BCBSNM Drug List Limitations, Exclusions, and Preauthorization Criteria

Blue Cross and Blue Shield of New Mexico

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 preauthorization criteria for most BCBSNM pharmacy plans.

Preauthorization criteria in this document applies to both Commercial and Medicaid lines of business, but slight differences in benefit exclusions and quantity limits may exist. Please refer to the BCBSNM Commercial and BlueSalud℠ Drug Lists posted on bcbsnm.com for additional information. We do our best to update this document on a regular basis, but not all drugs that require preauthorization may be listed. Because indications and dosing recommendations are subject to change, please consult the product package insert for the most current prescribing information.

Last revised May 2011.

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Rx = Rx benefit MED = Medical benefit ∅ = Not a covered benefit

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All Listed Medications Require Clinical Review

Key:

= Rx benefit
= Medical benefit
= Not a covered benefit

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

	Brand Name	Generic Name
Rx	ABSTRAL	fentanyl citrate
MED	ACTEMRA	toclizumab (BBW)
MED	ACTHAR HP	corticotropin
Rx	ACTIQ	fentanyl citrate
Rx	ADCIRCA	tadalafil
Rx	AFINITOR	everolimus
Rx	ALTINAC	tretinoin
Rx	AMPYRA	dalfampridine
Rx MED	ARANESP	darbepoetin
MED	AREDIA	pamidronate
Rx	ATRALIN	tretinoin
MED	AVASTIN	bevacizumab
Rx	AVITA	tretinoin
Rx	AVONEX	interferon Beta-1a
Rx	BETASERON	interferon Beta-1b
MED	BONIVA	ibandronate
MED	BOTOX	botulinum A
Rx	BYETTA	exenatide
Rx	CAYSTON	aztreonam
Rx	CELEBREX	celecoxib
Rx	CIMZIA	certolizumab pegol
MED	CINRYZE	C1 inhibitor
Rx	COPAXONE	glatiramer
MED	DEGARELIX	degarelix acetate
Rx	ENBREL	etanercept
Rx	Doxycycline and Minocycline BRANDED products (ADOXA, ALODOX, AVIDOXY, DORYX, MONODOX, ORACEA, ORAXYL, PERIOSTAT, VIBRAMYCIN, VIBRA-TABS, CLEERAVUE-M, DYNACIN, MINOCIN, MINOCIN PAC, SOLODYN)	
Rx	Enteral Feeding products **Note for BlueSalud:** Enteral feeding products may be covered if prior authorization criteria is met and are limited to a 30-day supply during any 30-day period. A copay will apply IF the member has a copay. (SCHIP, WDI).	
Rx MED	EPOGEN	epoetin alfa
Rx	EXALGO	hydromorphone extended release
Rx	EXJADE	degerasirox

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	Brand Name	Generic Name
Rx	EXTAVIA	interferon beta-1b
Rx	FENTORA	fentanyl citrate
MED	FLOLAN	epoprostenol sodium
Rx	FORTEO	teriparatide
Rx MED	G-CSF	filgrastim, pegfilgrastim
Rx	GILENYA	fingolimod
Rx	GLEEVEC	imatinib mesylate
Rx	Growth Hormones: ACCRETROPIN, GENOTROPIN, HUMATROPE, NORDITROPIN, NUTROPIN (AQ), NUTROPIN-DEPOT, OMNITROPE, PROTROPIN, SAIZEN, SEROSTIM, TEV-TROPIN, ZORBTIVE	somatropin
MED	HALAVEN	eribulin mesylate
MED	HERCEPTIN	trastuzumab
Rx	HEXALEN	altretamine
Rx	HUMIRA	adalimumab
MED	Immune Globulin Intravenous (IVIG)	immune globulin intravenous
Rx	INCRELEX	mecasermin
Rx	INFERGEN	interferon alfacon-1
Rx	IPLEX	mecasermin rinfabate
Rx	INTRON-A	interferon alfa 2b
MED	JEVTANA	cabazitaxel
Rx	KINERET	anakinra
MED	KRYSTEXXA	pegloticase
Rx	KUVAN	sapropterin dihydrochloride
Rx	LAMISIL	terbinafine
Rx	LETAIRIS	ambrisentan
MED	LEUKINE	sargramostim
Rx	LOTRONEX	alosetron hcl
MED	LUCENTIS	ranibizumab, pegaptanib sodium
Rx	LYSODREN	mitotane
MED	MACUGEN	ranibizumab, pegaptanib sodium
MED	MYOBLOC	botulinum toxin type b
Rx MED	NEULASTA	pegfilgrastim
Rx MED	NEUPOGEN	filgrastim
Rx	NEXAVAR	sorafenib
MED	NPLATE	romiplostim
Rx	ONSOLIS	fentanyl buccal soluble film
MED	ORENCIA	abatacept
MED	ORZUDEX	dexamethasone intravitreal inplant
Rx	PEGASYS	peginterferon alfa-2a and alfa 2b
Rx	PEG-INTRON	peginterferon alfa-2a and alfa 2b

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	Brand Name	Generic Name
Rx	PRADAXA	dabigatran
Rx MED	PROCRIT	epoetin alfa
MED	PROLEUKIN	aldesleukin
MED	PROLIA	denosumab
Rx	PROMACTA	eltrombopag
MED	PROVENGE	sipuleucel-T
Rx	PULMOZYME	dornase alfa
Rx	REBETOL	ribavirin
Rx	REBIF	interferon beta 1a
MED	RECLAST	zoledronic acid
MED	REMICADE	infliximab
Rx	RETIN-A	tretinoin
Rx	REVATIO	sildenafil citrate
Rx	REVLIMID	lenalidomide
Rx	RIBAPAK	ribavirin
Rx	RIBASPHERE	ribavirin
Rx	RIBATAB	ribavirin
MED	RITUXAN	rituximab
Rx	SANDOSTATIN	octreotide
Rx	SIMPONI	golimumab
Rx	SPORANOX	itraconazole
Rx	SPRYCEL	dasatinib
MED	STELARA	ustekinumab
Rx	SUTENT	sunitinib
Rx MED	SYNAGIS	palivizumab humanized monoclonal antibody
MED	SYNVISC, HYALGAN, SUPARTZ, EUFLEXXA, ORTHVISC	sodium hyaluronate
Rx	TARCEVA	erlotinib
Rx	TASIGNA	nilotinib
Rx	TAZORAC	tazarotene topical gel
Rx	TEMODAR	temozolomide
Rx	Testosterone: ANDRODERM, ANDROGEL, AXIRON, FORTESTA, STRIANT, TESTIM, TESTODERM	testosterone
Rx	THALOMID	thalidomide
MED	THYROGEN	thyrotropin alfa
Rx	TRACLEER	bosentan
Rx	TRETIN-X	tretinoin
Rx	TYKERB	lapatinib
MED	TYSABRI	natalizumab
Rx	TYVASO	treprostinil

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	Brand Name	Generic Name
MED	VECTIBIX	panitumumab
Rx	VENTAVIS	iloprost
Rx	VESANOID	tretinoin
Rx	VFEND	voriconazole
Rx	VICTOZA	liraglutide
Rx	VIVITROL	naltrexone
Rx	WELLBUTRIN SR and XL	bupropion
Rx	XELODA	capecitabine
Rx	XENAZINE	tetrabenazine
MED	XGEVA	denosumab
MED	XIAFLEX	collagenase clostridium histolyticum
Rx	XIFAXAN	rifaximin
Rx	XOLAIR	omalizumab
Rx	XYREM	sodium oxybate
Rx	ZAVESCA	miglustat
Rx	ZOLINZA	vorinostat
MED	ZOMETA	zoledronic acid
Rx	ZORTRESS	everolimus
Rx	ZYVOX	linezolid

Drug List Limitations

BCBSNM prescription drug benefit provides coverage for most drugs for our members. It is important to know and effectively communicate plan specific drug limitations so that benefit administration is consistent and customer satisfaction is maintained. The following limitations apply to most prescription benefits:

- **3-Tier and 4-Tier Prescription Drug Plans** – Includes a 30-day supply or 120 units, whichever is less per copay at retail pharmacies; or a 90-day supply or 360 units, whichever is less per copay at mail-order
- **25/50 Percent Prescription Drug Plan** – Includes a 30-day supply or 180 units, whichever is less at retail pharmacies; or a 90-day supply or 540 units, whichever is less per copay 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 4th tier benefit. Please refer to the 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 preauthorization. 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:

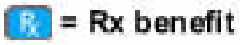
  • The use of generic cholesterol lowering drugs (simvastatin, lovastatin, pravastatin) before the branded drug products (LIPITOR, LESCOL, CRESTOR)

  • 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, brand PROTONIX, PREVACID. DEXILANT)

  • The use of a preferred blood glucose test strip (ACCU-CHEK, CONTOUR, OR BREEZE) before other brands of test strips

  For a complete list of Step Therapy medications, see the Drug List.
- **Quantity Limits** – Specific drug quantity limits are identified in the preface of the Drug List for both BCBSNM Commercial and BlueSalud (Medicaid) plans. Requests for larger quantities are to be referred to Health Services for review.



Drug List Exclusions

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

Drug Class	Representative Drugs in Class	BCBSNM Commercial Benefit Coverage	BCBSNM BlueSalud Benefit Coverage
Ø **Drugs used for smoking cessation:**	• ZYBAN • Nicotine, COMMIT, NICORETTE, and NICORETTE DS gum • HABITROL patch • NICODERM patch • NICOTROL patch, inhaler, and spray • Bupropion, WELLBUTRIN (Also used for depression – see Step Therapy Criteria) • CHANTIX	Covered for some plans; preauthorization is required for plans covering smoking cessation programs	Covered IF preauthorization criteria is met Two 90-day courses per calendar year
Ø **Drugs used for weight loss:**	• Phentermine, IONAMIN, ADIPEX-P, or PRO-FAST (SA, HS, SR) • Benzphetamine, DIDREX • Phendimetrazine, BONTRIL (PDM, SR), MELFIAT-105, PRELU-2 • Diethylpropion • XENICAL, ALLI (OTC) (orlistat)	Excluded	Excluded
Ø **Drugs used to treat erectile dysfunction:**	• VIAGRA • Alprostadil, MUSE, EDEX, CAVERJECT • LEVITRA • CIALIS	Excluded	Excluded
Ø **Drugs 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	Excluded	Excluded

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Drug Class	Representative Drugs in Class	BCBSNM Commercial Benefit Coverage	BCBSNM BlueSalud Benefit Coverage
Ø **Drugs to treat hair loss:**	• PROPECIA (Finasteride) • ROGAINE (monoxadil)	Excluded	Excluded
Ø **Drugs considered cosmetic:**	• Tretinoin, RENOVA, RETIN-A, ALTINAC • VANIQA (eflornithine) • Hydroquinone (various) • EGRIFTA (tesamorelin)	Excluded	Excluded
Ø **Drugs for international travel:**	• LARIUM/mefloquine • MALARONE (no generic • VIVOTIF BERNA (no generic)	Excluded	Excluded
Ø **Drugs for behavioral health:**	• Various	Covered	Prescriptions written by a behavorial health provider for BlueSalud members are covered by OptumHealth℠, a contracted behavioral health provider. BCBSNM does not cover prescriptions written for BlueSalud members by behavioral health providers.
Ø **Nonformulary drugs:**	• Various	Covered at 3rd tier copay and/or if preauthorization criteria is met	Preauthorization required
Ø **Compounded medications:**	• Various	Not covered for most plans	BCBSNM covers prescriptions written for traditional compounded drugs (medications with at least one ingredient that is a prescription drug) for BlueSalud members. BCBSNM does NOT cover compounds that contain drugs or combinations of drugs that have not been approved by the FDA.
Ø **Drugs considered investigational:**	• Various	Excluded	Excluded

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Drug Preauthorization

Requests for drug preauthorization are to be directed to Health Services. Changes to the list are published in the *Blue Review* provider newsletter and BCBSNM website (www.bcbsnm.com).

Current BCBSNM Medical Policy regarding "off-label use of FDA approved drugs" as prescribed by a physician to treat chronic, disabling, or life-threatening illnesses **may be considered medically necessary** when supported by robust clinical research that appears in peer-reviewed literature and is recognized by standard reference compendia specific for the indication in question.

New medications often will not have criteria developed. Available literature is frequently limited; therefore, coverage will be **restricted to approved FDA indications only. All requests for off-label use must be forwarded to the Pharmacy Department for review.**

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

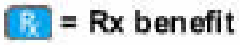
- Drug must have been approved by the FDA for at least one indication
- Must be prescribed by a participating licensed health care provider within his/her scope of practice
- With most benefits, drugs in clinical phase I or II trials are considered investigational/experimental and therefore not a covered benefit

Note: Not all medications requiring preauthorization may appear on the list. Many plans have "global" restrictions on such things as injectable products. Refer these types of requests to Health Services.

BlueSalud follows the same preauthorization criteria except as noted for smoking cessation, weight loss, and enteral feeding products.

Please 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 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 Preauthorization – Primarily Acquired at Retail Pharmacies

ACTIQ transmucosal (fentanyl citrate), FENTORA buccal tablet (fentanyl citrate), ONSOLIS (fentanyl buccal soluble film), OR ABSTRAL sublingual tablet (fentanyl citrate)

Treatment of:

- Breakthrough pain control for oncology patients **ONLY**
- Tolerant of opoid therapy
- Prescribed by either oncologist or pain management specialist

Maximum Daily Dose: 4 units per day

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

ADCIRCA (tadalafil)

Diagnosis of:

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

Usual Dose: 40mg (two 20mg tablets) once daily. Dividing the dose over the course of the day is NOT recommended.

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

AFINITOR, ZORTRESS (everolimus)

Diagnosis of:

- **Advanced renal cell Carcinoma (AFINITOR only):** For the treatment of patients with advanced renal cell carcinoma after failure of treatment with sunitinib (SUTENT) or sorafenib (NEXAVAR)
- **Subependymal giant cell Astrocytoma (SEGA) (AFINITOR only):** Associated with Tuberous Sclerosis (TS)
- **Renal transplantation (ZORTRESS only):** For the prophylaxis of organ rejection in adult patients at low to moderate immunologic risk receiving a kidney transplant.

Dosing considerations:

- **Usual dose:**

  AFFINITOR: 10mg once daily

  ZORTRESS: *Initial dose:* 0.75mg twice daily; *Maintenance dose:* titrate to serum target

- 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 initial, then 12 months thereafter if no change in dosing

FDA Black Box Warning

Immunosuppression, renal function, and graft thrombosis (Zortress only):
Increased susceptibility to infection and the possible development of malignancies, such as lymphoma and skin cancer, may result from immunosuppression.

AMPYRA (dalfampridine)

Diagnosis of:

- Multiple Sclerosis with documentation that patient is ambulatory
- Prescriber is a neurologist or has consulted a neurologist
- Baseline walking speed must be provided (using the 25-foot walk test, with a timed speed between 8 and 60 seconds). Re-authorizations will require documentation that walking speed (using the 25-foot walk test) has improved at least 20% from baseline.
- Contraindicated in patients with a history of seizure or moderate-severe renal impairment (CrCl less than 50mL/min)

Usual Dose: 10mg twice daily. No additional benefit was demonstrated at doses greater than 10mg twice daily and adverse reactions and discontinuations because adverse events were more frequent at higher doses.

Duration: Initial request: 3 months; Renewal: 12 months only with documented 20% improvement in walking speed

AVONEX (interferon beta-1a), BETASERON (interferon beta-1b), COPAXONE (glatiramer), EXTAVIA (interferon beta-1b), or REBIF (interferon beta-1a)

Diagnosis of:

- Relapsing, Remitting Multiple Sclerosis (RRMS only)

Usual Dose:

- **AVONEX:** 30mcg IM once weekly (pkg of 4 pre-filled syringes)
- **BETASERON:** 0.25mg SQ every other day; titrated from 0.0625mg QOD to 0.25mg QOD over a 6-week period
- **COPAXONE:** 20mg SQ once daily (pkg of 30 pre-filled syringes)
- **EXTAVIA:** 0.25mg SQ every other day; titrated from 0.0625mg QOD to 0.25mg QOD over a 6-week period (pkg of 15 "blister units," each containing a single use lyophilized powder vial, pre-filled diluent syringe, alcohol prep pads, vial adapter with needle)
- **REBIF:** 22mcg or 44mcg SQ 3 times weekly (pkg of 12 pre-filled syringes)

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

BYETTA (exenatide)

Diagnosis of:

- Type 2 Diabetes AND
- Monotherapy or adjunct therapy with a thiazolidinedione (TZD), metformin, sulfonylureas, and/or Lantus/Levemir but have not achieved adequate glycemic control (A1C>7)
- Metformin is recommended as first-line therapy

Usual Dose: Initiate at 5mcg twice daily; increase to 10mcg twice daily after 1 month based on response

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

Note: Exenatide is not a substitute for insulin. Exenatide should not be used in patients with Type 1 Diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings. The concurrent use of exenatide with short-acting insulin has not been studied and cannot be recommended.

CAYSTON (aztreonam)

Diagnosis of:

- Cystic Fibrosis in patients with documented evidence of colonization with Pseudomonas Aeruginosa
- Indicated for use in patients 7 years of age and older with FEV-1 of 25% to 75% predicted
- Must be administered ONLY with the Altera® Nebulizer System
- Treatment must be preceeded by use of an inhaled beta-agonist
- NOT for use in combination with TOBI; If alternating with TOBI, send to Pharmacy Manager for review

Usual Dose: One inhaled dose (1 single-use vial and 1 ampule of diluent) 3 times daily for 28 days (followed by 28 days off Cayston therapy)

Duration: 6 months

CELEBREX (celecoxib) – Step Therapy Criteria

Approved Diagnosis of:

- Osteoarthritis
- Rheumatoid Arthritis
- Juvenile Rheumatoid arthritis in patients 2 years of age and older
- Ankylosing Spondylitis
- Acute pain
- Primary Dysmenorrhea

and one of the following:

- Age 50 years old or greater
- 30-day trial of 1 generic NSAID in the last 180 days
- Past history of GI bleed
- Concomitant use of oral corticosteroids
- Concomitant use of anticoagulant use (e.g., warfarin) or
- Familial Adenomatous Polyposis (adjunct to usual care)

Usual Dose: 100mg to 400mg once or twice daily, according to diagnosis

Duration: 12 months

FDA Black Box Warning
Cardiovascular, gastrointestinal

CIMZIA (certolizumab pegol)

Diagnosis of:

- Crohn's Disease AND prior failure/intolerance/contraindication to conventional therapy (oral aminosalicylates, topical mesalamine, oral corticosteroids, or immunomodulators, such as azathioprine or cyclosporine)
- **Usual Dose for Crohn's Disease:** 400mg (two 200mg SQ doses) at weeks 0, 2, 4, followed by 400mg every 4 weeks

Diagnosis of:

- Rheumatoid Arthritis AND prior failure/intolerance/contraindication with at least 1 DMARD (such as methotrexate)
- **Usual Dose for Rheumatoid Arthritis:** 400mg (two 200mg SQ doses) at weeks 0, 2, 4, followed by 200mg every other week (400mg every 4 weeks can be considered for maintenance dosing)

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

Note: Initial dose may be billed through the Medical benefit, but subsequent doses should be routed through the Pharmacy benefit

Note: HUMIRA is the preferred product in this class.

FDA Black Box Warning
Risk of serious infection, risk of malignancies in children and adolescents

Doxycycline and Minocycline BRANDED products (ADOXA, ALODOX, AVIDOXY, DORYX, MONODOX, ORACEA, ORAXYL, PERIOSTAT, VIBRAMYCIN, VIBRA-TABS, CLEERAVUE-M, DYNACIN, MINOCIN, MINOCIN PAC, SOLODYN)

Diagnosis of:

- Moderate to severe Acne Vulgaris
- Therapeutic failure of oral generic formulary alternatives (regular-release minocycline, tetracycline, doxycycline, demeclocycline)

Usual Dose: Varies by product

Duration: 3 months ONLY

ENBREL (etanercept)

Diagnosis of:

- Moderate to severe Rheumatoid Arthritis (RA), Polyarticular Juvenile Idiopathic Arthritis in patients 2 years of age and older, Psoriatic Arthritis
- Ankylosing Spondylitis: trial/failure of 2 NSAIDs after 3 months use of each
- Moderate to severe chronic Plaque Psoriasis by rheumatologist and history of topical steroids AND methotrexate, cyclosporine, oral retinoids, OR UVB/PUVA and affected BSA>10% 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 Dose – Rheumatoid and Psoriatic Arthritis: 50mg once weekly (with or without methotrexate)

Usual Dose – Polyarticular Juvenile Idiopathic Arthritis: 0.8mg/kg weekly to a maximum of 50mg per week

Usual Dose – Psoriasis: 50mg twice weekly for 3 months, then 50mg once weekly

Usual Dose – Ankylosing Spondylitis: 50mg once weekly

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

Note: HUMIRA is the preferred product in this class.

FDA Black Box Warning
Risk of serious infections; risk of malignancies in children and adolescents

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%.)

For BlueSalud members: Enteral feeding products may be covered IF preauthorization criteria are met.

Duration: 12 months

EXALGO (hydromorphone extended release)

Diagnosis of :

- Moderate to severe pain in opioid-tolerant patients requiring continuous analgesia for an extended period of time
- Have failed or are intolerant of previous preferred long-acting narcotic analgesics (such as morphine sulfate ER, methadone, or fentanyl patch)

Usual Dose: 8–64mg once daily

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

FDA Black Box Warning
For use in opioid-tolerant patients ONLY

EXJADE (deferasirox)

Diagnosis of:

- Chronic iron overload due to blood transfusions

Usual Dose: Weight-based; 20mg/kg once daily

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

FDA Black Box Warning
Hepatic or renal failure; gastrointestinal hemorrhage

FORTEO (teriparatide)

Diagnosis of:

- Osteoporosis in postmenopausal women who are at high risk for fracture (defined as a T-score that -2.5 or lower). This includes women with a history of osteoporotic fracture, or who have multiple risk factors for fracture.
- 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
- Glucocorticoid-induced Osteoporosis in men and women at high risk for fracture
- Have failed or are intolerant of previous osteoporosis therapy (FOSAMAX, ACTONEL, BONIVA, SKELID, EVISTA, MIACALCIN)

Usual Dose: 20mcg SQ once daily

Duration: 12 months; maximum therapy of 24 months

FDA Black Box Warning
Potential risk of osteosarcoma

GILENYA (fingolimod)

Diagnosis of:

- Relapsing Multiple Sclerosis and prior use of a biological product (AVONEX, REBIF, BETASERON, or EXTAVIA) or COPAXONE

Usual Dose: 0.5mg orally once daily

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

GLEEVEC (imatinib mesylate)

Diagnosis of:

- Philadelphia Chromosome positive Chronic Myeloid Leukemia (CML)
- 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

Usual Dose: Varies according to diagnosis, but generally 100-800mg daily

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

Growth Hormones – PROTROPIN (somatrem), HUMATROPE, GENOTROPIN, NORDITROPIN, NUTROPIN (AQ), NUTROPIN-DEPOT, OMNITROPE, SAIZEN, SEROSTIM, TEV-TROPIN, ZORBTIVE
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

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Growth Hormones, cont.

- 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)
  - 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 somatropin is started. Approximate physiologic dose 10mcg/kg/day.
- Turner's Syndrome
- Children with Chronic Renal Insufficiency
- AIDS wasting or Cachexia
- Short Stature Homeobox (SHOX)–containing gene deficiency (HUMATROPE); for the treatment of short stature or growth failure in children with SHOX deficiency whose epiphyses are not closed
- Full-thickness skin loss associated with third degree burn NOS
- Prader-Willi Syndrome (FDA approved for GENOTROPIN)
- Growth failure associated with Noonan Syndrome (NORDITROPIN)
- Short Bowel Syndrome (ZORBTIVE)

Usual Dose: Weight-based, according to diagnosis

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 that 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.

Usual Dose: 260mg/m2/day, based upon body surface area (BSA)

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

FDA Black Box Warning
Neurotoxicity, hematological toxicity

HUMIRA (adalimumab)

Diagnosis by rheumatologist of moderate to severe:

- Rheumatoid Arthritis
- Ankylosing Spondylitis
- 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)
- Or moderate to severe chronic Plaque Psoriasis (affected BSA > 10%), confirmed by a rheumatologist, and history of use of topical steroids AND methotrexate, cyclosporine, oral retinoids, or UVB/PUVA.
- Or moderate to severe Crohn's Disease (confirmed by a gastroenterologist) and prior failure/intolerance/contraindication to conventional therapy (oral aminosalicylates, topical mesalamine, oral corticosteroids, or immunomodulators, such as azathioprine or cyclosporine)

Usual Dose: Varies according to diagnosis, but limited to 2 doses per month (every other week). Requests for weekly dosing should be referred to the Pharmacy Manager for review.

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

Note: HUMIRA is the preferred product in this class.

FDA Black Box Warning
Serious infections (e.g., Tuberculosis, invasive fungal infections, other opportunistic infections)

INCRELEX (mecasermin) or IPLEX (mecasermin rinfabate)

Diagnosis of:

- Insulin-like Growth Factor Deficiency (IGFD)

Usual Dose: Weight-based; maximum dose is 0.12mg/kg twice daily

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

INFERGEN (interferon alfacon-1)

Diagnosis of:

- Chronic Hepatitis C (non A, non B)

Usual Dose:

- **Monotherapy:** 9mcg 3 times weekly for 24 weeks (as initial treatment), or 15mcg 3 times weekly for up to 48 weeks (as re-treatment)
- **Combination Therapy:** 15mcg daily with ribavirin for 48 weeks (as re-treatment)

Note: *Must be 18 years of age and older.*

Duration: 6 months initial, then 12 months thereafter if no change in dosing; maximum therapy 2 years for Hepatitis C

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) with compensated liver disease and history of blood product exposure
- Chronic Hepatitis B, serum HBe Ag positive (1 year of age or older for this diagnosis only)
- Condylomata Acuminata involving external surfaces of the genital or perianal area
- Chronic Myelogenous Leukemia (CML) – Philadelphia chromosome-positive
- Non-Hodgkin's Lymphoma (clinically aggressive follicular NHL)
- Malignant Melanoma

Note: *Must be 18 years of age and older.*

Usual Dose: Varies according to diagnosis

Duration: 6 months initial, then 12 months thereafter if no change in dosing; maximum therapy 2 years for Hepatitis C

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)

Usual Dose: 100mg/day SQ

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

KUVAN (sapropterin dihydrochloride)

Note: Refer all requests for Kuvan to a pharmacist for review

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
- Tinea Capitis (only oral granules indicated for this diagnosis)
  Duration: 6-week course of therapy for the treatment of Tinea Capitis in patients 4 years of age and older

Usual Dose: 250mg once daily

Note: For treatment of onychomycosis, LAMISIL will not be approved if there is documentation of prior use of either SPORANOX or DIFLUCAN

LETAIRIS (ambrisentan)

Diagnosis of:

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

Usual Dose: Initiate at 5mg once daily; may be increased to 10mg once daily if tolerated. Doses higher than 10mg once daily have not been studied in patients with Pulmonary Arterial Hypertension.

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

FDA Black Box Warning

Serious risk of birth defects - contraindicated in pregnancy

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)

Usual Dose: Initiate at 0.5mg twice daily; may be increased to 1mg twice daily after 4 weeks if tolerated

Note: Discontinue Lotronex in patients who have not had adequate control of IBS symptoms after 4 weeks of treatment with 1mg twice daily.

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

FDA Black Box Warning

Gastrointestinal

LYSODREN (mitotane)

Diagnosis of:

- Inoperable Adrenal Cortical Carcinoma

Maximum Dose: 16gm per day

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

NEXAVAR (sorafenib)

Diagnosis of:

- Advanced Renal Cell Carcinoma
- Unresectable Hepatocellular Carcinoma

Usual Dose: 400mg (2 tablets) twice daily

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

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

Usual Dose:

Pegasys: 180mcg once weekly

Peg-Intron: 1.5mcg/kg/week (Adult); 60mgc/m^2/week (Pediatric)

Duration: 6 months initial, then 12 months (2 year maximum)

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

FDA Black Box Warning
Fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders

PRADAXA (dabigatran)

Diagnosis of:

- Reduction of risk of Stroke and Systemic Embolism in patients with Non-Valvular Atrial Fibrillation (a-fib)

Usual Dose: 150mg twice daily (75mg twice daily – Creatinine Clearance 15-30ml/min)

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

Note: Refer requests for off-label indications to a pharmacist for review

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 initial, then 12 months thereafter if no change in dosing

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

Usual Dose: 2.5mg once daily dosing only

Duration: 12 months

REBETOL, RIBAPAK, RIBASPHERE, RIBATAB (ribavirin)

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
  - Patient is 3 years of age or older
  - Product will be used IN COMBINATION with interferon alfa-2b (pegylated or non-pegylated)

Usual Dose: Weight-based

Duration: 6 months initial, then 12 months (2 year maximum)

Note: *Diagnosis must be confirmed by gastroenterologist. Will not be approved in patients with decompensated cirrhosis. Refer to medical director for use during pregnancy.*

FDA Black Box Warning
Hemolytic Anemia, significant teratogenic and/or embryocidal effects

RETIN-A, AVITA, or ALTINAC, ATRALIN, TRETIN-X (tretinoin) (RENOVA is not a covered benefit)

Diagnosis of:

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

Usual Dose: Apply once daily at bedtime

Duration: 12 months

Please Note: RENOVA is not a covered benefit since it is only indicated for cosmetic purposes.

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 (LETAIRIS, FLOLAN, REVATIO/VIAGRA/ADCIRCA, TRACLEER, TYVASO, or VENTAVIS)

Usual and Maximum Daily Dose: 20mg TID

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

REVLIMID (lenalidomide)

Diagnosis of:

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

Usual Dose – MDS: 10mg once daily

Usual Dose – Multiple Myeloma: 25mg once daily on days 1-21 of repeated 28-day cycles

Duration: 6 months, acquired through FDA approved restricted distribution program – REVASSIST

FDA Black Box Warning
Teratogenic effects, hematologic toxicity (neutropenia and thrombocytopenia), DVT&PE

SANDOSTATIN (octreotide)

Diagnosis of:

- Acromegaly
- Metastatic Carcinoid Tumor with severe diarrhea/flushing episodes
- Vasoactive Intestinal Peptide Tumors (VIPomas) with profuse watery diarrhea

Usual Dose: Varies according to diagnosis

Duration: 3 months initial, then 6 months thereafter

Note: Refer requests for off-label indications to a pharmacist for review

SIMPONI (golimumab)

Diagnosis of:

- Ankylosing Spondylitis
- Psoriatic Arthritis – alone or in combination with methotrexate
- Rheumatoid Arthritis (RA) – moderate to severe in combination with methotrexate

For the treatment of:

- Adults with moderately to severely active 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 Dose: 50mg subcutaneously once monthly

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

Note: Simponi is intended for use under the guidance and supervision of a health care provider. After proper training, a patient may self-inject if a health care provider determines that it is appropriate.

Note: HUMIRA is the preferred product in this class.

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

  Duration: 3 months

Diagnosis of:

- Empiric antifungal therapy in patients with Febrile Neutropenia
  Duration: 1 month

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

Usual Dose: Varies according to diagnosis, but generally 200–400mg daily

Note: For treatment of onychomycosis, SPORANOX will not be approved if there is documentation of prior use of either LAMISIL or DIFLUCAN

FDA Black Box Warning
CHF, numerous drug-drug interactions

SPRYCEL (dasatinib)

Diagnosis of:

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

Usual Dose – Chronic phase: 100mg once daily

Usual Dose – Accelerated phase or myeloid/lymphoid blast phase: 140mg once daily

Usual Dose – Acute Lymphoblastic Leukemia: 140mg once daily

Duration: 6 months

SUTENT (sunitinib)

Diagnosis of:

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

Usual Dose: 50mg once daily (4 weeks of treatment followed by 2 weeks off)

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

FDA Black Box Warning

Hepatotoxicity

TARCEVA (erlotinib)

Diagnosis of:

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

Usual Dose – NSCLC: 150mg once daily

Usual Dose – Pancreatic Cancer: 100mg once daily

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

TASIGNA (nilotinib)

Diagnosis of:

- Resistant or tolerant Chronic Myelogenous Leukemia (CML)
- Newly diagnosed Philadelphia chromosome–positive CML

Usual Dose – Resistant or intolerant CML: 400mg twice daily

Usual Dose – Newly diagnosed CML: 300mg twice daily

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

FDA Black Box Warning

QT prolongation and sudden deaths

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

Usual Dose: Apply once daily

Duration: 12 months

TEMODAR (temozolomide)

Diagnosis of:

- Anaplastic Astrocytoma
- Glioblastoma Multiforme

Usual Dose: Contact Pharmacy Manager for dosing considerations or questions

Duration: 6 months initial, then 12 months thereafter if no change in dosing; contact Pharmacy Manager for dosing considerations or questions

Testosterone (ANDROGEL, ANDRODERM, AXIRON, FORTESTA,TESTIM, STRIANT, or TESTODERM)

Diagnosis of:

- Low serum testosterone in males **ONLY**
  - Documented lab results of serum levels below 300ng/dL total testosterone
  - Restricted to males

Usual Dose: Varies according to diagnosis and patient response

Duration: 12 months

FDA Black Box Warning
Secondary exposure risk (Testosterone Gel and Solution ONLY)

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.

Usual Dose: Varies according to diagnosis and patient response

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

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 (LETAIRIS, FLOLAN, REVATIO/VIAGRA/ADCIRCA, TRACLEER, TYVASO, VENTAVIS)

Usual Dose: Initiate at 62.5mg twice daily; increase to a maximum of 125mg twice daily

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

FDA Black Box Warning
Hepatotoxicity, teratogenic effects

TYKERB (lapatinib)

Diagnosis of:

- Hormone-positive and HER-2 positive Advanced or metastatic Breast Cancer
- Combination therapy with capecitabine and
- Prior therapy including an anthracycline, taxane, or trastuzumab **-OR-**
- Combination therapy with letrozole when hormonal therapy is indicated

Usual Dose: Varies according to diagnosis and patient response

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

FDA Black Box Warning
Hepatotoxicity

TYVASO (treprostinil) inhalation solution

Diagnosis of:

- Documented pulmonary arterial hypertension with NYHA (New York Heart Association) Class III symptoms (marked limitation of physical activity; comfortable at rest)
- Concurrent therapy limited to any two agents at a time (LETAIRIS, FLOLAN, REVATIO/VIAGRA/ADCIRCA, TRACLEER, TYVASO, VENTAVIS)

Usual Dose: 4 separate treatment sessions daily, approximately 4 hours apart, during waking hours

- *Initial:* 3 breaths per treatment session
- *Titration:* Increase by an additional 3 breaths at approximately 1-2 week intervals (if tolerated)
- *Maintenance:* Target is 9 breaths per treatment session (as tolerated) 4 times daily

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

VENTAVIS (Iloprost)

Diagnosis of:

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

Maximum Dose: 5mcg 9 times daily

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

VESANOID (tretinoin)

Diagnosis of:

- Acute Promyelocytic Leukemia (APL) – Induction of remission

Usual Dose: 45mg/m^2/day based upon body surface area (BSA)

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

Usual Dose: Varies according to diagnosis, but generally 100–300mg every 12 hours

Duration: 1 month

VICTOZA (liraglutide)

Diagnosis of:

- Monotherapy or adjunct therapy with a thiazolidinedione (TZD), metformin, sulfonylureas, and/or Lantus/Levemir but have not achieved adequate glycemic control (A1C>7)
- Metformin recommended as first-line therapy
- Preferred product in this class is BYETTA

Usual Dose: Administer once daily

- *Initial:* 0.6mg daily for 1 week (to decrease GI symptoms during titration) and increase to 1.2mg daily after 1 week
- *Maximum Dose:* If the 1.2mg dose does not produce acceptable glycemic control, the dose may be increased to 1.8mg daily

Duration: 12 months

Note: Victoza is not a substitute for insulin. Victoza should not be used in patients with Type 1 Diabetes or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings. The concurrent use of Victoza with short-acting insulin has not been studied and cannot be recommended.

VIVITROL (naltrexone for extended-release injectable suspension)

Diagnosis of:

- Treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment with Vivitrol
- Prevention of relapse to opioid dependence, following opioid detoxification

Note: Patients should not be actively drinking or using opioids at the time of initial administration.

Usual Dose: 380mg IM every 4 weeks (once monthly). Should be administered by a healthcare professional as an IM gluteal injection.

Duration: 6 months initially, may be extended by an additional 6 months.

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

FDA Black Box Warning

Hepatotoxicity

WELLBUTRIN SR, WELLBUTRIN XL (bupropion)

Diagnosis of:

- Depression or Attention Deficit Hyperactivity Disorder (ADHD) as evidenced by:
  - Past trials of other medication used in the treatment of depression or ADHD
  - Has documented depression work up or psychiatric referral
- Seasonal Affective Disorder (SAD) (WELLBUTRIN XL only)

Usual Dose – SR: Varies according to diagnosis, but maximum recommended dose is 200mg twice daily

Usual Dose – XL: 450mg is maximum recommended dose

Duration: 12 months

FDA Black Box Warning

Suicidality in children, adolescents, and young adults

XELODA (capecitabine)

Diagnosis of:

- Colorectal Cancer
- Breast Cancer
- Gastric Cancer
- Esophageal Cancer

Usual Dose: Varies according to diagnosis; based upon body surface area (BSA)

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

FDA Black Box Warning

Capecitabine-warfarin drug interaction

XENAZINE (tetrabenazine)

Diagnosis of:

- Chorea associated with Huntington's Disease

Dosing considerations:

- 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
- Maximum dose (adult): 25mg/dose, 100mg per day

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

FDA Black Box Warning

Depression, suicidality

XIFAXAN (rifaximin)

Diagnosis of:

- Hepatic Encephalopathy: For reduction in risk of overt Hepatic Encephalopathy recurrence in patients 18 years of age and older.
- Traveler's Diarrhea: For the treatment of patients 12 years of age and older with Traveler's Diarrhea caused by noninvasive strains of Escherichia coli. Do not use rifaximin tablets in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than E. coli.

Note: Off-label indications (e.g., IBS, clostridium difficile diarrhea, etc.) should be referred to the pharmacy director for clinical review.

Usual Dose: Varies according to diagnosis; FDA-approved uses:

- Hepatic Encephalopathy: 550mg 2 times a day
- Traveler's Diarrhea: 200mg 3 times a day for 3 days

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

XOLAIR (omalizumab)

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 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.

= Rx benefit = Medical benefit = Not a covered benefit

XYREM (sodium oxybate)

Diagnosis of:

- Narcolepsy with symptoms of excessive daytime sleepiness and cataplexy

Usual Dose:

- *Initial:* 4.5gm/night, divided into 2 equal doses of 2.25gm
- *Maximum:* 9gm/night

Note: Xyrem is available through the Xyrem Success Program, using a centralized pharmacy

Duration: 3 months

FDA Black Box Warning
Central Nervous System Depressant with Abuse Potential

ZAVESCA (miglustat)

Diagnosis of:

- Gaucher Disease

Usual Dose: 100mg 3 times daily

Duration: 12 months

ZOLINZA (vorinostat)

Diagnosis of:

- Cutaneous T-Cell Lymphoma (CTCL)

Usual Dose: 400mg once daily

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

ZYVOX (linezolid)

Diagnosis of:

- Vancomycin-resistant Enterococcus Faecium or Enterococcus Faecalis
  Duration: 28 days
- Methicillin-resistant Staphylococcus Aureus or
- Methicillin-resistant Streptococcus Pyogenes or Streptococcus Agalactiae
  Duration: 14 days

Usual Dose: Varies according to diagnosis, but generally 400–600mg every 12 hours

Note: *Culture and sensitivities required.*

= Rx benefit = Medical benefit = Not a covered benefit

Medications Requiring Preathorization – Primarily Considered a Medical Benefit

All Listed Medications Require Clinical Review

MED ACTHAR HP (corticotropin)

Diagnosis of:

- **Conditions responsive to corticosteroids**
- **Endocrine disorders:** Nonsuppurative thyroiditis; hypercalcemia associated with cancer
- **Nervous system diseases:** Acute exacerbations of multiple sclerosis
- **Rheumatic disorders:** As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in the following: Psoriatic Arthritis; Rheumatoid Arthritis, including Juvenile Rheumatoid Arthritis (selected cases may require low-dose maintenance therapy); Ankylosing Spondylitis; acute and subacute Bursitis; acute nonspecific Tenosynovitis; Acute Gouty Arthritis; Posttraumatic Arthritis; Synovitis of Osteoarthritis; Epicondylitis
- **Collagen diseases:** During an exacerbation or as maintenance therapy in selected cases of the following: Systemic Lupus Erythematosus; Systemic Dermatomyositis (polymyositis); Acute Rheumatic Carditis
- **Dermatologic diseases:** Pemphigus; Bullous Dermatitis Herpetiformis; severe Erythema Multiforme (Stevens-Johnson Syndrome); Exfoliative Dermatitis; severe Psoriasis; severe Seborrheic Dermatitis; Mycosis Fungoides
- **Allergic states:** Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment, such as the following: Seasonal or perennial Allergic Rhinitis; Bronchial Asthma; Contact Dermatitis; Atopic Dermatitis; Serum Sickness
- **Ophthalmic diseases:** Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa, such as the following: Allergic Conjunctivitis; Keratitis; Herpes Zoster Ophthalmicus; Iritis and Iridocyclitis; diffuse posterior Uveitis and Choroiditis; Optic Neuritis; Sympathetic Ophthalmia; Chorioretinitis; anterior segment inflammation; allergic corneal marginal ulcer
- **Respiratory diseases:** Symptomatic Sarcoidosis; Loeffler Syndrome not manageable by other means; Berylliosis; fulminating or disseminated pulmonary Tuberculosis when used concurrently with antituberculous chemotherapy; Aspiration Pneumonitis
- **Hematologic disorders:** Acquired (autoimmune) Hemolytic Anemia; secondary Thrombocytopenia in adults; Erythro-Blastopenia (RBC anemia); congenital (erythroid) Hypoplastic Anemia
- **Neoplastic diseases:** For palliative management of leukemias and lymphomas in adults or acute leukemia of childhood
- **Edematous state:** To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to Lupus Erythematosus
- **GI diseases:** To tide the patient over a critical period of the disease in Ulcerative Colitis or Regional Enteritis
- **Miscellaneous:** Tuberculous Meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy; Trichinosis with neurologic or myocardial involvement
- **Infantile spasms:** Monotherapy in infants and children under 2 years of age
- **Diagnostic agent:** For diagnostic testing of adrenocortical function

Usual Dose: All conditions 40–80 units every 24–72 hours (except MS 80–120 units every 2 to 3 weeks)

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

MED ACTEMRA (toclizumab)

Diagnosis of:

- Rheumatoid Arthritis (moderate to severe); SHOULD BE AVOIDED in combination with biological DMARDs such as TNF antagonists, interleukin (IL)-1 receptor (R) antagonists, anti-CD20 monoclonal antibodies, and selective costimulation modulators because of the possibility of increased immunosuppression and increased risk of infection

Usual Dose: 4mg/kg every 4 weeks – may increase to 8mg/kg every 4 weeks. Maximum of 800mg per infusion.

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

FDA Black Box Warning

Patients treated with tocilizumab are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

MED AREDIA (pamidronate)

Diagnosis of:

- Hypercalcemia of Malignancy (HCM) (moderate to severe)
  Usual Dose/Duration: Usually one treatment – 60 to 90mg IV over 2 to 24 hours
- Osteolytic Bone Metastases (Breast Cancer)
  Usual Dose/Duration: 90mg IV infusion over 2 to 24 hours every 3 to 4 weeks
- Osteolytic Bone Lesions (Multiple Myeloma)
  Usual Dose/Duration: 90mg IV infusion over 4 hours monthly
- Paget's Disease
  Usual Dose/Duration: Usually 30mg IV infusion over 4 hours daily for 3 days (Total = 90mg)
- Immobilization-related Hypercalcemia (off-label) – refer all requests to medical director
  Usual Dose/Duration: 10 to 90mg administered as a single IV infusion. May be repeated if necessary to maintain normal calcium levels.
- Osteoporosis spinal cord injuries (off-label) – refer all requests to medical director
  Usual Dose/Duration: 30mg infusions (7.5mg/h for 4 hours) every 4 weeks for 6 cycles

Prevention of:

- Glucocorticoid-induced Osteoporosis (off-label) – refer all requests to medical director
  Usual Dose/Duration: Initial dose of 90mg IV, followed by 30mg IV every 3 months

MED AVASTIN (bevacizumab)

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

MED BONIVA (ibandronate sodium, IV solution)

Diagnosis, treatment, and prevention of:

- Osteoporosis in postmenopausal women or
- Bone Metastases (off label – ASCO guidelines) or
- Hypercalcemia of malignancy (off-label) or
- Postrenal transplant bone loss (off-label) AND
- Therapeutic failure of oral bisphosphenates (FOSAMAX, ACTONEL, BONIVA, MIACALCIN, EVISTA)

Usual Dose: One IV infusion of 3mg every 3 months

Duration: 12 months

MED BOTOX (Botulinum A)

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)

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BOTOX, cont.

- 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)

Note: Botox is considered investigational for chronic motor Tic disorder and Tics associated with Gilles de la Tourette Syndrome, facial wrinkles, gastroparesis, chronic low back pain, BPH, and tension headaches.

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.

CINRYZE (C1 inhibitor)

Diagnosis of:

- Hereditary Angioedema – routine prophylaxis

Usual Dose: 1,000mg via IV injection every 3 or 4 days

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

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 initial, then 12 months thereafter if no change in dosing

FLOLAN (epoprostenol sodium)

Diagnosis of:

- Primary Pulmonary Hypertension and Pulmonary Hypertension associated with the scleroderma spectrum of disease in NYHA Class III and Class IV patients and
- Unresponsive to other forms of therapy such as oxygen, inotropics, anticoagulants, calcium channel blockers and or diuretics or are candidates for these medications
- Currently considered investigational for the treatment of:
  - Ischemic Vascular Diseases
  - Congestive Heart Failure
  - Chronic Thromboembolic Disease
  - Chronic Obstructive Pulmonary Disease (COPD)
- Concurrent therapy limited to any two agents at a time (LETAIRUS, FLOLAN, REVATIO/VIAGRA, TRACLEER, VENTAVIS)

Dosing considerations:

- Administered by continuous IV infusion via a central venous catheter, or by inhalation

Duration: 6 months through home infusion company, hospital or physician office, then 12 months thereafter if no change in dosing

MED HALAVEN (eribulin mesylate)

Diagnosis of:

- Metastatic Breast Cancer – For the treatment of patients with Metastatic Breast Cancer who have previously received at least 2 chemotherapeutic regimens for the treatment of metastatic disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting

Usual Dosing: 1.4 mg/m^2 intravenously (IV) over 2 to 5 minutes on days 1 and 8 of a 21-day cycle

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

MED HERCEPTIN (trastuzumab)

Diagnosis of:

- Metastatic Breast Cancer with tumors over expressing the HER2 protein as defined as a 2+ or 3+ result from the Herceptest in the following regimens:
  - As a single agent in patients who have received > one chemo therapy regimens
  - In combination with TAXOL in patients who have not received chemotherapy for metastatic disease
- Adjuvant breast cancer treatment: For adjuvant treatment of human epidermal growth receptor 2 (HER2) overexpressing node positive or node negative (ER/PR negative or with one high risk feature)
- Metastatic HER2-overexpressing Gastric Cancer or Gastroesophageal Junction Adenocarcinoma in combination with other chemotherapy (cisplatin plus either capecitabine or 5-fluorouracil)

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

FDA Black Box Warning

Trastuzumab can result in subclinical and clinical cardiac failure manifesting as congestive heart failure (CHF) and decreased left ventricular ejection fraction (LVEF). Trastuzumab administration can result in serious infusion reactions and pulmonary toxicity.

MED Immune Globulin Intravenous (IVIG)
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

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Immune Globulin Intravenous (IVIG), cont.

- 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.

MED JEVTANA (cabazitaxel)

Diagnosis of:

- Prostate Cancer – In combination with prednisone for the treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen

Dosing:

- *Initial dosing:* 25mg/m^2 administered as a 1-hour intravenous (IV) infusion every 3 weeks in combination with oral prednisone 10mg administered daily throughout cabazitaxel treatment
- *Maintenance dosing:* The cabazitaxel dose should be reduced to 20mg/m^2 if patients experience adverse reactions

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

FDA Black Box Warning
Severe hypersensitivity reactions, neutropenia

MED KRYSTEXXA (pegloticase)

Diagnosis of:

- Chronic Gout – treatment in adult patients refractory to conventional therapy

Dosing: 8mg given as an intravenous (IV) infusion every 2 weeks

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

FDA Black Box Warning
Anaphylaxis and infusion reactions.

MED LEUKINE (sargramostim)

Diagnosis of:

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

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

MED LUCENTIS (ranibizumab) or MACUGEN (pegaptanib sodium)

Diagnosis of:

- Neovascular (wet) Age-related Macular Degeneration (AMD)
- Macular Edema following retinal vein occlusion (RVO)

Duration: 3 months

MED MYOBLOC (botulinum toxin type B)

Diagnosis of:

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

Duration: The duration of effect in patients responding to botulinum toxin type B treatment has been observed in studies to be between 12 and 16 weeks at doses of 5000 U or 10,000 U

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.

NEULASTA (pegfilgrastim)

Myleosuppresive Chemotherapy:

- To decrease the incidence of infection in patients with non-myeloid malignancies receiving myelosuppresive anticancer medications associated with a clinically significant incidence of Febrile Neutropenia
- NOT before 24 hours following chemotherapy administration
- Weight > 45kg
- NOT to be utilized in combination with other colony stimulating agents (e.g., NEOPOGEN, LEUKINE)

Usual Dose: 6mg SC once per chemotherapy cycle

Duration: 3 months

NEUPOGEN, G-CSF (filgrastim)

Diagnosis of:

- Prophylaxis in cytotoxic chemotherapy of high intensity where Neutropenia is expected (incidence of Febrile Neutropenia is 20% or higher)

Treatment:

- Myelosuppresive Chemotherapy – Chemotherapy-induced Neutropenia in non-myeloid malignancies
- Patients undergoing peripheral blood progenitor cell collection and therapy
- Severe Chronic Neutropenia (SCN), including Congenial Neutropenia, Cyclic Neutropenia, or Idiopathic Neutropenia
- Acute Myeloid Leukemia (AML) receiving induction or consolidation chemotherapy
- Cancer patients receiving bone marrow transplant

Usual Dose: Weight-based and varies according to diagnosis, but generally 5-10mcg/kg/day

Duration: 3 months

Limitations:

- Limited to use by Infection Disease and Hematology/Oncology providers
- Limited to one CSF agent at a time

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

MED NPLATE (romiplostim)

Diagnosis of:

- Thrombocytopenia Purpura (ITP) for those who have had an incomplete response to corticosteroids, imnuunoglobulins, or splenectomy
  - Use the lowest dose to achieve and maintain a platelet count of at least 50,000 x 10(3)/l – Should NOT be utilized in an attempt to normalize platelet counts
  - Only health care providers enrolled in the roiplostim NEXUS (Network of experts understanding and supporting NPLATE and patients) program may prescribe romiplostim
  - Concomitant medications (e.g., corticosteroids, danazol, azathioprine, IVIG, and anti-D immunoglobulin) may be used

Dosing considerations:

- *Initial dosing:* 1mcg per kg (actual body weight)
- *Maximum dose:* 10mcg/kg

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

MED ORENCIA (abatacept)

Diagnosis of:

- Rheumatoid Arthritis (RA) – moderate to severe (in adults)
- Juvenile Idiopathic Arthritis – moderate to severe (age 6 and older)

Usual Dose: Weight-based; 500 to 1,000mg; maximum dose = 1,000mg via IV infusion @ week 2 & 4, then Q 4 weeks

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

Note: Do not co-administer abatacept with TNF antagonists. Abatacept is not recommended for use concomitantly with other biologic RA therapy, such as anakinra.

MED ORZUDEX (dexamethasone intravitreal inplant)

Diagnosis of:

- Macular Edema following Branch Retinal Vein Occlusion (BRVO) or Central Retinal Vein Occlusion (CRVO)
- Treatment of non-infectious Uveitis affecting the posterior segment of the eye

Duration: Approve only one treatment per review

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

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)

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

PROLIA, XGEVA (denosumab)

PROLIA used for treatment of:

- Osteoporosis in postmenopausal women with high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or in patients who have failed or are intolerant to other available osteoporosis therapies AND
- Have failed or are intolerant of previous osteoporosis therapy (FOSAMAX, ACTONEL, BONIVA, SKELID, EVISTA, MIACALCIN)

XGEVA used for prevention of:

- Skeletal-related events in patients with bone metastases from solid tumors

Note: These medications SHOULD be administered by health care provider.

Usual Dose:

- **PROLIA:** 60mg SQ once every 6 months; all patients should receive 1,000mg of calcium daily and at least 400 units of vitamin D daily
- **XGEVA:** 120mg SC every 4 weeks

Duration: 12 months

MED PROLEUKIN (aldesleukin)

Diagnosis of:

- Metastatic Renal Cell Carcinoma or Metastatic Melanoma

Duration: 12 months – primarily through home IV or at physician's office; every 8 hours x 14 doses, 9 days of rest and repeat 14 doses; allow at least 7 weeks between treatment courses

FDA Black Box Warning

Cardioplumonary toxicities (associated with capillary leak syndrome), increased risk of disseminated infections

MED PROVENGE (sipuleucel-T)

Diagnosis of:

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

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

MED RECLAST (zoledronic acid)

Diagnosis of:

- Osteoporosis in postmenopausal women (prevention and treatment)
- Glucocorticoid-induced Osteoporosis in men and women (prevention and treatment)
- Osteoporosis in men
- Paget Disease in men and women
- Therapeutic failure of oral bisphosphenates (FOSAMAX, ACTONEL, BONIVA, MIACALCIN, EVISTA)

Usual Dose/Duration:

- The recommended treatment regimen is a single 5 mg infusion once a year given IV. Contraindicated in patients with renal insufficiency (i.e., CrCl < 35ml/min, Rx staff can calculate this parameter if necessary).
- 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.

Note: *Trial of one oral bisphosphonate or SERM for all diagnoses above*

Note: *Patients must be adequately supplemented with calcium and vitamin D if dietary intake is insufficient*

MED 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
- **Administration:** 5mg/kg IV given as an induction regiment over six weeks (initial, at two weeks and six weeks) followed by a maintenance regimen every eight weeks thereafter. For 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), Ankylosing Spondylitis, 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 regiment 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:

- 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 regiment 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

MED RITUXAN (rituximab)

Diagnosis of:

- Non-Hodgkins Lymphoma
  Usual Dose: 375mg/m^2 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/m^2 initial dose prior to start of chemotherapy and then 500mg/m^2 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/m^2 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)

MED STELARA (ustekinumab)

Diagnosis of:

- Plague Psoriasis, moderate to severe, in those (18 years of age or older) who are candidates for phototherapy or systemic therapy

Usual Dose: 45mg SC initially and 4 weeks later, then every 12 weeks thereafter (< 100kg); 90mg SC initially and 4 weeks later, then every 12 weeks thereafter (> 100kg); should only be administered by a health care provider who is capable to monitor patients closely with regular follow-up visits.

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

SYNAGIS (palivizumab humanized monoclonal antibody)

Prevention of RSV Disease:

- Birth to age < 24 months at start of RSV season (i.e., November 15) 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 15
  - Hemodynamically significant Congenital Heart Disease (CHD)
  - Severe immunodeficiency or
- Birth to age < 12 months with gestational age less than equal to 28 weeks 6 days severe neuromuscular disease, congential abnormality of the airway or
- Birth to age six months with gestational age of 29 to 31 weeks, 6 days or
- Birth to age 90 days with gestational age of 32 to 34 weeks, 6 days 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 32-34 weeks, 6 days 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.*

MED SYNVISC, HYALGAN, SUPARTZ, EUFLEXXA, or ORTHOVISC (sodium hyaluronate)

Diagnosis of:

- Symptomatic, painful Osteoarthritis (DJD) of the knee(s) AND
- Confirmed by X-ray osteophytes AND
- Reports of pain interfering with functional activities for a minimum of 6 months with morning stiffness lasting 30 minutes or less and crepitus on knee motion AND
- Pain can not be attributed to another form of joint disease AND
- Failure to respond adequately to a comprehensive treatment program of 6 months duration and those who meet any three of the following criteria:
  - Physical therapy
  - Home exercise program
  - Utilization of an orthotic device (e.g., knee brace, etc.)
  - Simple analgesics (e.g., acetaminophen, NSAIDs, topical analgesics, etc.)
  - Aspiration of the affected knee
  - Intra-articular corticosteroids
  - The patient is unable to utilize conservative therapy due to contraindications or intolerance

Usual Dose: One course of therapy as listed below.

SYNVISC-ONE:	**single injection only**
SYNVISC:	3 weekly intra-articular injections
HYALGAN:	5 weekly intra-articular injections
SUPARTZ:	5 weekly intra-articular injections
EUFLEXXA:	3 weekly intra-articular injections
ORTHOVISC:	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.*

MED THYROGEN (thyrotropin alfa)

Diagnosis of:

- Thyroid Cancer – adjunctive treatment for radioiodine ablation of thyroid tissue remnants

Dose: One kit (two IM injections/kit) per scheduled thyroglobulin testing with or without radioiodine imaging.

Duration: 1 month

MED TYSABRI (natalizumab)

Diagnosis of:

- Relapsing forms of Multiple Sclerosis – as monotherapy to delay the accumulation of physical disability and reduce the frequency of clinical exacerbations plus documented failure of other therapies (AVONEX, COPAXONE, BETASERON)
- Crohn's Disease – for inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's disease with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional Cohn's disease therapies and inhibitors of tumor necrosis factor alpha (TNF-α).

Please Note: Do not administer natalizumab in combination with immunosuppressants (e.g., azathioprine, cyclosporine, methotrexate, 6-mercaptopurine) or inhibitors of TNF-α

Usual Dose: 12 single-dose syringes per 30 days for 6 months. Maximum Dose = 300mg IV every 4 weeks.

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

FDA Black Box Warning

Natalizumab increases the risk of PML, an opportunistic viral infection of the brain that usually leads to death or severe disability

MED VECTIBIX (panitumumab)

Diagnosis of:

- Metastatic Colorectal Carcinoma - Positive EGFR (Epidermal Growth Factor Receptor)

Usual Dose: 6mg/kg via IV infusion every 14 days

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

FDA Black Box Warning

Dermatologic toxicities were reported in 89% of patients and severe in 12%. Severe infusion reactions occurred with the administration of panitumumab in approximately 1% of patients. Severe infusion reactions were identified by reports of anaphylactic reaction, bronchospasm, fever, chills, and hypotension.

MED XIAFLEX (collagenase clostridium histolyticum)

Diagnosis of:

- Dupuytren's Contracture with a palpable cord (Adults ONLY)

Usual Dose: 0.58mg per injection into a palpable cord with a contracture of a metacarpophalangeal joint or a proximal interphalangeal joint. Approximately 24 hours after injection, perform a finger extension procedure if the contracture persists. Injections and finger extension procedures may be administered up to 3 times per cord at approximately 4-week intervals.

Duration: 12 months only

MED ZOMETA (zoledronic acid)

Diagnosis of:

- Hypercalcemia of Malignancy (HCM)
  Usual Dose: Usually one treatment of 4mg IV over 15 minutes
  Duration: 6 months
- Osteolytic Bone Metastases from solid tumors
  Usual Dose: 4mg IV infusion over 15 minutes every 3 to 4 weeks
  Duration: 6 months
- Osteolytic Bone Lesions of multiple myeloma
  Usual Dose: 4mg IV infusion over 15 minutes every 3 to 4 weeks
  Duration: 12 months
- Osteoporosis – Refer all requests to medical director (see RECLAST)

Immunizations

Immunization Restrictions.

Please review benefit booklets for specific exclusions:

- Immunizations for travel and/or work-related purposes are not covered.

Vaccines often requested include:

- Typhoid
- Yellow fever
- Cholera vaccine
- Plague vaccine
- BCG vaccine
- Meningococcal vaccine – Menomune-A/C/Y/W-135 (Please note: Not recommended for routine use in U.S. Consider vaccination for household or institutional contacts of meningococcal disease as adjunct therapy to appropriate antibiotic therapy)

Childhood Immunizations:

Routine childhood immunizations are eligible for benefit coverage subject to the terms of the subscriber's contract for routine immunizations and in accordance with BCBSNM Preventive Health Care Guidelines, and Federal /state regulations on immunizations.

BCBSNM considers "routine immunizations" to be those immunizations that are formally recommended by the Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control and Prevention (CDC) as appropriate for all U.S. residents of a given age group. To be recognized by BCBSNM as formal, the ACIP recommendations must be in published form.

Routine immunizations do NOT include those that are used or recommended to prevent disease in epidemiologically definable populations who are in special circumstances, including, but not limited to, circumstances related to travel, education, or employment. Immunizations recommended or administered solely because of a member's travel, education, employment, or similar circumstances are NOT "routine immunizations" for the purpose of BCBSNM policy.

2011 ACIP Immunization Schedules may be accessed at:
http://www.cdc.gov/vaccines/recs/schedules/default.htm

The FDA website lists vaccines that are currently licensed for use in the U.S.:
http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm