| Reference number(s) |
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| 3824-A |

# JURISDICTION SPECIFIC MEDICARE PART B

## XOLAIR (omalizumab)

### POLICY

#### I. 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 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. The FDA-labeled indications and recognized compendia (off-label) uses are listed below:

A. Moderate to severe persistent asthma
B. Chronic spontaneous urticaria
C. Nasal polyps
D. Latex allergy prophylaxis
E. Peanut allergy prophylaxis

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

#### II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
A. Relevant medical history, physical examination, results of pertinent diagnostic tests or procedures
B. Medical record with name of drug administered, route of administration, dosage, duration of the administration.

#### III. CRITERIA FOR APPROVAL

**A. Moderate to Severe Persistent Asthma**
Authorization of 12 months may be granted for treatment of moderate to severe persistent asthma when all of the following criteria are met:
1. The member meets either of the following:
    i. The member has moderate persistent asthma as defined by one of the following pre-treatment symptoms or measurements:
        a. Daily symptoms
        b. Daily use of inhaled short-acting beta2-agonist
        c. Some limitation with normal activity

d. Exacerbations requiring oral systemic corticosteroids at least twice per year
e. Nighttime symptoms greater than one time per week but not nightly
f. FEV1 greater than 60% but less than 80% of predicted value
g. FEV1/FVC reduced by 5%

ii. The member has severe persistent asthma as defined by one of the following pre-treatment symptoms or measurements:
a. Symptoms throughout the day
b. Use of inhaled short-acting beta2-agonist several times per day
c. Extremely limited normal activity
d. Exacerbations requiring oral systemic corticosteroids at least twice per year
e. Nighttime symptoms often occurring seven days per week
f. FEV1 less than 60% of predicted value
g. FEV1/FVC reduced by more than 5%

2. The requested drug will not be used for the treatment of acute bronchospasm or status asthmaticus.
3. 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.

**B. Chronic Spontaneous Urticaria**

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

1. The member remains symptomatic despite H1 antihistamine treatment.
2. 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.

**C. Nasal Polyps**

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

**1.** The member has had an inadequate response with intranasal corticosteroid treatment.
**2.** 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.

**D. Allergy to Latex**

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.

**E. Peanut Allergy Prophylaxis**

Authorization of 12 months may be granted for treatment of peanut 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.

## IV. DOSAGE AND ADMINISTRATION

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

## V. REFERENCES

1. Drugs and Biologicals LCD (L33394) Version R14. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed March 16, 2022.
2. Billing and Coding: Omalizumab (A52448) Version R5. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed March 16, 2022.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R8. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed March 16, 2022.
4. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com (March 11, 2022).
5. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed March 18, 2022.
6. Xolair [package insert]. South San Francisco, CA: Genentech, Inc.; July 2021.




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