

# STANDARD MEDICARE PART B MANAGEMENT

## XOLAIR (omalizumab)

### POLICY

#### I. INDICATIONS

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

##### A. FDA-Approved Indications<sup>1</sup>

1. Allergic Asthma  
Treatment of moderate to severe persistent asthma in patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids
2. Chronic Idiopathic Urticaria  
Treatment of chronic idiopathic urticarial in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment
3. Nasal polyps  
Xolair is indicated for add-on maintenance treatment of nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.

##### *Limitations of use*

- A. *Not indicated for other allergic conditions or other forms of urticaria*
- B. *Not indicated for relief of acute bronchospasm or status asthmaticus*

##### B. Compendial Uses<sup>2,6</sup>

1. Prophylaxis of seasonal or perennial allergic rhinitis
2. Anaphylaxis prophylaxis for patients with peanut allergies at risk for accidental exposure
3. Latex allergy prophylaxis for patients unable to avoid latex
4. Adjunct to immunotherapy for seasonal allergic rhinitis
5. Immune checkpoint inhibitor-related toxicities
6. Systemic mastocytosis

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. Asthma:
  1. Initial Requests:

- i. Member's chart or medical record showing pre-treatment IgE level
  - ii. Chart notes, medical record documentation, or claims history supporting previous medications tried. If therapy is not advisable, documentation of clinical reason to avoid therapy
- 2. Continuation requests: Chart notes or medical record documentation supporting benefit from therapy
- B. CIU:
  - 1. Initial Requests: Chart notes, medical record documentation, or claims history showing prior therapy with an H1 antihistamine
  - 2. Continuation Requests: Chart notes or medical record documentation supporting benefit from therapy
- C. Nasal polyps:
  - 1. Initial Requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy
  - 2. Continuation Requests: Chart notes or medical record documentation supporting benefit from therapy
- D. Immune checkpoint inhibitor-related toxicity:
  - 1. Initial Requests: Member's chart notes or medical record showing pre-treatment IgE level
  - 2. Continuation Requests: Chart notes or medical record documentation supporting benefit from therapy
- E. Systemic mastocytosis:
  - 1. Initial Requests:
    - i. Chart notes or medical record documentation supporting diagnosis of systemic mastocytosis
    - ii. Chart notes or medical record documentation or claims history of prerequisite therapies (if applicable)
  - 2. Continuation Requests: Chart notes or medical record documentation supporting benefit from therapy
- F. Prophylaxis of seasonal or perennial allergic rhinitis
  - 1. Initial Requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy
  - 2. Continuation Requests: Chart notes or medical record documentation supporting benefit from therapy
- G. Peanut allergy anaphylaxis prophylaxis and latex allergy prophylaxis:
  - 1. Initial Requests: Chart notes or medical record documentation of allergy
  - 2. Continuation Requests: Chart notes or medical record documentation supporting benefit from therapy
- H. Adjunct to immunotherapy for seasonal allergic rhinitis:
  - 1. Initial Requests: Chart notes or medical record documentation of immunotherapy use
  - 2. Continuation Requests: Chart notes or medical record documentation supporting benefit from therapy

### III. CRITERIA FOR INITIAL APPROVAL

#### A. Allergic asthma<sup>1</sup>

Authorization of 12 months may be granted for treatment of allergic asthma when all of the following criteria are met:

- 1. Member is 6 years of age or older
- 2. Member is using optimized doses of inhaled corticosteroid without adequate asthma control or has a clinical reason to avoid this therapy.
- 3. Member is using optimized doses of one of the following agents without adequate asthma control or the member has a clinical reason to avoid these therapies:
  - i. Long acting beta<sub>2</sub>-agonist
  - ii. Leukotriene modifier
  - iii. Sustained-release theophylline
- 4. Member has a positive skin test or in vitro reactivity to at least one perennial aeroallergen.
- 5. Member has a pre-treatment IgE level greater than or equal to 30 IU/mL.

#### B. Chronic idiopathic urticaria<sup>1,7</sup>

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

1. Member is 12 years of age or older.
2. Member has experienced a spontaneous onset of wheals, angioedema, or both, for at least 6 weeks.
3. Member remains symptomatic despite treatment with an H<sub>1</sub> antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine) for at least 2 weeks.
4. Member has been evaluated for other causes of urticaria, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis).

### C. Nasal polyps<sup>1</sup>

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

1. Member is 18 years of age or older
2. Member has had an inadequate response with intranasal corticosteroid treatment, unless contraindicated or not tolerated.
3. Member will be using a daily intranasal corticosteroid while being treated with Xolair, unless contraindicated or not tolerated.

### D. Immune checkpoint inhibitor-related toxicity<sup>6</sup>

Authorization of 1 month may be granted for treatment of immune checkpoint inhibitor-related toxicity when both of the following are met:

1. The member has a refractory case of immune-therapy related severe (G3) pruritus
2. The member has elevated IgE levels

### E. Systemic mastocytosis<sup>6</sup>

Authorization of 12 months may be granted for the treatment of systemic mastocytosis when both of the following are met:

1. The major and at least one minor diagnostic criterion for systemic mastocytosis are present or three or more minor diagnostic criteria are present (see Appendix)
2. Xolair will be used in any of the following treatment settings:
  - i. Used as stepwise prophylactic treatment for chronic mast cell mediator-related cardiovascular and pulmonary symptoms when the member has tried both of the following:
    - a. H1 blockers and H2 blockers
    - b. Corticosteroids
  - ii. Used for prevention of unprovoked anaphylaxis
  - iii. Used for prevention of hymenoptera or food-induced anaphylaxis, with negative specific IgE or negative skin test
  - iv. Used improve tolerability of venom immunotherapy

### F. Prophylaxis of seasonal or perennial allergic rhinitis<sup>2</sup>

Authorization of 12 months may be granted for prophylaxis of seasonal or perennial allergic rhinitis in patients who previously had inadequate symptom control with a combination of intranasal steroids and an intranasal antihistamine.

### G. Peanut allergy anaphylaxis prophylaxis<sup>2</sup>

Authorization of 12 months may be granted for prophylaxis of anaphylaxis due to a peanut allergy in patients with a history of immediate hypersensitivity.

### H. Latex allergy prophylaxis<sup>2</sup>

Authorization of 12 months may be granted for the prophylaxis of latex allergy symptoms in patients with a proven latex allergy and who are unable to avoid occupational latex (e.g., healthcare workers).

#### I. **Adjunct to immunotherapy<sup>2</sup>**

Authorization of 3 months may be granted as an adjunct to immunotherapy for seasonal allergic rhinitis.

#### IV. **CONTINUATION OF THERAPY**

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization of 12 months may be granted when all of the following criteria are met:

1. The member is currently receiving therapy with Xolair.
2. Xolair is being used to treat an indication enumerated in Section III.
3. The member is receiving benefit from therapy.

#### V. **APPENDIX**

2017 WHO Diagnostic Criteria for Systemic Mastocytosis<sup>8</sup>

- A. Major Criteria: multifocal, dense infiltrates of mast cells (at least 15 mast cells in aggregates) detected in sections of bone marrow and/or other extracutaneous organs
- B. Minor Criteria
  1. In biopsy sections of bone marrow or other extracutaneous organs, greater than 25% of mast cells in the infiltrate are spindle-shaped or have atypical morphology of greater than 25% of all mast cells in bone marrow aspirate smears are immature or atypical
  2. Detection of an activating point mutation at codon 816 of KIT in the bone marrow, blood, or another extracutaneous organ
  3. Mast cells in bone marrow, blood, or other extracutaneous organs express CD25, with or without CD2, in addition to normal mast cell markers
  4. Serum total tryptase persistently greater than 20 ng/mL (unless there is an associated myeloid neoplasm, in which case this parameter is not valid)

#### VI. **REFERENCES**

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3. Strunk RC, Bloomberg GR. Omalizumab for asthma. *N Engl J Med*. 2006;354(25):2689-2695.
4. Maurer M, Rosen K, Hsieh HJ, et al. Omalizumab for the treatment of chronic idiopathic or spontaneous urticaria. *N Engl J Med*. 2013;368(10):924-935.
5. Seidman MD, Gurgel RK, Lin SY, et al. Clinical Practice Guideline: Allergic Rhinitis. *Otolaryngology – Head and Neck Surg*. 2015;151(IS):S1-S43.
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8. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Systemic Mastocytosis. Version 1.2020. [https://www.nccn.org/professionals/physician\\_gls/pdf/mastocytosis.pdf](https://www.nccn.org/professionals/physician_gls/pdf/mastocytosis.pdf). Accessed March 15, 2021.