (Prolia) to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer, providers must document one ICD-9-CM diagnosis code within range of 174.0 – 174.9

When using denosumab (XGEVA) for the treatment of bone metastases from solid tumors, providers must document ICD-9-CM diagnosis code 198.5.

When using Denosumab (XGEVA) for the treatment of giant cell tumor of bone, providers must document one ICD-9-CM diagnosis code within the range of 213.0 – 213.99 or 238.0.

When using denosumab (XGEVA) for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy, providers must document one ICD-9-CM diagnosis code within the range of 140 – 209.79 and ICD-9-CM diagnosis code 275.42 for reimbursement.

Billing

HCPCS code J0897 (injection, denosumab, 1 mg).

The correct National Drug Code (NDC) must be included on the claim(s) in order to correctly price the drug.

Dexamethasone Intravitreal Implant	Policy for intravitreal dexamethasone (HCPCS code J7312) is located in the <i>Ophthalmology</i> section of the appropriate Part 2 manual.
Dolasetron	Providers may be reimbursed for dolasetron mesylate when used for the prevention or treatment of postoperative nausea and/or vomiting.
Dosage	<p>Adults: The recommended intravenous dose is 12.5 mg given as a single dose approximately 15 minutes before the cessation of anesthesia (prevention) or as soon as nausea and vomiting presents (treatment).</p> <p>Pediatric Patients: The recommended intravenous dose in pediatric patients 2 years of age and older is 0.35 mg/kg, with a maximum dose of 12.5 mg, given as a single dose approximately 15 minutes before the cessation of anesthesia or as soon as nausea and vomiting presents.</p>
Billing	HCPCS code J1260 (injection, dolasetron mesylate, 10 mg) 1 unit = 10 mg
Doripenem	Doripenem, 10 mg (HCPCS code J1267) has a usual dosage of 500 mg every eight hours with a maximum daily dosage of 1,500 mg. For quantities exceeding the daily limitation, appropriate documentation is required.

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Doxercalciferol

Doxercalciferol is reimbursable for the treatment of secondary hyperparathyroidism in patients with chronic kidney disease on dialysis.

Dosage

The recommended initial dose of doxercalciferol is 4 mcg administered intravenously as a bolus dose three times weekly at the end of dialysis. The maximum dosage should not exceed 18 mcg weekly.

Billing

HCPCS code J1270 (injection, doxercalciferol, 1 mcg)
1 unit = 1 mcg

Note: Code J1270 cannot be block billed.