Injectable Drugs Requiring Pre-Service Approval

(Effective May 1, 2013)

POSITIVE HEALTHCARE™
An affiliate of AIDS Healthcare Foundation

Generic Name	Brand Name	J Codes	Max J code unit per year	Clinical Criteria required for Coverage
Abatacept	Orencia	J0129, 10 mg	1500	**Non-Formulary** Medical necessity review required. FL LCD- L29051
Adalimumab	Humira	J0135, 20 mg	62	1) For patients with rheumatoid arthritis with failure, intolerance or contraindications to methotrexate. Limit dosing to 40 mg Q 2 weeks. 2) For patients with psoriatic arthritis who failed methotrexate. Limit dosing to 40 mg Q 2 weeks. 3) For patients with psoriasis who have failed phototherapy, at least one topical treatment, and at least one systemic agent. Limit dosing to 80 mg at week 1, then 40 mg Q 2 weeks. 4) For patients with active ankylosing spondylitis. Not covered for complete ankylosis. Limit dosing to 40 mg Q 2 weeks. 5) For patients with moderate to severe refractory Crohn's disease who have failed steroids and one of the following: azathioprine, mercaptopurine or methotrexate. It is recommended that only responders to induction therapy continue with longer term maintenance therapy. Limit dosing to induction dosing of 160 mg week 0, 80 mg week 2, then 40 mg Q 2 weeks.
Antihemophilic Factor	Factor VIII, IX	J7180 J7183-87 J7189-95		Confirmation of diagnosis one time only per member FL LCD - L29187
bevacizumab	Avastin	J9035		FDA indication only FL LCD Intravitreal Bevacizumab - L29959

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Generic Name	Brand Name	J Codes	Max J code unit per year	Clinical Criteria required for Coverage
Cabazitaxel	Jevtana	J9043, 1 mg		1) For use in combination with prednisone for treatment of patients with hormone-refractory metastatic prostate (HRMP) cancer previously treated with a docetaxel-containing treatment regimen; AND 2) Patient has ECOG performance status of 0-2.
Collagenase clostridium histolyticum	Xiaflex	J0775, 0.01 mg		**Non-Formulary** Medical necessity review required. FL LCD - L31243
Darbepoetin	Aranesp	J0881, 1 mcg J0882, 1 mcg		**Non-Formulary** Medical necessity review required. Procrit is the preferred agent. Darbepoetin will be covered when a clinical rationale is provided describing why epoetin alfa cannot be used. FL LCD - L29168 CA LCD - L29888
Denosumab	Prolia	J0897, 1 mg	120	**Non-Formulary** Medical Necessity Review required

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Epoetin alfa	Epogen, Procrit	J0885, 1000 Units J0886, 1000 Units		1) To treat HIV anemia, which is defined as anemia, or associated with treatment of HIV and comorbidities, or due to chronic debilitating illness: i) Hematocrit < 30, hemoglobin < 10, if patient is symptomatic or has significant cardiopulmonary compromise and < 8 no matter patient history. 2) For chemotherapy-induced anemia: Note: Only prescribers enrolled in the ESA APPRISE Oncology Program may prescribe and/or dispense ESA. a) ESA treatment is approved for the anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia if: i) ESA treatment duration for each course of chemotherapy includes the 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regimen ii) The hemoglobin level immediately prior to initiation or maintenance of ESA treatment is <10 g/dL (or the hematocrit is <30%). 3) Treatment of anemia associated with chronic renal failure Note: i) Using ESAs to target a hemoglobin level of greater than 11 g/dL increases the risk of serious adverse cardiovascular reactions and has not been shown to provide additional benefit. a) For patients with CKD on dialysis: i) Initiate Erythropoetin treatment when the hemoglobin level is less than 10 g/dL. b) For patients with CKD not on dialysis: i) Consider initiating ESA treatment only when the hemoglobin level is less than 10 g/dL and the following co (1) The rate of hemoglobin decline indicates the likelihood of requiring a RBC transfusion and, (2) Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal 4) Surgery a) 300 Units/kg per day subcutaneously for 15 days total: administered daily for 10 days before surgery, on th b) 600 Units/kg subcutaneously in 4 doses administered 21, 14, and 7 days before surgery and on the day of FL - LCD L29168 CA - LCD - L29888

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Generic Name	Brand Name	J Codes	Max J code unit per year	Clinical Criteria required for Coverage
Etanercept	Enbrel	J1438, 25 mg	128	1) For use as a second-line therapy in: a) Adult patients with rheumatoid arthritis who have failed methotrexate. b) Pediatric patients with juvenile rheumatoid arthritis who have failed methotrexate. 2) For use in treatment of psoriatic arthritis in patients failing methotrexate. 3) For treatment of active ankylosing spondylitis. Not covered for complete ankylosis. 4) For treatment of psoriasis in patients with extensive, severe disease and who meet all of the following criteria: a) Failed topical psoriasis treatments. b) Failed a 12-week trial of phototherapy. c) Failed at least one systemic agent (e.g., cyclosporine, methotrexate). Limit dosing as follows: RA/AS/PsA—50 mg every week OR 2 x 25 mg given the same day or 3-4 days apart every week. Plaque Psoriasis—50 mg twice weekly x 3 months, then 50 mg per week. JRA—0.8 mg/kg per week (max 50 mg/week).
Filgrastim and pegfilgrastim	Neupogen Neulasta	J1440 J1441 J2505		Neupogen: 1. Immunocompromised patient and/or patient on ganciclovir or valganciclovir, interferon, or RBV therapy with ANC < 500. 2. With ANC < 1,000 for patients on cancer chemotherapy. Neulasta- please request substitution with Neupogen FL LCD - L29254
Growth hormone Somatropin	Genotropin; Humatrope; Norditropin NordiFlex; Nutropin; Omnitrope; Saizen; Serostim; Tev-Tropin; Zorbtive	J2941		Self injectable and not eligible for office administration Medical necessity review required.
Hyaluronic acid, intra-articular	Supartz/Hyalgan Euflexxa Orthovisc Synvisc/Synvisc One	J7321 J7323 J7324 J7325 J7326		Medical necessity review required. 1) Physician certified that there is radiological evidence of significant OA of the knee, AND 2) Patient has failed or is intolerant to all conservative treatments (acetaminophen, any NSAID, and corticosteroid injection)

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Generic Name	Brand Name	J Codes	Max J code unit per year	Clinical Criteria required for Coverage
Ibandronate	Boniva	J1740, 1 mg	12	**Non-formulary** Medical necessity review required. FL LCD - L32100
Immunoglobulin subcutaneous	Hizentra	J1559, 100mg		**Non-Formulary** Medical necessity review required. For patients with primary immunodeficiency
Immunoglobulin subcutaneous	Vivaglobin	J1562, 100 mg		**Non-formulary** Medical necessity review required. .
Infliximab	Remicade	J1745, 10 mg		1) For patients with rheumatoid arthritis with failure, intolerance or contraindications to methotrexate. 2) For patient with Crohn's disease who have failed, been intolerant to, or have contraindications to steroids, AND salicylates, AND azathioprine (or mercaptopurine). 3) For use in patients with active ankylosing spondylitis. Not covered for complete ankylosis. 4) For use in severe, refractory sarcoidosis with failure/intolerance to high dose corticosteroids and at least one steroid-sparing agent, such as methotrexate or azathioprine. 5) For patient with ulcerative colitis who have failed, been intolerant to, or have contraindications to steroids, AND salicylates, AND azathioprine (or mercaptopurine). 6) For treatment of psoriatic arthritis in patients who failed methotrexate. 7) For patients with psoriasis who have failed phototherapy, at least one topical treatment, and at least one systemic agent. Prior to initiation of infliximab therapy, providers need to perform a pre-treatment assessment for latent Tuberculous infection with the Tuberculin skin test. FL LCD - L29198

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Generic Name	Brand Name	J Codes	Max J code unit per year	Clinical Criteria required for Coverage
IVIG	Gamunex Octagam Gammagard liquid Flebogamma Privigen Other immune globulins	J1561 J1568 J1569 J1572 J1459 J1566 J1557 J1599		Privigen, Flebogamma, Carimune (others Non-formulary) Medical Necessity Review Required 1) Immune thrombocytopenic purpura. 2) Primary humoral immunodeficiency. 3) Kawasaki Syndrome. 4) Guillian-Barre Syndrome (polyradiculoneuropathy). 5) Myasthenia gravis unresponsive to plasmapheresis or have contraindications to plasmapheresis (e.g., lack a venous access, pre-existing clotting problems) and high dose steroids. 6) Chronic inflammatory demyelinating polyneuropathy (CIDP). 7) Mulitfocal motor neuropathy (MMN). 8) B-cell chronic lymphocytic leukemia or multiple myeloma who have had 3 life-threatening infections within 1 year. Not covered for diagnosis of only AIDS. FL LCD - L29205
Naltrexone IM	Vivitrol	J2315, 1mg		**Non-Formulary** Medical necessity review required.
Natalizumab	Tysabri	J2323, 1 mg	3900	**Non-formulary** Not covered for HIV/AIDS patients. PML side effect.
Octreotide	Sandostatin	J2353 - depot J2354		**Non-Formulary** Medical necessity review required.
Omalizumab	Xolair	J2357		Call for criteria. FL LCD - L29240

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Generic Name	Brand Name	J Codes	Max J code unit per year	Clinical Criteria required for Coverage
Onabotulinumtoxin A RimabotulinumtoxinB AbobotulinumtoxinA IncobotulinumtoxinA	Botox Myobloc Dysport Xeomin	J0585: Type A per unit J0587: Type B per 100 units J0586 per 5 units J0588, Per 1 unit		**Non Formulary:** Not approved for cosmetic purposes. Prevention of migraine, not covered. For coverage, Patient has been seen by a Neurologist who recommends the trial of Botox. 1) Torticollis (cervical dystonia), other focal dystonia, hemifacial spasms, dysphonia, strabismus, or blepharospasm. 2) Hyperhidrosis. 3) Anal fissures not responding to treatment with topical nitroglycerin ointment. 4) Achalasia in patients who are not candidates for pneumatic dilation. 5) Vocal cord granuloma. 6) Cerebral palsy. 7) Limb spasticity after stroke with documented functional impairment, hygiene complications or infection due to spasticity. Myobloc, Dysport, and Xeomin will be considered only if clinical failure of Botox in above circumstances. FL LCD - L29088 CA LCD - L28242 (Palmetto)
Rituximab (needs pre-approval for non-oncology diagnoses only)	Rituxan	J9310, 100 mg		Rheumatoid arthritis patients who have clinically failed, been intolerant to, or have contraindications to methotrexate and one formulary TNF antagonist. FL LCD - L29271

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Generic Name	Brand Name	J Codes	Max J code unit per year	Clinical Criteria required for Coverage
Sipuleucel-T	Provenge	Q2043 J3490 C9273		Medical Necessity Review Required. (same criteria as Noridian criteria for Medicare patients) 1) A diagnosis of prostate cancer (ICD-9-CM) 185—Malignant neoplasm, prostate. Documentation must demonstrate the patient was asymptomatic or very minimally symptomatic and had metastatic castrate resistant (hormone refractory) disease. 2) Evidence of metastases to soft tissue or bone. 3) Testosterone levels < 50 ng/dL or below lowest level of normal. 4) Two sequential rising PSA levels obtained 2-3 weeks apart or other evidence of disease progression. 5) Restriction of cancer therapy to Provenge alone. Patient may not be receiving simultaneous chemotherapy or other immunosuppressive therapy. Allow a maximum of three infusions per lifetime. Note: This is a drug with extremely limited availability.
Tocilizumab	Actemra	J3262, 1 mg	9600	**Non-Formulary** Medical necessity review required.
(ado)-Trastuzumab emtansine	Kadcyla	J9999		**NF Criteria:** For the treatment of patients with HER2-positive, metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either: • Received prior therapy for metastatic disease, or • Developed disease recurrence during or within six months of completing adjuvant therapy. The recommended dose of KADCYLA is 3.6 mg/kg given as an intravenous infusion every 3 weeks (21-day cycle). KADCYLA is supplied as a lyophilized powder in single-use vials: 100 mg per vial and 160 mg per vial. The appropriate vial size should be used in order to minimize wastage. The dosage will be based on 10 mg for reimbursement purposes, so please be sure to submit the units or number of services accordingly. For example: Patient received 90 mg and 10 mg was wastage, document waste on the claim.

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Generic Name	Brand Name	J Codes	Max J code unit per year	Clinical Criteria required for Coverage
Ustekinumab	Stelara	J3357, 1 mg		**Non-Formulary** Medical necessity review required.
Zoledronic acid 5mg IV	Reclast	J3488, 1 mg		1) Treatment of Paget's disease. 2) Treatment in the following patients with GI intolerance to at least one oral bisphosphonate. □ Patients with postmenopausal osteoporosis as defined by: a) History of fracture from low impact injury OR bone mineral density (BMD) T-score less than or equal to -2.5 at the total hip, femoral neck, or lumbar spine (at least two vertebral levels measured in the posterior-anterior projection) □ Treatment and prevention of glucocorticoid-induced osteoporosis in men and women who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and who are expected to remain on glucocorticoids for at least 12 months PLUS one or more additional risk factors: a) Femoral neck or lumbar spine BMD T score of -1 or lower. b) Osteopenia on plain film. c) Frail (for example, weight < 60 kg) FL LCD - L32100

Medicare doesn't develop criteria for all injectable drugs. If no criteria are listed, the medication must be considered medically necessary (i.e. considered to be a standard medical treatment) for it to be covered by Medicare.