

Specialty Pharmacy Program

Xolair® (omalizumab)

DESCRIPTION

Xolair is a recombinant DNA-derived humanized monoclonal antibody that selectively binds to human immunoglobulin E (IgE). The product inhibits the binding of IgE to a high-affinity IgE receptor on the surface of mast cells and basophils. Reduction in the surface bound IgE limits the degree or release of mediators of the allergic response, and thus may decrease the frequency of asthma exacerbations.

Xolair 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.

APPROVAL DURATION

Approval duration: 1 year

APPROVAL CRITERIA

- I. Patient must meet all of the following criteria:
 - A. Patient has a diagnosis of Moderate Persistent or Severe Persistent Asthma* AND
 - B. Patient is 12 years of age or older AND
 - C. Patient's symptoms are inadequately controlled with combination controller therapy (medium to high dose inhaled corticosteroids plus long acting beta-2 agonists or Leukotriene receptor antagonists), or cannot tolerate these medications AND
 - D. Patient has a positive skin test or in vitro reactivity to a perennial aeroallergen, AND
 - E. Patient has an FEV₁ < 80% predicted AND
 - F. Patient's IgE level is equal to or greater than 30 IU/ml.

* Classification of Asthma Severity in Children ≥12 Years of Age and Adults

Component	Intermittent	Persistent		
		Mild	Moderate*	Severe*
Symptoms	≤2 days/week	>2 days/week but not daily	Daily	Throughout the day
Nighttime awakenings	≤2 times/month	3-4 times/month	>1 time/week but not nightly	Often 7 times/week
Short-acting beta ₂ -agonist use for symptom control	≤2 days/week	>2 days/week but not daily and not more than 1 time 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%[†]
Exacerbation requiring oral corticosteroids	0-1/year	≥2/year	≥2/year	≥2/year

* Asthma severity must be moderate to severe persistent for approval.

[†] Normal ranges for FEV₁/FVC by age: 8-19 years, 85%; 20-39 years, 80%; 40-59 years, 75%; 60-80 years, 70%.
Abbreviations: FEV₁ = forced expiratory volume in 1 second; FVC = forced vital capacity.