MVP Health Care Medical Policy

Medicare Part B: Xolair® (omalizumab)

Type of Policy:	**Medical Therapy *(administered by the pharmacy department)***
Prior Approval Date:	**11/01/2023**
Approval Date:	**04/01/2024**
Effective Date:	**06/01/2024**
Related Policies:	**Select Injectables for Asthma**

Drugs Requiring Prior Authorization (covered under the medical benefit)
J2357 Xolair® (omalizumab)

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

Overview/Summary of Evidence

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

Xolair (omalizumab) is FDA approved for:

- Moderate to severe persistent asthma in adults and pediatric patients 6 years of age and older who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids
- Chronic idiopathic urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.
- Nasal polyps in adults' patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment
- IgE-mediated food allergy in adult and pediatric patients at least 1 year of age and older for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods

A. Treatment with Xolair for ALL indications will be considered when the following criteria is met. Please see section B for indication specific criteria.

- Members must meet age requirements based on the FDA approved labeling for the applicable FDA approved indication **AND**
- Must be prescribed for an FDA approved indication
- Self-administration of Xolair is a Medicare Part D benefit and follows the Medicare Part D Prior Authorization criteria requirements.

B. Treatment for Xolair will be considered for the following indications:

1. For moderate to severe persistent asthma:

a. 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.

b. Documentation by the prescriber must meet the following criteria:

- Requests must be submitted by a participating plan allergist, immunologist, or pulmonologist who has managed the patient for at least six months
- 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 (daytime or nighttime)

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. FEV_1 or PEF ≤80% predicted
5. PEF variability >30%
6. Increasing use of short acting beta2 agonist or use >2 days/week for symptom relief

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

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

e. 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)

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

g. Documentation that other medical and environmental conditions known to exacerbate asthma have been evaluated and treated.

Initial authorization for 3 months

Extension of therapy up to 12 months. Clinical documentation showing a positive clinical response must be provided.

2. For chronic idiopathic urticaria:

a. Documentation by the prescriber must meet the following criteria:
   - Requests must be submitted by an allergist, immunologist, or pulmonologist who has managed the member for at least six months
   - 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**
   - Member 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 Second Generation H1 antihistamine
       - H2 antihistamine
       - First-generation H1 antihistamine at night
       - Leukotriene receptor antagonist

Initial authorization for 3 months

Extension of therapy up to 12 months based on improvement in chronic idiopathic urticaria on Xolair therapy. Improvement in chronic idiopathic urticaria includes but is not limited to a decrease in itching or a decrease in hive count.

3. For chronic rhinosinusitis with nasal polyps

a. The use of Xolair may be considered medically necessary if all the following criteria are met:
   - Confirmed diagnosis of nasal polyps. Chart notes must document diagnosis confirmation by examination, endoscopy, or sinus computed tomography (CT) scan.
   - Prescribed by or in consultation with an allergist, otolaryngologist or immunologist
   - Xolair (omalizumab) will be add on maintenance in combination with an intranasal corticosteroid
   - Documented failure, contraindication, intolerance, or allergy to at least one intranasal corticosteroid indicated to treat nasal polyps

Initial coverage will be for 3 months.

Requests for continuation of therapy must be accompanied by current chart notes identifying a continued benefit. Extension of therapy for up to one year will be based upon a positive clinical response.

4. **IgE-mediated Food Allergies**
    - **a.** Xolair may be considered for coverage for IgE-mediated Food Allergies when the following criteria is met:
        - Chart notes documenting a confirmed diagnosis of one or more IgE-mediated food allergy which is confirmed by one of the following below AND performed by a board certified allergist/immunologist:
            1. A positive skin prick test ≥4mm wheal OR
            2. Documentation of member total serum IgE (kIU/L) ≥ 6 kIU/L measured no longer than three months prior to request OR
            3. Documentation of a positive double-blind placebo-controlled food challenge (DBPCFC) with a single dose of food protein as performed by an allergist or immunologist
        - Prescribed by or in consultation with a board certified allergist/immunologist
        - Provider attestation that Xolair will be used in conjunction with food allergen avoidance
        - Documentation of member's current body weight

Initial coverage will be for 3 months.

Continued authorization up to 12 months must be accompanied by current chart notes identifying the following:

- Current body weight to verify dosing
- Provider attestation of food allergen avoidance

Exclusions

For all indications:

- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling

- Combination use with other biologics (e.g., Cinqair, Dupixent, Fasenra, Nucala)

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, acute bronchospasm or status asthmaticus
- current treatment has not been optimized using applicable alternatives such as
    1. high dose inhaled corticosteroids (ICS)
    2. leukotriene modifiers or theophylline if preferred therapies (ICS, LABA/LAMA) are not appropriate.
    3. long-acting beta agonists
    4. allergy injections (immunotherapy)
    5. member compliance
    6. inhaler technique
    7. environmental controls

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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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.
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11. Acute and Chronic Urticaria: Evaluation and Treatment - American Family Physician (aafp.org)
12. A Comparison of the United States and International Perspective on Chronic Urticaria Guidelines (jaci-inpractice.org)