

FIDELIS CARE NEW YORK – DEPARTMENT OF PHARMACY SERVICES
J-Code Prior Authorizations & Required Clinical Information
 Medicare Advantage and Dual Advantage

| Brand | Generic | J-Code | Covered Uses | Required Medical Information and Criteria |
|---------------------|----------------------|--------|--|--|
| Depo-Provera | Medroxyprogesterone | J0150 | Endometrial cancer Renal cancer | <ul style="list-style-type: none"> • Medical records supporting patient's dx of corresponding cancer and medication history |
| Lioresal | Baclofen intrathecal | J0476 | Intractable spasticity Diagnostic purposes | <ul style="list-style-type: none"> • Spinal cord injury, multiple sclerosis, or other spinal disease • Previous trial of baclofen oral therapy • For additional information, please refer to local coverage determination article, L28529, on the CMS coverage database website |
| Botox | Onabotulinum toxinA | J0585 | Spasticity/dystonia Blepharospasm Achalasia Anal fissure Primary axillary hyperhidrosis Sialorrhea Urinary incontinence Headache/migraine | <ul style="list-style-type: none"> • Medical history for dx of spasticity detailing primary cause if applicable • Previous trial of conventional therapy for dx of achalasia and anal fissure • Medical records detailing severity of hyperhidrosis • Medical history for dx of sialorrhea and previous trial of conventional therapy (anticholinergics and speech therapy) • Previous trial with an anticholinergic medication for overactive bladder dx, detrusor overactivity related to a neurologic condition • Previous trial of conventional agents , ≥15 headaches per month with ≥4 hours/day duration for ≥3 months for dx of headache/migraine • For additional information, please refer to local coverage determination article,L26841, on the CMS coverage database website |

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| Dysport | Abobotulinum toxinA | J0586 | Spasticity Blepharospasm Achalasia Anal fissure Sialorrhea Urinary incontinence Headache/migraine | <ul style="list-style-type: none"> • Medical history for dx of spasticity detailing primary cause if applicable • Previous trial of conventional therapy for dx of achalasia and anal fissure • Medical history for dx of sialorrhea and previous trial of conventional therapy (anticholinergics and speech therapy) • Previous trial with an anticholinergic medication for overactive bladder dx, detrusor overactivity related to a neurologic condition • Previous trial of conventional agents , ≥15 headaches per month with ≥4 hours/day duration for ≥3 months for dx of headache/migraine • For additional information, please refer to local coverage determination article,L26841, on the CMS coverage database website |
| Myobloc | Rimabotulinum toxinB | J0587 | Spasticity Blepharospasm Achalasia Anal fissure Primary axillary hyperhidrosis Sialorrhea Urinary incontinence Headache/migraine | <ul style="list-style-type: none"> • Medical history for dx of spasticity detailing primary cause if applicable • Previous trial of conventional therapy for dx of achalasia and anal fissure • Medical records detailing severity of hyperhidrosis • Medical history for dx of sialorrhea and previous trial of conventional therapy (anticholinergics and speech therapy) • Previous trial with an anticholinergic medication for overactive bladder dx, detrusor overactivity related to a neurologic condition • Previous trial of conventional agents , ≥15 headaches per month with ≥4 hours/day duration for ≥3 months for dx of headache/migraine • For additional information, please refer to local coverage determination article,L26841, on the CMS coverage database website |

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| Xeomin | Incobotulinum toxin A | J0588 | Spasticity Blepharospasm Achalasia Anal fissure Sialorrhea Urinary incontinence Headache/migraine | <ul style="list-style-type: none"> • Medical history for dx of spasticity detailing primary cause if applicable • Previous trial of conventional therapy for dx of achalasia and anal fissure • Medical history for dx of sialorrhea and previous trial of conventional therapy (anticholinergics and speech therapy) • Previous trial with an anticholinergic medication for overactive bladder dx, detrusor overactivity related to a neurologic condition • Previous trial of conventional agents , ≥15 headaches per month with ≥4 hours/day duration for ≥3 months for dx of headache/migraine • For additional information, please refer to local coverage determination article,L26841, on the CMS coverage database website |
| Novarel, Pregnyl (Multiple) | Chorionic gonadotropin | J0725 | Diagnostic purposes | <ul style="list-style-type: none"> • Appropriate clinical documentation per indication • For additional information, please refer to national coverage determination article,190.27, on the CMS coverage database website |
| Prolia, Xgeva | Denosumab | J0897 | Prolia: postmenopausal osteoporosis, osteoporosis in men, osteopenia in men receiving androgen deprivation therapy, osteopenia in women receiving aromatase inhibitor therapy, osteoporosis in patients with significant renal failure Xgeva: prophylaxis of skeletal related events in patients with bone metastases, unresectable giant cell tumor of bone | <ul style="list-style-type: none"> • Patients age, sex, menopausal status • Medical history of osteoporotic fracture or risk factors for fractures • Bone mineral density (T score), serum creatinine, calcium, vitamin D • Concurrent calcium and vitamin D intake • Previous medication trials and outcomes • Documented corresponding cancer and use of chemotherapy agent if applicable • For additional information, please refer to local coverage article, A50361, on the CMS coverage database website |

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| Privigen, GamaStan, Gammaplex Carimune (Multiple brand names) | IV immune Globulin | J1459 J1557 J1561 J1566 J1569 J1572 J1599 | Primary humoral immunodeficiency Recurrent severe infection and documented severe deficiency or absence of IgG subclass Deficiency of humoral immunity Immune thrombocytopenic purpura Chronic lymphocytic leukemia with associated hypogammaglobulinemia Symptomatic HIV <13 years who are immunologically abnormal with CD4+ count of $\geq 200/\text{mm}^3$ Bone marrow/stem cell transplantation ≥ 20 years Solid organ transplantation Kawasaki disease Autoimmune mucocutaneous blistering disease Scleromyxedema Humoral or vascular allograft rejection Hemolytic uremic syndrome Hemolytic anemia ≤ 18 years Polymyositis and dermatomyositis Sensitized renal transplant recipients Sepsis Kidney disease CMV infection Von Willebrand disorder Uveitis Toxic shock syndrome Respiratory syncytial virus infection HIV-associated thrombocytopenia West Nile virus infection Treatment of post-transfusion purpura Stiff man syndrome Recurrent-relapsing inflammatory optic neuropathy Auto immune retinopathy Evidence-based supported neurological illness | <ul style="list-style-type: none"> • Gamma globulin blood level results, IgG serum concentrations • Patient weight, serum creatinine/BUN, hemoglobin, hematocrit, platelets, anti-neutrophil antibodies, immunization history • Dx for primary humoral immunodeficiency: congenital agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome, X-linked agammaglobulinemia, or severe combined immunodeficiency • CMV testing results for bone marrow/stem cell transplantation and solid organ transplantation dx • Medical history for Kawasaki disease dx • Dx for autoimmune mucocutaneous blistering disease: pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane pemphigoid, or epidermolysis bullosa acquisita • Previous trial with conventional therapy for dx of autoimmune mucocutaneous blistering disease and scleromyxedema • Medical history of hepatomegaly/hepatosplenomegaly for dx hemolytic anemia • Failed treatment with diazepam for dx of stiff man syndrome • Approval for neurological illness varies dependent upon indication, medical record documentation, laboratory monitoring, and clinical monitoring • For additional information, please refer to local coverage article, A47381, on the CMS coverage database website |

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| Boniva | Ibandronate | J1740 | Postmenopausal osteoporosis Bone metastasis Complication of transplant – osteoporosis Hypercalcemia of malignancy Paget’s disease Corticosteroid-induced osteoporosis Senile osteoporosis in male patients | <ul style="list-style-type: none"> • Bone mineral density (T score), serum creatinine, calcium, vitamin D, phosphorus, and magnesium levels • Concurrent calcium and vitamin D intake • For additional information, please refer to local coverage article, A46087, on the CMS coverage database website |
| Remicade | Infliximab | J1745 | Crohn’s disease Rheumatoid arthritis Psoriatic arthropathy and ankylosing spondylitis Ulcerative colitis Plaque psoriasis Adult onset Still's disease Hidradenitis suppurativa, severe, refractory Juvenile idiopathic arthritis (severe), refractory to other therapies Synovitis Uveitis, refractory; adjunct Wegener's granulomatosis, refractory, in combination with corticosteroids Sarcoid refractory to treatment with steroids and other standard drug regimens Takayasu’s arteritis for patient’s who have not responded to the standard therapies | <ul style="list-style-type: none"> • Patient weight, tuberculin skin test results, hepatitis B screening • Failed trial with conventional therapy depending on dx • Concomitant use of methotrexate for dx of RA unless patient is intolerant to or has contraindications to methotrexate • For additional information, please refer to local coverage article, A46764, on the CMS coverage database website |

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| Natrecor | Nesiritide | J2324 | Non covered benefit | <ul style="list-style-type: none"> For additional information, please refer to national coverage determination article, 200.1, on the CMS coverage database website |
| Xolair | Omalizumab | J2357 | Allergic asthma | <ul style="list-style-type: none"> Moderate to severe persistent asthma ≥12 years of age IgE levels, positive allergy tests Failed trial with inhaled corticosteroids For additional information, please refer to local coverage article, A46088, on the CMS coverage database website |
| Lucentis | Ranibizumab | J2778 | Macular edema following retinal vein occlusion Diabetic macular edema | <ul style="list-style-type: none"> Intraocular pressure, baseline visual acuity For additional information, please refer to local coverage article, A46091, on the CMS coverage database website |
| Thyrogen | Thyrotropin | J3240 | Monitoring recurrence of thyroid cancer | <ul style="list-style-type: none"> Medical history outlining patient's thyroid cancer including medication history TSH levels For additional information, please refer to local coverage article, A48211, on the CMS coverage database website |
| Remodulin | Treprostinil | J3285 | Pulmonary arterial hypertension | <ul style="list-style-type: none"> Patient weight, blood pressure, pulmonary arterial pressure Medical history of patient's symptoms and related diagnoses Failed therapy to conventional oral medications For additional information, please refer to local coverage article, A50220 and L11499, on the CMS coverage database website |
| Visudyne | Verteporfin | J3396 | Subfoveal choroidal neovascularization Age related macular degeneration, associated with classic subfoveal choroidal neovascularization Histoplasmosis, ocular, presumed; associated with classic subfoveal choroidal neovascularization Myopia, pathologic; associated with classic subfoveal choroidal neovascularization | <ul style="list-style-type: none"> Medical records detailing patient's history of macular degeneration For additional information, please refer to local coverage article, A50633, on the CMS coverage database website |

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| | Unclassified drugs; Unclassified biologics | J3490 J3590 | | <ul style="list-style-type: none"> • Appropriate clinical documentation per indication |
| | Laetrile Amygdalin | J3570 | Non-covered benefit | <ul style="list-style-type: none"> • For additional information, please refer to national coverage determination article, 30.7, on the CMS coverage database website |
| Synvisc (Multiple) | Hyaluronic acid | J7321 J7323 J7324 J7325 J7326 | Osteoarthritis of the knee or shoulder joint | <ul style="list-style-type: none"> • Failed trial with conventional therapy and exercise/physical therapy • Synvisc-One and Gel-One limited to dx of osteoarthritis of the knee • For additional information, please refer to local coverage article, A46100, on the CMS coverage database website |
| Thymoglobulin | Antithymocyte globulin | J7511 | Renal transplant rejection | <ul style="list-style-type: none"> • Concomitant use of standard immunosuppressive therapy • Patient weight, CBC with differential, platelet count, renal function • For additional information, please refer to local coverage determination article, L11531, on the CMS coverage database website |
| Sandimmune | Cyclosporine | J7516 | Kidney, liver, and heart transplant rejection prophylaxis | <ul style="list-style-type: none"> • Concomitant use of adrenal corticosteroids for kidney, liver, and heart transplant • Patient weight, CBC with differential, liver enzyme, serum creatinine, and BUN levels • For additional information, please refer to local coverage determination article, L11531, on the CMS coverage database website |
| CellCept | Mycophenolate mofetil | J7517 | Kidney, liver, and heart transplant rejection prophylaxis | <ul style="list-style-type: none"> • Concomitant use of cyclosporine and corticosteroids • Patient weight, CBC with differential, liver enzyme, serum creatinine, and BUN levels • For additional information, please refer to local coverage determination article, L11531, on the CMS coverage database website |
| Myfortic | Mycophenolic acid | J7518 | Kidney transplant rejection prophylaxis | <ul style="list-style-type: none"> • Concomitant use of cyclosporine and corticosteroids • Patient weight, CBC with differential, serum creatinine, and BUN levels • For additional information, please refer to local coverage determination article, L11531, on the CMS coverage database website |

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| Rapamune | Sirolimus | J7520 | Kidney transplant rejection prophylaxis | <ul style="list-style-type: none"> • Patient weight, CBC with differential, serum creatinine, and BUN levels • For additional information, please refer to local coverage determination article, L11531, on the CMS coverage database website |
| Prograf | Tacrolimus | J7525 | Heart, kidney, liver, transplant rejection prophylaxis | <ul style="list-style-type: none"> • Concomitant use of azathioprine or mycophenolate mofetil and adrenal corticosteroids for heart and kidney transplant • Concomitant use of adrenal corticosteroids for liver transplant • Patient weight, CBC with differential, calcium, magnesium, potassium, liver enzyme, serum creatinine, and BUN levels • For additional information, please refer to local coverage determination article, L11531, on the CMS coverage database website |
| Afinitor | Everolimus | J7527 | Angiomyolipoma of kidney Breast cancer, hormone receptor positive, HER2 negative Liver transplant rejection prophylaxis Neuroendocrine tumor, pancreatic Renal cell carcinoma, Renal transplant rejection prophylaxis Subependymal giant cell astrocytoma | <ul style="list-style-type: none"> • CBC with differential, liver function tests, serum creatinine, BUN, immunization history • Failed trial with tyrosine kinase inhibitor (i.e. sunitinib) for dx renal cell carcinoma • For additional information, please refer to local coverage determination article, L11531, on the CMS coverage database website |
| | Immunosuppressive drug not otherwise classified | J7599 | | <ul style="list-style-type: none"> • Appropriate clinical documentation per indication • For additional information, please refer to local coverage determination article, L11531, on the CMS coverage database website |
| | Levalbuterol comp | J7607 | Non-covered benefit | <ul style="list-style-type: none"> • For additional information, please refer to local coverage determination article, L11499, on the CMS coverage database website |
| Mucomyst | Acetylcysteine | J7608 | Persistent thick or tenacious pulmonary secretions | <ul style="list-style-type: none"> • For additional information, please refer to local coverage determination article, L11499, on the CMS coverage database website |

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| | Albuterol comp | J7609 J7610 | Non-covered benefit | <ul style="list-style-type: none"> For additional information, please refer to local coverage determination article, L11499, on the CMS coverage database website |
| | Beclomethasone inhalation comp | J7622 | Non-covered benefit | <ul style="list-style-type: none"> For additional information, please refer to local coverage determination article, L11499, on the CMS coverage database website |
| | Betamethasone inhalation comp | J7624 | Non-covered benefit | <ul style="list-style-type: none"> For additional information, please refer to local coverage determination article, L11499, on the CMS coverage database website |
| | Budesonide inhalation | J7626 | Obstructive pulmonary disease | <ul style="list-style-type: none"> For additional information, please refer to local coverage determination article, L11499, on the CMS coverage database website |
| | Bitolterol inhalation comp | J7629 | Non-covered benefit | <ul style="list-style-type: none"> For additional information, please refer to local coverage determination article, L11499, on the CMS coverage database website |
| | Budesonide inhalation | J7634 | Non-covered benefit | <ul style="list-style-type: none"> For additional information, please refer to local coverage determination article, L11499, on the CMS coverage database website |
| | Atropine inhalation comp | J7635 J7636 | Non-covered benefit | <ul style="list-style-type: none"> For additional information, please refer to local coverage determination article, L11499, on the CMS coverage database website |
| | Dexamethasone inhalation comp | J7637 J7638 | Non-covered benefit | <ul style="list-style-type: none"> For additional information, please refer to local coverage determination article, L11499, on the CMS coverage database website |
| Pulmozyme | Dornase alfa | J7639 | Cystic fibrosis | <ul style="list-style-type: none"> Pulmonary function tests (i.e. FEV1, FVC) For additional information, please refer to local coverage determination article, L11499, on the CMS coverage database website |
| | Flunisolide inhalation comp | J7641 | Non-covered benefit | <ul style="list-style-type: none"> For additional information, please refer to local coverage determination article, L11499, on the CMS coverage database website |
| | Glycopyrrolate inhalation comp | J7642 J7643 | Non-covered benefit | <ul style="list-style-type: none"> For additional information, please refer to local coverage determination article, L11499, on the CMS coverage database website |

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| | Terbutaline inhalation comp | J7680 J7681 | Non-covered benefit | <ul style="list-style-type: none"> For additional information, please refer to local coverage determination article, L11499, on the CMS coverage database website |
| | Triamcinolone inhalation comp | J7683 J7684 | Non-covered benefit | <ul style="list-style-type: none"> For additional information, please refer to local coverage determination article, L11499, on the CMS coverage database website |
| | Tobramycin comp | J7685 | Non-covered benefit | <ul style="list-style-type: none"> For additional information, please refer to local coverage determination article, L11499, on the CMS coverage database website |
| Tyvaso | Treprostinil inhalation | J7686 | Pulmonary arterial hypertension | <ul style="list-style-type: none"> Patient weight, blood pressure, pulmonary arterial pressure Medical history of patient's symptoms and related diagnoses Failed therapy to conventional oral medications For additional information, please refer to local coverage determination article, L11499, on the CMS coverage database website |
| | Antiemetic drug NOS | J8597 | | <ul style="list-style-type: none"> Appropriate clinical documentation per indication For additional information, please refer to local coverage determination article, L5057, on the CMS coverage database website |
| Cesamet | Nabilone | J8650 | Refractory nausea and vomiting associated with cancer chemotherapy | <ul style="list-style-type: none"> Medical records documenting patient's cancer and chemotherapy regimen For additional information, please refer to local coverage determination article, L5058, on the CMS coverage database website |
| | Oral prescription drug NOS | J8999 | | <ul style="list-style-type: none"> Appropriate clinical documentation per indication For additional information, please refer to local coverage determination article, L5057, on the CMS coverage database website |
| Vantas | Histrelin implant | J9225 | Palliative and adjuvant treatment of prostate cancer Precocious puberty for children with disability | <ul style="list-style-type: none"> Medical records documenting patient's cancer and medication history For additional information, please refer to local coverage article, A49923, on the CMS coverage database website |

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| Rituxan | Rituximab | J9310 | Non-hodgkin's lymphoma Rheumatoid arthritis Acute lymphocytic leukemia Acquired blood factor deficiency Autoimmune hemolytic anemia B-cell lymphoma Central nervous system cancers – leptomeningeal metastases Chronic lymphoid leukemia, in combination for first-line treatment Chronic lymphoid leukemia, relapsed or refractory Evans syndrome, refractory to immunosuppressive therapy Graft-versus-host disease, chronic, Steroid-refractory Hodgkin's disease CD20-positive, as monotherapy Human herpesvirus 8 (HHV-8) infection Minimal change disease, refractory, steroid-dependent or steroid- resistant Multicentric Castleman's disease (MCD) Pemphigus vulgaris, severe Post-transplant lymphoproliferative disorder Primary Sjögren's syndrome Systemic lupus erythematosus, refractory to immunosuppressive therapy Thrombocytopenic purpura, immune or idiopathic Waldenstrom's macroglobulinemia Wegener's granulomatosis | <ul style="list-style-type: none"> • Patient weight, height, CBC with differential, platelet count • Hepatitis B screening • Failed trial with TNF blockers + oral DMARD for dx rheumatoid arthritis • Panel reactive antibody levels for dx pre-transplant to suppress panel reactive anti- HLA antibodies • For additional information, please refer to local coverage article, A49636, on the CMS coverage database website |

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| | | | (severe), refractory, in combination with corticosteroids Relapsing-remitting multiple sclerosis Microscopic polyangitis in combination with glucocorticoids Pre-transplant to suppress panel reactive anti- HLA antibodies Dermatomyositis and polymyositis, refractory to standard therapies Grave's disease/ophthalmopathy, refractory to standard therapies | |
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