



**Blue Cross and Blue Shield  
of New Mexico**

# **Drug List Limitations, Exclusions, and Prior Authorization Criteria for Commercial Health Plans**

The Blue Cross and Blue Shield of New Mexico (BCBSNM) Pharmacy Benefit provides coverage of most drugs for our members. Effective communication about specific drug limitations is important for consistent benefit administration and customer satisfaction. The following information includes the drug limitations, exclusions, and prior authorization criteria for most BCBSNM pharmacy plans.

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# Drug Limitations

## 3-Tier and 4-Tier Prescription Drug Plans:

Includes 30-day supply or 120 units, whichever is less per copay at retail pharmacies; or 90-day supply or 360 units, whichever is less per two or two-and-a-half retail copays at mail-order (depending on plan).

## 25/50 Percent Prescription Drug Plan:

Includes 30-day supply or up to 180 units, whichever is less at retail pharmacies; or 90-day supply or up to 540 units, whichever is less at mail-order.

## Specialty Pharmacy Program:

Specialty medications are used to treat serious or chronic conditions such as cancer, multiple sclerosis, pulmonary hypertension, hepatitis, and rheumatoid arthritis. Specialty medications are available in both injectable and oral forms; these are intended to be administered by a patient or family member. Specialty medications are dispensed by a specialty pharmacy provider and limited to a 30-day supply. For plans participating in the Specialty Pharmacy Program, specialty medications may be covered under a 4<sup>th</sup> tier benefit. Please refer to your Prescription Drug Plan Rider or Benefit Summary for further details. Please pay special attention to which copayment or coinsurance applies for these medications. All Specialty Pharmacy drugs require prior authorization. See the [Specialty Drug List](#) for a listing of specialty drugs.

## Step Therapy:

Requires the use of a generic drug within the same drug class be tried and failed before a branded product may be used. Examples of Step Therapies include:

- The use of generic cholesterol lowering drugs (simvastatin, lovastatin, pravastatin) before the branded drug products (LIPITOR, LESCOL, CRESTOR)
- The use of generic antidepressants (bupropion, paroxetine, fluoxetine, citalopram) before the branded drug products (CYMBALTA, EFFEXOR XR, LEXAPRO)
- The use of generic omeprazole for gastroesophageal reflux disease (GERD) before the following drug products (ACIPHEX, pantoprazole and brand PROTONIX, PREVACID)

## Quantity Limits:

Drug-specific quantity limits are identified on the Dispensing Limit (DL) list below.

Requests for larger quantities are referred to the BCBSNM Health Services Department for review.

### Legend

- F Tier 2 copay applies
- NF Tier 3 copay applies
- \* Not available through mail-order

Drug	DL	Notes
ABILIFY	30/30 days	NF
ACTIQ	120/30 days	NF
ALDARA	12 (1 box)/21 days for 16 weeks	F*
ALINIA	60ml/30 days	NF
ALOXI	5/30 days	NF
AMBIEN	30/30 days	NF
AMBIEN CR	30/30 days	NF
AMERGE 1mg, 2.5mg	9/30 days	NF
AXERT 6.25mg, 12.5mg	12/30 days	NF
ANZEMET	6/30 days	NF
BONIVA	1/30 days	NF
CELEBREX	60/30 days	NF
CIPRO XR 500mg, 1g	3/30 days	NF*



Drug	DL	Notes
CRESTOR	30/30 days	F
DIFLUCAN (fluconazole) (all strengths)	14/30 days	F
DHE-45 150mg	10/30 days	NF
DURAGESIC	10/30 days	NF
EDLUAR	30/30 days	NF
EMEND	12/30 days	NF*
EMLA	30gm tube/60 days	F
FENTORA	120/30 days	NF
FRAGMIN	30/90 days	NF*
FROVA	18/30 days	NF
GELNIQUE	30 /30 days	NF
IMITREX Inj Kits	3/30 days	NF
IMITREX Inj Vials	6/30 days	NF
IMITREX Nasal 5mg	1 x 1 pack of 6/30 days	NF
IMITREX Nasal 20mg	1 x 1 pack of 6/30 days	NF
IMITREX Tabs	18/30 days	NF
KADIAN	120/30 days	F
KYTRIL	15/30 days	F
LOVENOX	30/90 days	F*
LUNESTA	30/30 days	NF
MAXALT (MLT)	12/30 days	F
MIGRANAL NS	2 x 1 pack of 4/30 days	NF
NAMENDA 5mg	30/30 days	NF
NAMENDA 10mg	60/30 days	NF
NAMENDA Titration Pak	49 (1 Pak) 365 days	NF
NUVIGIL	30/30 days	NF
ONGLYZA	30/30 days	NF
ONSOLIS	120/30 days	NF
PLAN B	4/year	NF
PRILOSEC (omeprazole)	30/30 days	F
PRISTIQ	30/30 days	NF
PROMACTA	90/30 days	NF
PROVIGIL	30/30 days	NF
REGRANEX	15/30 days	F*
RELENZA	2 treatments (40 disks)/year	NF*
RELPAK	12/30 days	NF
RE VIA	180/360 days	F
ROZEREM	30/30 days	NF
RYZOLT	30/30 days	NF
SANCUSO	1 patch/30 days	NF
SAVELLA	60/30 days – 1 kit/30 days	NF
SONATA	30/30 days	NF
STADOL NS	6ml (2 bottles)/30 days	F
TAMIFLU	2 treatments (20 caps)/year	NF*
TORADOL 10mg tabs	20/30 days	NF
ULTRAM	240/30 days	NF
ULTRAM ER	30/30 days	NF
XANAX XR	60/30 days	NF
XENAZINE	120/30 days	NF
XOPENEX HFA	30 units/30 days	NF
ZITHROMAX 250mg	12/30 days	F
ZOFRAN	15/30 days	F
ZOMIG, ZOMIG (ZMT 2.5mg)	12/30 days	F
ZOMIG, ZOMIG (ZMT 5mg)	6/30 days	F
ZYVOX susp	150ml/180 days	NF
ZYVOX tabs	20/180 days	NF



# Drug Exclusions

Certain classes of medications may be excluded from the benefit and therefore are not covered. Examples of common exclusions are:

## Drugs used for smoking cessation:

- ZYBAN
- Nicotine, COMMIT, NICORETTE, NICORETTE DS gum
- HABITROL patch
- NICODERM patch
- NICOTROL patch, inhaler, spray
- Bupropion, WELLBUTRIN (Also used for depression – see Step Therapy Criteria)
- CHANTIX
- **Note:** Prior authorization is required for plans covering smoking cessation programs.

## Drugs used for weight loss:

- MERIDIA
- Phentermine, IONAMIN, ADIPEX-P, PRO-FAST (SA, HS, SR)
- Benzphetamine, DIDREX
- Phendimetrazine, BONTRIL (PDM, SR), MELFIAT-105, PRELU-2
- Diethylpropion
- XENICAL, ALLI (OTC) (orlistat)

## Drugs used to treat erectile dysfunction:

- VIAGRA
- Alprostadil, MUSE, EDEX, CAVERJECT
- LEVITRA
- CIALIS

## Drugs used to treat infertility:

- Ganirelix
- FACTRL (gonadorelin)
- Chorionic Gonadotropin, PROFASI, CHORON 10, GONIC, NAVAREL, PREGNYL
- FOLLISTIM AQ (follitropin beta)
- GONAL-F (follitropin alfa)
- BRAVELLE (urofollitropin)
- MENOPUR, REPRONEX (menotropins)
- Clomiphene, CLOMID, SEROPHENE, MILOPHENE

## Drugs used to treat hair loss:

- PROPECIA (finasteride)
- ROGAINE (monoxidil)

## Drugs considered cosmetic:

- Tretinoin, RENOVA, RETIN-A, ALTINAC
- VANIQA (eflornithine)
- Hydroquinone (various)

## Drugs considered off-label/investigational

**Drugs for international travel** (e.g., LARIUM/mefloquine, MALARONE/no generic, VIVOTIF BERNA/no generic)

## Compounded Medications



# Drug Prior Authorization

Contact the BCBSNM Health Services Department for drug prior authorization. Changes to the prior authorization list are published in the *Blue Review* newsletter, and posted on the website.

BCBSNM allows for certain off-label uses of drugs when the off-label use has reputable medical literature supporting its safe and effective use. BCBSNM uses the following criteria in evaluating off-label medication use:

- Drug must be approved by the FDA for at least one indication
- Drug must be prescribed by a participating licensed health care provider within their scope of practice
- With most benefits, drugs in clinical phase 1 or 2 trials are considered experimental and therefore not a covered benefit

**Note:** Not all medication requiring prior authorization may appear on this list. Many plans have “global” restrictions on such things as injectable products. Refer these types of requests to BCBSNM Health Services.

**Note:** For all medications on the preauthorization list:

- Hypersensitivity to any of the medications is a contraindication for use
- Inclusion in the list by itself does not imply that the drug listed will be approved
- Uses other than those defined in the criteria must meet the BCBSNM criteria for approval of new technologies and off-label use

## Medications Requiring Prior Authorization – Primarily Acquired at Retail Pharmacies

### **ACTIQ (fentanyl citrate)**

**Treatment of:**

- Breakthrough pain control for oncology patients **ONLY**

**Duration:** 6 months (quantity limited to 120 units per month)

### **FDA Black Box Warning**

Abuse potential, fatal overdose due to respiratory depression, fatal pediatric poisoning

### **AFINITOR (everolimus)**

**Diagnosis of:**

- Advanced Renal Cell Carcinoma following treatment failure with either sunitinib (SUTENT) or sorafenib (NEXAVAR)

**Dosing considerations:**

- Usual daily dose = 10mg
- Dosing adjustments (5mg) due to hepatic impairment and/or strong CYP3A4 inducers (dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, Phenobarbital), or
- Dosing adjustments (maximum of 20mg) with strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin, atazanavir, nefazodone, saquinavir, telithromycin, ritonavir, indinavir, nelfinavir, delavirdine, fosamprenavir, voriconazole, aprepitant, erythromycin, fluconazole, grapefruit juice, verapamil, diltiazem)

**Duration:** 6 months



## **BYETTA (exenatide)**

### **Diagnosis of:**

- Type 2 Diabetes and
- Adjunct therapy with a thiazolidinedione (TZD) and/or metformin and/or sulfonylureas or a combination of metformin and a sulfonylurea, or a combination of metformin and a TZD but have not achieved adequate glycemic control (NOT ON INSULIN)

**Duration:** 12 months

## **CELEBREX (celecoxib) Step Therapy Criteria**

### **Diagnosis of:**

- Various acute and chronic pain syndromes
- Age 50 years old or greater or
- 30-day trial of one generic NSAID in the last 180 days

**Duration:** 12 months

### **FDA Black Box Warning**

Cardiovascular, gastrointestinal

## **COPAXONE (glatiramer), REBIF, AVONEX (interferon beta-1a), or BETASERON (Interferon Beta-1b)**

### **Diagnosis of:**

- Relapsing, Remitting Multiple Sclerosis (RRMS only)

**Duration:** 6 months initially

## **Enteral Feeding Products (Nutritional Supplements)**

### **Nonprescription enteral nutritional products and special medical foods only when:**

- Delivered by a medically necessary enteral access tube that has been surgically placed (e.g., gastrostomy, jejunostomy) or
- Meeting the definition of special medical foods used to treat and to compensate for the metabolic abnormality of persons with genetic inborn errors of metabolism in order to maintain their adequate nutritional status

### **Supply considerations:**

- Benefits are limited to the purchase of a 30-day supply during any 30-day period and are subject to coinsurance. (Most BCBSNM Plans cover 50%.)

**Duration:** 12 months



## **ENBREL (etanercept)**

### **Diagnosis of:**

- Moderate to severe Rheumatoid Arthritis (RA), Polyarticular Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Plaque Psoriasis, or Ankylosing Spondylitis (AS)

### **Therapeutic failure of adequate trial of at least one of the following:**

- PLAQUENIL (hydroxychloroquine)
- SOLGANAL or RIDAURA (gold)
- methotrexate
- imuran (azathioprine)
- CUPRIMINE (penicillimine)
- AZULFIDINE(sulfasalazine)
- ARAVA (leflunomide)

**Duration:** 6 months initial treatment, for a quantity of 8/25mg doses or 4/50mg doses per month; re-evaluate every 6 months

## **EXJADE (deferasirox)**

### **Diagnosis of:**

- Chronic iron overload due to blood transfusions

**Duration:** 6 months

## **FENTORA (fentanyl citrate)**

### **Treatment of:**

- Pain control for oncology patients **ONLY**

**Duration:** 6 months (quantity limited to 120 units per month)

### **FDA Black Box Warning**

Abuse potential, fatal overdose due to respiratory depression, fatal pediatric poisoning

## **FORTEO (teriparatide)**

### **Diagnosis of:**

- Osteoporosis in postmenopausal women who are at high risk for fracture. This includes women with a history of osteoporotic fracture, or who have multiple risk factors for fracture, or
- Primary or Hypogonadal Osteoporosis in men who are at high risk for fracture; treatment to increase bone mass. This includes men with a history of osteoporotic fracture, or who have multiple risk factors for fracture, and
- Have failed or are intolerant of previous osteoporosis therapy (FOSAMAX, ACTONEL, MIACALCIN)

**Duration:** 12 months; maximum therapy of 24 months

### **FDA Black Box Warning**

Osteosarcoma (rats)



## **GLEEVEC (imatinib mesylate)**

### **Diagnosis of:**

- Philadelphia Chromosome positive Chronic Myeloid Leukemia (CML), or Acute Lymphoblastic Leukemia (ALL)
- Gastro Intestinal Stromal Tumor (GIST) with positive protein tyrosine kinase KIT (C-KIT)
- Aggressive Systemic Mastocytosis – Adults with Aggressive Systemic Mastocytosis without the D816V C-KIT mutation or with C-KIT mutational status unknown
- Dermatofibrosarcoma Protuberans
- Hypereosinophilic Syndrome and/or Chronic Eosinophilic Leukemia
- Myelodysplastic/Myeloproliferative diseases

**Duration:** 6 months

## **Growth Hormone – PROTROPIN (somatrem), HUMATROPE, GENOTROPIN, NORDITROPIN, NUTROPIN (AQ), NUTROPIN-DEPOT, OMNITROPE**

**Preferred Product: OMNITROPE**

### **Diagnosis of:**

- Neonatal Hypopituitarism and Hypoglycemia
- Proven growth deficiency in children:
  - Fail two provocative growth hormone stimulation tests (L-dopa, clonidine, glucagon, propranolol, arginine, or insulin – Peak <10ug/L) (24-hour monitoring of IGF or IGFBP are considered experimental) and
  - Have a height >2.5 standard deviations below the median for age or growth velocity is below the 10th percentile when compared with expected growth velocity for chronological age using standard growth chart with at least 3 data points to indicate velocity and
  - A yearly growth rate of <4.5 cm/yr and a bone age of two standard deviations below chronological age
- Growth hormone deficiency in adults:
  - Have no contraindications to therapy; active malignancy, benign intracranial hypertension, proliferative or pre-proliferative diabetic retinopathy and
  - Negative response to standard growth hormone stimulation test (Peak <5ug/L) and growth hormone deficiency syndrome alone or with multiple hormone deficiencies (Hypopituitarism) as a result of pituitary disease, hypothalamic disease, surgery, or radiation therapy or
  - Growth hormone deficiency during childhood with growth hormone deficiency syndrome confirmed as an adult before replacement therapy with somatrem is started. Approximate physiologic dose 10mcg/kg/day.
- Turner's Syndrome
- Children with Chronic Renal Insufficiency
- AIDS wasting or Cachexia
- Full-thickness skin loss associated with third degree burn NOS
- Prader-Willi Syndrome (FDA approved for GENOTROPIN)
- Growth failure associated with Noonan Syndrome (NORDITROPIN)

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### **Growth Hormone, *continued***

**Duration:** 6 months – Growth hormone approved through Specialty Pharmacy Program providers only.

**For continuation of therapy every six months:**

- Must be compliant with therapy
- Have a growth velocity of >2.5cm/yr in the first 6 months and >4.5cm/yr or more thereafter in children. Usually discontinued around 13 to 16 years of age when growth velocity is less than 2cm/yr, when epiphyseal fusion occurs, or when height reaches 5th percentile of expected adult height based upon mean height of parents

### **HEXALEN (altretamine)**

**Diagnosis of:**

- Ovarian Cancer – For use as a single agent in the treatment of patients with persistent or recurrent ovarian cancer following first-line therapy with cisplatin or alkylating agent-based combination.

**Duration:** 6 months

**FDA Black Box Warning**

Neurotoxicity, hematological toxicity

### **HUMIRA (adalimumab)**

**Diagnosis by rheumatologist of moderate to severe:**

- Rheumatoid Arthritis
- Ankylosing Spondylitis
- Crohn's Disease
- Juvenile Idiopathic Arthritis
- Plaque Psoriasis
- Psoriatic Arthritis and

**Therapeutic failure of adequate trial of at least one of the following:**

- PLAQUENIL (hydroxychloroquine)
- SOLGANAL or RIDAURA (gold)
- Methotrexate
- IMURAN (azathioprine)
- CUPRIMINE (penicillimine)
- AZULFIDINE (sulfasalazine)
- ARAVA (leflunomide)

**Duration:** 6 months initial; 12 months thereafter. Limited to 2 doses per month.

**FDA Black Box Warning**

Serious infections (e.g., Tuberculosis, invasive fungal infections, other opportunistic infections)



## **INCRELEX (mecasermin)**

### **Diagnosis of:**

- Insulin-like Growth Factor Deficiency (IGFD)

**Duration:** 6 months

## **INFERGEN (interferon alfacon-1)**

### **Diagnosis of:**

- Chronic Hepatitis C (non A, non B) or
- Hairy Cell Leukemia and
- 18 years of age or older

**Duration:** 6 months

### **FDA Black Box Warning**

Fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders

## **INTRON-A (interferon alfa 2b)**

### **Diagnosis of:**

- Hairy Cell Leukemia
- AIDS-related Kaposi's Sarcoma
- Chronic Hepatitis C (non A, non B)
- Chronic Hepatitis B, serum HBe Ag positive
- Condylomata Acuminata involving external surfaces of the genital or perianal area
- Chronic Myelogenous Leukemia (CML) – Philadelphia chromosome-positive
- Multiple Myeloma
- Non-Hodgkin's Lymphoma, low- or intermediate-grade disease
- Malignant Melanoma
- 18 years of age and older

**Duration:** 6 months

### **FDA Black Box Warning**

Fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders



## **KINERET (anakinra)**

### **Diagnosis of:**

- Moderate to severe Rheumatoid Arthritis (RA) by rheumatologist
- Not currently on ENBREL or REMICADE and
- Therapeutic failure of adequate trial of at least one of the following:
  - PLAGUENIL (hydroxychloroquine)
  - SOLGANAL or RIDAURA (gold)
  - Methotrexate
  - IMURAN (azathioprine)
  - CUPRIMINE (penicillimine)
  - AZULFIDINE (sulfasalazine)
  - ARAVA (leflunomide)

**Duration:** 6 months initial treatment, for a quantity of thirty 100mg injections per month; 12 months thereafter

## **LAMISIL (terbinafine)**

### **Diagnosis of:**

- Fingernail Onychomycosis  
**Duration:** 6-week course of therapy; one course per lifetime as documented by BCBSNM
- Toenail Onychomycosis  
**Duration:** 12-week course of therapy; one course per lifetime as documented by BCBSNM

**Exclusion:** Documentation of prior use of either SPORANOX or DIFLUCAN

## **LEUKINE (Sargramostim)**

### **Diagnosis of:**

- Acute Myelogenous Leukemia following induction chemotherapy
- Autologous peripheral blood progenitor cells – mobilization and following transplantation
- Myeloid reconstitution after autologous bone marrow transplantation (BMT)
- Myeloid reconstitution after allogeneic bone marrow transplantation
- Bone marrow transplantation failure or engraftment delay

**Duration:** 3 months

## **LOTRONEX (alosetron hcl)**

### **Diagnosis of:**

- Severe diarrhea-predominant Irritable Bowel Syndrome (IBS) in women who have chronic IBS symptoms (generally lasting 6 months or longer)

**Duration:** 6 months

### **FDA Black Box Warning**

Gastrointestinal



## LYSODREN (mitotane)

### Diagnosis of:

- Inoperable Adrenal Cortical Carcinoma

**Duration:** 3 months (If no clinical benefits are observed after 3 months at the maximum tolerated dose, the case would generally be considered a clinical failure.)

### **FDA** Black Box Warning

Adrenal suppression

## NEUPOGEN G-CSF (filgrastim) and NEULASTA (pegfilgrastin)

### Diagnosis of:

- Chemotherapy-induced Neutropenia in non-myeloid malignancies
- Prophylaxis in cytotoxic chemotherapy of high intensity where Neutropenia is expected
- Neutropenia associated with HIV
- Aplastic Anemia
- Alloimmune Neonatal Neutropenia
- Congenital or drug-induced Agranulocytosis
- Severe Chronic Neutropenia (SCN)
- Acute Myeloid Leukemia (AML) receiving induction or consolidation chemotherapy
- Bone marrow transplant

**Duration:** 3 months

**Note:** *Not to be approved for “prime” responses to chemotherapy in patients by administering prior to and/or concurrent with chemotherapy.*

## NEXAVAR (sorafenib)

### Diagnosis of:

- Advanced Renal Cell Carcinoma
- Unresectable Hepatocellular Carcinoma

**Duration:** 6 months

## NPLATE (romiplostim)

### Diagnosis of:

- Thrombocytopenia Purpura (ITP) who have had an incomplete response to corticosteroids, immunoglobulins, or splenectomy
  - Should NOT be utilized in an attempt to normalize platelet counts
  - Only health care providers enrolled in the romiplostim NEXUS (Network of experts understanding and supporting NPLATE and patients) program may prescribe romiplostim
  - Initial dosing = 1mcg per kg (actual body weight) – Maximum dose = 10mcg/kg
  - Concomitant medications (e.g., corticosteroids, danazol, azathioprine, IVIG, and anti-D immunoglobulin) may be used

**Duration:** 6 months



## **ONSOLIS (fentanyl buccal soluble film)**

### **Treatment of:**

- Breakthrough pain control for oncology patients **ONLY**

**Duration:** 6 months (quantity limited to 120 units per month)

## **PEGASYS (peginterferon alfa-2a) and PEG-INTRON (peginterferon alfa-2b)**

### **Preferred Product: PEGASYS**

### **Diagnosis of:**

- Chronic Hepatitis C – Diagnosis by gastroenterologist of Chronic Hepatitis C in patients with compensated liver disease and meets the following criteria:
  - Patient seropositive for HCV RNA and
  - Elevated serum alanine aminotransferase

**Duration:** 6 months; may be renewed one additional time only

**Note:** *Do not approve in patients with decompensated cirrhosis. Refer to medical director for use during pregnancy.*

### **Diagnosis of:**

- Chronic Hepatitis B – Adult patients with HBeAg-positive and HBeAg-negative Chronic Hepatitis B Virus (HBV) infection who have compensated liver disease (PEGASYS only)

**Duration:** 6 months; may be renewed one additional time only

### **FDA Black Box Warning**

Fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders

## **PROCRIT, EPOGEN (erythropoietin), or ARANESP (darbepoetin alpha)**

### **Diagnosis of:**

- Anemia of chronic renal failure or
- Anemia with HIV infection and retrovir, AZT therapy < 4200mg/w or
- Chemotherapy-induced anemia with non-myeloid malignancy or
- Reduction of allogeneic blood transfusion in surgery patients and
- HGB < 10g/dl

**Duration:** 3 months

### **FDA Black Box Warning**

Increased mortality, tumor progression, recurrence, cardiovascular or thromboembolic events



## **PROMACTA (eltrombopag)**

### **Diagnosis of:**

- Chronic Immune (Idiopathic) Thrombocytopenic Purpura (ITP)
  - Patients who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy
  - Should not be used in an attempt to normalize platelet counts (maintain count above 50,000)
  - Prescribed by providers enrolled in PROMACTA CARES program
  - Maximum daily dose = 75mg

**Duration:** 6 months

### **FDA Black Box Warning**

Risk of hepatotoxicity requires lab monitoring of liver function tests prior to and during therapy

## **PULMOZYME, rhDNase (dornase alfa)**

### **Diagnosis of:**

- Cystic Fibrosis
  - Five years of age or older and
  - Baseline forced vital capacity (FVC) > 40% of predicted

**Duration:** 12 months; once daily dosing only

## **Ribavirin, REBETOL, RIBASPHERE, RIBATAB, RIBAPAK**

### **Diagnosis of:**

- Chronic Hepatitis C in patients with compensated liver disease and meets the following criteria:
  - Patient seropositive for HCV RNA and
  - Elevated serum alanine aminotransferase

**Duration:** 6 months; may be renewed one additional time only

**Note:** *Must be confirmed by gastroenterologist. Will be approved in patients with decompensated cirrhosis.*

### **FDA Black Box Warning**

Hemolytic Anemia, significant teratogenic and/or embryocidal effects

## **RETIN-A, AVITA, or ALTINAC (tretinoin) (Renova not a covered benefit)**

### **Diagnosis of:**

- Acne Vulgaris in patients age > 40 years
- Actinic Keratosis in patients age > 40 years

**Duration:** 12 months

### **FDA Black Box Warning**

Retinoic Acid-APL Syndrome, Leukocytosis, teratogenic effects



## **REVATIO (sildenafil citrate)**

### **Diagnosis of:**

- Pulmonary Arterial Hypertension (PAH)
- Concurrent therapy limited to any two agents at a time (TRACLEER, VENTAVIS, FLOLAN, REVATIO/VIAGRA, REMODULIN, or LETAIRIS)

**Duration:** 6 months – Limited to a quantity of 90 in 30 days

## **REVLIMID (lenalidomide)**

### **Diagnosis of:**

- MDS – Myelodysplastic Syndrome
- Multiple Myeloma (combination with dexamethasone, after at least one prior therapy – thalidomide)

**Duration:** 6 months

### **FDA Black Box Warning**

Teratogenic effects, hematologic toxicity (neutropenia and thrombocytopenia), DVT&PE

## **SIMPONI (golimumab)**

### **Diagnosis of:**

- Ankylosing Spondylitis
- Psoriatic Arthritis
- Rheumatoid Arthritis

### **For the treatment of:**

- Adults with moderately to severely active Rheumatoid Arthritis (RA) in combination with methotrexate and
- Therapeutic failure of adequate trial of at least one of the following:
  - PLAQUENIL (hydroxychloroquine)
  - SOLGANAL or RIDAURA (gold)
  - Methotrexate
  - IMURAN (azathioprine)
  - CUPRIMINE (penicillimine)
  - AZULFIDINE (sulfasalazine)
  - ARAVA (leflunomide)
- Usual dosing = 50mg subcutaneously monthly

**Duration:** 6 months

### **FDA Black Box Warning**

Serious infections (e.g., Tuberculosis, invasive fungal infections, and other opportunistic infections)



## **SPORANOX (itraconazole)**

### **Diagnosis of:**

- Histoplasmosis or blastomycosis infection
- Aspergillosis in patients who are intolerant of or refractory to amphotericin B therapy
- Febrile Neutropenia, empiric (oral solution)

**Duration:** 60 days

### **Diagnosis of:**

- Fingernail Onychomycosis  
**Duration:** 6-week course of therapy; one course per lifetime as documented by BCBSNM
- Toenail Onychomycosis  
**Duration:** 12-week course of therapy; one course per lifetime as documented by BCBSNM

**Exclusion:** Documentation of prior use of either SPORANOX or DIFLUCAN

### **FDA Black Box Warning**

CHF, numerous drug-drug interactions

## **SPRYCEL (dasatinib)**

### **Diagnosis of:**

- Chronic Myeloid Leukemia (CML)
- Acute Lymphoblastic Leukemia (ALL)

**Duration:** 6 months

## **SUTENT (sunitinib)**

### **Diagnosis of:**

- GI Stromal Tumor (GIST)
- Advanced Renal Cell Carcinoma (RCC)

**Duration:** 6 months

## **TARCEVA (erlotinib)**

### **Diagnosis of:**

- Non-Small Cell Lung Cancer (NSCLC)
- Pancreatic Cancer

**Duration:** 6 months



## **TAZORAC (tazarotene topical gel)**

### **Diagnosis of:**

- Psoriasis in patients age > 40 years
- Acne Vulgaris in patients age > 40 years
- Actinic Keratosis in patients age > 40 years

**Duration:** 12 months

## **TEMODAR (temozolomide)**

### **Diagnosis of:**

- Anaplastic Astrocytoma
- Glioblastoma Multiforme

**Duration:** 6 months

## **Testosterone (ANDROGEL, ANDRODERM, TESTIM, STRIANT, or TESTODERM)**

### **Diagnosis of:**

- Low serum testosterone in males **ONLY**
  - Documented lab results of serum levels below reference range
  - Restricted to males

**Duration:** 12 months

## **THALOMID (thalidomide)**

### **Diagnosis of:**

- Multiple Myeloma:
  - In combination with dexamethasone, for the treatment of patients with newly diagnosed Multiple Myeloma
- Erythema Nodosum Leprosum:
  - *Acute treatment:* Acute treatment of the cutaneous manifestations of moderate to severe Erythema Nodosum Leprosum. Not indicated as monotherapy for such Erythema Nodosum Leprosum treatment in the presence of moderate to severe Neuritis.
  - *Maintenance therapy:* For prevention and suppression of the cutaneous manifestations of Erythema Nodosum Leprosum recurrence.

### **Orphan Status:**

- Clinical manifestations of mycobacterial infection caused by Mycobacterium Tuberculosis and Non-Tuberculous Mycobacteria; Crohn's Disease; HIV-associated Wasting Syndrome; Kaposi Sarcoma; Lupus Erythematosus; Multiple Myeloma; Myelofibrosis with Myeloid Metaplasia; primary brain malignancies; treatment and maintenance of Reactional Lepromatous Leprosy; treatment and prevention of GVHD; treatment and recurrent Aphthous Stomatitis; treatment and prevention of recurrent Aphthous Ulcer in severely, terminally immunocompromised patients.

**Duration:** 6 months through STEPS

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## **THALOMID (thalidomide), *continued***

**Note:** *Thalidomide is approved for marketing only under a special restricted distribution program approved by the FDA called “System for Thalidomide Education and Prescribing Safety” (STEPS). Only program registered pharmacists and prescribers are allowed to possess and use the product.*

### **FDA Black Box Warning**

Teratogenic effects, DVT&PE

## **TRACLEER (bosentan)**

### **Diagnosis of:**

- Pulmonary Arterial Hypertension (PAH)
- Concurrent therapy limited to any two agents at a time (TRACLEER, VENTAVIS, FLOLAN, REVATIO/VIAGRA, REMODULIN, or LETAIRIS)

**Duration:** 6 months

### **FDA Black Box Warning**

Hepatotoxicity, teratogenic effects

## **TYKERB (lapatinib)**

### **Diagnosis of:**

- Advanced or metastatic Breast Cancer in combination therapy with capecitabine and
- Prior therapy including: anthracycline, taxane, or trastuzumab

**Duration:** 6 months

## **VENTAVIS (Iloprost)**

### **Diagnosis of:**

- Pulmonary Arterial Hypertension (PAH)
- Concurrent therapy limited to any two agents at a time (TRACLEER, VENTAVIS, FLOLAN, REVATIO/VIAGRA, REMODULIN, or LETAIRIS)

**Duration:** 6 months

## **VESANOID (tretinoin)**

### **Diagnosis of:**

- Acute Promyelocytic Leukemia (APL) – Induction of remission

**Duration:** 3 months (remission induction), 12 months (remission maintenance)

### **FDA Black Box Warning**

Retinoic Acid-APL Syndrome, Leukocytosis, teratogenic effects



## **VFEND (voriconazole)**

### **Diagnosis of:**

- Candidemia in non-neutropenic patients
- Esophageal Candidiasis after treatment failure to fluconazole
- Invasive Aspergillosis
- Serious infections caused by fusarium species or S. apiospermum

**Duration:** 1 month

## **WELLBUTRIN SR, WELLBUTRIN XL (bupropion)**

### **Diagnosis of:**

- Depression
- ADHD
- Seasonal Affective Disorder (WELLBUTRIN XL only)

**Duration:** 12 months

### **FDA Black Box Warning**

Suicidality in children, adolescents, and young adults

## **XELODA (capecitabine)**

### **Diagnosis of:**

- Colorectal Cancer
- Breast Cancer

**Duration:** 6 months

### **FDA Black Box Warning**

Capecitabine-warfarin drug interaction

## **XENAZINE (tetrabenazine)**

### **Diagnosis of:**

- Chorea associated with Huntington's Disease

### **Dosing considerations:**

- Maximum dose (adult): 25mg/dose, 100mg per day
- For CYP2D6 poor metabolizers: 25mg/dose, 50mg per day
- For CYP2D6 intermediate to extensive metabolizers: 37.5mg/dose, 100mg per day
- Dosing greater than 25mg per day should be divided into three equal doses

**Duration:** 6 months

### **FDA Black Box Warning**

Depression, suicidality



## **XOLAIR (omalizumab)**

### **Diagnosis of:**

- Severe, persistent Asthma – patient falls within recommended dosing guidelines with:
  - Age  $\geq$  12 years old and
  - Concurrent use of corticosteroid and current use of a long-acting beta 2 agonist and
  - Allergy testing – positive skin test to perennial aeroallergen and
  - Weight  $\leq$  150kg and
  - IgE serum levels  $\leq$  700iu and
  - FEV-1  $<$  80%

**Duration:** 6 months

### **FDA Black Box Warning**

Anaphylaxis, presenting as bronchospasm, hypotension, syncope, urticaria, etc.

## **ZAVESCA (miglustat)**

### **Diagnosis of:**

- Gaucher Disease

**Duration:** 12 months

## **ZOLINZA (vorinostat)**

### **Diagnosis of:**

- Cutaneous T-Cell Lymphoma (CTCL)

**Duration:** 6 months

## **ZYVOX (linezolid)**

### **Diagnosis of:**

- Vancomycin-resistant Enterococcus Faecium or Enterococcus Faecalis or
- Methicillin-resistant Staphylococcus Aureus or
- Methicillin-resistant Streptococcus Pyogenes or Streptococcus Agalactiae

**Duration:** Maximum duration of therapy is 14 days including inpatient therapy (max = 28 days)

**Note:** *Culture and sensitivities required.*



## Medications Requiring Prior Authorization – Primarily Considered a Medical Benefit

### AVASTIN (bevacizumab)

#### Diagnosis of:

- Metastatic Carcinoma of the colon or rectum
- Metastatic human epidermal growth factor receptor 2 (HER2) – negative breast cancer
- Glioblastoma
- Nonsquamous non-small cell lung cancer
- Wet macular degeneration

**Duration:** 6 months

#### **FDA Black Box Warning**

GI perforations, surgery and wound healing complications, hemorrhage

### BONIVA (ibandronate Sodium, IV Solution)

#### Diagnosis and prevention of:

- Documented Postmenopausal Osteoporosis
- Therapeutic failure of oral bisphosphonates (FOSAMAX, ACTONEL, BONIVA, MIACALCIN, EVISTA)

**Duration:** One IV infusion every 3 months for 12 months

### BOTOX (Botulinum A)

#### Diagnosis of:

- Strabismus
- Blepharospasm
- VII cranial (facial) nerve disorders
- Axillary Hyperhidrosis
- Cervical Dystonia
- Off-label indications for Spasticity or Dystonia resulting in functional impairment of joint function and/or pain in patients with the following 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

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### **BOTOX (Botulinum A), *continued***

- Spasmodic Torticollis
- Patients with Achalasia who:
  - Have not responded to dilatation therapy
  - Considered poor surgical candidates

**Duration:** One injection every 3 months as needed

### **DEGARELIX (degarelix acetate)**

#### **Diagnosis of:**

- Advanced prostate cancer

#### **Dosing considerations:**

- Initial dosing = 240mg
- Maintenance dosing = 80mg every 28 days
- Subcutaneous administration **ONLY** – NOT for IV administration

**Duration:** 6 months

### **Gamma globulin (IVIG, Gammar-IV)**

#### **Diagnosis of immunodeficiencies associated with:**

- Congenital Agammaglobulinemia or Hypogammaglobulinemia
- Wiskott-Aldrich Syndrome
- Idiopathic Thrombocytopenic Purpura (ITP)

#### **Prevention of:**

- Graft vs. host disease in bone marrow transplants

#### **Prevention of infection associated with:**

- HIV
- Bone marrow transplants
- B-Cell Chronic Lymphocytic Leukemia
- Refractory Dermatomyositis
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
- Guillain-Barre Syndrome
- Multifocal Motor Neuropathy with documented anti GM1 antibodies and conduction block
- Fetal Alloimmune Thrombocytopenia
- Kawasaki Syndrome

**Duration:** 6 months



## **RECLAST (zoledronic acid)**

### **Diagnosis and prevention of:**

- Osteoporosis in postmenopausal women
- Glucocorticoid-induced Osteoporosis (men and women)

### **Diagnosis of:**

- Osteoporosis in men
- Paget Disease (men and women)
- Therapeutic failure of oral bisphosphonates (FOSAMAX, ACTONEL, BONIVA, MIACALCIN, EVISTA)

**Duration:** The recommended treatment regimen is a single 5mg infusion once a year given IV. Re-treatment with zoledronic acid sooner than 12 months may be considered in patients who have relapsed, based on increases in serum alkaline phosphatase, or in those patients who failed to achieve normalization of their serum alkaline phosphatase, or in those patients with symptoms. The recommended prevention regimen is a single 5mg infusion IV every 24 months.

## **REMICADE (infliximab)**

### **Diagnosis of:**

- Moderate to severe Crohn's Disease, Fistulizing Crohn's, or Ulcerative Colitis –
- **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
- **Dosing considerations:** 5mg/kg IV over 6 weeks (initial, at 2 weeks and 6 weeks), then every 8 weeks thereafter.

### **Diagnosis of:**

- Moderate to severe Rheumatoid Arthritis, Ankylosing Spondylitis, or Psoriatic Arthritis
  - Significant joint involvement (12 tender or 10 swollen joints) and
  - Inadequate therapeutic response to methotrexate
- **Dosing considerations:** 3 mg/kg dose at zero, 2 and 6 weeks, every 8 weeks thereafter.

**Duration:** 6 months

### **FDA Black Box Warning**

Serious infections, Hepatosplenic T-Cell Lymphomas



## **RITUXAN (rituximab)**

### **Diagnosis of:**

- Non-Hodgkins Lymphoma
- Severe RA after failure on TNF therapy
- ITP with platelets < 50,000/dl

### **Dosing considerations:**

- Dose for most conditions: 375mg/m<sup>2</sup> x 4 doses
- Dose for RA: 1000mg every other week x 2 doses (send for review if additional doses are requested)

**Duration:** 1 series of infusion

### **FDA Black Box Warning**

Fatal infusion reactions, Tumor Lysis Syndrome, severe mucocutaneous reactions, Progressive Multifocal Leukoencephalopathy (PML)

## **SYNAGIS (palivizumab humanized monoclonal antibody)**

### **Prevention of RSV Disease:**

- Birth to age < 24 months at start of RSV season (i.e., November 1) with underlying risk factors:
  - Have not received a course of therapy the previous year and
  - Chronic Lung Disease (CLD) of prematurity requiring oxygen or pulmonary medications within six months prior to November 1
  - Hemodynamically significant Congenital Heart Disease (CHD)
  - Severe immunodeficiency or
- Birth to age < 12 months with gestational age less than equal to 28 weeks or
- Birth to age six months with gestational age of 29 to 32 weeks or
- Birth to age three months with gestational age of 32 to 35 weeks with one of the following two risk factors: child care attendance or sibling(s) younger than 5 years old

### **Dosing Considerations:**

- 15mg/kg IM monthly
- Usually 5 doses are sufficient to provide coverage for the infant into April
- Only 3 doses maximum recommended for children born at 32-35 weeks gestation. Administration of palivizumab is not recommended for these infants after they reach 90 days of age.

**Duration:** Approved for monthly injection through RSV season.

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



## **SYNVISC, HYALGAN, SUPARTZ, EUFLEXXA, or ORTHOVISC (sodium hyaluronate)**

### **Diagnosis of:**

- Osteoarthritis (DJD) of the knee(s) and
- Failure to respond adequately to:
  - Conservative non-pharmacologic therapy (e.g., lifestyle changes, physical therapy, etc.)
  - Simple analgesics (e.g., acetaminophen, NSAIDs, etc.)
  - Intra-articular corticosteroids

**Duration:** One course of therapy as listed below.

### **SYNVISC-ONE: single injection only**

<b>SYNVISC:</b>	3 weekly intra-articular injections
<b>HYALGAN:</b>	5 weekly intra-articular injections
<b>SUPARTZ:</b>	5 weekly intra-articular injections
<b>EUFLEXXA:</b>	3 weekly intra-articular injections
<b>ORTHOVISC:</b>	3–4 weekly intra-articular injections

**Note:** *Requests for retreatment will be considered after a review of member-related data that supports appropriate clinical efficacy and patient tolerability. A single course of therapy with any of the agents (SYNVISC, HYALGAN, SUPARTZ, EUFLEXXA, or ORTHOVISC) listed above should provide effective relief for at least 6 months. Efficacy may be defined as significant pain relief (e.g., documented reduction in oral APAP, NSAIDs, or controlled substance pain relievers), increase in physical activities, or improved ability to perform activities of daily living.*

## **ZOMETA (zoledronic acid)**

### **Diagnosis of:**

- Hypercalcemia of malignancy (HCM)  
Dosing consideration: Usually one treatment – 4mg IV over 15 minutes
- Osteolytic bone metastases  
Dosing consideration: 4mg IV infusion over 15 minutes every 3 to 4 weeks
- Osteolytic bone lesions of multiple myeloma  
Dosing consideration: 4mg IV infusion over 15 minutes every 3 to 4 weeks
- Osteoporosis – (see RECLAST)

**Duration:** 12 months

