Commercial/Healthcare Exchange PA Criteria

Effective: June 2005

Prior Authorization: Xolair™ (omalizumab)

Products Affected: Xolair (omalizumab)

Medication Description:
Asthma: Xolair is an IgG monoclonal antibody (recombinant DNA derived) which inhibits IgE binding to the high-affinity IgE receptor on mast cells and basophils. By decreasing bound IgE, the activation and release of mediators in the allergic response (early and late phase) is limited. Serum free IgE levels and the number of high-affinity IgE receptors are decreased.

Covered Uses:

1. **Asthma,** in patients ≥ 6 years of age with moderate to severe persistent disease 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 has been shown to decrease the incidence of asthma exacerbations in these patients. Limitations of Use: Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus. It is also not indicated for the treatment of other allergic conditions.
2. **Chronic idiopathic urticaria**, in patients ≥ 12 years of age who remain symptomatic despite H1 antihistamine treatment. Limitation of Use: Xolair is not indicated for the treatment of other forms of urticaria.
3. **Nasal polyps**, as add-on maintenance treatment in patients ≥ 18 years of age with an inadequate response to nasal corticosteroids.

Exclusion Criteria:

1. Treatment of acute bronchospasm or status asthmaticus.
2. Treatment of other allergic conditions.
3. Treatment forms of urticaria other than chronic idiopathic urticaria

Required Medical Information:

1. Diagnosis
2. Previous therapies tried
3. Pulmonary Function tests
4. Laboratory test for allergen-specific IgE antibodies

Age Restrictions:

Asthma: 6 years of age or older
Chronic Idiopathic Urticaria: 12 years of age or older
Nasal Polyps: 18 years of age or older

Prescriber Restrictions: Prescribed by, or in consultation with, an allergist, immunologist, or pulmonologist

Coverage Duration:

Asthma: Initial- 4 months Continuation: 12 months
Chronic Idiopathic Urticaria- Initial:4 months Continuation: 12 months
Nasal Polyps- Initial: 6 months Continuation: 12 months

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Other Criteria:

FDA-Approved Indications

1. **Asthma.** Approve Xolair for the duration noted if the patient meets one of the following conditions (A **or** B):
   - **A.** Initial Therapy. Approve 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.** Patient has a baseline immunoglobulin E (IgE) level ≥ 30 IU/mL; **AND**
       Note: "Baseline" is defined as prior to receiving any Xolair or anti-interleukin 4/13 therapy (i.e., Dupixent® [dupilumab subcutaneous injection]).
     - **iii.** Patient has a baseline positive skin test or *in vitro* test (i.e., a blood test) for allergen-specific immunoglobulin E (IgE) for one or more perennial aeroallergens and/or for one or more seasonal aeroallergens; **AND**
       Note: "Baseline" is defined as prior to receiving any Xolair or anti-interleukin 4/13 therapy (i.e. Dupixent [dupilumab subcutaneous injection]). Examples of perennial aeroallergens are house dust mite, animal dander, cockroach, feathers, and mold spores. Examples of seasonal aeroallergens are grass, pollen, and weeds.
     - **iv.** Patient has received at least 3 consecutive months of combination therapy with BOTH of the following (a **and** b):
       - **a.** An inhaled corticosteroid; **AND**
       - **b.** At least one additional asthma controller or asthma maintenance medication; **AND**
         Note: Examples of additional asthma controller or asthma maintenance medications are inhaled long-acting $beta_2$-agonists, inhaled long-acting muscarinic antagonists, leukotriene receptor antagonists, Dupixent (dupilumab subcutaneous injection), and theophylline. Use of a combination inhaler containing both an inhaled corticosteroid and additional asthma controller/maintenance medication(s) would fulfil the requirement for both criteria a **and** b.
     - **v.** Patient has asthma that is uncontrolled or was uncontrolled at baseline as defined by ONE of the following (a, b, c, d, **or** e):
       - **a.** Patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; **OR**
       - **b.** Patient experienced one or more asthma exacerbation(s) requiring hospitalization or an Emergency Department visit in the previous year; **OR**
       - **c.** Patient has a forced expiratory volume in 1 second (FEV_1) < 80% predicted; **OR**
       - **d.** Patient has an FEV_1/forced vital capacity (FVC) < 0.80; **OR**
       - **e.** Patient has asthma that worsens upon tapering of oral corticosteroid therapy; **AND**
         Note: "Baseline" is defined as prior to receiving any Xolair or anti-interleukin 4/13 therapy (i.e. Dupixent [dupilumab subcutaneous injection]).
     - **vi.** The medication is prescribed by or in consultation with an allergist, immunologist, or pulmonologist.

   - **B.** Patient is Currently Receiving Xolair. Approve for 1 year if the patient meets the following criteria (i, ii, **and** iii):
     - **i.** Patient has already received at least 4 months of therapy with Xolair; **AND**
       Note: A patient who has received < 4 months of therapy or who is restarting therapy with Xolair should be considered under criterion 1A (Asthma, Initial Therapy).
     - **ii.** Patient continues to receive therapy with one inhaled corticosteroid or one inhaled corticosteroid-containing combination inhaler; **AND**
     - **iii.** Patient has responded to therapy as determined by the prescriber.
       Note: Examples of a response to Xolair therapy are decreased asthma exacerbations; decreased asthma symptoms; decreased hospitalizations, emergency department/urgent care, or medical clinic visits due to asthma; decreased reliever/rescue medication use; and improved lung function parameters.

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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 for 4 months if the patient meets the following criteria (i, ii, **and** iii):
     - **i.** Patient is ≥ 12 years of age; **AND**
     - **ii.** Patient has/had urticaria for > 6 weeks (prior to treatment with Xolair), with symptoms present > 3 days per week despite daily non-sedating H_1 antihistamine therapy with doses that have been titrated up to a maximum of four times the standard FDA-approved dose; **AND**
       Note: Examples of non-sedating H_1 antihistamine therapy are cetirizine, desloratadine, fexofenadine, levocetirizine, and loratadine.
     - **iii.** The medication is prescribed by, or in consultation with an allergist, immunologist, or dermatologist.

   - **B.** Patient is Currently Receiving Xolair. Approve Xolair for 1 year if the patient meets the following criteria (i **and** ii):
     - **i.** Patient has already received at least 4 months of therapy with Xolair; **AND**
       Note: A patient who has received < 4 months of therapy or who is restarting therapy with Xolair should be considered under criterion 2A (Chronic Idiopathic Urticaria, Initial Therapy).
     - **ii.** Patient has responded to therapy as determined by the prescriber.
       Note: Examples of a response to Xolair therapy are decreased severity of itching, decreased number and/or size of hives.

3. **Nasal Polyps.** Approve Xolair for the duration noted if the patient meets one of the following conditions (A **or** B):
   - **A.** Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, iii, iv, v, vi **and** vii):
     - **i.** Patient is ≥ 18 years of age; **AND**
     - **ii.** Patient has chronic rhinosinusitis with nasal polyposis as evidenced by direct examination, endoscopy, or sinus computed tomography (CT) scan; **AND**
     - **iii.** Patient has experienced two or more of the following symptoms for at least 6 months: nasal congestion, nasal obstruction, nasal discharge, and/or reduction/loss of smell; **AND**
     - **iv.** Patient has a baseline immunoglobulin E (IgE) level ≥ 30 IU/mL; **AND**
       Note: "Baseline" is defined as prior to receiving any Xolair or anti-interleukin 4/13 therapy (i.e., Dupixent [dupilumab subcutaneous injection]).
     - **v.** Patient meets BOTH of the following (a **and** b):
       - **a.** Patient has received at least 3 months of therapy with an intranasal corticosteroid; **AND**
       - **b.** Patient will continue to receive therapy with an intranasal corticosteroid concomitantly with Xolair; **AND**
     - **vi.** Patient meets ONE of the following (a, b **or** c):
       - **a.** Patient has received at least one course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years; **OR**
       - **b.** Patient has a contraindication to systemic corticosteroid therapy; **OR**
       - **c.** Patient has had prior surgery for nasal polyps; **AND**
     - **vii.** The medication is prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist (ear, nose and throat [ENT] physician specialist).

   - **B.** Patient is currently receiving Xolair. Approve for 1 year if the patient meets the following criteria (i, ii, **and** iii):
     - **i.** Patient has already received at least 6 months of therapy with Xolair; **AND**
       Note: A patient who has received < 6 months of therapy or who is restarting therapy with Xolair should be considered under criterion 3A (Nasal Polyps, Initial Therapy).
     - **ii.** Patient continues to receive therapy with an intranasal corticosteroid; **AND**
     - **iii.** Patient has responded to Xolair therapy as determined by the prescriber.

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Note: Examples of a response to Xolair therapy are reduced nasal polyp size, improved nasal congestion, reduced sinus opacification, decreased sino-nasal symptoms, and/or improved sense of smell.

References:

1. Xolair subcutaneous injection [package insert]. South San Francisco, CA and East Hanover, NJ: Genentech, Inc. and Novartis Pharmaceuticals Corporation
2. The Joint Task Force on Practice Parameters (JTFPP) represented the American Academy of Allergy, Asthma and Immunology (AAAAI); the American College of Allergy, Asthma and Immunology (ACAAI); and the Joint Council of Allergy, Asthma and Immunology (JCAAI) in developing the parameters of these guidelines. Bernstein J, et al. JACI 2014; 133, 1270-1277.

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Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	June 2005
2	Policy Update	Updated Template from CCI to EH Updated exclusion criteria to include: Treatment of acute bronchospasm or status asthmaticus, Treatment of other allergic conditions, Treatment forms of urticaria other than chronic idiopathic urticaria CCI Revision Record: 11/12, 3/14, 2/15, 8/16, 11/16	All	2/4/2020
3	Policy Update	Updated criteria to include new indication of nasal polyps	Covered uses, Age restrictions, Coverage duration, and Other Criteria	12/9/2021

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