DRAFT Medical Coverage Policy | Injectable Agents for Asthma and Chronic Idiopathic Urticaria – Fasenra, Nucala, Xolair, Cinqair

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OVERVIEW

This policy documents coverage guidelines required for the use of Omalizumab (Xolair), Mepolizumab (Nucala), Reslizumab (Cinqair) and Benralizumab (Fasenra). Omalizumab is a treatment for moderate to severe persistent allergic asthma and chronic idiopathic urticaria (CIU) in appropriate patients. Mepolizumab, Reslizumab and Benralizumab are treatments for severe asthma in appropriate patients.

MEDICAL CRITERIA

Omalizumab (Xolair)

BlueCHiP for Medicare

Omalizumab is covered for the following uses:

• Moderate to severe persistent asthma for patients 12 years of age or above with who have had a positive skin test or invitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.
• Chronic idiopathic urticaria for patients 12 years of age or above who remain symptomatic despite H1 antihistamine treatment
• Latex allergy
• Peanut allergy

Moderate persistent asthma

Moderate persistent asthma is defined by the National Heart, Lung, and Blood Institute (NHLBI) as:

• Daily symptoms
• Daily use of inhaled short-acting beta 2-agonist
• Some limitation with normal activity
• Exacerbations requiring oral systemic corticosterioids > 2/year
• Nighttime symptoms greater than 1 time a week but not nightly
• FEV1 >60% but <80% predicted
• FEF1/FVC reduced 5%

Severe persistent asthma

Severe persistent asthma is defined by the National Heart, Lung, and Blood Institute (NHLBI) as:

• Symptoms throughout the day
• Use of inhaled short-acting beta 2-agonist several times per day
• Extremely limited normal activity
• Exacerbations requiring oral systemic corticosterioids > 2/year
• Nighttime symptoms often 7x/week
• FEV1 <60% predicted
• FEV1/FVC reduced >5%

NHLBI normal ranges by age for FEV 1/FVC

• 8-19 years of age – 85%;
• 20-39 years of age – 80%;

• 40-59 years of age – 75%;
• 60-80 years of age – 70%.

The presence of one of these features of severity (moderate or severe) is sufficient to place a patient in that category. These clinical features are based on pre-treatment symptoms and measurements.

Commercial Products

Initial use of Xolair (omalizumab) will be approved when the following are met:

1. ONE of the following:
    a. ALL of the following:
        i. The patient does not have any FDA labeled contraindications to Xolair
        AND
        ii. Xolair will not be used with an injectable IL-5 inhibitor indicated for asthma (e.g. Nucala, Cinqair)
        AND
        iii. The patient has ONE of the following diagnoses:
            a. Moderate to severe persistent asthma **OR**
            b. Chronic idiopathic urticaria **OR**
            c. The patient has another FDA approved diagnosis
        AND
        iv. If the diagnosis is moderate to severe persistent asthma, the patient meets ALL of the following:
            a. If the patient is 6 to less than 12 years of age, the patient meets BOTH of the following:
                i. The pretreatment IgE level is 30 IU/mL to 1300 IU/mL **AND**
                ii. The patient's weight is 20 kg to 150 kg
            AND
            b. If the patient is 12 years of age and above, the patient meets ALL of the following:
                i. The pretreatment IgE level is 30 IU/mL to 700 IU/mL **AND**
                ii. The patient's weight is 30 kg to 150 kg **AND**
                iii. The patient has a baseline FEV_1 <80% predicted
            AND
            c. Allergic asthma has been confirmed by a positive skin test or in vitro reactivity test (RAST) to a perennial aeroallergen
            AND
            d. The patient has ONE of the following:
                i. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months **OR**
                ii. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months **OR**
                iii. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered
            AND
            e. ONE of the following:
                i. The patient's symptoms are not adequately controlled with at least a 3 month trial of high-dose inhaled corticosteroid (ICS) plus long-acting beta2-agonist (LABA) **OR**

ii. The patient's symptoms are not adequately controlled with at least a 3 month trial of a LABA plus either a leukotriene antagonist, LAMA or theophylline

AND

f. The requested dose is within dosing based on pre-treatment serum IgE level and the patient's body weight as defined in FDA approved labeling AND does not exceed 375 mg every 2 weeks

AND

v. If the diagnosis is chronic idiopathic urticaria, the patient meets ALL of the following:

a. The patient is 12 years of age and above

AND

b. The patient has a history of chronic idiopathic urticaria for at least 6 months

AND

c. The patient has a history of hives and itching

AND

d. ONE of the following:

i. There is documentation that the patient has had at least a 4-week trial and failure of an optimal dose of a non-sedating H1 antihistamine; examples include:

i. Hydroxyzine 25-50 mg up to four times daily
ii. Diphenhydramine 50 mg up to four times daily
iii. Cetirizine 10 mg two times daily
iv. Desloratidine 5 mg two times daily
v. Loratidine 10-20 mg two times daily
vi. Fexofenadine 180 mg two times daily
vii. Levocetirizine 5 mg two times daily

OR

ii. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to H1 antihistamine therapy

AND

e. ONE of the following:

i. There is documentation that the patient has tried and failed at least 4 weeks of therapy with montelukast

OR

ii. The patient has an intolerance, FDA labeled contraindication or hypersensitivity to therapy with motelukast

AND

f. ONE of the following:

i. The patient has tried and had an inadequate response to a short burst (3-10 days) of an oral corticosteroid

OR

ii. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to therapy with an oral corticosteroid

AND

g. The dose is within the FDA labeled dose not to exceed 300 mg every 4 weeks

AND

vi. If another FDA approved diagnosis, the dosing is within the FDA approved dosing limit

OR

2. ALL of the following:
    a. There is documentation that the patient is currently being treated with Xolair for an FDA approved indication
    AND
    b. The patient does not have any FDA labeled contraindications to Xolair
    AND
    c. Xolair will not be used with an injectable IL-5 inhibitor indicated for asthma (e.g. Nucala, Cinqair)
    AND
    d. The requested dose is within the FDA approved dosing limit

Xolair will also be approved when the following are met:

1. The patient does not have any FDA labeled contraindications to Xolair
AND
2. Xolair will not be used with an injectable IL-5 inhibitor indicated for asthma (e.g. Nucala, Cinqair)
AND
3. The use of Xolair is for an indication that is supported by compendia. (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the dose is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic use
AND
4. The requested dose is within FDA labeling or dose is supported by compendia. (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the dose is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic dose.

Continued use (renewal) of Xolair (omalizumab) will be approved when ALL of the following are met:

1. The patient has been previously approved for Xolair
AND
2. The patient does not have any FDA labeled contraindications to Xolair
AND
3. Xolair will not be used in combination with an injectable IL-5 inhibitor indicated for asthma (e.g. Nucala, Cinqair)
AND
4. If the diagnosis is moderate to severe persistent asthma, the patient meets ALL of the following:
    a. The patient's weight is within the FDA indicated range for their age (i.e. 20 kg to 150 kg for patients age 6 to less than 12 years and 30 kg to 150 kg for patients 12 years of age and above)
    AND
    b. The patient has had clinical response or disease stabilization as defined by ONE of the following:
        i. Increase in percent predicted FEV_1 from baseline **OR**
        ii. Decrease in the dose of inhaled corticosteroid required to control the patient's asthma **OR**
        iii. Decrease in need for treatment with systemic corticosteroids **OR**
        iv. Decrease in number of hospitalizations, need for mechanical ventilation, or visits to the emergency room or urgent care due to exacerbations of asthma

    AND

    c. ONE of the following:

i. The patient is currently treated and is compliant with standard therapy (e.g. inhaled corticosteroids, long acting beta-2 agonists (LABA), leukotriene receptor antagonists (LTRA), Long-acting muscarinic antagonist (LAMA), theophylline) **OR**
ii. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL standard therapies

AND

d. The dose is within dosing based on pre-treatment serum IgE level and the patient's body weight as defined in FDA approved labeling AND does not exceed 375 mg every 2 weeks

AND

5. If the diagnosis is chronic idiopathic urticaria, the patient meets ALL of the following:
   a. Improvement in symptoms (e.g. number of hives, size of hives, reduction in itching)
   AND
   b. The dose is within the FDA labeled dose (i.e. 300 mg every 4 weeks)

Xolair will also be approved when the following are met:

1. The patient has been previously approved for Xolair
   AND
2. The patient does not have any FDA labeled contraindications to Xolair
   AND
3. Xolair will not be used in combination with an injectable IL-5 inhibitor indicated for asthma (e.g. Nucala, Cinqair)
   AND
4. The use of Xolair is for an indication that is supported by compendia. (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the use is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic use
   AND
5. The requested dose is within FDA labeling or dose is supported by compendia. (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the dose is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic dose.

Cinqair® (reslizumab)
Fasenra™ (benralizumab)
Nucala® (mepolizumab)

BlueCHiP for Medicare and Commercial Products

Initial Evaluation
Cinqair (reslizumab), **Fasenra** (benralizumab), and **Nucala** (mepolizumab) will be approved when ALL of the following are met

1. ONE of the following:
   a. The patient has a diagnosis of severe eosinophilic asthma and ALL of the following:
      i. The patient is within the FDA labeled age for the requested agent:
         1. Cinqair: 18 years of age or over
         2. Fasenra: 12 years of age or over
         3. Nucala: 12 years of age or over

      AND

      ii. The patient's diagnosis has been confirmed by ONE of the following eosinophilic counts for the requested agent:
         1. If the requested agent is Cinqair, the patient has a blood eosinophilic count greater than or equal to 400 cells/MicroLiter within the previous 12 months

OR

2. If the requested agent is Fasenra, the patient has a blood eosinophilic count greater than or equal to 150 cells/microLiter
   OR
3. If the requested agent is Nucala, the patient has ONE of the following:
   a. Blood eosinophilic count greater than or equal to 150 cells/microLiter prior to initiation (within the previous 6 weeks) of therapy with the requested agent **OR**
   b. Blood eosinophilic count greater than or equal to 300 cells/microLiter within the previous 12 months **OR**
   c. Sputum eosinophilic count greater than 3%

AND

iii. ONE of the following:
   1. If the requested agent is Fasenra AND the patient is aged 12 years to 17 years, the patient has a baseline Forced Expiratory Volume (FEV_1) that is less than 90% of predicted
      OR
   2. The patient has a baseline FEV_1 that is less than 80% of predicted

AND

iv. The patient has ONE of the following:
   1. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months **OR**
   2. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months **OR**
   3. Controlled asthma that worsens when the doses of inhaled or systemic corticosteroids are tapered

v. ONE of the following:
   1. The patient is currently treated with a maximally tolerated inhaled corticosteroid within the past 90 days **OR**
   2. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to inhaled corticosteroids

AND

vi. ONE of the following:
   1. The patient is currently treated with ONE of the following within the past 90 days:
      a. A long-acting beta-2 agonist (LABA) **OR**
      b. A leukotriene receptor antagonist (LRTA) **OR**
      c. Long-acting muscarinic antagonist (LAMA) **OR**
      d. Theophylline
      OR
   2. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LRTA), long-acting muscarinic antagonist (LAMA), AND theophylline

OR

b. The patient has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) and ALL of the following:
   i. The requested agent is Nucala
      AND
   ii. The patient is 18 years of age or over
      AND

iii. The patient has a history of EGPA for at least 6 months with a history of relapsing or refractory disease
AND
iv. The patient's diagnosis of EGPA was confirmed by ONE of the following:
1. The patient meets 4 of the following:
a. History of asthma (wheezing or the finding of diffuse high pitched wheezes in expiration)
b. Greater than 10% eosinophils on differential leukocyte count
c. Mononeuropathy (including multiplex) or polyneuropathy
d. Migratory or transient pulmonary opacities detected radiographically
e. Paranasal sinus abnormality
f. Biopsy containing blood vessel showing the accumulation of eosinophils in extravascular areas
OR
2. The patient meets ALL of the following:
a. Medical history of asthma **AND**
b. Peak peripheral blood eosinophilia > 1500 cells/microL **AND**
c. Systemic vasculitis involving two or more extra-pulmonary organs
AND
v. ONE of the following:
1. The patient is currently on maximally tolerated oral corticosteroid therapy within the past 90 days **OR**
2. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to oral corticosteroid therapy
AND
vi. ONE of the following:
1. The patient has tried and failed an oral immunosuppressant (i.e., azathioprine, methotrexate) in the past 90 days **OR**
2. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to immunosuppressants

OR

c. Another FDA approved indication

AND

2. The patient will NOT receive the requested agent in combination with Xolair or with another interleukin 5 (IL-5) inhibitor (e.g. Cinqair, Fasenra, Nucala) indicated for the requested indication
AND
3. The patient does NOT have any FDA labeled contraindications to the requested agent
AND
4. The requested dose is within the FDA labeled dose for the requested indication

Length of Approval: 6 months for severe eosinophilic asthma, 12 months for EGPA and all other FDA approved indications

The requested agent will also be approved when the following are met:
1. The patient does not have any FDA labeled contraindications to the requested agent
AND
2. The patient will not receive the requested agent in combination with Xolair or with another interleukin 5 (IL-5) inhibitor indicated for asthma (e.g. Cinqair, Fasenra, Nucala)
AND
3. The use of the target agent is for an indication that is supported by compendia. (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or

the prescriber has submitted additional documentation (the use is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic use (approval by the Clinical Review Pharmacist required).

AND

4. The requested dose is within FDA labeling or dose is supported by compendia. (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the dose is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic dose (approval by the Clinical Review Pharmacist required)

Length of Approval: Up to 12 months

Renewal Evaluation

Cinqair (reslizumab), **Fasenra** (benralizumab), and **Nucala** (mepolizumab) will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the Prime Therapeutics or BCBSRI PA or Medical Review process

   AND

2. ONE of the following:
   a. The patient has a diagnosis of severe eosinophilic asthma AND BOTH of the following:
      i. The patient has had clinical response or disease stabilization as defined by ONE of the following:
         1. Increase in percent predicted Forced Expiratory Volume (FEV_1) from baseline **OR**
         2. Decrease in the dose of inhaled corticosteroids required to control the patient's asthma **OR**
         3. Decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **OR**
         4. Decrease in number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to exacerbations of asthma

      AND

      ii. ONE of the following:
         1. The patient is currently treated and is compliant with standard therapy (e.g. inhaled corticosteroids, long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LRTA), long-acting muscarinic antagonist (LAMA), theophylline) within the past 90 days **OR**
         2. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL standard therapies

   OR

   b. The patient has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) AND ALL of the following:
      i. The requested agent is Nucala

      AND

      ii. The patient has had clinical response or disease stabilization as defined by ONE of the following:
         1. Remission achieved with the requested agent **OR**
         2. Decrease in corticosteroid maintenance dose required for control of symptoms related to EGPA **OR**
         3. Decrease in hospitalization due to symptoms of EGPA **OR**
         4. Dose of maintenance corticosteroid therapy and/or immunosuppressant therapy was not increased

      AND

iii. ONE of the following:
1. The patient is currently treated and is compliant with maintenance therapy with oral corticosteroids within the past 90 days **OR**
2. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to oral corticosteroids

OR

c. The patient has another FDA approved indication

AND

3. The patient will NOT receive the requested agent in combination with Xolair or with another interleukin 5 (IL-5) inhibitor (e.g. Cinqair, Fasenra, Nucala) indicated for the requested indication
AND
4. The patient does NOT have any FDA labeled contraindications to the requested agent
AND
5. The requested dose is within the FDA labeled dose for the requested indication
Length of approval: 12 months

The requested agent will also be approved when the following are met:

1. The patient has been previously approved for the requested agent through the Prime Therapeutics or BCBSRI PA or Medical Review process
AND
2. The patient does not have any FDA labeled contraindications to the requested agent
AND
3. The patient will not receive the requested agent in combination with Xolair or with another interleukin 5 (IL-5) inhibitor indicated for asthma (e.g. Cinqair, Fasenra, Nucala)
AND
4. The use of the target agent is for an indication that is supported by compendia. (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the use is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic use (approval by the Clinical Review Pharmacist required).
AND
5. The requested dose is within FDA labeling or dose is supported by compendia. (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the dose is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic dose (approval by the Clinical Review Pharmacist required)

PRIOR AUTHORIZATION

BlueCHiP for Medicare and Commercial Products
Prior authorization review is required for BlueCHiP for Medicare and recommended for Commercial products.

POLICY STATEMENT

Injectable agents for asthma and chronic idiopathic urticaria, Omalizumab, Mepolizumab, Reslizumab and Benralizumab are medically necessary for BlueCHiP for Medicare and Commercial products when all of the above medical criteria are met.

COVERAGE

Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable Specialty Pharmacy guidelines.

Specialty Drug Coverage:

For contracts with specialty drug coverage, please refer to the member agreement for benefits and preauthorization guidelines.

BACKGROUND

Omalizumab (Xolair)

Moderate to Severe Allergic (IgE-mediated) Asthma:
Omalizumab is indicated for moderate to severe allergic asthma. Allergic asthma is triggered by inhalation of allergens. IgE is the antibody responsible for activation of allergic reactions and is important to the pathogenesis of allergic asthma and the development and persistence of inflammation. The Global Initiative for Asthma (GINA) guidelines define moderate asthma as that which is well controlled with low dose inhaled corticosteroids (ICS) in combination with a long acting beta agonist (LABA). Severe asthma is defined as "asthma that requires treatment with high dose ICS plus a second controller and/or systemic corticosteroids to prevent it from becoming 'uncontrolled' or which remains 'uncontrolled' despite this therapy." Both GINA and the National Asthma Education and Prevention Program (NAEPP) recommend use of omalizumab as add on therapy for patients who have failed to respond to standard therapy and have IgE-mediated allergic asthma.

Chronic Idiopathic Urticaria (CIU)
Chronic urticaria is a cutaneous mast cell degranulation lasting more than 6 weeks characterized by hives or wheals. The wheals usually last less than 24 hours with itching being the most common symptom. Diagnosis involves evaluation of labs including a complete blood count with differential, stool samples (assessing for parasitic activity), erythrocyte sedimentation rate, antinuclear antibody, hepatitis B and C titers, serum cryoglobulin and complement assays, thyroid function testing, and Chronic Urticaria index.

The standard of care is non-sedating antihistamines. Additional agents may be added on and/or substituted including leukotriene antagonists, systemic corticosteroids, immunomodulators, anti-inflammatory agents, and thyroid medications for patients who failed to respond to antihistamines.

Cinqair® (reslizumab)
Fasenra™ (benralizumab)
Nucala® (mepolizumab)

Severe Asthma Phenotype and Eosinophilic Asthma Subphenotype
Severe asthma is defined as "asthma that requires treatment with high dose inhaled corticosteroids (ICS) plus a second controller and/or systemic corticosteroids to prevent it from becoming 'uncontrolled' or which remains 'uncontrolled' despite this therapy." Despite the availability of multiple asthma treatments, a substantial proportion of patients with severe asthma continue to have uncontrolled disease. Thirty to forty percent of severe asthma patients still need regular bursts of systemic steroids to control their asthma. Severe asthma has a considerable amount of variability in its pattern of inflammation, and this variability causes multiple phenotypical differences that influence treatment response.

Eosinophilic asthma is a subphenotype of severe asthma characterized by elevated sputum and blood eosinophil levels as well as increased asthma severity, atopy, late-onset disease, and steroid refractoriness. Several biomarkers including blood eosinophilic counts and sputum eosinophilic counts are used in diagnosing severe asthma with an eosinophilic phenotype. As with other severe forms of asthma, the Gold Standard/International Guidelines treatment for severe asthma, including eosinophilic asthma, is high dose ICS plus a long acting beta-2 agonist (LABA), leukotriene modifier or theophylline and/or continuous systemic corticosteroids as background therapy. Newer therapies that specifically target formation of eosinophils may also be utilized. Cinqair (reslizumab), Fasenra (benralizumab), and Nucala (mepolizumab) are examples of such agents FDA indicated for severe eosinophilic asthma.

CODING

BlueCHiP for Medicare and Commercial Products

The following HCPCS codes for biological supply are medically necessary the when medical criteria are met:

J2182 Injection, mepolizumab, 1 mg
J2357 Injection, omalizumab, 5 mg
J2786 Injection, reslizumab, 1 mg
J0517 Injection, benralizumab, 1 mg (New Code Effective 1/1/2019)
C9466 Injection, benralizumab, 1 mg (Code Deleted Effective 12/31/2018)

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, May 2018
Provider Update, January 2018
Provider Update, November 2016
Provider Update, December 2015
Provider Update, September 2013
Provider Update, May 2012
Provider Update, September 2011

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