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. 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.

<u>FDA-Approved Indications</u>

1. Allergic Asthma:
   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.
   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):
   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 H_1 antihistamine treatment.
   Limitations of use: Xolair is not indicated for treatment of other forms of urticaria.

3. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):
   Xolair is indicated for add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.

4. IgE-mediated food allergy
   Xolair is indicated for the reduction of allergic reactions (Type 1), including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy. Xolair is to be used in conjunction with food allergen avoidance.
   Limitations of use: Xolair is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Asthma:
   1. Initial Requests:
      a. Member's chart notes or medical record showing pre-treatment IgE level
      b. 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 notes or medical record documentation, or claims history supporting previous medications tried showing an inadequate treatment response to a second-generation H_1 antihistamine
   2. Continuation Requests: Chart notes or medical record documentation supporting response to therapy

C. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):
   1. Initial Requests:
      a. Member's chart notes 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)
      b. 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

D. IgE-mediated food allergy:
   1. Initial Requests: Chart notes, medical record documentation, or laboratory tests showing the following (if applicable):
      a. Pre-treatment allergen-specific IgE level
      b. Skin-prick test wheal diameter
      c. Pre-treatment serum IgE level
      d. Positive result of a physician controlled oral food challenge
      e. History of a systemic reaction to a food
   2. Continuation Requests: Chart notes or medical record documentation supporting positive response to therapy (e.g., decrease in hypersensitivity to food-allergen).

Prescriber Specialties

The medication must be prescribed by or in consultation with one of the following:

A. Asthma: allergist/immunologist or pulmonologist
B. Chronic Spontaneous Urticaria (CSU): allergist/immunologist or dermatologist
C. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP): allergist/immunologist or otolaryngologist

D. IgE-mediated food allergy: allergist/immunologist

Criteria for Initial Approval

A. Asthma

1. Authorization of **6 months** may be granted for members 6 years of age or older who have previously received a biologic drug (e.g., Fasenra, Nucala, Tezspire, Dupixent, Cinqair) indicated for asthma.

2. Authorization of **6 months** may be granted for treatment of moderate to severe persistent asthma when ALL of the following criteria are met:
   A. Member is 6 years of age or older
   B. Member has a positive skin test or in vitro reactivity to at least one perennial aeroallergen
   C. Member has a pre-treatment IgE level greater than or equal to 30 IU/mL
   D. Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
      i. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment
      ii. One or more asthma exacerbation resulting in hospitalization or emergency medical care visit
      iii. Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)
   E. Member has inadequate asthma control despite current treatment with both of the following medications at maximally tolerated doses:
      i. Medium-to-high-dose inhaled corticosteroid
      ii. Additional controller (i.e., long-acting beta$_2$-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
   F. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Xolair
   G. Member will not use Xolair concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala, Tezspire).
   H. 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 (hives), 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. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Authorization of **6 months** may be granted for adult members who have previously received a biologic drug (e.g., Dupixent, Nucala, Tezspire) indicated for chronic rhinosinusitis with nasal polyps (CRSwNP)

Authorization of **6 months** may be granted for treatment of CRSwNP 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 symptoms of nasal blockage, congestion, or obstruction plus one of the following symptoms:
    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, Tezspire)
7. The requested dose is within the FDA labeled dose for the requested indication

D. IgE-mediated food allergy

Authorization of **6 months** may be granted for the reduction of IgE-mediated food allergy reactions when ALL of the following criteria are met:

1. Member is 1 year of age or older
2. The diagnosis of IgE-mediated food allergy has been confirmed by either of the following:
    a. Pre-treatment allergen-specific IgE level greater than or equal to 6 IU/mL.
    b. Skin-prick test (SPC) with wheal diameter greater than or equal to 4 mm.
3. Member has one of the following:
    a. A positive physician controlled oral food challenge (e.g., moderate to severe skin, respiratory, or gastrointestinal [GI] symptoms).
    b. History of a systemic reaction to a food.
4. Member has a pre-treatment serum IgE level greater than or equal to 30 IU/mL.
5. Member will continue to follow a food-allergen avoidance diet.

<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. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Authorization of **12 months** may be granted for continuation of treatment of CRSwNP 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 continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated
4. Member will not use Xolair concomitantly with other biologics indicated for nasal polyps (e.g., Dupixent, Nucala)
5. The requested dose is within the FDA labeled dose for the requested indication

D. IgE-mediated food allergy

Authorization of **12 months** may be granted the reduction of IgE-mediated food allergy reactions when ALL of the following criteria are met:

1. Member is 1 year of age or older
2. Member has achieved or maintained a positive clinical response to therapy as evidenced by a decrease in hypersensitivity (e.g., moderate to severe skin, respiratory or GI symptoms) to food-allergen.
3. Member will continue to maintain a food-allergen avoidance diet.

Other

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

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

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

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 and autoinjector	2 syringes per 28 days	Chronic spontaneous urticaria: 150 or 300 mg every 4 weeks Chronic rhinosinusitis with nasal polyps: 75 mg to 600 mg every 2 or 4 weeks IgE-mediated food allergy: 75 mg to 600 mg every 2 or 4 weeks
Xolair 150 mg prefilled syringe and autoinjector	4 syringes per 28 days	
Xolair 300 mg prefilled syringe and autoinjector	4 syringes per 28 days	

APPENDIX

Examples of histamine H_1 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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