

CRITERIA FOR PRIOR AUTHORIZATION

Xolair® (omalizumab)

PROVIDER GROUP Pharmacy
Professional

MANUAL GUIDELINES The following drug requires prior authorization:
Omalizumab (Xolair®)

CRITERIA FOR ALLERGIC ASTHMA Must meet all of the following:

- Must be prescribed by or in consultation with a pulmonologist, allergist, or immunologist
- Patient must have a diagnosis of moderate to severe persistent asthma diagnosis for at least 1 year (diagnosis must be based upon NHLBI criteria – see attached table)
- Patient must have a positive skin test or in vitro reactivity to a perennial aeroallergen
- Patient must be 6 years of age or older
- Patient must be taking and be compliant with a high-dose inhaled corticosteroid and a long-acting beta₂-agonist
- Patient must have symptoms that are not well controlled while compliant with asthma controller medication (based upon NHLBI criteria – see attached table)
- Dosing must be based upon attached table

RENEWAL CRITERIA FOR ASTHMA Must meet all of the following:

- Documentation of monthly injections. If patient has missed 2 or more injections the renewal request will be denied based upon non-compliance
- Patient must have documented improvement in lung function test: FEV1 of at least 12% or PEF of at least 20%
- Patient must have a documented decrease in the number of asthma exacerbations and symptomatic improvement per physician assessment

CRITERIA FOR CHRONIC IDIOPATHIC URTICARIA Must meet all of the following:

- Must be prescribed by or in consultation with an allergist, immunologist, or dermatologist
- Patient must have a diagnosis of chronic idiopathic urticaria
- Patient must be 12 years of age or older
- Patient must be symptomatic despite H1 antihistamine treatment
- Dosing must not exceed 300mg every 4 weeks

LENGTH OF APPROVAL 6 months

DRUG UTILIZATION REVIEW COMMITTEE CHAIR

PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

DATE

DATE

Classification of Asthma Severity

Adapted from NHLBI Guidelines for the Diagnosis and Management of Asthma*

Components of Severity		Classification of Asthma Severity ≥12 years of age			
		Intermittent	Persistent		
			Mild	Moderate	Severe
Impairment Normal FEV₁/FVC: 8-19 yr 85% 20-39 yr 80% 40-59 yr 75% 60-80 yr 70%	Symptoms	≤2 days/week	>2 days/week but not daily	Daily	Throughout Day
	Nighttime awakenings	≤2x/month	3-4x/month	>1x/week but not nightly	Often 7x/week
	Short-acting beta ₂ -agonist use for symptom control (not prevention of EIB)	≤2 days/week	>2 days/week but not daily, and not more than 1x on any day	Daily	Several times per day
	Interference with normal activity	None	Minor limitation	Some limitation	Extremely limited
	Lung Function	<ul style="list-style-type: none"> • Normal FEV₁ between exacerbations • FEV₁ >80% predicted • FEV₁/FVC normal 	<ul style="list-style-type: none"> • FEV₁ >80% predicted • FEV₁/FVC normal 	<ul style="list-style-type: none"> • FEV₁ >60% but <80% predicted • FEV₁/FVC reduced 5% 	<ul style="list-style-type: none"> • FEV₁ <60% predicted • FEV₁/FVC reduced >5%

Classification of Asthma Control

Adapted from NHLBI Guidelines for the Diagnosis and Management of Asthma*

Components of Control		Classification of Asthma Control ≥12 years of age		
		Well Controlled	Not Well Controlled	Very Poorly Controlled
Impairment	Symptoms	≤2 days/week	>2 days/week but not daily	Throughout the day
	Nighttime awakenings	≤2x/month	1-3x/week	≥4x/week
	Interference with normal activity	None	Some limitation	Extremely limited
	Short-acting beta ₂ -agonist use for symptom control (not prevention of EIB)	≤2 days/week	>2 days/week	Several times per day
	FEV ₁ or peak flow	>80% predicted/personal best	60-80% predicted/personal best	<60% predicted/personal best
	Validated questionnaires <ul style="list-style-type: none"> • ATAQ • ACQ • ACT 	<ul style="list-style-type: none"> • 0 • ≤0.75* • ≥20 	<ul style="list-style-type: none"> • 1-2 • ≥1.5 • 16-19 	<ul style="list-style-type: none"> • 3-4 • N/A • ≤15

*ACQ values of 0.76-1.4 are indeterminate regarding well-controlled asthma

PA Criteria

Dosing Table 1

Administration every 4 weeks

Xolair Dose (mg) administered by subcutaneous injection

Pre-treatment Serum IgE (IU/mL)	Body Weight			
	30-60 kg	> 60-70 kg	> 70-90 kg	> 90-150 kg
≥30-100	150mg	150mg	150mg	300mg
>100-200	300mg	300mg	300mg	See Dosing Table 2
>200-300	300mg			
>300-400				
>400-500				
>500-600				

Dosing Table 2

Administration every 2 weeks

Xolair Dose (mg) administered by subcutaneous injection

Pre-treatment Serum IgE (IU/mL)	Body Weight			
	30-60 kg	>60-70 kg	>70-90 kg	>90-150 kg
≥30-100	See Dosing Table 1			
>100-200				225mg
>200-300	225mg		225mg	300mg
>300-400	225mg	225mg	300mg	Do Not Dose
>400-500	300mg	300mg	375mg	
>500-600	300mg	375mg		
>600-700	375mg			

***References:**

Xolair® [package insert]. South San Francisco, CA: Genetech, Inc; March 2014.

National Heart, Lung, and Blood Institute. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma 2007. Bethesda, MD: National Institutes of Health; August 2007. NIH Publication 07-4051.