

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Xolair (omalizumab)

CLASSIFICATION

- Anti-asthma, monoclonal antibody

DESCRIPTION

- Omalizumab inhibits the binding of IgE to the high-affinity IgE receptor (RI) on the surface of mast cells and basophils. Reduction in surface-bound IgE on RI-bearing cells limits the degree of release of mediators of the allergic response. Treatment with omalizumab also reduces the number of RI receptors on basophils in atopic patients.
- Omalizumab is an adjunct in patients with severe persistent asthma who are inadequately controlled with combination of high-dose ICS and long-acting beta-agonist and concurrently have allergies (National Heart, Lung, and Blood Institute, 2007).
- Subcutaneous and intravenous omalizumab reduced asthma exacerbations and/or asthma symptoms in patients with moderate to severe persistent asthma inadequately controlled on inhaled corticosteroids; steroid requirements were significantly reduced during omalizumab therapy, although this was not always significant relative to placebo.
- Omalizumab has produced variable results with regards to changes in forced expiratory volume in 1 second (FEV1)
- Efficacy in allergic asthma has been demonstrated with therapy up to 52 weeks in both adults and children.
- Subcutaneous omalizumab has been associated with an improvement in quality of life.
- Efficacy has not been compared to inhaled corticosteroids
- The intravenous route of administration is not approved by the U.S. Food and Drug Administration

FORMULARY COVERAGE

Prior authorization: Required

Good Health Formulary: Medical benefit (T6)

Commercial Formulary: Medical benefit (T6)

Medicare Part D coverage: T4

COVERAGE CRITERIA

Xolair (omalizumab) meets the definition of **medical necessity** for the following:

- **IgE-mediated allergic asthma:** For adults and adolescents (12 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, the recommended dose is 150 to 375 milligrams every 2 to 4 weeks.

Xolair (omalizumab) is considered **experimental** for the following:

- Treatment of Mild Persistent or Mild Intermittent Asthma
- Initial treatment of allergic asthma
- Asthma without baseline pretreatment serum total IgE between 30 IU/ml and 700 IU/ml
- Allergic rhinitis prophylaxis (seasonal or perennial)
- Allergy to peanuts (protection)
- Allergy to latex (protection)

Required Provider Specialty:

- Approval is limited to Pulmonology and Allergist

DOSAGE/ADMINISTRATION:

- Xolair is administered by subcutaneous (SC) injection and should be administered by a healthcare professional. This is due to difficult preparation, dosing variations, and possibility of anaphylaxis.
- The manufacturer-recommended dose and dosing frequency are determined by body weight (kilograms) and serum IgE level (international units/milliliter) measured BEFORE start of treatment. Total IgE levels (unbound and complexed) are increased during omalizumab treatment and remain elevated for up to 1 year after discontinuation of treatment. Therefore, after the first dose, serum IgE levels should not be used for dose determination unless treatment has been interrupted for more than 1 year. Subcutaneous dosing is presented in the following table:

ADMINISTRATION EVERY 4 WEEKS (Milligrams of omalizumab)				
<i>Pre-treatment Serum IgE (IU/mL)</i>	<i>Body Weight (kg)</i>			
	30-60	61-70	71-90	91-150
30-100	150	150	150	300
101-200	300	300	300	
201-300	300			

ADMINISTRATION EVERY 2 WEEKS (Milligrams of omalizumab)				
<i>Pre-treatment Serum IgE (IU/mL)</i>	<i>Body Weight (kg)</i>			
	30-60	61-70	71-90	91-150
101-200				225
201-300		225	225	300
301-400	225	225	300	X
401-500	300	300	375	X
501-600	300	375	X	X
601-700	375	X	X	X

X = DO NOT DOSE

PRECAUTIONS:

- Anaphylactic reactions (eg, bronchospasm, hypotension, syncope, urticaria, angioedema) may occur with first dose or beyond one year of therapy
- Acute bronchospasm, acute asthma exacerbations, or status asthmaticus; do not use omalizumab for these indications
- Corticosteroid use (systemic or inhaled); avoid abrupt corticosteroid discontinuation with initiation of omalizumab
- Eosinophilic conditions (eg, vasculitis consistent with Churg-Strauss syndrome) have been rarely reported, often in association with oral corticosteroid therapy reduction; monitor patients for vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy
- Malignant neoplasms have been rarely reported

Billing/Coding information

HCPCS Code:

J2357	injection, omalizumab, 5 mg
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Associated CPT Coding:

96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
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Associated ICD-9 Coding:

493.00	Extrinsic asthma, unspecified
493.01	Extrinsic asthma with status asthmaticus
493.02	Extrinsic asthma with (acute) exacerbation

COST

AWP (March 2010): 150 mg vial: \$694.58

COMMITTEE APPROVAL:

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GUIDELINE UPDATE INFORMATION:

03/2010	Policy creation

REFERENCES:

- DRUGDEX®, accessed 03/29/2010
- Product Information: XOLAIR(R) subcutaneous solution, omalizumab subcutaneous solution. Genentech Inc, South San Francisco, CA, 2007