MVP Health Care Medical Policy

Xolair® (omalizumab)

Type of Policy: **Medical Therapy *(administered by the pharmacy department)***
Prior Approval Date: **07/01/2023**
Approval Date: **04/01/2024**
Effective Date: **04/01/2024**
Related Policies: **Dupixent, Select Injectables for Asthma**

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

Drugs Requiring Prior Authorization (covered under the pharmacy benefit)
Xolair (omalizumab) pre-filled syringes

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

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

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 allergies in adult and pediatric patients aged 1 year and older for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. To be used in conjunction with food allergen avoidance.

A. For all indications, the following criteria must be met in addition to the specific diagnosis criteria below.

- Members must meet age requirements based on the FDA approved labeling for the applicable FDA approved indicated. **AND**
- Must be prescribed for an FDA approved indication
- Xolair injection for office administration may be considered for coverage if the following is provided:
    - Rationale and documentation are provided identifying why the member or caregiver is unable to self-administer using the pre-filled syringe **OR**
    - Member has coverage under Medicare Part B and meets the criteria for a provider administered drug.
    - See **Medicare Variation** for self-administration requirements.

B. Moderate to severe persistent asthma

Xolair may be considered for coverage for moderate to severe persistent asthma when the following criteria is met:

- 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.

- 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:
            - Continual or daily symptoms (daytime or nighttime)
            - Limited physical activity or exacerbations affecting activities of daily living (ADL's)
            - Frequent exacerbations or exacerbations at least 2 times a week which may last days
            - FEV_1 or PEF ≤80% predicted
            - PEF variability >30%
            - Increasing use of short acting beta2 agonist or use >2 days/week for symptom relief
- 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
        - Specific relevant allergic sensitivities to perennial aeroallergens (dust mites, mold, animal dander, cockroaches, etc.) determined by:
            - Skin tests or
            - *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.
    - Documentation that other medical and environmental conditions known to exacerbate asthma have been evaluated and treated.

Initial approval will be for 3 months

Continued authorizations will be approved up to 3 years when current documentation indicates the following:

- Improvement in asthma control, which 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.
- Increase in percent predicted FEV1 from baseline
- Xolair is used in addition to an ICS containing maintenance medication
- The following must also be considered when renewing Xolair for asthma
  - 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.

C. Chronic idiopathic urticaria:

Xolair may be considered for coverage for chronic idiopathic urticaria when the following criteria is met:

- 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 approval will be for for a 3-months

Continued authorization will be up to 3 years if current chart notes document that the member has a continued benefit to therapy. Improvement in chronic

idiopathic urticaria includes but is not limited to a decrease in itching or a decrease in hive count. Extension requests where Xolair did not have the full desired effect or considered a clinical failure will require clinical rationale for continuing.

D. Chronic Rhinosinusitis with nasal polyps

Xolair may be considered for coverage for Chronic Rhinosinusitis with nasal polyps when the following criteria is 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 immunologistAttestation that Xolair will be add on maintenance in combination with an intranasal corticosteroid
- Documented trial and failure of three (3) months, to at least one intranasal corticosteroid indicated to treat nasal polyps
- Documented failure, contraindication, intolerance, or allergy to other therapy used in the management of nasal polyps such as nasal saline irrigations, or antileukotriene agents (i.e. montelukast, zafirlukast, zileuton)
- Documentation of prior oral corticosteroid therapy and/or sinus surgery

Initial coverage will be for 6 months.

Continued authorization up to 12 monthsmust be accompanied by current chart notes identifying a continued benefit and compliance with combination therapy. Claims history must show compliance with combination therapy

E. IgE-mediated Food Allergies

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 an 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 6 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

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

Medications that are a pharmacy benefit are covered and billed to New York State Fee-For-Service (FFS) program. They are defined as medications that go through a retail or specialty pharmacy, including self-administered injectable products. Pharmacy medications are subject to FFS's clinical criteria including (but not limited to) coverage, quantity limit, step therapy, and prior authorization. Pharmacy benefit information can be found here: https://www.emedny.org/info/fullform.pdf

Medicare Variation:
Self-administration of Xolair is a Medicare Part D benefit and follows the Medicare Part D Prior Authorization criteria requirements.

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
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For chronic idiopathic urticaria:

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

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References

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3. U.S. Department of Health and Human Services (2003). Key clinical activities for quality asthma care: recommendation of the national asthma education and prevention program. National Asthma Education and Prevention Program.
4. Rosenwasser, L.J. & Nash, D.B. (2003). Incorporating omalizumab into asthma treatment guidelines: consensus panel recommendations. P&T 28(6) 400-10.
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.
10. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group | NHLBI, NIH
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)

Member Product	Medical Management Requirements*
New York Products	
HMO	Prior Authorization
PPO in Plan	Prior Authorization
PPO OOP	Prior Authorization
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
Essential Plan	Prior Authorization
MVP Medicaid Managed Care	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Child Health Plus	Prior Authorization
MVP Harmonious Health Care Plan	Pharmacy benefit carved out to Medicaid FFS, Medical benefit Prior Authorization
MVP Medicare Gold Giveback	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare WellSelect Plus PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Patriot Plan PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Complete D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP DualAccess Plus D-SNP HMO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
Healthy NY	Prior Authorization
MVP Premier	Prior Authorization
MVP Premier Plus	Prior Authorization
MVP Premier Plus HDHP	Prior Authorization
MVP Secure	Prior Authorization
MVP EPO	Prior Authorization
MVP EPO HDHP	Prior Authorization
MVP PPO	Prior Authorization
MVP PPO HDHP	Prior Authorization
Student Health Plans	Prior Authorization
ASO	See SPD
Vermont Products	
POS in Plan	Prior Authorization
POS OOP	Prior Authorization
MVP Medicare Preferred Gold HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP Medicare Secure Plus HMO POS	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Select PPO	Refer to the MVP website for the Medicare Part B and Part D policies.

UVM Health Advantage Secure PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
UVM Health Advantage Preferred PPO	Refer to the MVP website for the Medicare Part B and Part D policies.
MVP VT HMO	Prior Authorization
MVP VT Plus HMO	Prior Authorization
MVP VT HDHP HMO	Prior Authorization
MVP VT Plus HDHP HMO	Prior Authorization
MVP Secure	Prior Authorization
ASO	See SPD
♦ Note: Prior authorization requirements for HDHP products are the same as the base product (e.g. HDHP HMO auth requirements are the same as listed for HMO).	
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***Medical Management Requirements**

Prior Auth	Prior Authorization Required
Potential for Retrospective Review	No Prior Authorization Required. May be subject to Retrospective Review.
Retro Review	Retrospective Review Required
Not Covered	Service is not a covered benefit.
See SPD	See Specific Plan Design