



Omalizumab (Xolair) Coverage Criteria

Description:

Omalizumab (Xolair) is a recombinant humanized immunoglobulin G (IgG)_{1k} monoclonal antibody which selectively binds to human immunoglobulin E (IgE), thus inhibiting IgE from binding to the surface of mast cells and basophils (at the high-affinity IgE receptor [FcεRI]), and resulting in a decrease of mediators released in the allergic response. Omalizumab treatment also reduces the number of FcεRI receptors on basophils in atopic patients. Omalizumab (Xolair) is indicated for use in patients ≥ 6 years of age with moderate to severe persistent asthma and who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids (ICSs). Xolair decreases the incidence of asthma exacerbations in these patients. Safety and efficacy of Xolair in pediatric patients with asthma aged < 6 years have not been established. Xolair is also indicated for the treatment of adults and adolescents (aged ≥ 12 years) with chronic idiopathic urticaria who remain symptomatic despite H1 antihistamine treatment.¹ In chronic idiopathic urticaria, Xolair binds to IgE and lowers free IgE levels; subsequently, FcεRI on cells down-regulate. How these effects of Xolair result in an improvement in chronic idiopathic urticaria is not known.

Omalizumab is **NOT** indicated for the treatment of other allergic conditions, other forms of urticaria, for relief of acute bronchospasm, or status asthmaticus.

Policy:

Prior authorization is recommended for prescription benefit coverage of Omalizumab (Xolair). Because of the specialized skills required for evaluation and diagnosis of patients treated with Omalizumab (Xolair), as well as the monitoring required for adverse events and long-term efficacy, initial and continuing approval requires Omalizumab (Xolair) to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for the duration listed below.

Omalizumab (Xolair) can be covered through either Amida Care's pharmacy or medical benefit.

Prior Authorization Criteria:

1. Asthma in Patients with Moderate to Severe Persistent Disease. Approve Xolair for the duration noted if the patient meets one of the following conditions (A or B):

- A. **Initial Therapy.** Approve Xolair for **4 months** if the patient meets the following criteria (i, ii, iii, iv, v and vi):
- i. Patient is ≥ 6 years of age; **AND**
 - ii. Xolair is prescribed by or in consultation with an allergist, immunologist, or pulmonologist **AND**
 - iii. Baseline (prior to treatment with Xolair or anti-interleukin [IL]-4/13 therapy [Dupixent]) IgE level is ≥ 30 IU/mL; **AND**

- iv. The patient has a baseline (prior to treatment with Xolair) positive skin test or in vitro testing (i.e., a blood test for allergen-specific IgE antibodies such as an enzyme-linked immunoabsorbant assay [e.g., ImmunoCAP™, ELISA] or the radioallergosorbent test [RAST]) for one or more perennial aeroallergens (e.g., house dust mite [*Dermatophagoides farinae*, *D. pteronyssinus*], animal dander [dog, cat], cockroach, feathers, mold spores)¹, AND/OR for one or more seasonal aeroallergens (grass, pollen, weeds); **AND**
- v. Patient has received at least 3 consecutive months of combination therapy with BOTH of the following (a and b):
 - a. An inhaled corticosteroid (ICS) [e.g., Aerospans, Alvesco, ArmonAir RespiClick, Arnuity Ellipta, Asmanex Twisthaler/HFA, Flovent Diskus/HFA, Pulmicort Flexhaler, Qvar/Qvar RediHaler, budesonide suspension for inhalation {Pulmicort Respules, generics}];
AND
 - b. At least one additional asthma controller/maintenance medication (e.g., a long-acting beta2-agonist [LABA] {e.g., Serevent Diskus}; an inhaled long-acting muscarinic antagonist [LAMA] {e.g., Spiriva Respimat}; a leukotriene receptor antagonist [LTRA] {e.g., montelukast tablets/granules (Singulair, generics), zafirlukast tablets (Accolate, generics)}; theophylline [e.g., Theo 24, TheoChron ER, generics]); **AND**
 - i. **NOTE:** An exception to the requirement for a trial of one additional asthma controller/maintenance medication (criterion b) can be made if the patient has already received anti-IL-4/13 therapy (Dupixent) used concomitantly with an ICS for at least 3 consecutive months.
 - ii. **NOTE:** Use of a combination inhaler containing both an ICS and a LABA would fulfil the requirement for both criteria a and b (e.g., Advair Diskus/HFA, AirDuo RespiClick, Breo Ellipta, Dulera, Symbicort)
- vi. Patient's asthma is uncontrolled or was uncontrolled prior to receiving any Xolair or anti-IL-4/13 therapy (Dupixent) therapy as defined by at least ONE of the following (a, b, c, d, or e):
 - a. The patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; **OR**
 - b. The patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year; **OR**
 - c. Patient has a forced expiratory volume in 1 second (FEV1) < 80% predicted; **OR**
 - d. Patient has an FEV1/forced vital capacity (FVC) < 0.80; **OR**
 - e. The patient's asthma worsens upon tapering of oral corticosteroid therapy;

B. Patients Continuing Xolair Therapy. Approve Xolair for **1 year** if the patient meets the following criteria (i, ii, and iii):

- i. The patient has already received at least 4 months of therapy with Xolair (Note: Patients who have received < 4 months of therapy or those who are restarting therapy with Xolair should be

considered under criterion 1 [Asthma in Patients with Moderate to Severe Persistent Disease, Initial Therapy]);

AND

- ii. Patient continues to receive therapy with one inhaled corticosteroid (ICS) or one ICS-containing combination inhaler

AND

- iii. The patient has responded to therapy (e.g., decreased asthma symptoms or exacerbations; decreased hospitalizations, emergency room, urgent care, or physician visits due to asthma; decreased reliever/rescue medication use; increased lung function parameters [forced expiratory volume in 1 second {FEV₁}, peak expiratory flow{PEF}], as determined by the prescribing physician.

2. Chronic Idiopathic Urticaria (Chronic Spontaneous Urticaria). Approve Xolair for the duration noted if the patient meets one of the following conditions (A or B):

A. Initial Therapy. Approve Xolair for **4 months** if the patient meets the following criteria (i, ii, and iii):

- i. Patient is ≥ 12 years of age;

AND

- ii. Xolair is prescribed by, or in consultation with, an allergist, immunologist, or dermatologist;

AND

- iii. Patient has/had urticaria for > 6 weeks (prior to treatment with Xolair), with symptoms present > 3 days per week despite daily non-sedating H1 antihistamine therapy (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine) with doses that have been titrated up to a maximum of four times the standard FDA-approved dose; **OR**

B. **Patients Continuing Xolair Therapy.** Approve Xolair for **1 year** if the patient meets the following criteria (i and ii):

- i. The patient has already received at least 4 months of therapy with Xolair (Note: Patients who have received < 4 months of therapy or those who are restarting therapy with Xolair should be considered under criterion 2 [Chronic Idiopathic Urticaria {Chronic Spontaneous Urticaria}, Initial Therapy]);

AND

- ii. The patient has responded to therapy (e.g., decreased severity of itching, decreased number and/or size of hives) as determined by the prescribing physician.

3. Allergic Rhinitis, Seasonal or Perennial. Approve Xolair for the duration noted if the patient meets one of the following conditions (A or B):

A. Initial Therapy. Approve Xolair for **4 months** if the patient meets the following criteria (i, ii, iii, iv, v, and vi):

- i. Patient is ≥ 12 years of age; **AND**

- ii. Xolair is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; **AND**

- iii. Baseline (prior to treatment with Xolair) IgE level is ≥ 30 IU/mL; **AND**

- iv. Patient has seasonal or perennial allergic rhinitis as demonstrated by baseline (prior to treatment with Xolair) positive skin testing (e.g., grass, tree, or weed pollen, mold spores, house dust mite, animal dander, cockroach) AND/OR baseline (prior to treatment with Xolair) positive *in vitro* testing (i.e., a blood test for allergen-specific IgE antibodies) for one or more relevant allergens (e.g., grass, tree, or weed pollen; mold spores; house dust mite; animal dander; cockroach); **AND**
- v. Patient has tried therapy with at least one drug from TWO of the following groups of drugs at the same time (a, b, c, or d):
 - a. Oral second-generation/less-sedating antihistamines (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, or loratadine) [Rx or OTC]; **OR**
 - b. Intranasal antihistamines (e.g., azelastine nasal spray [Astepro, generics], or olopatadine nasal spray [Patanase, generics]); **OR**
 - c. Intranasal corticosteroids (e.g., fluticasone); **OR**
 - d. Montelukast; **AND**
- vi. Patient meets one of the following (a, b, or c):
 - a. Patient has had immunotherapy, is receiving immunotherapy, or will be receiving immunotherapy;
OR
 - b. There is no immunotherapy available for the allergen identified as causing clinically significant allergy;
OR
 - c. The patient has contraindications to immunotherapy (e.g., patients receiving beta blockers or patients with medical conditions that reduce their ability to survive a systemic allergic reaction [e.g., markedly compromised lung function, poorly controlled asthma, unstable angina, recent myocardial infarction or significant dysrhythmia, uncontrolled hypertension, failure of a major organ system such as renal failure]);

B. Patients Continuing Xolair Therapy. Approve Xolair for **1 year** if the patient meets the following criteria (i and ii):

- i. The patient has already received at least 4 months of therapy with Xolair (Note: Patients who have received < 4 months of therapy or those who are restarting therapy with Xolair should be considered under criterion 3 [Allergic Rhinitis, Seasonal or Perennial, Initial Therapy]); **AND**
- ii. The patient has responded to therapy (e.g., decreased symptoms of sneezing; itchy nose; watery, red, or itchy eyes; itchy throat; nasal congestion) as determined by the prescribing physician.

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