

When requesting Xolair® (omalizumab), 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 indications.

FDA-approved indications¹

- Xolair® (omalizumab) is indicated for the treatment of moderate to severe persistent asthma in individuals with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids.
- Xolair® (omalizumab) is indicated for the treatment of chronic idiopathic urticaria in individuals who remain symptomatic despite treatment with a histamine-1 (H1) antihistamine.

Approved Off-label Compendial use²

- None

Coverage Guidelines

Moderate to Severe Persistent Asthma

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

- Diagnosis of moderate to severe persistent allergic asthma confirmed by appropriate diagnostic testing^{1,3}
- ≥6 years of age¹
- Has a positive skin test or in vitro reactivity to a perennial aeroallergen^{1,3}
- Has inadequate control of symptoms after 3 months of consecutive treatment with the following^{1,3}:
 - o High-dose corticosteroid
 - o Long-acting beta agonist or leukotriene inhibitors
- Age 12 years and over: Has baseline serum total Immunoglobulin E (IgE) levels between 30 Units/mL and 700 Units/mL¹
- Age 6 years to <12 years: Has baseline serum total Immunoglobulin E (IgE) levels between 30 Units/mL and up to 1300 Units/mL
- Has a body weight that is 150 kg or less¹

Chronic Idiopathic Urticaria

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

- Confirmed diagnosis of chronic idiopathic urticaria^{1,4}
- Has inadequate control of symptoms despite treatment with a histamine-1 receptor antihistamine¹
- ≥12 years of age¹

Approval duration: 12 months

Additional Information for Prescribers¹

Our prescribers are alerted to the following safety concerns as educational points/reminders:

- Administer in a healthcare setting prepared to manage anaphylaxis that can be life-threatening and observe individuals for an appropriate period of time after administration; individuals with a history of anaphylaxis to foods, medications or other causes are at increased risk of anaphylaxis due to Xolair[®] (omalizumab).
- Do not abruptly discontinue corticosteroids upon initiation of Xolair[®] (omalizumab) therapy.
- Stop Xolair[®] (omalizumab) if individuals develop signs and symptoms similar to serum sickness.
- Be alert to signs and symptoms of vasculitis, including eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy, especially upon reduction of oral corticosteroids.
- Do not use Xolair[®] (omalizumab) for other allergic conditions, other forms of urticaria, for acute bronchospasm or during status asthmaticus.
- Re-testing of total IgE levels during treatment with Xolair[®] (omalizumab) cannot be used to determine dosage adjustments in asthma as IgE levels are elevated during treatment and remain elevated for up to one year after Xolair[®] (omalizumab) discontinuation.

References

1. Xolair[®] prescribing information. South San Francisco, CA: Genentech, Inc.: July 2016.
2. Klasco RK (Ed): DRUGDEX[®] system. Thomson Micromedex, Greenwood Village, CO. Accessed February 24, 2017. <https://www.micromedexsolutions.com>
3. Guidelines for the Diagnosis and Management of Asthma. National Institutes of Health, Expert Panel Report 3, National Heart, Lung, and Blood Institute. Full Report 2007. Accessed February 24, 2017. <https://www.nhlbi.nih.gov/files/docs/guidelines/asthgdln.pdf>
4. Bernstein JA, Lang DM, Khan DA. The diagnosis and management of acute and chronic urticaria: 2014 update. *J Allergy Clin Immunol*. 2014;133:1270-1277.