

# Jurisdiction Specific Medicare Part B Xolair-Omlyclo

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Xolair	omalizumab
Omlyclo	omalizumab-igec

## Covered Uses

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

- The FDA-labeled indications and recognized compendia (off-label) uses are below:
  - Moderate to severe persistent asthma
  - Chronic rhinosinusitis with nasal polyps (CRSwNP)
  - IgE-mediated food allergy
  - Chronic spontaneous urticaria (CSU)
  - Latex allergy prophylaxis
- Compendial uses- ICD-10 codes supported by the Medicare Administrative Contractor
  - The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

## Coverage Criteria

## Moderate to Severe Persistent Asthma<sup>1-3</sup>

Authorization of 12 months may be granted for treatment of moderate to severe persistent asthma when all of the following criteria are met:

- The member meets either of the following:
  - The member has moderate persistent asthma as defined by one of the following pre-treatment symptoms or measurements:
    - Daily symptoms
    - Daily use of inhaled short-acting beta2-agonist
    - Some limitation with normal activity
    - Exacerbations requiring oral systemic corticosteroids at least twice per year
    - Nighttime symptoms greater than one time per week but not nightly
    - FEV<sub>1</sub> greater than 60% but less than 80% of predicted value
    - FEV<sub>1</sub>/FVC reduced by 5%
  - The member has severe persistent asthma as defined by one of the following pre-treatment symptoms or measurements:
    - Symptoms throughout the day
    - Use of inhaled short-acting beta2-agonist several times per day
    - Extremely limited normal activity
    - Exacerbations requiring oral systemic corticosteroids at least twice per year
    - Nighttime symptoms often occurring seven days per week
    - FEV<sub>1</sub> less than 60% of predicted value
    - FEV<sub>1</sub>/FVC reduced by more than 5%
- The requested drug will not be used for the treatment of acute bronchospasm or status asthmaticus.
- The member will receive the requested drug in a doctor's office or clinic setting and be observed for an appropriate period of time after each treatment by healthcare providers prepared to manage anaphylaxis.

## Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)<sup>1-3,6,7</sup>

Authorization of 12 months may be granted for add-on treatment of CRSwNP when all of the following criteria are met:

- The member has had an inadequate response with intranasal corticosteroid treatment.
- The member will receive the requested drug in a doctor's office or clinic setting and be observed for an appropriate period of time after each treatment by healthcare providers prepared to manage anaphylaxis.

## IgE-Mediated Food Allergy<sup>1-3,6,7</sup>

Authorization of 12 months may be granted for reduction of allergic reactions (Type 1), including anaphylaxis, when all of the following criteria are met:

- The member has a confirmed diagnosis of one or more food allergies.

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- The member will receive the requested drug in a doctor's office or clinic setting and be observed for an appropriate period of time after each treatment by healthcare providers prepared to manage anaphylaxis.

## Chronic Spontaneous Urticaria (CSU)<sup>1-3,6,7</sup>

Authorization of 12 months may be granted for treatment of chronic spontaneous urticaria when all of the following criteria are met:

- The member remains symptomatic despite H1 antihistamine treatment.
- The member will receive the requested drug in a doctor's office or clinic setting and be observed for an appropriate period of time after each treatment by healthcare providers prepared to manage anaphylaxis.

## Allergy to Latex<sup>1-4</sup>

Authorization of 12 months may be granted for treatment of latex allergy when the member will receive the requested drug in a doctor's office or clinic setting and be observed for an appropriate period of time after each treatment by healthcare providers prepared to manage anaphylaxis.

## All Other Indications<sup>2</sup>

Authorization of 12 months may be granted for treatment of all other approvable indications listed in LCA A524448.

# Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

# References

1. Drugs and Biologicals LCD (L33394) Version R16. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed March 10, 2025.
2. Billing and Coding: Omalizumab (A52448) Version R6. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed March 10, 2025.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R9. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed March 10, 2025.
4. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com> (March 1, 2025).
5. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed March 1, 2025.
6. Xolair [package insert]. South San Francisco, CA: Genentech, Inc.; February 2024.

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Reference number(s)
3824-A

7. Omlyclo [package insert]. Jersey City, NJ: Celltrion USA, Inc.; March 2025.