

Medical Policy



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Title: Xolair® Prior Authorization Criteria

Prior Authorization Form:

http://www.bcbsks.com/CustomerService/Forms/pdf/15-728_Xolair_PriorAuth.pdf

Professional

Original Effective Date: August 2003

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May 24, 2006;

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Institutional

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Brand	Generic	Dosage Form
Xolair®	omalizumab	injection

DESCRIPTION

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.

POLICY

The intent of the criteria is to ensure patients who are prescribed omalizumab therapy are appropriately selected according to product labeling and/or clinical studies and/or guidelines. Due to the strict dosing in product labeling, approval quantities for dosing are subject to review.

The role of omalizumab in the management of asthma has not yet been clearly defined.² The prior authorization (PA) criteria will require adherence to the Food and Drug Administration (FDA) labeled indication and dosing recommendations. Patients approved for omalizumab must be 12 years of age or older, pretreatment IgE levels must be greater than or equal to 30 International Units (IU) per milliliter, and weight greater than or equal to 30 kilograms.¹ The labeled indication for omalizumab is for the treatment of the diagnosis of moderate to severe allergic asthma.¹ Confirmation of an allergic

component to the patient's asthma diagnosis must be demonstrated by a positive allergen-specific skin prick test or by a radioallergosorbent (RAST) test on a serum sample.³ Patients enrolled in clinical trials evaluating omalizumab were specifically sensitive to perennial aeroallergens (i.e., dust mites, cockroaches, and dog or cat dander).⁴ Use of omalizumab in patients with other allergens, such as molds or pollens, or patients with negative allergy skin tests has not been evaluated.⁴

Global Initiative for Asthma (GINA) guidelines revised in 2006 and the National Heart, Blood, and Lung Institute (NHBLI) Guidelines for the Diagnosis and Management of Asthma revised in January 2007 (draft form as of 3/26/2007) and an Allergy & Immunology Practice Parameter, "Attaining optimal asthma control", now suggest that the assessment and monitoring of asthma include concepts of severity, control, and responsiveness to therapy.^{3,5,6} The classification of asthma by severity is considered useful when making management decisions at the initial assessment of the patient or for research purposes.^{3,5} The assessment of asthma control is important for monitoring and adjusting therapy. Defining asthma as controlled, partly controlled, or uncontrolled takes into account the severity of the underlying disease as well as its responsiveness to treatment.³ These definitions recognize that severity is not a constant feature but may change over months or years. The GINA characteristics of controlled, poorly controlled, and uncontrolled asthma are summarized in Table 1 below.³

Table 1: Levels of Asthma Control

Characteristic	Controlled (All of the following)	Partly Controlled (Any measure present in any week)	Uncontrolled
Daytime symptoms	None (twice or less/week)	More than twice per week	Three or more features of partly controlled asthma present in any week
Limitations on activities	None	Any	
Nocturnal symptoms/awakenings	None	Any	
Need for reliever/Rescue treatment	None (twice or less/week)	More than twice per week	
Lung function (PEF or FEV ₁)	Normal	< 80% of predicted or personal best (if known)	
Exacerbations	None	One or more per year	One in any week

The FDA approved labeling for omalizumab indicates use in moderate to severe persistent asthma.¹ Because of changes in definitions found in guidelines, the PA criteria for omalizumab will require a diagnosis of allergic asthma that is not controlled by medications recommended in a step-wise approach before the use of Xolair. The 2006 GINA guidelines recommend omalizumab (anti-IgE treatment) in step 5 as adjunctive therapy (see table 2). Addition of omalizumab to other controller medications has been shown to improve control of allergic asthma when control has not been achieved on treatment with combinations of other controllers including high doses of inhaled or oral glucocorticosteroids.⁷⁻⁹ Prerequisite agents before the addition of omalizumab include inhaled corticosteroids and a long-acting β_2 -agonist, and a leukotriene modifier or

theophylline.^{3,6} Omalizumab may be approved if there is allergy, contraindication, or intolerance to a specified prerequisite agent(s) and other requirements are met.

Table 2. Treatment Steps for Control of Asthma Symptoms

Step 1	Step 2	Step 3	Step 4	Step 5
Asthma Education Environmental Control				
Rapid-acting β_2 -agonist as needed	Rapid-acting β_2 -agonist as needed			
Controller Options (inhaled anticholinergics, short-acting oral β_2 -agonists, some long-acting β_2 -agonists, short-acting theophylline)	Select One	Select One	Add one or more	Add one or both
	Low dose inhaled ICS	Low-dose ICS plus long-acting β_2 -agonist	Medium- or high-dose ICS plus long-acting β_2 -agonist	Oral glucocorticosteroid (lowest dose)
	Leukotriene modifier	Medium- or high-dose ICS	Leukotriene modifier	Anti-IgE treatment
		Low-dose ICS plus leukotriene modifier	Sustained release theophylline	
	Low-dose ICS plus sustained release theophylline			

ICS=inhaled glucocorticosteroid

Initial approvals for omalizumab will be for 12 months. Dose requests must meet the parameters included in the dosing chart provided in the manufacturer's prescribing information or for patients in the "do not dose" range, Xolair may be approved for the maximum recommended dose according to body weight (dose at 375 mg every 2 weeks for 30-90 kg or 300 mg every 2 weeks for > 90-150 kg). If dose for weight and/or IgE does not fall within the manufacturers dosing chart, refer to the medical director. Renewals will be considered if the patient has been on therapy and meets the age, IgE, weight, and allergic asthma requirements as specified in the initial approval and if previous omalizumab therapy indicates improvement in asthma symptoms or maintenance of asthma control. Improvement may be evidenced by decreased exacerbations, a decrease in asthma symptoms, a decrease in use of rescue medications, or improved lung function.⁶ Renewal of omalizumab will also involve evaluation of weight and dose.

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Xolair (omalizumab)

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 \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 (all are met), continue to 3. If no, deny.
3. Is the patient currently using an inhaled corticosteroid?
If yes, continue to 5. If no, continue to 4.
4. Does the patient have an allergy, contraindication, intolerance or documented failure to corticosteroids?
If yes, continue to 5. If no, deny.
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 allergy, intolerance, contraindication or documented failure to long acting β_2 -agonist ?
If yes, continue to 7. If no, deny.
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 allergy, intolerance, contraindication or documented failure to a leukotriene modifier or theophylline?
If yes, continue to 9. If no, deny.
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 to 10. If no, deny.
10. Is the requested dose within the dosing parameters provided in the product labeling?
If yes, approve for 12 months. If no, Xolair will be approved for the recommended dose according to body weight and/or pretreatment IgE. If the recommended dose is in the "do not dose" range, Xolair may be approved for the maximum recommended dose according to body weight (dose at 375 mg every 2 weeks for 30-90 kg or 300 mg every 2 weeks for > 90-150 kg). If dose for weight and/or IgE does not fall within the manufacturers dosing chart, refer to the medical director.

Renewal Evaluation

1. Has the patient been previously treated with Xolair (omalizumab)?
If yes, continue to 2. If no, see initial evaluation.

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)If yes (all are met), continue to 3. If no (1 or more not met), deny.

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, deny.

4. Has there been a change in weight requiring a dose adjustment?
If yes, continue to 5. If no, approve for 12 months for previous quantity per month.

5. Has the dose of Xolair (omalizumab) been adjusted for any significant weight changes? (See Table 3. Xolair Dosing and Administration) Please provide amount requested per month.
If yes, continue to 6. If no, correct and allow for the policy recommended dose.

6. Is the requested amount within the dosing parameters provided in product labeling?
If yes, approve for 12 months. If no, correct and allow for the policy recommended dose. If the recommended dose is in the "do not dose" range Xolair may be approved for the maximum recommended dose according to body weight (dose at 375 mg every 2 weeks for 30-90 kg or 300 mg every 2 weeks for > 90-150 kg). If dose for weight and/or IgE does not fall within the manufacturer's dosing chart, refer to the medical director.

CONCLUSION

The prior authorization criteria for Xolair (omalizumab) ensures that patients are appropriately selected for therapy based on product labeling and asthma guidelines while adhering to the dosing guidelines for age, weight, and pretreatment IgE levels as recommended by this policy. In addition to meeting the dosing parameters, a positive allergen test is required along with documentation of previous therapy as outlined in the treatment steps for control of asthma symptoms in Global Initiative for Asthma guidelines. For renewal of therapy, all policy dosing parameters must continue to be met with omalizumab contributing to the improvement or maintenance of asthma symptoms. All approvals are for twelve month intervals.

Table 3. Xolair Dosing and Administration¹

Pre-treatment serum IgE (IU/mL)	Body weight (kg)			
	30-60	> 60-70	> 70-90	> 90-150
≥ 30-100	150 mg q 4 wks	150 mg q 4 wks	150 mg q 4 wks	300 mg q 4 wks
> 100-200	300 mg q 4 wks	300 mg q 4 wks	300 mg q 4 wks	225 mg q 2 wks
> 200-300	300 mg q 4 wks	225 mg q 2 wks	225 mg q 2 wks	300 mg q 2 wks
> 300-400	225 mg q 2 wks	225 mg q 2 wks	300 mg q 2 wks	
> 400-500	300 mg q 2 wks	300 mg q 2 wks	375 mg q 2 wks	
> 500-600	300 mg q 2 wks	375 mg q 2 wks		
> 600-700	375 mg q 2 wks			
			Do Not Dose	

For weight and IgE level combinations not found on the chart, refer to the medical director.

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