

## omalizumab (Xolair®)

To Initiate a Coverage Review, call 1 800 753-2851

| Covered Medication   |
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| ➤ Xolair® (omalizumab)   |
| What It Does and How It's Used   |
| <ul style="list-style-type: none"> <li>➤ Asthma is a chronic inflammatory disorder of the airways characterized by restricted airflow both in and out of the lungs. Allergic asthma is triggered by exposure to environmental substances (allergens) such as trees, grass, weeds, pollen, molds, animal dander, dust mites and cockroach droppings.</li> <li>➤ The symptoms of allergic and nonallergic asthma are the same. They include coughing, wheezing, shortness of breath or rapid breathing, and chest tightness.</li> <li>➤ Asthma affects approximately 17 million of Americans. About 60% have allergic asthma. Three million are children and 7 million are adults.</li> <li>➤ Skin testing may be used to determine which environmental substances may be causing the allergic symptoms.</li> <li>➤ IgE (Immunoglobulin E) is an antibody in the human immune system that plays a critical role in the allergic process. When the body is in contact with an allergen, it produces IgE antibody directed against that allergen. When the individual is re-exposed to that allergen, IgE generates the release of substances such as histamine that trigger allergic symptoms and worsen asthma.</li> <li>➤ Optimal therapy for patients with moderate to severe persistent asthma includes inhaled steroids and long-acting beta<sub>2</sub>-agonists (e.g., salmeterol). These drugs are used to keep the airway open and decrease swelling in the lung tissue.</li> <li>➤ Xolair® is the first in a new class of monoclonal antibody-based therapies that target IgE. Xolair® acts as an IgE blocker by stopping the allergic reaction before it starts, thus allowing the patient to avoid allergy symptoms that often trigger an asthma attack or lead to an attack.</li> <li>➤ Xolair® is used for the treatment of moderate to severe persistent asthma due to perennial (yearly) allergens and whose symptoms are inadequately controlled with inhaled steroids. Xolair® has been shown to decrease the incidence of asthma attacks and inhaled steroid requirements in these patients.</li> <li>➤ Xolair® is administered at doses of 150 to 375 mg subcutaneously by a physician every 2 or 4 weeks. The dose and frequency of administration are determined by IgE levels before the start of treatment and the patient's weight.</li> </ul> |

| Rationale for Coverage Authorization  |
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| To provide coverage for Xolair® for use in the treatment of inadequately controlled moderate to severe persistent asthma and to reduce exposure to cost associated with use for conditions for which the effectiveness of Xolair® is not known. |

| Benefit Design   |
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| Coverage is determined through prior authorization for every claim.  |
| Coverage Authorization Criteria  |
| This prescription benefit provides coverage for omalizumab (Xolair®) in accord with the following criteria:  |
| <ol style="list-style-type: none"> <li>1. Coverage is provided as maintenance therapy for prophylaxis of asthma exacerbations in patients with moderate to severe allergic asthma in the following circumstances: <ul style="list-style-type: none"> <li>• the patient is ≥ 6 years of age</li> <li>• the patient's baseline serum IgE level is &gt;25 IU/mL</li> </ul> <p style="text-align: center;">AND</p> <ol style="list-style-type: none"> <li>1. The patient is currently receiving therapy with an inhaled steroid or oral steroid unless the patient should not receive steroids.</li> </ol> <p style="text-align: center;">AND</p> <ol style="list-style-type: none"> <li>2. The patient has inadequately controlled asthma defined as having had two or more ER visits for an asthma exacerbation AND/OR ≥ 2 courses of short pulse oral or parenteral corticosteroids for exacerbations within the previous 12 months.</li> </ol> <p style="text-align: center;">OR</p> <ol style="list-style-type: none"> <li>3. The dose of inhaled or systemic steroid must be reduced to help control adverse side effects, and addition of Xolair® is the only option that may achieve the needed dosage reduction.</li> </ol> </li> </ol> |
| Coverage is provided for up to six 150-mg vials per every 30 days for a 12-month period. For patients already receiving Xolair®, coverage is provided when there is continued clinical benefit as evidenced by reductions in   |

asthma exacerbations from baseline.

The prescriber shall be informed of the following:

Healthcare professionals administering Xolair<sup>®</sup> should be prepared to manage life-threatening anaphylaxis and should observe their Xolair<sup>®</sup>-treated patients for at least 2 hours after Xolair<sup>®</sup> is given. Patients under treatment with Xolair<sup>®</sup> should be fully informed about the signs and symptoms of anaphylaxis, their chance of developing delayed anaphylaxis following Xolair<sup>®</sup> treatment, and how to treat it when it occurs.

#### **References**

Product Information: Omalizumab (Xolair<sup>®</sup> – Genentech, Inc.) 2006.

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Milgrom H, Fick RB Jr, et al. Treatment of Allergic Asthma with Monoclonal Anti-IgE Antibody. *N Engl J Med* 1999; 341:1966-1973.

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