Medical Review
Drugs and Criteria

BlueCross BlueShield of New Mexico

Medications Requiring Preauthorization – Primarily Considered a Medical Benefit

Blue Cross and Blue Shield of New Mexico (BCBSNM) provides coverage for the list of medications below when certain criteria are met. Effective communication about specific drug limitations and/or criteria for use is important for consistent benefit administration and customer satisfaction. The following information includes preauthorization criteria for the BCBSNM Medicaid plan (Blue Cross Community Centennial[SM]). Please refer to the specific BCBSNM Medical Policy for further information about medications in this list as well as medications not included in this list. For information on medications covered through the pharmacy benefit please refer to www.bcbsnm.com/provider/pharmacy/index.html on the BCBSNM website.

Medication Therapy Index

All Listed Medications Require Clinical Review

Search Tip: For fast look up, use "Control F" to find drugs within this document.

Brand Name	Generic Name
ACTHAR HP	corticotropin
ARANESP	darbepoetin
AVASTIN	bevacizumab
BENLYSTA	belimumab
BOTOX	botulinum A
EPOGEN	epoetin alfa
Immune Globulin Intravenous (IVIG)	immune globulin intravenous
MYOBLOC	botulinum toxin type b
PROCRIT	epoetin alfa
PROVENGE	sipuleucel-T
REMICADE	infliximab
RITUXAN	rituximab
SYNAGIS	palivizumab humanized monoclonal antibody
XOLAIR	omalizumab

ACTHAR HP (corticotropin) – J0800

Note: Refer all requests for ACTHAR HP to a BCBSNM pharmacist for review.

AVASTIN (bevacizumab) – J9035 (10mg) or C9257 (0.25mg)

Diagnosis of:

- Metastatic Carcinoma of the colon or rectum
- Metastatic Renal Cell Carcinoma in combination with approved interferon alfa
- Wet Macular Degeneration
- Glioblastoma/Astrocytoma
- Nonsquamous Non-Small Cell Lung Cancer (NSCLC) (in combination with carboplatin and paclitaxel for the first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic NSCLC)

Dosage: 5–15mg/Kg every 2–3 weeks

Duration: 6 months initial, then 12 months thereafter if no change in dosing

FDA Black Box Warning
GI perforations, surgery and wound healing complications, severe or fatal hemorrhage

BENLYSTA (belimumab) – J0490

Diagnosis of:

Active, autoantibody-positive Systemic Lupus Erythematosis (SLE) in patients receiving standard therapy (corticosteroids, antimalarials, immunosuppressives, or NSAIDS)

Dosage: 10mg/kg at 2-week intervals for the first 3 doses, then 10mg/kg every 4 weeks thereafter

Note: *The efficacy of Benlysta has not been evaluated in with severe active lupus nephritis or severe active central nervous system lupus. Benlysta has not been studied in combination with other biologics or intravenous cyclophosphamide. Use of Benlysta is not recommended in these situations.*

Duration: 6 months initial, then 12 months thereafter if no change in dosing

BOTOX (onabotulinum toxin A) – J0585

Diagnosis of:

- Strabismus and Blepharospasm associated with Dystonia
- VII cranial (facial) nerve disorders
- Axillary Hyperhidrosis
- Cervical Dystonia
- Upper limb spasiticity in flexor muscles of the elbow, wrist, and fingers
- Prophylaxis of Chronic Migraine Headache in adult patients (with headache for >15 days per month and with headache lasting 4 hours a day or longer)
- Off-label indications for Spasticity or Dystonia resulting in functional impairment of joint function and/or pain in patients with hereditary, degenerative, or demyelinating diseases of the CNS:
  - Orofacial Dyskinesia
  - Organic Writer's Cramp
  - Focal Dystonia
  - Hereditary Spastic Paraplegia
  - Neuromyelitis Optica
  - Schilder's Disease
  - Spastic Hemiplegia
  - Infantile Cerebral Palsy
  - Multiple Sclerosis
  - Spasmodic Torticollis, Dysphonia
- Spasticity related to Stroke:
  - Torticollis (whether congential, due to childbirth injury, or trauma)
  - Treatment of chronic anal fissure
  - Spinal cord or traumatic brain injury
  - Incontinence due to detrusor over-reactivity, either idiopathic or due to neurogenic causes
  - Sialorrhea associated with advanced Parkinson's Disease
- Patients with Achalasia who:
  - Have not responded to dilatation therapy
  - Considered poor surgical candidates
- Gustatory Sweating (Frey Syndrome)

Duration: One injection every 3 months as needed (up to 1 year)

FDA Black Box Warning

Postmarketing reports indicate that the effects of all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, and breathing difficulties.

Immune Globulin Intravenous (IVIG) – J1572, J1569, C9270, J1561, J1559, J1568, J1459, J2791, J1566, J1599

Refer to BCBSNM Medical Policies for complete details

Diagnosis of:

- Primary Humoral Immunodeficiencies including but not limited to:
  - Congenital Agammaglobulinemia or Hypogammaglobulinemia
  - Wiskott-Aldrich Syndrome
  - Common Variable Immunodeficiency (CVID)
  - X-linked Immunodeficiency
  - Severe Combined Immunodeficiency (e.g., X-SCID, jak3, etc.)
- Idiopathic Thrombocytopenic Purpura (ITP)
- AIDs, children under 16 years of age
- HIV associated thrombocytopenia (significant bleeding or platelet count < 20,000/dl and failure of RhIG in Rh-positive patients)
- Refractory Dermatomyositis
- Acute/Chronic Inflammatory Demylinating Polyneuropathy (CIDP) including Guillain-Barre Syndrome
- Autoimmune Neutropenia
- Multifocal Motor Neuropathy with documented anti GM1 antibodies and conduction block
- Autoimmune Mucotaneous Blistering Disease (e.g., Pemphigus Vulgaris, etc.)
- Hyperimmunoglobulin E (HIE) Syndrome (Job's Syndrome, Hyper IgE Syndrome)
- Fetal Alloimmune Thrombocytopenia
- Infections, Neonates (high-risk, pre-term, low-birth weight, as prophylaxis and/or treatment adjunct)
- Autoimmune Hemolytic Anemia
- Lambert-Eaton Myastheic Syndrome (LEMS)
- Inflammatory Myopathis (corticosteroid resistant or contraindicated)
- Multiple Sclerosis (severe manifestations of RRMS only, failure/intolerance of other standard therapies)
- Myasthenia Gravis
- Neonatal Autoimmune Thrombocytopenia, severe (when other interventions have failed or are contraindicated)
- Fetal Neonatal Alloimmune Thrombocytopenia (F/NAIT)
- Post-transfusion Purpura, severe
- Pure Red Cell Aplasia
- Solid Organ Transplants
- Stiff Person Syndrome
- Multiple Myeloma – Plateau Phase (i.e., greater than 3 months since diagnosis)

- Systemic Lupus Erythematosus (SLE) (severe active illness for whom other interventions have been unsuccessful or intolerable)
- Toxic Shock Syndrome (infection is refractory to several hours of aggressive therapy)
- Vasculitis Syndromes (severe active illness for whom other interventions have been unsuccessful or intolerable)
- Kawasaki Syndrome

Prevention of:

- Graft vs. host disease in bone marrow transplants

Prevention of infection associated with:

- HIV
- Bone marrow transplants
- B-Cell Chronic Lymphocytic Leukemia

Duration: 6 months initial, then 12 months thereafter if no change in dosing (Direct to Coram when possible)

FDA Black Box Warning
Immune globulin intravenous (human) products have been reported to be associated with renal dysfunction, acute renal failure, osmotic nephrosis, and death.

MYOBLOC (rimabotulinum toxin B) – J0587

Diagnosis of:

- Cervical Dystonia (CD) – to reduce the severity of abnormal head position and neck pain associated with CD

Duration: One injection every 3 months as needed (up to 1 year)

FDA Black Box Warning
Postmarketing reports indicate that the effects of rimabotulinumtoxin B and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects.

PROCRIT, EPOGEN (erythropoietin), or ARANESP (darbepoetin alpha) – J0886, J0885, J0882, J0881

Diagnosis of:

- Anemia of chronic renal failure (Rx Benefit) or
- Anemia with HIV infection and retrovir, AZT therapy < 4200mg/w (Rx Benefit) or
- Chemotherapy-induced anemia with non-myeloid malignancy (Medical Benefit) or
- Reduction of allogeneic blood transfusion in surgery patients (Medical Benefit) AND
- Non-dialysis patients with symptomatic anemia considered for therapy should have a hemoglobin less than 10gm/dl (Rx Benefit); dialysis patients (Medical Benefit)

Note: Prior Authorization is NOT required if services are requested from a Fresenius provider's for renal dialysis patients

Dosing: PROCRIT or EPOGEN is weekly, ARANESP is every other week

Duration: 3 months

FDA Black Box Warning
Increased mortality, tumor progression, recurrence, cardiovascular or thromboembolic events

PROVENGE (sipuleucel-T) – C9273

Diagnosis of:

- Prostate Cancer – For treatment of asymptomatic or minimally symptomatic metastatic, Castrate Resistant (hormone refractory) Prostate Cancer (CRPC)

Note: Must refer to Pharmacy Director/Medical Director for coverage determination.

REMICADE (infliximab) – J1745

Diagnosis of:

- Moderate to severe Crohn's Disease, Fistulizing Crohn's Disease, Ulcerative Colitis, Pediatric Ulcerative Colitis, or Pediatric Crohn's Disease
- **Required documentation:**
  - Trial of mesalamine (ASACOL or PENTASA) for at least 8 weeks or
  - Trial of oral corticosteroids for at least 8 weeks or
  - Trial of mercaptopurine for at least 6 months or
  - Trial of azathioprine for at least 6 months
- **Administration:** 5mg/kg IV given as an induction regimen over six weeks (initial, at two weeks and six weeks) followed by a maintenance regimen every eight weeks thereafter. For Crohn's Disease adult patients who respond and then lose their response, consider treatment with 10mg/kg. Patients who do not respond by week 14 are unlikely to respond with continued dosing; consider discontinuing infliximab in these patients.
- **Duration:** Approve for six months, then re-evaluate

Diagnosis of:

- Moderate to severe Rheumatoid Arthritis (RA) or Psoriatic Arthritis
  - Significant joint involvement (12 tender or 10 swollen joints) and
  - Inadequate therapeutic response to methotrexate (should be continued with infliximab during treatment for RA)
- **Administration:** 5mg/kg (3mg/kg for RA) IV given as an induction regimen over 6 weeks (initial, at 2 weeks and 6 weeks) followed by a maintenance regimen every 8 weeks thereafter.
- **Duration:** Approve for 6 months then re-evaluate

Diagnosis of:

- Ankylosing Spondylitis
  - Trial/failure of 2 NSAIDS after 3 months use of each
- **Administration:** 5mg/kg given as an induction regimen at 0, 2, and 6 weeks, followed by a maintenance regiment of 5mg/kg every 6 weeks thereafter
- **Duration:** Approve for 6 months, then re-evaluate

Diagnosis of:

- Plaque Psoriasis and
  - Affected Body Surface Area (BSA) > 10% and
  - Inadequate therapeutic response to topical steroids, methotrexate, cyclosporine, oral retinoids or UVB/PUVA.
- **Administration:** 5mg/kg IV given as an induction regimen over 6 weeks (initial, at 2 weeks and 6 weeks) followed by a maintenance regimen every 8 weeks thereafter.
- **Duration:** Approve for 6 months then re-evaluate

FDA Black Box Warning

Risk of serious infections, Hepatosplenic T-Cell Lymphomas, and other malignancies

RITUXAN (rituximab) – J9310

Diagnosis of:

- Non-Hodgkins Lymphoma
  Usual Dose: 375mg/m2 weekly for up to 8 doses (send for review if additional doses are requested)

- Chronic Lymphocytic Leukemia (initial or relapsed in combination with fludarabine and cyclophosphamide)
  Usual Dose: 375mg/m2 initial dose prior to start of chemotherapy and then 500mg/m2 on day one of each additional day cycle x 5 doses

- Severe Rheumatoid Arthritis (RA) after failure on TNF therapy (given in combination with Methotrexate)
  Usual Dose: 1,000mg every 2 weeks x 2 doses only (send for review if additional doses are requested)

- Advanced Follicular Lymphoma – Maintenance treatment
  Usual Dose: 375mg/m2 weekly x 4–8 weeks

Duration: There are no currently FDA approved maintenance schedules for RITUXAN. Retreatment requires evidence of a) adequate clinical response and b) at least a period of 24 weeks since previous dosing.

May be considered medically necessary (see BCBSNM medical policies) for the following NON-FDA approved indications for cancer and hematologic conditions:

- Autoimmune Hemolytic Anemia
- B-cell Lymphoma
- Evans Syndrome, refractory to immunosuppressive therapy
- Graft-Versus-Host-Disease (GVHD), chronic, steroid refractory
- Hodgkin's Disease, CD-20 positive (monotherapy)
- Pemphigus Vulgaris (severe)
- Post-transplant Lymphoproliferative Disorder
- Waldenstrom's Macroglobulinemia
- Wegener's Granulomatosis (severe), refractory in combination with corticosteroids

FDA Black Box Warning
Fatal infusion reactions, Tumor Lysis Syndrome, severe mucocutaneous reactions, Progressive Multifocal Leukoencephalopathy (PML)

SYNAGIS (palivizumab humanized monoclonal antibody) – J3490, 90378

Prevention of RSV Disease:

- Birth to age < 24 months at start of RSV season (i.e., November 15)
  - Chronic Lung Disease (CLD) of prematurity in children born at less than 32 weeks, 0 days gestation who required at least 28 days of supplemental oxygen after birth and who continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy) within 6 months of the start of the second RSV season

  OR
- Birth to age < 12 months with gestational age less than 29 weeks,0 days
- Birth to age < 12 months with gestational age < 32 weeks, 0 days AND chronic lung disease of prematurity (defined as use of greater than 21% oxygen for at least 28 days after birth)
- Birth to age < 12 months with hemodynamically significant heart disease (CHD), who are receiving medication to control congestive heart failure and will require cardiac surgical procedures OR infants with moderate to severe pulmonary hypertension. Documentation of a recommendation for prophylaxis from a cardiologist must be provided for patients with cyanotic heart disease.
- Birth to age < 12 months with severe immunodeficiency
- Birth to age < 12 months with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the upper airways

Additional Guidance:

- There is insufficient data available to recommend palivizumab prophylaxis for children with Cystic Fibrosis or Down Syndrome
- Palivizumab prophylaxis is not recommended to prevent healthcare-associated (nosocomial) RSV disease
- Palivizumab monthly prophylaxis should be discontinued in any child who is hospitalized for RSV
- Palivizumab monthly prophylaxis is not recommended for otherwise healthy infants born at or after 29 weeks, 0 days gestation
- Palivizumab prophylaxis may be **considered** for children younger than 24 months who undergo cardiac transplantation during the RSV season
- Palivizumab prophylaxis may be **considered** for children younger than 24 months who will be profoundly immunocompromised during the RSV season

Dosing Considerations:

- 15mg/kg IM monthly
- 5 monthly doses (beginning in November) are sufficient to provide coverage for the infant into April. Administration of more than 5 doses is not recommended within the continental U.S.
- Infants who qualify for palivizumab therapy AND are born during the RSV season may require **less** than 5 doses

Duration: Approved for monthly injection through RSV season.

Note: *All SYNAGIS requests are to be routed through BCBSNM's Specialty Pharmacy vendor.*

XOLAIR (omalizumab) – J2357

Diagnosis of:

- Severe, Persistent Asthma – restricted to treatment of individuals:
  - Age ≥ 12 years old AND
  - FEV-1 < 80% AND
  - Positive allergy test (positive skin test to perennial aeroallergen) AND
  - Prescribed by a pulmonologist, allergist, or immunologist AND
  - Documented current use of an inhaled corticosteroid for at least 3 months AND
  - Documented current use of a long-acting beta 2-agonist or a leukotriene inhibitor for at least 3 months AND
  - Experiencing exacerbations of asthma symptoms
  - Fall within recommended dosing guidelines set by manufacturer based on baseline IgE serum levels between 30 and 700iu/ml and weight less than 150kg
  - Review requested dose with medical director or pharmacy manager

Usual Dose: 150–375mg SQ every 2 or 4 weeks

Duration: 6 months initial, then 12 months thereafter if no change in dosing

FDA Black Box Warning
Anaphylaxis, presenting as bronchospasm, hypotension, syncope, urticaria, etc.