MEDICAL POLICY STATEMENT		
Original Effective Date	**Next Annual Review Date**	**Last Review / Revision Date**
06/15/2011	**02/15/2017**	**03/09/2016**
Policy Name		**Policy Number**
Xolair/Nucala/Cinqair		**SRx-0013**
Policy Type		
☒ **Medical**	☐ **Administrative**	☐ **Payment**

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

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A. SUBJECT

- **Omalizumab (Xolair)**
- **Mepolizumab (Nucala)**
- **Reslizumab (Cinqair)**

B. BACKGROUND

The CareSource Medication Policies are therapy class policies that are used as a guide when determining health care coverage for our members with benefit plans covering prescription drugs. Medication Policies are written on selected prescription drugs requiring prior authorization or Step-Therapy. The Medication Policy is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

The intent of the Omalizumab (Xolair) Mepolizumab (Nucala), Reslizumab (Cinqair) (PA) Program is to encourage appropriate selection of patients for therapy according to product labeling and/or clinical guidelines and/or clinical studies, and also to encourage use of preferred agents.

C. DEFINITIONS

D. POLICY

I. CareSource will approve the use of **omalizumab (Xolair)** and consider its use as medically necessary when the following criteria have been met for:

A. Prior Authorization Criteria for Moderate to Severe Persistent Allergic Asthma
Omalizumab (Xolair) is indicated for reducing signs and symptoms in children and adults 6 years of age and older with moderate to severe persistent allergic asthma whose asthma symptoms are not controlled by medium to high doses of inhaled

corticosteroids plus long acting beta2 agonists or leukotriene modifiers.

1. Prior Authorization Criteria:
   1.1 Initial course is indicated when ALL of the following are present:
      a. Prescribed by a pulmonologist or allergist for the diagnosis of asthma
      b. Age 6 years or older
      c. Forced expiratory volume in 1 second (FEV1) less than 80% predicted
      d. Allergy testing performed, as indicated by 1 or more of the following:
      e. Positive skin testing for perennial aeroallergen
      f. Reactivity to at least one aeroallergen documented by elevated serum IgE level
      i. Have a baseline plasma immunoglobulin E (IgE) level above 30 IU/ml
      g. Omalizumab not being used as monotherapy for asthma
      h. Has the member's asthma been inadequately controlled with a 3 month trial with one of the following:
      i. medium to high doses of inhaled corticosteroids plus long acting beta2-agonists
      j. High dose inhaled corticosteroid and a Leukotriene Receptor Antagonists
2. Reauthorization of subsequent course is indicated when **ALL** of the following are present:
   2.1 Omalizumab is not being used as monotherapy for asthma
   2.2 Patient has demonstrated improvement during 16 weeks of omalizumab therapy, as indicated by **1 or more** of the following:
      a. Decreased frequency of emergency department visits
      b. Decreased frequency of hospitalizations due to asthma symptoms
      c. Increase in percent predicted FEV1 from pretreatment baseline
      d. Improved functional ability (ie, decreased effect of asthma on ability to exercise, function in school or at work, or quality of sleep)
      e. Decreased utilization of rescue medications

3. Prior Authorization Criteria for **Chronic Idiopathic Urticaria**:
   Omalizumab (Xolair) is indicated for treatment in members 12 years of age or ~~and~~ older with chronic idiopathic urticari who remain symptomatic as a fourth line course of therapy
   3.1 Prescribed by a dermatologist or allergist, or under the recommendation of a dermatologist or allergist.
   3.2 Has the patient tried one of the following:
      a. The member tried and failed a second generation antihistamine at the maximal FDA-approved dosage
      b. The member tried and failed two second generation antihistamines given at the same time
      c. The member tried and failed a second generation antihistamine and a H2 antagonist given at the same time
      d. The member tried and a second generation antihistamine and a leukotriene receptor antagonist
      e. The member tried and failed a second generation antihistamine and a first generation antihistamine given at the same time
   3.3 The patient has tried and failed hydroxyzine or doxepin
   3.3 No known underlying cause of chronic urticarial

B. CareSource will approve the use of **Mepolizumab (Nucula)** and consider its use as medically necessary when the following criteria have been met:
   1. Prior Authorization Criteria:

1.1 Initial course is indicated when **ALL** of the following are present:
   a. Prescribed by, or in consultation with, a pulmonologist, allergist or immunologist for the diagnosis of asthma with eosinophilic phenotype
   b. Have a baseline peripheral blood eosinophil count greater or equal to 150 cells/mcL at initiation of therapy or 300 cells/microliter in the past 12 months
      (1) A three month trial with a high-dose inhaled corticosteroids (ICS) and long-acting inhaled beta-2 agonists

2. Reauthorization of subsequent course is indicated when **ALL** of the following are present:
   2.2 Patient has demonstrated improvement during mepolizumab therapy, as indicated by **1 or more** of the following:
      a. Decreased frequency of emergency department visits
      b. Decreased frequency of hospitalizations
      c. Improved functional ability (i.e., decreased effect of asthma on ability to exercise, function in school or at work, or quality of sleep)
      d. Decreased utilization of rescue medications
   2.3 Mepolizumab not being used as monotherapy for asthma

C. CareSource will approve the use of Reslizumab (Cinqair) and consider its use as medically necessary when the following criteria have been met:
   1. **Prior Authorization Criteria:**
      Reslizumab (Cinqair) is indicated in patients diagnosed with severe eosinophilic asthma
      1.1 Initial course of reslizumab (Cinqair) meets the definition of **medical necessity** when **ALL** of the following criteria are met:
         a. 18 years of age and older:
         b. Reslizumab is prescribed by a board certified allergist, immunologist, or pulmonologist
         c. A blood eosinophil count of at least 400 cells/microliter
      1.2 Individual has experienced **at least 1 asthma** exacerbation **requiring treatment with a corticosteroid with the last year**
         a. Has the member's asthma been inadequately controlled with a 3 month trial with one of the following:
            (1) Medium to high doses of inhaled corticosteroids plus long acting beta2-agonists
            (2) High dose inhaled corticosteroid and a Leukotriene Receptor Antagonists
      1.3 Reslizumab is not used in combination with mepolizumab (Nucala) or omalizumab (Xolair)
      1.4 Continuation of reslizumab (Cinqair) meets the definition of **medical necessity** for members meeting the following criteria:
         a. Patient has demonstrated improvement during mepolizumab therapy, as indicated by **1 or more** of the following:
            (1) Decreased frequency of emergency department visits\
            (2) Decreased frequency of hospitalizations
            (3) Improved functional ability (i.e., decreased effect of asthma on ability to exercise, function in school or at work, or quality of sleep)
            (4) Decreased utilization of rescue medications
      1.5 Mepolizumab not being used as monotherapy for asthma

Note: Documented diagnosis must be confirmed by portions of the individual's medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but not limited to test reports, chart notes from provider's office or hospital admission notes.

All other uses of Omalizumab (Xolair), Mepolizumab (Nucala), Reslizumab (Cinqair) are considered experimental/investigational and therefore, will follow CareSource's Medical Necessity Off-Label policy.

Refer to the product package insert for dosing, administration and safety guidelines.

CONDITIONS OF COVERAGE

HCPCS	J2357 Xolair
	J3590 Nucala
	J3590 Cinqair

CPT

CONDITIONS OF COVERAGE

Office, Outpatient

Xolair should only be administered in a healthcare setting by healthcare providers due to the risk of anaphylaxis. Anaphylaxis, presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been reported to occur after administration of Xolair.

Note: CareSource supports administering injectable medications in various settings, as long as those services are furnished in the most appropriate and cost effective setting that are supportive of the patient's medical condition and unique needs and condition. The decision on the most appropriate setting for administration is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of the specific medication.

AUTHORIZATION PERIOD

Approved authorizations are valid for 16 weeks. Continued treatment may be considered when the member has shown biological response to treatment. **ALL** authorizations are subject to continued eligibility.

E. REVIEW/REVISION HISTORY

Date Issued:	6/15/2011
Date Reviewed:	06/15/2011, 03/15/2013, 06/15/2014, 02/15/2015, 03/09/2016
Date Revised:	02/15/2015 – Revision to criteria 03/09//2016 – Added criteria for mepolizumab (Nucala) 09/07/2016 – Reduced age from 12 to 6 years old for omalizumab (Xolair) as approved by the FDA July 2016

F. REFERENCES

1. Xolair® [package insert]. South San Francisco, CA: Genentech, Inc., July 2016.
2. Buhl R. Omalizumab (Xolair) improves quality of life in adult patients with allergic asthma: A review. Respir Med. 2003;97(2):123-129.
3. Finn A, Gross G, van Bavel J, et al. Omalizumab improves asthma-related quality of life in patients with severe allergic asthma. J Allergy Clin Immunol. 2003;111(2):278-284
4. Bang LM, Plosker GL. Omalizumab: A review of its use in the management of allergic asthma. Treat Respir Med. 2004;3(3):183-199
5. Food and Drug Administration (FDA) Center for Drug Evaluation and Research. Transcript for the November 18, 2009 Meeting of the Pulmonary-Allergy Drugs Advisory Committee. Available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Pulmona ry-AllergyDrugsAdvisoryCommittee/UCM198005.pdf.%20. (February 25, 2010)
6. Xolair (Omalizumab) for Subcutaneous Use. Prescribing Information. Genentech, Inc. March 2014. Available at:http://www.gene.com/gene/products/information/pdf/xolair-prescribing.pdf. (May 19, 2014).
7. National Heart, Lung, and Blood Institute. National Asthma Education and Prevention Program: Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. 2008. Available at: http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.pdf (March 23, 2011).
8. Omalizumab for the treatment of chronic idiopathic or spontaneous urticaria.
9. Maurer M, Rosén K, Hsieh HJ, Saini S, Grattan C, Gimenéz-Arnau A, Agarwal S, Doyle R, Canvin J, Kaplan A, Casale T N Engl J Med. 2013;368(10):924.
10. Nucala® [package insert].Philadelphia, PA: GlaxoSmithKline LLC ; 4 Nov 2015.
11. Walford HH, Doherty TA. Diagnosis and management of eosinophilic asthma: a US perspective. J Asthma Allergy. 2014;7:53–65.
12. Cinqair [package insert], Teva, **05/2016**

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.