Reference number(s)
2546-A

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
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
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

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. CRITERIA FOR INITIAL APPROVAL

A. Allergic asthma
Authorization of 12 months may be granted for treatment of allergic asthma when all of the following criteria are met:
1. Member is using optimized doses of inhaled corticosteroid without adequate asthma control or has a clinical reason to avoid this therapy.

2. 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$_2$-agonist
   ii. Leukotriene modifier
   iii. Sustained-release theophylline
3. Member has a positive skin test or in vitro reactivity to at least one perennial aeroallergen.
4. Member has a pre-treatment IgE level greater than or equal to 30 IU/mL.

B. Chronic idiopathic urticaria
Authorization of 12 months may be granted for treatment of chronic idiopathic urticaria when the member has experienced a spontaneous onset of wheals, angioedema, or both, for at least 6 weeks.

C. Nasal polyps
Authorization of 12 months may be granted for treatment of nasal polyps when all of the following criteria are met:
1. Member has had an inadequate response with intranasal corticosteroid treatment, unless contraindicated or not tolerated.
2. Member will be using a daily intranasal corticosteroid while being treated with Xolair, unless contraindicated or not tolerated.

D. Prophylaxis of seasonal or perennial allergic rhinitis
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.

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

F. Latex allergy prophylaxis
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).

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

III. 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 24 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 II.
3. The medication has been effective for treating the diagnosis or condition.

IV. REFERENCES

1. Xolair [package insert]. South San Francisco, CA: Genentech, Inc.; November 2020.

2. Micromedex (electronic version). IBM Watson Health. Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com/ (March 10, 2020).
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.