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OMALIZUMAB (Xolair[®]) Preauthorization Criteria for Approval

Medications and Dosage Forms Included in Criteria

Generic Name	Brand Name	Dosage Form
Omalizumab	Xolair [®]	Subcutaneous injection

FDA Approved Indications¹

Xolair (omalizumab) is indicated for adults and adolescents (12 years of age and above) 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. Xolair has been shown to decrease the incidence of asthma exacerbations in these patients. Safety and efficacy have not been established in other allergic conditions.

Description

The purpose of the Xolair (omalizumab) preauthorization criteria is to ensure patients that are prescribed Xolair therapy are meet requirements based on asthma guidelines and product labeling while maintaining dosing appropriate for age, weight, and pretreatment serum IgE levels as recommended in the product labeling. Additionally, positive allergen tests and previous therapy are required during the evaluation of the preauthorization request. Previous therapy documentation should follow current treatment guidelines as outlined in Global Initiative for Asthma. Preauthorization requests that meet criteria are approved for 12 months and renewal therapy is evaluated yearly as dosing and response to treatment (improvement of maintenance of asthma symptoms) must continually meet the preauthorization criteria.

Criteria

Initial Evaluation

1. Has the patient been previously treated with Xolair (omalizumab)?
If yes, see renewal criteria.
If no, continue to 2.
2. Does the patient meet all of the following requirements?
 - a. 12 years of age or older
 - b. Pretreatment IgE level ≥ 30 IU/mL
 - c. Weight ≥ 30 kg (≥ 66 lbs.)
 - d. Allergic asthma confirmed by skin testing or *in vitro* reactivity (RAST) testingIf yes to a-d, continue to 3.
If no (1 or more not met), do not approve.
3. Is the patient currently using an inhaled corticosteroid?
If yes, continue to 5 (verify in prescription claims history within last 90 days).
If no, continue to 4.
4. Does the patient have an allergy, contraindication, intolerance, or documented failure to corticosteroids?
If yes, further review is required.
If no, do not approve.

5. Is the patient currently treated with a long-acting β_2 -agonist?
If yes, continue to 7.
If no, continue to 6.
6. Does the patient have an allergy, intolerance, contraindication, or documented failure to long-acting β_2 -agonist?
If yes, continue to 7.
If no, do not approve.
7. Is the patient being treated with a leukotriene modifier or theophylline?
If yes, continue to 9.
If no, continue to 8.
8. Does the patient have an allergy, intolerance, contraindication, or documented failure to a leukotriene modifier or theophylline?
If yes, continue to 9.
If no, do not approve.
9. Does the patient experience exacerbations of asthma symptoms requiring increased inhaled corticosteroid dosing, increased daily use of β_2 -agonist rescue medication, or systemic steroids?
If yes, continue 10.
If no, do not approve.
10. Dosing guidelines are based on IgE levels and weight, please provide the patient's weight, IgE level and requested quantity per month. (See Table 1)
Continue to 11.
11. Is the requested dose above the dosing parameters provided in product labeling?
If yes, do not approve and forward to physician reviewer.
If no, approve for 12 months for the requested quantity of vials per month.

Renewal Evaluation

1. Has the patient been previously treated with Xolair (omalizumab)?
If yes, continue to 2.
If no, see initial evaluation provided above.
2. Does the patient meet all of the following requirements?
 - a. 12 years of age or older
 - b. Pretreatment IgE level \geq 30 IU/mL
 - c. Weight \geq 30 kg (\geq 66 lbs.)
 - d. Allergic asthma confirmed by skin testing or *in vitro* reactivity (RAST) testingIf yes to a-d, continue to 3.
If no (1 or more not met), do not approve.
3. Does the physician's assessment of the patient indicate that Xolair (omalizumab) is contributing to improvement in asthma symptoms or maintenance of asthma control?
If yes, continue to 4.
If no, do not approve.
4. Is the patient continuing inhaled corticosteroid therapy?
If yes, continue to 5 (verify in prescription claims history within last 90 days).
If no, further review required.

5. Has there been a change in weight requiring a dose adjustment?
If yes, continue to 6.
If no, approve for 12 months for previous quantity per month.
6. Has the dose of Xolair (omalizumab) been adjusted for any significant weight changes? (See Table 1) New amount requested must be provided.
If yes, continue to 7.
If no, do not approve and forward to physician reviewer.
7. Is the requested dose above the dosing parameters provided in product labeling?
If yes, do not approve and forward to physician reviewer.
If no, approve for 12 months for the requested quantity of vials per month.

Table 1 – Xolair (omalizumab) Doses (mg) and Administration¹

Pre-treatment Serum IgE (IU/mL)	Body Weight (kg)			
	30-60	>60-70	>70-90	>90-150
≥30-100	150 q 4 weeks	150 q 4 weeks	150 q 4 weeks	300 q 4 weeks
>100-200	300 q 4 weeks	300 q 4 weeks	300 q 4 weeks	225 q 2 weeks
>200-300	300 q 4 weeks	225 q 2 weeks	225 q 2 weeks	300 q 2 weeks
>300-400	225 q 2 weeks	225 q 2 weeks	300 q 2 weeks	
>400-500	300 q 2 weeks	300 q 2 weeks	375 q 2 weeks	
>500-600	300 q 2 weeks	375 q 2 weeks		
>600-700	375 q 2 weeks			

For weight and IgE level combinations outside this chart, no dosing is provided and should not be administered.

Rationale

The purpose of the Xolair (omalizumab) preauthorization criteria is to ensure patients that are prescribed Xolair therapy are meet requirements based on asthma guidelines and product labeling while maintaining dosing appropriate for age, weight, and pretreatment serum IgE levels as recommended in the product labeling. Quantities will be evaluated based on the dosing guidelines provided in the product labeling.

Omalizumab inhibits the binding of IgE to a high-affinity IgE receptor on the surface of mast cells and basophils.¹ Reduction in surface-bound IgE on the high-affinity IgE receptor-bearing cells limits the degree of release of mediators of the allergic response.¹ Protocols utilized in the studies have provided strict recommendations on the use of omalizumab and the role in chronic asthma management is unknown.¹⁻³ Therefore, patients must meet criteria recommended in the product labeling. Patients approved for omalizumab must be 12 years of age or older, pretreatment IgE level greater than 30 International units (IU) per milliliter, weigh greater than or equal to 30 kilograms (greater than or equal to 66 pounds), and documentation of allergic asthma confirmed by a positive allergen-specific skin prick test or by a serum radioallergosorbent (RAST) test.⁴ Clinical trials enrolled patient's positive for perennial aeroallergen sensitivity to dust mites, cockroaches, or cat or dog dander.^{3,5} Omalizumab use in patients with sensitivity to other aeroallergens (e.g., molds, pollens) or negative allergy skin tests has not been evaluated.³

Asthma guidelines and practice parameters designed to assist in the diagnosis, treatment, and management of asthma suggest that assessment and monitoring of asthma include severity, control, and responsiveness to therapy.^{4,6} Asthma severity is useful when making decisions on management at the initial assessment and subsequent assessments to monitor and adjust treatment.^{4,5} Treatment is recommended to control the manifestations of the disease and the classification of asthma control should be made when the clinical features of the disease are minimized and therapy goals are met.^{4,5} The National Heart, Blood, and Lung Institute (NHLBI) Guidelines for the Diagnosis and Management of Asthma classification for assessing asthma control in adults and adolescents 12 years of age or older are detailed below (Table 2).

Explanation of PA Criteria

Approvals of omalizumab preauthorization requests are for a 12 month duration upon meeting the requirements within the PA Criteria shown above (initial and renewal evaluations). Within the preauthorization, the dose requested must meet the dosing guidelines established in the product labeling and as shown in Table 1. Requests for dosages outside of these guidelines do not meet the criteria for approval. Renewal requests must continue to meet the dosing guidelines based on weight and serum IgE levels, age, and documentation of improvement in asthma symptoms or maintenance of asthma control while on therapy. Improvement may be defined as decreased asthma symptoms, decreased use of SABA for quick relief, decrease in the number of exacerbations, improved functioning, and increase in FEV₁.⁵

References

1. Xolair[®] (omalizumab) [package insert]. South San Francisco, CA: Genentech, Inc., July 2007.
2. Sin DD, Man J, Sharpe H, et al. Pharmacological management to reduce exacerbations in adults with asthma: a systematic review and meta-analysis. *JAMA* 2004;292(3):367-76.
3. Strunk RC, Bloomberg GR. Omalizumab for asthma. *N Engl J Med* 2006;354(25):2689-95.
4. Global Initiatives for Asthma: Global Strategy for Asthma Management and Prevention 2007. Updated December 2007. Available at: <http://www.ginasthma.com>.
5. Expert panel report: guidelines for the diagnosis and management of asthma (EPR-3 2007). NIH Publication No. 08-4051. Bethesda, MD: U.S. Department of Health and Human Services; National Institutes of Health; National Heart, Lung, and Blood Institute; National Asthma Education and Prevention Program, 2007.
6. Li JT, Oppenheimer J, Bernstein IL, Nicklas RA. Attaining optimal asthma control: A practice parameter. *J Allergy Clin Immunol* 2005;116:S3-11.
7. Walker S, Monteil M, Phelan K, Lasserson TJ, Walters EH. Anti-IgE for chronic asthma in adults and children. *Cochrane Database of Systematic Reviews* 2006, Issue 2. Art. No.: CD003559. DOI: 10.1002/14651858.CD003559.pub3.
8. Busse W, Corren J, Lanier BQ, et al. Omalizumab, anti-IgE recombinant humanized monoclonal antibody, for the treatment of severe allergic asthma. *J Allergy Clin Immunol* 2001;108(2):184-90.
9. Milgrom H, Fick RB, Su JQ, et al. Treatment of allergic asthma with monoclonal anti-IgE antibody. *N Engl J Med* 1999;341(26):1966-73.

Billing/Coding

CODES	NUMBER	DESCRIPTION
GPI	44603060002120	Omalizumab for injection 150 mg
HCPCS	J2357	Injection, omalizumab, 5 mg
	C9217	Injection, omalizumab, per 5 mg
	S0107	Injection, omalizumab, 25 mg

Type of Service	Prescription Drug	
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Place of Service	Outpatient	
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Update Information

Date	Action	Reason
07/01/08	Replace PA criteria	New PA criteria

Preauthorization Criteria History

06/26/08	Reviewed by QMC
07/01/08	Preauthorization criteria original effective date
June 2009	Next Review