

Clinical Policy Title:	Xolair (omalizumab)
Policy Number:	RxA.912
Drug(s) Applied:	Xolair (omalizumab)
Original Policy Date:	11/1/2025
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	Amazon Business Only

Criteria

I. Initial Approval Criteria

A. Asthma, moderate to severe persistent (must meet all):

1. Diagnosis of moderate to severe persistent asthma;
2. Patient has a positive skin test or in vitro reactivity to a perennial aero-allergen;
3. Patient has experienced ≥ 2 exacerbations with in the last 12 months, requiring one of the following (i or ii):
 - i. Systemic corticosteroid treatment;
 - ii. Hospital admission;
4. For 6 years of age or older but less than 12 years: Patient is currently being treated with one of the following, unless there is a contraindication or intolerance (i or ii):
 - i. Both of the following (1 AND 2):
 1. Medium-dose inhaled corticosteroids;
 2. Controller medication (e.g., long-acting beta-2 agonist (LABA) or leukotriene modifier (LTRA));
 - ii. Medium-dosed combination ICS/LABA product;
5. For 12 years of age or older: Patient is currently being treated with one of the following, unless there is a contraindication or intolerance (i or ii)
 - i. Both of the following (1 AND B):
 1. High-dose inhaled corticosteroids;
 2. Controller medication (e.g., long-acting beta-2 agonist (LABA) or leukotriene modifier (LTRA)); OR
 - ii. Max-dosed combination ICS/LABA product.

Approval duration

All Lines of Business (except Medicare): 12 months

B. Chronic rhinosinusitis with nasal polyps (CRSwNP) (must meet all):

1. Diagnosis of CRSwNP;
2. Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone);
3. Used in combination with another agent for CRSwNP.

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Approval duration

All Lines of Business (except Medicare): 12 months

C. IgE-mediated food allergy (must meet all):

1. Diagnosis of IgE-mediated food allergy has been confirmed by both of the following (i AND ii):
 - i. History of significant (type I) allergic reaction(s) to the food (e.g., hives, swelling, wheezing, hypotension, gastrointestinal symptoms, syncope) that meets both of the following (1 AND 2):
 1. Prescriber deems past allergic reaction to the food significant enough to require a prescription for injectable epinephrine;
 2. Xolair® is prescribed concurrently with injectable epinephrine;
 - ii. One of the following:
 1. Food specific skin prick testing;
 2. IgE antibody in vitro testing;
 3. Oral food challenge;
2. Pre-treatment serum IgE greater than or equal to 30 IU/mL;
3. Patient will continue to follow a food-allergen diet.

Approval duration

All Lines of Business (except Medicare): 12 months

D. Chronic Spontaneous Urticaria (CSU) (must meet all):

1. Diagnosis of Chronic Spontaneous Urticaria (CSU);
2. Patient is symptomatic;
3. Trial and failure, unless contraindicated or clinically significant adverse effects are experienced, to at least 2 weeks of at least two H1 antihistamine (e.g., cetirizine, loratadine) at four times the standard FDA-approved dose.

Approval duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Asthma, moderate to severe allergic (must meet all)

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy
2. Demonstrated adherence to asthma controller therapy that includes an ICS plus a controller medication, unless there is a contraindication or intolerance.

Approval duration

All Lines of Business (except Medicare): 12 months

B. Chronic rhinosinusitis with nasal polyps (CRSwNP) (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy

- Demonstrated adherence to an intranasal corticosteroid, unless contraindicated or clinically significant adverse effects are experienced.

Approval duration

All Lines of Business (except Medicare): 12 months

C. IgE-mediated food allergy:

- Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval duration

All Lines of Business (except Medicare): 12 months

D. Chronic Spontaneous Urticaria (CSU):

- Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval duration

All Lines of Business (except Medicare): 12 months

References

- Xolair [package insert] South San Francisco, CA; Genentech, Inc.; February 2024. Accessed December 2024.
- UpToDate Inc. (2024). *Omalizumab* [Drug Information]. *UpToDate*. Retrieved December 12, 2024, from <http://online.lexi.com>.
- Cloutier MM, Baptist AP, Blake KV, et al. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program (NAEPP) Coordinating Committee Expert Panel Working Group. *J Allergy Clin Immunol*. 2020 Dec;146(6):1217-1270.
- Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023. Available from: <https://ginasthma.org/2023-gina-main-report/>. Accessed on: December 12, 2024.
- National Asthma Education and Prevention Program: Expert panel report III: Guidelines for the diagnosis and management of asthma. Bethesda, MD: National Heart, Lung, and Blood Institute, 2007. (NIH publication no. 08-4051). Available at: https://www.epa.gov/sites/default/files/2021-05/documents/sites_default_files_publications_asthmamanagementguidelinesreport-2-4-21.pdf. Accessed December 12, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy Updates: <ul style="list-style-type: none"> Removed pre-treatment IgE Removed sensitivity to aeroallergens Added at least 2 exacerbations and dependent on systemic corticosteroids or hospitalization for asthma 	7/15/2025	7/31/2025

• Updated trial/failure for asthma		
Policy approved by P&T Committee		4/10/2025
Policy reviewed	12/11/2025	12/11/2025