Xolair (omalizumab)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Xolair (omalizumab) drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines, and clinical studies.

FDA-Approved Indications

1. Allergic Asthma:
    a. Xolair is indicated for patients 6 years of age and older with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.
    b. Limitations of use: Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus, or for treatment of other allergic conditions.
2. Chronic Spontaneous Urticaria (CSU):
    a. Xolair is indicated for the treatment of adults and adolescents 12 years of age and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment.
    b. Limitations of use: Xolair is not indicated for treatment of other forms of urticaria.
3. Nasal Polyps:
    a. 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.

POLICY

Required Documentation

The following information is necessary to initiate the prior authorization review:

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
2. Continuation Requests: Chart notes or medical record documentation supporting improvement in asthma control

B. Chronic Spontaneous Urticaria (CSU)
1. Initial Requests: Member's chart or medical record documentation, or claims history supporting previous medications tried showing an inadequate treatment response to a second-generation H1 antihistamine
2. Continuation Requests: Chart notes or medical record documentation supporting response to therapy

C. Nasal Polyps:
1. Initial Requests:
    i. Member's chart or medical record showing nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) details (e.g., location, size), or Meltzer Clinical Score or endoscopic nasal polyp score (NPS) (where applicable)
    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 response to therapy

Prescriber Specialties

For Asthma:
- Xolair must be prescribed by or in consultation with an allergist/immunologist or pulmonologist

For Chronic Spontaneous Urticaria (CSU):
- Xolair must be prescribed by or in consultation with an allergist/immunologist or dermatologist

For Nasal Polyps:
- Xolair must be prescribed by or in consultation with an allergist/immunologist or otolaryngologist

Criteria for Initial Approval

A. Asthma

Authorization of 6 months may be granted for treatment of moderate to severe persistent asthma when ALL of the following criteria are met:
1. Member is 6 years of age or older
2. Member has a positive skin test or in vitro reactivity to at least one perennial aeroallergen
3. Member has a pre-treatment IgE level greater than or equal to 30 IU/mL
4. Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
    a. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment
    b. One or more asthma exacerbation resulting in hospitalization or emergency medical care visit
    c. Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)
5. Member has inadequate asthma control despite current treatment with both of the following medications at optimized doses:
    a). Medium-to-high-dose inhaled corticosteroid

b). Additional controller (i.e., long acting beta$_2$-agonist, long acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)

6. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Xolair
7. Member will not use Xolair concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala, Tezspire).
8. The requested dose is based on pre-treatment serum IgE level and the individual's body weight as defined in FDA approved labeling AND does not exceed 375mg every 2 weeks

B. Chronic Spontaneous Urticaria (CSU)

Authorization of 6 months may be granted for treatment of chronic spontaneous urticaria when ALL of the following criteria are met:

1. Member is 12 years of age or older
2. Member remains symptomatic despite treatment with up-dosing (up to four times the recommended dose [see Appendix] in accordance with EAACI/GA^{2}LEN/EDF/WAO guidelines) of a second-generation H_1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine) for at least 2 weeks
3. Member has been evaluated for other causes of urticaria, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis)
4. Member has experienced a spontaneous onset of wheals, angioedema, or both, for at least 6 weeks
5. The requested dose is within the FDA labeled dose AND does not exceed 300mg every 4 weeks

C. Nasal Polyps

Authorization of 6 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 bilateral nasal polyposis and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 2 months unless contraindicated or not tolerated
3. Member has one of the following:
    a. A bilateral nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril
    b. Meltzer Clinical Score of 2 or higher in both nostrils
    c. A total endoscopic nasal polyp score (NPS) of at least 5 with a minimum score of 2 for each nostril
4. Member has nasal obstruction plus one additional symptom:
    a. Rhinorrhea (anterior/posterior); or
    b. Reduction or loss of smell; or
    c. Facial pain or pressure
5. Member will continue to use a daily intranasal corticosteroid while being treated with Xolair, unless contraindicated or not tolerated
6. Member will not use Xolair concomitantly with other biologics indicated for nasal polyps (e.g., Dupixent, Nucala)
7. The requested dose is within the FDA labeled dose for the requested indication

<u>Continuation of Therapy</u>

A. Asthma

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

1. Member is 6 years of age or older
2. Asthma control has improved on Xolair treatment as demonstrated by at least one of the following:
    a. A reduction in the frequency and/or severity of symptoms and exacerbations
    b. A reduction in the daily maintenance oral corticosteroid dose
3. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Xolair
4. Member will not use Xolair concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala, Tezspire)
5. The requested dose is based on pre-treatment IgE level and the individual's body weight as defined in FDA approved labeling AND does not exceed 375mg every 2 weeks

B. Chronic Spontaneous Urticaria

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

1. Member is 12 years of age or older
2. Member has experienced a positive response (e.g., improved symptoms, decrease in weekly urticaria activity score [UAS7]) since initiation of therapy
3. The requested dose is within the FDA labeled dose AND does not exceed 300mg every 4 weeks

C. Nasal Polyps

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

1. Member is 18 years of age or older
2. Member has experienced a response as evidenced by improvement in signs and symptoms (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sinonasal inflammation, hyposmia and/or facial pressure or pain or reduction in corticosteroid use)
3. Member will not use Xolair concomitantly with other biologics indicated for nasal polyps (e.g., Dupixent, Nucala)
4. The requested dose is within the FDA labeled dose for the requested indication

Xolair is considered **not medically necessary** for members who do not meet the criteria set forth above.

Other

Note: If the member is a current smoker or vaper, they should be counseled on the harmful effects of smoking and vaping on pulmonary conditions and available smoking and vaping cessation options.

Dosing and Administration

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

Quantity Limits Apply

Medication	Standard Limit	FDA-recommended dosing
Xolair 150 mg vial	8 vials per 28 days	Asthma: 75 to 375 mg every 2 or 4 weeks

Xolair 75 mg prefilled syringe	2 syringes per 28 days	Chronic spontaneous urticaria: 150 or 300 mg every 4 weeks Nasal polyps: 75 mg to 600 mg every 2 or 4 weeks
Xolair 150 mg prefilled syringe	8 syringes per 28 days	

APPENDIX

Examples of histamine H1 blockers and standard recommended dosage:

Drug	Recommended Dosage
Cetirizine (Zyrtec®)	5-10 mg daily
Desloratadine (Clarinex®)	5 mg daily
Fexofenadine (Allegra®)	180 mg daily
Loratadine (Claritin®)	10 mg daily
Levocetirizine (Xyzal®)	5 mg daily

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J2357 Injection, omalizumab, 5mg

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POLICY HISTORY

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