Xolair® (omalizumab)
Prior Authorization Criteria
Drug Protocol Management
MassHealth/Commercial/Exchange

Policy

Xolair is a monoclonal antibody and IgE blocker indicated for moderate to severe persistent allergic asthma and chronic idiopathic urticaria (CIU). Approval for Xolair (omalizumab) will be granted when all the following criteria and conditions have been met and documentation has been submitted.

Xolair is NOT indicated for acute asthma exacerbations, acute bronchospasms or status asthmaticus.

Asthma Criteria:

1. Member is at least 6 years of age or older. Requests for members under the age of 6 will be reviewed on a case-by-case basis.
2. Member must be under the active care of a pulmonologist or allergist and prescription must be written by pulmonologist or allergist.
3. Member must not be an active smoker.
4. Member must have moderate/severe persistent allergy-related asthma as evidenced by at least 2 of the following:
   - Daily or continual symptoms such as cough, wheezing, chest tightness or difficulty breathing
   - Nighttime symptoms occurring 3 times a month or greater
   - Lung function test FEV1 is greater than 60% but less than 80% of predicted (moderate) or less than 60% of predicted (severe)

Labs:

1. Prescriber must submit total IgE level & specific allergy testing results conducted within past 2 years to allergens (RAST or SPT).
2. IgE levels must be between 30-1300 IU/mL for children and between 30-700 IU/mL for adults. NOTE: IgE levels outside of these ranges will be reviewed on a case-by-case basis.
3. Member has a positive skin test or *in vitro* testing (i.e., a blood test for allergen-specific IgE antibodies such as the radioallergosorbent test (RAST)) for one or more perennial aeroallergens.
4. Member must have pre-bronchodilator FEV1 performed within the past 6 months.

Medications:

1. Member must be maintained on and adherent*to (taking at least 80% of daily doses) ***high dose*** inhaled steroids (**see Appendix A**) in combination with a long-acting inhaled beta-2 agonist (e.g. Serevent®, Foradil®, Arcapta® Neohaler) and a leukotriene modifier (e.g., Singulair®, Accolate®, or Zyflo)
   OR
   high dose Advair Diskus® (≥ 500/50; twice daily) or
   high dose Advair HFA® (≥ 115/21; 2 puffs twice daily) or
   high dose Symbicort® (≥ 160/4.5; 2 puffs twice daily) or
   high dose Dulera® (≥ 200/5; 2 puffs twice daily) or
   high dose Breo ® (≥ 200/25;1 puff daily)
   OR

Member is current taking daily systemic steroid therapy

AND

2. Member has at least 1 claim in the last 6 months for a bronchodilator to control acute symptoms (e.g. albuterol, metaproterenol, Maxair®, Proventil®, Ventolin®, Xopenex®, etc.)

*Adherence is defined as prescription fills of at least 70% during the previous 120 days

Symptomatic:

Despite adequate adherence to above therapy, member must be actively symptomatic as evidenced by:

1. Daily use of bronchodilator therapy OR
2. An asthma-related hospitalization or emergency room visit within the past 12 months OR
3. More than 2 systemic steroid bursts within the past 6 months for an asthma exacerbation.

Initial Approval Duration & Administration Requirement:

Initial approval of Xolair will be granted for 6 months if member meets ALL criteria and documentation has been submitted.

Recertification:

Requests for continuation of Xolair will be approved for 12 months when clinical information is submitted documenting improvement as evidenced by a decrease in the frequency of exacerbations, a decrease in systemic steroid requirement, decrease in emergency room visits and/or hospitalizations due to asthma and improvement in lung function tests. Providers must confirm that Xolair will be administered only in a healthcare setting.

Limitations:

Requested dosing above the manufacturer recommendations will be reviewed on a case-by-case basis. (Refer to manufacturer prescribing guidelines).

APPENDIX A: Comparative Daily Dosages for Inhaled Corticosteroids in Adults

Medication	Adult Daily High Doses
Beclomethasone MDI	>480 mcg
Budesonide DPI	>1,080 mcg
Ciclesonide MDI	>640 mcg
Flunisolide MDI	>640 mcg
Fluticasone MDI	>440 mcg
Fluticasone DPI	>500 mcg
Mometasone DPI	>440 mcg

Chronic Idiopathic Urticaria (CIU) Criteria:

Coverage for Xolair® (omalizumab) will be granted for chronic idiopathic urticaria (CIU) when all the following conditions have been met and documentation submitted:

1. Diagnosis is chronic idiopathic urticaria (CIU) (also referred to as chronic urticaria)
   Note: Not indicated for other allergic conditions or other forms of urticaria

2. Member as at least 12 years of age
   Note: Requests for members under the age of 12 will be reviewed on a case-by-case basis.
3. Member must be under the active care of an allergist, dermatologist or immunologist specializing in the treatment of CIU.
4. Member has had a documented inadequate response with two (2) different histamine (H_1) blockers despite adherence to therapy:
   a. Non-sedating antihistamines (e.g., cetirizine, fexofenadine, loratadine, desloratadine, levocetirizine, etc.)
   b. First-generation antihistamines (e.g., brompheniramine, clemastine, chlorpheniramine, cyproheptadine, diphenhydramine, hydroxyzine, etc.)

   Note: Maximum tolerated doses (up to 4 times recommended doses)
5. Member has had a documented inadequate response with an antihistamine (H_2) blocker (e.g., ranitidine, famotidine, cimetidine, etc.) used in combination with a histamine (H_1) blocker despite adherence to therapy
6. Member has had a documented inadequate response with montelukast used in combination with a histamine (H_1) blocker despite adherence to therapy

Dosing:
Xolair® (omalizumab) is administered as 150mg or 300mg by subcutaneous injection every 4 weeks.

Approval Duration:
Initial requests will be approved for 3 months.

Recertification requests:
Prescriber must include documentation of improvement in the signs and symptoms of CIU per prescriber assessment and/or, if applicable, a decrease/discontinuation of any steroid therapy requirement. May be approved for 6 months.

References

1. Xolair [prescribing information]. Genentech USA, Inc. and Novartis Pharmaceuticals Corporation; 2017.
2. National Asthma Education and Prevention Program (NAEPP). Expert Panel Report 3 (EPR-3): Guidelines for the Diagnosis and Management of Asthma. Clinical Practice Guidelines, National Institutes of Health, National Heart, Lung, and Blood Institute, NIH Publication No. 08-4051, prepublication 2007. http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.pdf.
3. Lieberman P, Nicklas RA, Randolph C, et al. Anaphylaxis--a practice parameter update 2015. Ann Allergy Asthma Immunol. 2015;115(5):341-384.[PubMed 26505932]10.1016/j.anai.2015.07.019
4. Global Initiative for Asthma. Global strategy for asthma management and prevention. http://www.ginasthma.org. Updated 2016. Accessed June 8, 2016.
5. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. Eur Respir J. 2014;43(2):343-373.[PubMed 24337046]
6. Evaluating and managing chronic idiopathic urticaria in adults. JAAPA. 2018 Jul;31(7):22-26. doi: 10.1097/01.JAA.0000534976.46365.1 [PubMed 29899715]
7. Send to
8. Anti-IgE treatment, airway inflammation and remodelling in severe allergic asthma: current knowledge and future perspectives
9. Eur Respir Rev. 2015 Dec;24(138):594-601. doi: 10.1183/16000617.00001715. [PubMed 26621973]
10. Omalizumab for asthma in adults and children. Cochrane Database Syst Rev. 2014 Jan 13;(1):CD003559. doi: 10.1002/14651858.CD003559.pub4. [PubMed 24414989]

11. Management of Chronic Spontaneous Urticaria in Routine Clinical Practice Following the EAACI/GA(2)LEN/EDF/WAO Guidelines. Actas Dermosifiliogr. 2017 May;108(4):346-353. doi: 10.1016/j.ad.2016.12.012. Epub 2017 Feb 20. [PubMed 28219634]
12. Asthma Guidelines: Guidelines Summary, Classification Guidelines https://emedicine.medscape.com/article/296301-guidelines Nov 19, 2017

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