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	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.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

A. SUBJECT

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

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) (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 adolescents and adults 12 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 12 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:
   (1) Positive skin testing for perennial aeroallergen
   (2) Reactivity to at least one aeroallergen documented by elevated serum IgE level
e. Asthma present for **1 year or more**
f. Have a baseline plasma immunoglobulin E (IgE) level above 30 IU/ml
g. Moderate to severe asthma, as indicated by **1 or more** of the following:
   (1) Continuous or frequent need for oral corticosteroid therapy (eg, 4 or more times per year)
   (2) Multiple recent emergency department visits
   (3) Multiple recent hospitalizations
h. Significant functional impairment, as indicated by **1 or more** of the following:
   (1) Activity limitation
   (2) Decreased ability to function in school or at work
   (3) Nocturnal symptoms or nighttime awakenings at least once per week
i. Omalizumab not being used as monotherapy for asthma
j. Symptom evaluation indicates **1 or more** of the following:
   (1) Need for supervised asthma drug administration for patient not adherent to treatment with oral and inhaled medication
   (2) Symptoms inadequately controlled after **3 or more** months of therapy with inhaled corticosteroids combined with long-acting inhaled beta-agonists
   (3) Symptoms requiring significant oral or parenteral corticosteroid use

2. Reauthorization of subsequent course is indicated when **ALL** of the following are present:
   2.1 Patient met all criteria for initial administration.
   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)

Note: According to the NHLBI, patients with **moderate persistent asthma** exhibit some of the following characteristics:

- Daily symptoms
- Daily use of inhaled short-acting beta2-agonists
- Exacerbations affect activity
- Exacerbations >2 times a week; may last days
- Nighttime awakenings > 1x/week but not nightly
- FEV1 (predicted) 60-80%

Patients with **severe persistent asthma** exhibit some of the following characteristics:

- Continual symptoms
- Use of inhaled short-acting beta2-agonist several times per day

- Limited physical activity
- Frequent exacerbations
- Frequent nighttime awakenings often 7x/week
- FEV1(predicted) <60%

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 Symptoms of CIU do not improve to treatment with antihistamines at FDA-approved dosages, according to the step-care protocol for first, second and third lines of therapy (e.g. H1 & H2 antihistamines & leukotriene receptor agonists) for a trial period of at least 8 weeks.
   3.3 No known underlying cause of chronic urticaria

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:
      Mepolizumab (Nucula) is indicated in patients 12 years of age and older for add-on maintenance treatment of patients with severe asthma, and with an eosinophilic phenotype.
      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. Age 18 or older
         c. Have a baseline peripheral blood eosinophil count greater or equal to 150 cells/mcL within the previous 6 weeks or sputum eosinophil count greater than or equal to 3%
         d. Moderate to severe asthma, as indicated by **1 or more** of the following:
            (1) Continuous or frequent need for oral corticosteroid therapy (eg, 4 or more times per year)
            (2) Multiple recent emergency department visits
            (3) Multiple recent hospitalizations
         e. Significant functional impairment, as indicated by 1 or more of the following:
            (1) Activity limitation
            (2) Decreased ability to function in school or at work
            (3) Nocturnal symptoms or nighttime awakenings at least once per week
         f. History of 2 or more exacerbations in the previous year despite the regular use of the following agents to maintain asthma control:
            (1) High-dose inhaled corticosteroids and additional controller PLUS
            (2) Oral corticosteroids
         g. Mepolizumab prescribed in combination with BOTH of the following:
            (1) An inhaled corticosteroid (ICS)
            (2) An inhaled long acting beta-2 agonist (LABA)
         h. Symptoms inadequately controlled after **3 or more** months of **one** of the following groups of conventional therapy
            (1) Inhaled corticosteroids combined with long-acting inhaled beta-agonists OR
            (2) Inhaled corticosteroids combined with long-acting anticholinergics OR

combined with montelukast

2. Reauthorization of subsequent course is indicated when **ALL** of the following are present:
   2.1 Patient met all criteria for initial administration
   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)
   2.3 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) 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
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)

F. REFERENCES

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