

Omalizumab Products (Xolair, Omlyclo)

When requesting an omalizumab product (Xolair, Omlyclo), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

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.

Chronic Spontaneous Urticaria

Xolair is indicated for the treatment of adults and adolescents 12 years of age and older with chronic spontaneous urticaria who remain symptomatic despite H1 antihistamine treatment.

Chronic Rhinosinusitis with Nasal Polyps

Xolair is indicated for add-on maintenance treatment of chronic rhinosinusitis with nasal polyps in adults patients 18 years of age and older with inadequate response to nasal corticosteroids.

IgE-Mediated Food Allergy

Xolair is indicated for the reduction of allergic reactions (Type I), 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.

Coverage Guidelines

Asthma

The individual must meet all of the following criteria for initial authorization:

1. Has a baseline serum total immunoglobulin E (IgE) level greater than or equal to 30 IU/mL prior to receiving any treatment with an omalizumab product or another monoclonal antibody therapy that may lower IgE levels;
2. Has a baseline positive skin test or *in vitro* test (i.e., a blood test) for allergen-specific IgE for one or more perennial aeroallergens and/or for one or more seasonal aeroallergens prior to receiving any treatment with an omalizumab product or another monoclonal antibody therapy that may interfere with allergen testing;
3. Has received at least 3 consecutive months of combination therapy with an inhaled corticosteroid and one additional asthma controller/maintenance

medication (e.g., monoclonal antibody therapies, inhaled long-acting beta₂-agonists, inhaled long-acting muscarinic antagonists, a combination inhaler containing both an inhaled corticosteroid and a long acting beta₂-agonist);

4. Asthma is/was uncontrolled prior to starting an omalizumab product or another monoclonal antibody therapy (e.g., Cinqair, Dupixent, Fasenra, Nucala, Tezspire) defined by ONE of the following:
 - a. Has experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR
 - b. Has experienced one or more asthma exacerbation(s) requiring hospitalizations, emergency room visits, or urgent care visits in the previous year; OR
 - c. Has a forced expiratory volume in 1 second (FEV₁) less than 80% predicted; OR
 - d. Has an FEV₁/forced vital capacity (FVC) less than 0.80; OR
 - e. Asthma worsens upon tapering of oral corticosteroid therapy;
5. Is 6 years of age or older;
6. An omalizumab product is prescribed by or in consultation with an allergist, immunologist, or pulmonologist.

The individual must meet all of the following criteria for re-authorization:

1. Has already received at least 4 months of an omalizumab therapy (*NOTE: Patients who have received less than 4 months of therapy or those who are restarting therapy with an omalizumab product should be considered under initial criteria*);
2. Continues to receive therapy with one inhaled corticosteroid (ICS) or one ICS-containing combination inhaler (i.e., Flovent Diskus/HFA, ArmonAir RespiClick, Arnuity);
3. Has responded to an omalizumab therapy (i.e., decreased asthma symptoms or exacerbations; decreased hospitalizations, emergency room visits, urgent care visits, or medical clinic visits due to asthma; decreased reliever/rescue medication use; increased lung function parameters).

Approval duration (initial): 4 months

Approval duration (renewal): 12 months

Chronic Spontaneous Urticaria

The individual must meet all of the following criteria for initial authorization:

1. Had urticaria for at least 6 weeks;
2. Has tried high-dose oral second-generation H₁ antihistamine therapy (i.e., highest dose tolerated by the patient and can be up to four times the FDA-approved dose). Examples are cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine.
3. Is 12 years of age or older;
4. An omalizumab product is prescribed by or in consultation with an allergist, immunologist, or dermatologist.

The patient must meet both of the following criteria for re-authorization:

1. Has already received at least 6 months of an omalizumab product (*NOTE: Patients who have received less than 6 months of therapy or those who are restarting therapy with an omalizumab product should be considered under initial criteria*);
2. Has experienced a beneficial clinical response, defined by one of the following: decreased itch severity, decreased number of hives, or decreased size of hives.

Approval duration (initial): 6 months

Approval duration (renewal): 12 months

Chronic Rhinosinusitis with Nasal Polyps

The individual must meet all of the following criteria for initial authorization:

1. Has a baseline IgE level greater than or equal to 30 IU/mL prior to receiving any treatment with an omalizumab product or another monoclonal antibody therapy that may lower IgE levels;
2. Has chronic rhinosinusitis with nasal polyps as evidenced by direct examination, endoscopy, or sinus computed tomography (CT) scan;
3. Has had the diagnosis of chronic rhinosinusitis with nasal polyps for at least 6 months;
4. Has experienced two or more of the following symptoms for at least 8 weeks: nasal congestion, nasal obstruction, nasal discharge, and/or reduction/loss of smell;
5. Has received at least 4 weeks of therapy with an intranasal corticosteroid and will continue to receive an intranasal corticosteroid concomitantly with an omalizumab product;
6. Meets one of the following:
 - a. Has received at least one course of treatment with a systemic corticosteroid within the previous year (*note: one course of a systemic corticosteroid is at least 3 consecutive days of treatment of one long-acting injectable dose*); OR
 - b. Has a contraindication to systemic corticosteroid therapy; OR
 - c. Has had prior surgery for nasal polyps;
7. Is 18 years of age or older;
8. An omalizumab product is prescribed by or in consultation with an allergist, immunologist, or otolaryngologist (i.e., ear, nose, and throat [ENT] physician specialist).

The individual must meet all of the following criteria for re-authorization:

1. Has already received at least 6 months of an omalizumab product (*NOTE: Patients who have received less than 6 months of therapy or those who are restarting therapy with an omalizumab product should be considered under initial criteria*);
2. Continues to receive an intranasal corticosteroid therapy;
3. Has responded to an omalizumab therapy (i.e., reduced nasal polyp size, improved nasal congestion, reduced sinus opacification, decreased sino-nasal symptoms, and/or improved sense of smell).

Approval duration (initial): 6 months

Approval duration (renewal): 12 months

IgE-Mediated Food Allergy

The individual must meet all of the following criteria for approval:

1. Is one year of age or older;
2. Has a baseline IgE level greater than or equal to 30 IU/mL prior to receiving any treatment with an omalizumab product or another monoclonal antibody therapy that may lower IgE levels;
3. Meets one of the following:
 - a. Has a positive skin prick test (SPT) response to one or more foods; OR
 - b. Has a positive *in vitro* test (i.e., a blood test) for IgE to one or more foods;
4. Has a history of an allergic reaction to a food that met each of the following:
 - a. Demonstrated signs and symptoms of a significant systemic allergic reaction (e.g., hives, swelling, wheezing, hypotension, or gastrointestinal symptoms); AND
 - b. This reaction occurred within a short period of time following a known ingestion of the food; AND
 - c. The prescriber deemed this reaction significant enough to require a prescription for an epinephrine self-administered injectable or nasal product (e.g., EpiPen, EpiPen Jr., Auvi-Q, generic epinephrine auto-injectors, and Neffy);
5. An omalizumab product will be used in conjunction with a food allergen-avoidant diet;
6. An omalizumab product is prescribed by or in consultation with an allergist or immunologist.

Approval duration: 12 months

Dosing Recommendations

Asthma

The recommended dose of Xolair is 75 mg to 375 mg by subcutaneous injection every 2 or 4 weeks based on serum total IgE level measured before the start of treatment and by body weight.

Chronic Spontaneous Urticaria

The recommended dose of Xolair is 150 mg or 300 mg by subcutaneous injection every 4 weeks.

Chronic Rhinosinusitis with Nasal Polyps

The recommended dose of Xolair is 75 mg to 600 mg by subcutaneous injection every 2 or 4 weeks based on serum total IgE level measure before the start of treatment and by body weight.

IgE-Mediated Food Allergy

The recommended dose of Xolair is 75 mg to 600 mg by subcutaneous injection every 2 or 4 weeks based on serum total IgE level measured before the start of treatment and by body weight.

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