

Xolair (omalizumab)
Effective 01/01/2020

Plan	<input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Asthma: Omalizumab is an IgG monoclonal antibody (recombinant DNA derived) which inhibits IgE binding to the high-affinity IgE receptor on mast cells and basophils. By decreasing bound IgE, the activation and release of mediators in the allergic response (early and late phase) is limited. Serum free IgE levels and the number of high-affinity IgE receptors are decreased.

Chronic idiopathic urticaria: Omalizumab binds to IgE and lowers free IgE levels. Subsequently, IgE receptors (FcεRI) on cells down-regulate. Omalizumab is not indicated for acute asthma exacerbations, acute bronchospasms or status asthmaticus.

Coverage Guidelines

Approval of Xolair will be granted if the member meets all following criteria and documentation has been submitted:

Asthma

1. Authorization may be granted for members who are currently receiving treatment with Xolair for moderate to severe allergic-related asthma excluding when the product is obtained as samples or via manufacturer's patient assistance program
- OR**
2. Member is diagnosed with moderate to severe allergy-related asthma
 3. Member is ≥ 6 years of age
 4. Prescriber is an asthma specialist (i.e., allergist, immunologist, pulmonologist)
 5. Member remains symptomatic despite adherence to one of the following:
 - combination inhaler containing an inhaled corticosteroid and a long-acting β -agonist

- combination of an inhaled corticosteroid and a long-acting β -agonist inhaler as separate inhalers
 - chronic oral corticosteroids
6. Member's baseline serum IgE is between 30 IU/mL to 700 IU/mL
 7. Member has evidence of specific allergic sensitivity (i.e., positive skin test or radioallergosorbent test [RAST] for IgE

Chronic Idiopathic Urticaria (CIU)

1. Authorization may be granted for members who are currently receiving treatment with Xolair for CIU excluding when the product is obtained as samples or via manufacturer's patient assistance program
OR
2. Member is ≥ 12 years of age
3. Prescriber is an allergist/immunologist or dermatologist, or consultation notes from an allergist/immunologist or dermatologist regarding the diagnosis and treatment recommendations are submitted
4. Member has had an inadequate response, adverse reaction or a contraindication to **all** the following therapy combinations:
 - Treatment with at least two H1 antihistamines
 - Treatment with one H1 antihistamine taken in combination with a leukotriene antagonist
 - Treatment with one H1 antihistamine taken in combination with an H2 antihistamine

Continuation of Therapy

Reauthorization may be granted upon receipt of clinical documentation of improvement of asthma (i.e., decrease in oral steroid requirement, decrease in exacerbations, decreased asthma-related ED visits or hospitalizations) and CIU (i.e., decrease in antihistamine or steroid requirement, reduction in CIU flares).

Limitations

1. Initial approvals will be granted for 6 months
2. Reauthorizations will be granted based on diagnosis:
 - a. Asthma: 12 months
 - b. CIU: 6 months
3. Providers must confirm that Xolair will be administered only in a healthcare setting.

References

1. Xolair (omalizumab) [prescribing information]. San Francisco, CA: Genentech Inc; September 2018.
2. Marzano AV, Genovese G, Casazza G, et al. Predictors of response to omalizumab and relapse in chronic spontaneous urticaria: a study of 470 patients. J Eur Acad Dermatol Venereol 2019; 33:918
3. Bernstein JA, Lang DM, Khan DA, Craig T, Dreyfus D, Hsieh F, et al. The diagnosis and management of acute and chronic urticaria: 2014 update. J Allergy Clin Immunol. 2014;133(5):1270-
4. 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



5. Global Initiative for Asthma. Global strategy for asthma management and prevention. <http://www.ginasthma.org>. Updated 2019.
6. 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]
7. 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]
8. Omalizumab for asthma in adults and children. *Cochrane Database Syst Rev*. 2014 Jan 13;(1):CD003559. doi: 10.1002/14651858.CD003559.pub4. [PubMed 24414989]
9. 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]
10. Asthma Guidelines: Guidelines Summary, Classification Guidelines <https://emedicine.medscape.com/article/296301-guidelines> Nov 19, 2017
11. Tharp MD, Bernstein JA, Kavati A, et al. Benefits and Harms of Omalizumab Treatment in Adolescent and Adult Patients With Chronic Idiopathic (Spontaneous) Urticaria: A Meta-analysis of "Real-world" Evidence. *JAMA Dermatol* 2019; 155:29
12. Sobieraj DM, Baker WL, Nguyen E, et al. Association of Inhaled Corticosteroids and Long-Acting Muscarinic Antagonists With Asthma Control in Patients With Uncontrolled, Persistent Asthma: A Systematic Review and Meta-analysis. *JAMA* 2018; 319:1473

Review History

- 06/2003 - Implemented
- 09/26/05 - Reviewed/Updated
- 09/25/06 - Reviewed/Updated
- 09/24/07 - Reviewed/Updated
- 09/22/08 - Reviewed/Updated
- 09/21/09 - Reviewed/Updated
- 09/27/10 - Reviewed/Updated
- 09/19/11 - Reviewed/Updated
- 09/24/12 - Reviewed/Updated
- 09/23/13 - Reviewed/Updated
- 09/22/14 - Reviewed/Updated
- 09/21/15 - Reviewed/Updated
- 09/19/16 - Reviewed/Updated
- 09/18/17 - Reviewed/Updated
- 09/24/18 - Reviewed/Updated
- 09/18/19 - Deleted Leukine and spirometry requirement to align with MH

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