MVP Health Care Medicaid Medical Policy

Xolair® (omalizumab)

Type of Policy:	**Medical Therapy *(administered by the pharmacy department)***
Prior Approval Date:	**7/1/2019**
Approval Date:	**12/02/2019**
Effective Date:	**12/02/2019**
Related Policies:	**NA**

Codes Requiring Prior Authorization (covered under the medical benefit)
J2357 Injection, omalizumab, 5 mg

Administration Codes
96372 Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
96401 Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic

Overview
Omalizumab (Xolair®) is a recombinant DNA-derived humanized IgG1k monoclonal antibody that selectively binds to human immunoglobulin E (IgE). It inhibits the binding of IgE to the high-affinity IgE receptor (FceRI) on the surface of mast cells and basophils and reduces the number of FceRI receptors on basophils. It is administered once or twice a month, with dosing based on the member's weight and IgE level. Xolair inhibits inflammation at its source versus suppressing inflammation once it has occurred. Symptom improvement is seen by four weeks from the start of treatment.

The Food and Drug Administration (FDA) reports that serious and life-threatening anaphylactic reactions have occurred in patients after treatment with Xolair®. Usually these reactions occur within two hours of receiving a Xolair subcutaneous injection. However, new reports include patients who had delayed anaphylaxis—with onset two to 24 hours or even longer after receiving Xolair treatment. Anaphylaxis may occur after *any* dose of Xolair (including the first dose), even if the patient had no allergic reaction to the first dose. The symptoms and signs of anaphylaxis in these reported patients include bronchospasm, hypotension, syncope, urticaria, and angioedema of the throat or tongue. Health care professionals who administer Xolair should be prepared to manage life-threatening anaphylaxis and should observe their Xolair-treated patients for at least two hours after the drug is given. Patients under treatment with Xolair should be fully informed about the signs and symptoms of anaphylaxis, their chance of developing delayed anaphylaxis following Xolair treatment, and how to treat it when it occurs.

Indications/Criteria

On label use of Xolair is covered under the member's medical benefit and does not require prior authorization. Off label use is subject to prior authorization and must meet MVP's clinical coverage criteria for Experimental or Investigational Procedures Experimental or Investigational Procedures, Behavioral Health Services, Drugs and Treatments, Off-Label use of FDA Approved Drugs, and Clinical Trials Policy.

Xolair (omalizumab) is FDA approved for:

- Subcutaneous injection in adults and adolescents with moderate to severe persistent asthma who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids; AND
- Chronic idiopathic urticaria in adults and adolescents who remain symptomatic despite H1 antihistamine treatment.

Approved medication must be administered in an office setting and is covered under the medical benefit.

Patient must meet the following criteria for all requests:

- Requests must be submitted by a participating plan allergist, immunologist, or pulmonologist who has managed the patient for at least six months; AND
- Patients must be at least 6 years of age for asthma treatment and 12 years of age for chronic idiopathic urticaria; AND
- Patient must meet the criteria below for either the treatment for moderate to severe persistent asthma OR chronic idiopathic urticaria

For approval considerations for moderate to severe persistent asthma:

The NHLBI Expert Panel recommends that omalizumab may be considered as adjunctive therapy in step 5 or 6 care for patients who have allergies and severe persistent asthma that is inadequately controlled with the combination of high-dose ICS and LABA[6].

Documentation by the prescriber must meet the following criteria:

- NIH-NHLBI classification of severe persistent asthma, for > 1 year, with claims history and/or medical chart documentation of all the following:
  1. Continual or daily symptoms
  2. Limited physical activity or exacerbations affecting activities of daily living (ADL's)
  3. Frequent exacerbations or exacerbations at least 2 times a week which may last days
  4. Nighttime symptoms more frequent than one time per week
  5. FEV_1 or PEF ≤80% predicted
  6. PEF variability >30%
  7. Increasing use of short acting beta2 agonist or use >2 days/week for symptom relief

- Evidence of compliance with:
  1. High dose Inhaled Corticosteroids (ICS) required for daily control
  2. Inadequate control on combination therapy (moderate dose ICS and a Long-Acting Beta-Agonist) for at least 6 months
  3. Oral Corticosteroid use of at least two courses within the past 12 months for asthmatic exacerbations or the inability to wean from systemic corticosteroids

- Specific relevant allergic sensitivities to perennial aeroallergens (dust mites, mold, animal dander, cockroaches, etc) determined by:
  1. Skin tests or
  2. *In vitro* testing

- Use in accordance with product literature or supporting clinical documentation for consideration on a case-by-case basis when outside published dosing limits:
    - Baseline IgE level (>30 IU/ml and ≤700 IU/ml)
    - Body Weight (≤150 kg)

- Be a non-smoker by history or have a successful smoking cessation for at least 6 weeks.

For approval considerations for chronic idiopathic urticaria:
Documentation by the prescriber must meet the following criteria:
- Urticaria is persistent or recurring over 6 weeks in duration; AND
- Individual lesions of urticaria lasting less than 24hours (if longer than 24 hours then urticarial vasculitis must first be ruled out, which may include ESR, complement assays, and biopsy); AND
- Other causes for urticaria (such as occupational, insect sting/bite, medications, food, infection, physical sensitivity) has been ruled out; AND
- Patient has remained symptomatic despite:
    - At least a two-week trial of a maximally tolerated dose of a potent H1 antihistamine (such as Hydroxyzine or Doxepin) in combination with <u>one</u> of the following:

        - Another H1 antihistamine (2nd gen)
        - H2 antihistamine
        - Systemic corticosteroids
        - Leukotriene receptor antagonist

Initial authorization for a 3-month trial to evaluate outcomes and responses to therapy. Approval for up to 3 years based on follow up documentation from the prescriber showing an appropriate response to therapy. Appropriate response for asthma includes but is not limited to: Improved function and quality of life, reduction in the lost days of work or school due to asthma, reduction in ER/hospital/office visits due to asthma, or decreased use of other asthma medications. Appropriate response for chronic idiopathic urticaria includes but is not limited to a decrease in itching or a decrease in hive count.

The following must also be considered when renewing Xolair for asthma:
When renewing Xolair, doses would be adjusted if there are significant changes in body weight. Re-testing of IgE levels should not be used as a guide for dose adjustment unless Xolair therapy has been interrupted for a minimum of one year.

Medicaid Variation:
Extensions of therapy will be up to 1 year.

Exclusions

Xolair (omalizumab) is not considered medically necessary and, therefore, is not covered when any of the following are true:
- members do not meet the above criteria
- member has experienced a hypersensitivity reaction to omalizumab (Xolair)
- member meet the below criteria for exclusions below for the specific indication omalizumab is being used to treat

When used for moderate to severe persistent asthma:

- current smokers
- a diagnosis other than allergic asthma, including allergic rhinitis, other allergic conditions, non-allergic asthma, allergic bronchopulmonary aspergillosis
- current treatment has not been optimized using alternatives such as
    1. high dose inhaled corticosteroids (ICS)
    2. leukotriene modifiers or theophylline
    3. long-acting beta agonists
    4. allergy injections (immunotherapy)
    5. member compliance or
    6. environmental controls
- omalizumab (Xolair) is not indicated for the treatment of acute bronchospasm or status asthmaticus
- other medical and environmental conditions known to exacerbate asthma have not been evaluated and treated.

When used for chronic idiopathic urticaria:

- a diagnosis other than chronic idiopathic urticaria
- omalizumab (Xolair) is not indicated for acute urticaria, urticarial vasculitis, or urticaria with a known cause

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References

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5. US Food and Drug Administration Alert (February 2007) online at www.fda.gov
6. National Asthma Education and Prevention Program. Guidelines for the diagnosis and management of asthma: expert panel report 3. Bethesda, Md.: U.S. Dept. of Health and Human Services, Public Health Service, National Institutes of Health, National Heart, Lung, and Blood Institute, 2007; NIH publication no. 08-5846.
7. National Government Services, Inc. Article for omalizumab (e.g. Xolair) – Related to LCD L25820 (A46088). Original Article Effective Date 12/01/2007. Article Revision Effective Date 6/5/2009. Available: http://www.ngsmedicare.com
8. Joint Task Force on Practice Parameters. The diagnosis and management of acute and chronic urticaria: a 2014 update. J Allergy Clin Immunol 2014; 133 (5): 1270-77.
9. Schaefer P. Urticaria: Evaluation and Treatment. Am Fam Physician. 2011;83(9):1078-84.