

BLUE CROSS AND BLUE SHIELD OF OKLAHOMA PROGRAM OBJECTIVES – 3-TIER FORMULARY

Cholesterol Lowering

HMG Quantity Limits

Quantity Limit Criteria for HMG-CoA Reductase Inhibitors (Altprev[®], Crestor[®], Lescol[®], Lescol XL[®], Lipitor[®], Mevacor[®], Pravachol[®], Zocor[®]):
HMG-CoA reductase inhibitor medications are commonly referred to as the “statins” and are used to lower cholesterol. The intent of the quantity limit criteria for HMG-CoA reductase inhibitors is to recommend the appropriate quantity per day based on Food and Drug Administration (FDA) approved indications and dosing schedule. With the exceptions of Mevacor, generic lovastatin, immediate release Lescol and 20mg Zocor, the recommended daily dosing schedule for HMG-CoA reductase inhibitors is once per day. This program includes currently available brand and generic products. There are no additional criteria for approval of greater quantities.

Zetia Step Therapy

Step Therapy Criteria for Zetia[®] :

Zetia is used to lower cholesterol. The intent of the step therapy criteria for Zetia is to recommend use of Zetia as adjunctive (or add on) therapy to HMG-CoA reductase inhibitors (or statins) based on Food and Drug Administration (FDA) approved prescribing information and/or clinical studies and/or treatment guidelines.

Hypertension

ACE/ARB Step Therapy

Step Therapy Criteria for Angiotensin Converting Enzyme Inhibitors (ACEI) and Angiotensin II Receptor Antagonists (ARB):

ACEI medications included in this program: Accupril[®], Accuretic[®], Aceon[®], Altace[®], Capoten[®], Capozide[®], Lotensin[®], Lotensin HCT[®], Mavik[®], Monopril[®], Prinivil[®], Prinzide[®], Univasc[®], Uniretic[®], Vasotec[®], Vaseretic[®], Zestril[®], Zestoretic[®]

ARB medications included in this program: Atacand[®], Atacand HCT[®], Avapro[®], Avalide[®], Benicar[®], Benicar HCT[™], Cozaar[®], Hyzaar[®], Diovan[®], Diovan HCT[®], Micardis[®], Micardis HCT[®], Teveten[®], Teveten HCT[®]

ACEI and ARB medications are used for the treatment of hypertension (high blood pressure), heart failure and kidney disease. The intent of the step therapy criteria for these medications is to recommend the use of a generic ACEI prior to a brand name ACEI or a brand or generic ACEI prior to an ARB based on Food and Drug Administration (FDA) approved indications and dosing schedule, and/or clinical studies and/or treatment guidelines.

Diabetes

Regranex Prior Authorization

Prior Authorization Criteria for Regranex[®] :

Regranex is a topical gel used for the treatment (debridement) of diabetic wounds on lower limbs and feet. It should be used in conjunction with standard diabetic wound care for a specified period of time for healing to occur. The intent of the prior authorization criteria for Regranex is to recommend the appropriate selection of patients for treatment for the appropriate length of therapy based on Food and Drug Administration (FDA) approved indications and dosing schedule, and/or clinical studies and/or treatment guidelines.

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Pain

Ketorolac Quantity Limits

Quantity Limit Criteria for ketorolac (brand name Toradol[®]):

Ketorolac is a nonsteroidal anti-inflammatory drug (NSAID) indicated for short-term use for the management of moderately severe pain. The intent of the quantity limit criteria for ketorolac is to allow the quantity of 21 doses per month based on the Food and Drug Administration (FDA) approved dosing schedule that recommends therapy with ketorolac should not exceed 5 days of treatment with 4 doses per day. There are no additional criteria for approval of greater quantities.

Celebrex Quantity Limits

Quantity Limit Criteria for Celebrex[®] :

Celebrex is a cyclooxygenase-2 (COX-2) inhibitor medication used to treat inflammation and reduce pain. The intent of the quantity limit criteria for Celebrex is to recommend the quantity of 2 capsules per day based on Food and Drug Administration (FDA) approved indications and daily dosing schedule. There are no additional criteria for approval of greater quantities.

Migraine Quantity Limits

Triptans

Quantity Limit and Post-Quantity Limit Criteria for Amerge[®] , Axert[®] , Frova[®] , Imitrex[®] , Maxalt[®] , Zomig[®] , Relpax[®] :

These medications are indicated for the treatment, but not prevention, of migraine headaches. Imitrex injection is indicated for the treatment of migraine headaches and cluster headaches. The intent of the quantity limit criteria for these medications is to recommend the appropriate monthly quantity of tablets for the treatment of 3 migraine headaches per month based on Food and Drug Administration (FDA) approved dosing schedule, and/or clinical studies and/or treatment guidelines. The quantity limit accommodates the use of Imitrex injection or nasal spray for the treatment of 6 headache days per month. The intent of the post-quantity limit criteria is to recommend appropriate preventative therapy for patients who experience more than 3 migraine headaches per month based on the treatment guidelines of the American Academy of Neurology (AAN).

Migranal

Quantity Limit and Post-Quantity Limit Criteria for Migranal[®] :

Migranal nasal spray is indicated for the treatment, but not prevention, of migraine headaches. The intent of the quantity limit criteria for Migranal is to recommend the appropriate monthly quantity for treatment of 3 migraine headaches per month based on Food and Drug Administration (FDA) approved dosing schedule, and/or clinical studies and/or treatment guidelines. The intent of the post-quantity limit criteria is to recommend appropriate preventative therapy for patients who experience more than 3 headaches per month based on the treatment guidelines of the American Academy of Neurology (AAN).

Stadol NS

Quantity Limit and Post-Quantity Limit Criteria for Stadol[®] :

Stadol nasal spray is a narcotic medication indicated for the management of pain and is often used for treatment of migraine headaches. The intent of the quantity limit criteria for Stadol is to recommend the monthly quantity of 3 packages based on Food and Drug Administration (FDA) approved dosing schedule, and/or clinical studies and/or treatment guidelines. The intent of the post-quantity limit criteria is to recommend appropriate preventative therapy for patients who experience more than 3 headaches per month based on the treatment guidelines of the American Academy of Neurology (AAN).

Depression

Effexor, Effexor XR and Cymbalta Step Therapy

Step Therapy Criteria for Cymbalta[®] , Effexor[®] and Effexor XR[®] :

Cymbalta is indicated for the treatment of depression and for the management of neuropathic pain associated with diabetes. Effexor and Effexor XR are used for the treatment of depression. The intent of the step therapy criteria for Cymbalta, Effexor and Effexor XR is to recommend first line use of any generic selective serotonin reuptake inhibitor (SSRI) prior to the use of these brand name products for the treatment of depression, based on Food and Drug Administration (FDA) approved prescribing information and/or clinical studies and/or treatment guidelines.

Wellbutrin and Wellbutrin SR Step Therapy

Step Therapy Criteria for Wellbutrin[®] and Wellbutrin SR[®] :

Wellbutrin and Wellbutrin SR are indicated for the treatment of depression. The intent of the step therapy criteria for Wellbutrin and Wellbutrin SR is to recommend first line use of generic bupropion prior to the use of the brand name products for the treatment of depression based on Food and Drug Administration (FDA) approved prescribing information and/or clinical studies and/or treatment guidelines.

Asthma/COPD

Oral Inhaler Quantity Limits

Quantity Limit Criteria for Oral Inhalers (Advair Diskus[®], Aerobid[®], Alupent[®], Asmanex[®], Atrovent[®], Azmacort[®], Combivent[®], Flovent[®], Foradil[®], Intal[®], Maxair[®], Proventil[®], Pulmicort[®], Qvar[®], Serevent Diskus[®], Spiriva[®], Tilade[®], Ventolin HFA[®]):

The oral inhalers are used for management of respiratory symptoms associated with asthma and chronic obstructive pulmonary disease (COPD). The intent of the quantity limit criteria for oral inhalers is to recommend the appropriate number of inhalers per month based on the Food and Drug Administration (FDA) approved daily dosing schedule. This program includes currently available brand and generic products. There are no additional criteria for approval of greater quantities.

Leukotriene Modifier Step Therapy

Step Therapy Criteria for Leukotriene Modifiers (Accolate[®] 20 mg and Singulair[®] 10 mg):

Accolate is indicated for the prevention and management of asthma. Singulair is indicated for the prevention and management of asthma and for the relief of nasal allergy symptoms. The step therapy recommendations for the use of Accolate and Singulair are based on Food and Drug Administration (FDA) approved indications and/or clinical studies and/or treatment guidelines. The intent of the step therapy criteria for Accolate is to recommend first line use of an

orally inhaled steroid prior to the use of Accolate. The intent of the step therapy criteria for Singulair is to recommend first line use of an orally inhaled steroid for patients with asthma or first line use of a nasally inhaled steroid or non-sedating antihistamine for patients with nasal allergies.

Women's Health

Bisphosphonate Quantity Limits

Quantity Limit Criteria for Bisphosphonates (Actonel[®], Boniva[®], Fosamax[®]):

The bisphosphonates are indicated for the treatment and prevention of osteoporosis. The intent of the quantity limit criteria for the bisphosphonates is to recommend the appropriate monthly quantity of tablets or doses of oral solution based on the Food and Drug Administration (FDA) approved dosing schedule. There are no additional criteria for approval of greater quantities.

Specialty

Xolair Prior Authorization

Prior Authorization Criteria for Xolair[®] :

Xolair is an injectable medication indicated for the management of moderate to severe asthma.

Xolair is indicated for adults and adolescents (12 years of age and above) with moderate to severe persistent asthma who have a positive skin test to an allergen and whose symptoms are not adequately controlled with inhaled corticosteroids. The intent of the prior authorization criteria for Xolair is to recommend the appropriate selection of patients for treatment with Xolair at the appropriate dose based on Food and Drug Administration (FDA) approved indications and dosing schedule, and/or clinical studies and/or treatment guidelines.

Enbrel Step Therapy

Step Therapy Criteria for Enbrel[®] :

Enbrel is an injectable medication, self-administered by patients, for the treatment of rheumatoid arthritis or psoriasis. The intent of the step therapy criteria for Enbrel is to recommend use of first line medications prior to Enbrel based on Food and Drug Administration (FDA) approved indications and dosing schedule, and/or clinical studies and/or treatment guidelines. Methotrexate is the first line alternative for patients with rheumatoid arthritis. For patients with psoriasis, first line alternatives

include topical medications such as corticosteroids, coal tar, Dovonex[®], Tazorac[®], and Micanolor oral medications such as methotrexate, cyclosporine,

Oxsoralen[®] and Soriatane[®] .

Humira and Kineret Step Therapy

Step Therapy Criteria for Humira[®] and Kineret[®] :

Humira and Kineret are injectable medications, self-administered by patients, for the treatment of rheumatoid arthritis. The intent of the step therapy criteria for Humira and Kineret is to recommend the use of methotrexate as first line therapy prior to Humira or Kineret based on Food and Drug Administration (FDA) approved indications and dosing schedule, and/or clinical studies and/or treatment guidelines.

Raptiva Step Therapy

Step Therapy Criteria for Raptiva[®] :

Raptiva is an injectable medication used for the treatment of moderate to severe psoriasis. Raptiva is self-administered by the patient. The intent of the step therapy criteria for Raptiva is to recommend the use of first line topical or oral medications prior to the use of these injectable medications based on Food and Drug Administration (FDA) approved indications and dosing schedule, and/or clinical studies and/or treatment guidelines. First line alternatives include topical medications such as corticosteroids, coal tar, Dovonex[®], Tazorac[®], and Micanol[®], or oral medications such as methotrexate, cyclosporine, Oxsoralen[®] and Soriatane[®] .

Hepatitis C Prior Authorization

Prior Authorization Criteria for Hepatitis C Agents (Pegasys[®], Copegus[®], PEG-Intron[®]):

These agents are injectable medications, self-administered by the patient, for the treatment of hepatitis C virus (HCV) and other indications. The intent of the prior authorization criteria for the hepatitis C agents is to recommend the appropriate selection of patients for treatment of HCV with these medications for the appropriate length of therapy based on Food and Drug Administration (FDA) approved indications and dosing schedule, and/or clinical studies and/or treatment guidelines.

Forteo Prior Authorization

Prior Authorization Criteria for Forteo[®] :

Forteo is an injectable medication, self administered by the patient, for treatment of osteoporosis. The intent of the prior authorization criteria for Forteo is to recommend its use as second line therapy for patients with a confirmed diagnosis of osteoporosis based on Food and Drug Administration (FDA) approved indications and dosing schedule, and/or clinical studies and/or

treatment guidelines. First line medication alternatives include Fosamax[®], Actonel[®], Boniva[®] or Evista[®] for women and Fosamax[®], Actonel[®] or Boniva[®] for men.

Epilepsy

Anticonvulsant (Topamax, Zonegran, Gabitril) Step Therapy

Step Therapy Criteria for Topamax[®], Zonegran[®] and Gabitril[®] :

Topamax, Zonegran and Gabitril are used as adjunctive (or add on) therapy with other anti-seizure medications for the treatment of seizure disorders. Topamax is also indicated for the prevention of migraine headaches. The step therapy recommendations for the use of Topamax, Zonegran and Gabitril are based on Food and Drug Administration (FDA) approved indications and/or clinical studies and/or treatment guidelines. The intent of the step therapy criteria for Topamax, Zonegran and Gabitril is to recommend use of these medications for the treatment of seizure disorders as concomitant therapy with other anti-seizure medications such as phenobarbital, primidone, phenytoin, carbamazepine, valproic acid or divalproex. The intent of the step therapy criteria for Topamax is to also recommend its use for prevention of migraine headaches as third line therapy after the use of two other preventative medications such as amitriptyline, divalproex, propranolol, verapamil or gabapentin.

Allergies

Nasal Inhaler Quantity Limits

Quantity Limit Criteria for Nasal Inhalers (Atrovent[®], Beconase AQ[®], Flonase[®], Nasacort AQ[®], Nasonex[®], Nasarel[®], Rhinocort AQ[®]):

The nasal inhalers are used for the management of nasal symptoms associated with allergies. The intent of the nasal inhaler quantity limit criteria is to recommend the appropriate number of inhalers per month based on the Food and Drug Administration (FDA) approved maximum daily dosing schedule. There are no additional criteria for approval of greater quantities.

Leukotriene Modifier Step Therapy

Step Therapy Criteria for Leukotriene Modifiers (Accolate[®] 20 mg and Singulair[®] 10 mg):

Accolate is indicated for the prevention and management of asthma. Singulair is indicated for the prevention and management of asthma and for the relief of nasal allergy symptoms. The step therapy recommendations for the use of Accolate and Singulair are based on Food and Drug Administration (FDA) approved indications and/or clinical studies and/or treatment guidelines. The intent of the step therapy criteria for Accolate is to recommend first line use of an

orally inhaled steroid prior to the use of Accolate. The intent of the step therapy criteria for Singulair is to recommend first line use of an orally inhaled steroid for patients with asthma or first line use of a nasally inhaled steroid or non-sedating antihistamine for patients with nasal allergies.

Miscellaneous

Erectile Dysfunction Quantity Limits

Quantity Limit for Oral Erectile Dysfunction Agents (Viagra[®], Cialis[®], Levitra[®]):

These medications are indicated for treatment of erectile dysfunction in men. The intent of the quantity limit criteria for oral erectile dysfunction agents is to recommend the monthly quantity limit of 6 tablets per month, for any combination of the three products, for male patients based on Food and Drug Administration (FDA) approved indications and dosing schedule, and/or clinical studies and/or treatment. There are no additional criteria for approval of greater quantities.

Atopic Dermatitis (Elidel and Protopic) Step Therapy

Step Therapy Criteria for Atopic Dermatitis Agents (Elidel[®] and Protopic[®]):

The intent of the step therapy criteria for the atopic dermatitis agents (Elidel and Protopic) is to recommend first line use of generic topical corticosteroids prior to the use of Elidel or Protopic based on Food and Drug Administration (FDA) approved prescribing information and/or clinical studies and/or treatment guidelines.

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