

**Medical Coverage Policy | Injectable Agents for Asthma and Chronic Idiopathic Urticaria – Omalizumab (Xolair), Mepolizumab (Nucala), Reslizumab (Cinqair)**



**EFFECTIVE DATE:** 03|01|2018  
**POLICY LAST UPDATED:** 11|21|2017

## OVERVIEW

This policy documents coverage guidelines required for the use of Omalizumab (Xolair), Mepolizumab (Nucala) and Reslizumab (Cinqair). Omalizumab is a treatment for moderate to severe persistent allergic asthma and chronic idiopathic urticaria (CIU) in appropriate patients. Mepolizumab and Reslizumab 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 corticosteroids > 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 corticosteroids > 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<sub>1</sub> <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<sub>1</sub> 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.

**Mepolizumab (Nucala) and Reslizumab (Cinqair)**  
**BlueCHIP for Medicare and Commercial Products**

**Initial Evaluation**

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

- 1. The patient does not have any FDA labeled contraindications to the requested agent

**AND**

- 2. The patient has ONE of the following diagnoses:

- a. Severe eosinophilic asthma **OR**
- b. Another FDA approved indication

**AND**

- 3. If the diagnosis is severe eosinophilic asthma, the patient meets ONE of the following:

- a. There is documentation that the patient is currently being treated with the requested agent **OR**

- b. The patient meets 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. 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 requesting Cinqair, the patient has a blood eosinophilic count greater than or equal to 400 cells/MicroLiter within the previous 12 months  
**AND**
  2. If requesting 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. The patient has a baseline Forced Expiratory Volume (FEV<sub>1</sub>) less than 80% 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

**AND**

- v. ONE of the following:
1. The patient is currently treated with a maximally tolerated inhaled corticosteroid plus one or more other controller medications (e.g., LABA, leukotriene antagonist, anticholinergic) for at least 6 months (verified in claims history)  
**OR**
  2. The patient is receiving a maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)] for at least the past 6 months (verified in claims history)

**AND**

4. 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, Nucala)

**AND**

5. The dose is within the FDA labeled dose

**Cinqair** (reslizumab) and **Nucala** (mepolizumab) 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, 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  
**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.

### **Renewal Evaluation**

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

1. The patient has been previously approved for the requested agent  
**AND**
  2. The patient does not have any FDA labeled contraindications to the requested agent  
**AND**
  3. If the diagnosis is severe eosinophilic asthma, the patient meets ALL of the following:
    - a. The patient has had clinical response or disease stabilization as defined by ONE of the following:
      - i. Increase in percent predicted Forced Expiratory Volume (FEV<sub>1</sub>) from baseline **OR**
      - ii. Decrease in the dose of inhaled corticosteroids required to control the patient's asthma **OR**
      - iii. Decrease in need for treatment with systemic corticosteroids **OR**
      - iv. Decrease in number of hospitalizations or visits to urgent care or emergency room due to exacerbations of asthma**AND**
  - b. ONE of the following:
    - i. The patient is currently treated and is compliant with standard therapy (e.g. inhaled corticosteroids, long-acting beta-2 agonist) (verified in claims history)
- AND**
4. 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, Nucala)  
**AND**
5. The dose is within the FDA labeled dose

**Cinqair** (reslizumab) and **Nucala** (mepolizumab) will also be approved when the following are met:

1. The patient has been previously approved for the requested agent  
**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, 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.  
**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.

### **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 and Reslizumab, 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.

### **Mepolizumab (Nucala) and Reslizumab (Cinqair)**

#### **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. Nucala (mepolizumab) and Cinqair (reslizumab) 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

## RELATED POLICIES

Not applicable

## PUBLISHED

Provider Update, January 2018

Provider Update, November 2016

Provider Update, December 2015

Provider Update, September 2013

Provider Update, May 2012

Provider Update, September 2011

Provider Update, December 2010

## REFERENCES

1. Centers for Medicare and Medicaid Services (CMS). Local Coverage Article (LCA): Omalizumab (e.g., Xolair®) – Related to LCD L33394 (A52448)
2. Xolair product information. Genentech, Inc. July 2016.
3. National Asthma Education and Prevention Program (NAEPP) Expert Panel Report 3. Guidelines for the Diagnosis and Management of Asthma. Published 2007. Available at <http://www.nhlbi.nih.gov/files/docs/guidelines/asthsumm.pdf>. Accessed August 2016.
4. Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention, Global Initiative for Asthma (GINA) 2016 guidelines. Available at [www.ginasthma.org](http://www.ginasthma.org). Accessed August 2016
5. National Asthma Education and Prevention Program. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma (EPR-3). July 2007. Available at: <http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm>. Accessed January 2017.
6. American Academy of Allergy Asthma & Immunology: Allergic asthma. Available at: [www.aaaai.org](http://www.aaaai.org) accessed in August 2016.
7. Lanier B, Bridges T, Kulus M, et al. Omalizumab for the treatment of exacerbations in children with inadequately controlled allergic (IgE-mediated) asthma. J Allergy Clin Immunol. 2009 Dec;124(6):1210-6.
8. Nucala package insert. GlaxoSmithKline LLC. November 2015.
9. National Asthma Education and Prevention Program (NAEPP) Expert Panel Report 3. Guidelines for the Diagnosis and Management of Asthma. Published 2007. Available at <http://www.nhlbi.nih.gov/files/docs/guidelines/asthsumm.pdf> Accessed January 2017
10. National Institute for Health and Care Excellence (NICE). Asthma: Diagnosis and monitoring of asthma in adults, children, and young people. 2015 guidelines. Available at <https://www.nice.org.uk/guidance/gid-cgwave0640/resources/asthma-diagnosis-and-monitoring-draft-guideline2>. Accessed September 2016

11. Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention, Global Initiative for Asthma (GINA) 2016 guidelines. Available at [www.ginasthma.org](http://www.ginasthma.org) Accessed September 2016.
12. Walford H and Doherty T. Diagnosis and management of eosinophilic asthma: a US perspective. *Journal of Asthma and allergy* 2014;7: 53-65
13. American Academy of Allergy, Asthma and Immunology; American College of Allergy, Asthma and Immunology and Joint Council of Allergy, Asthma, and Immunology. Attaining optimal asthma control: a practice parameter. *J Allergy Clin Immunol.* 2005; 116(5):S3-S11.
14. Bel H, Wenzel, SE, et al. Oral Glucocorticoid-Sparing Effect of Mepolizumab in Eosinophilic Asthma. *The New England Journal of Medicine* 2014; 371(13): 1189-1197.
15. Nair P. Anti-Interleukin-5 Monoclonal Antibody to Treat Severe Eosinophilic Asthma. *The New England Journal of Medicine* 2014; 371(13): 1249-1251.
16. Cinqair package insert. Teva. June 2016.

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