



Prior Authorization Approval Criteria

Xolair (omalizumab)

Generic name: omalizumab (anti IgE)

Brand name: Xolair

Medication class: Anti-IgE Monoclonal antibody

FDA -approved uses: moderate to severe persistent asthma

Usual dose: 150 – 375 mg SC every 2 or 4 weeks

Table 1: Xolair doses (mg) every 4 weeks

Pretreatment serum IgE (IU/ml)	Body weight (kg)			
	30-60	>60-70	>70-90	>90-150
≥ 30-100	150	150	150	300
>100-200	300	300	300	See Table 2
>200-300	300			
>300-400				
>400-500				
>500-600				

Table 2: Xolair doses (mg) every 2 weeks

Pre-treatment serum IgE (IU/ml)	Body weight (kg)			
	30-60	>60-70	>70-90	>90-150
≥ 30-100	See Table 1			225
>100-200				225
>200-300	225	225	300	DO NOT USE
>300-400	225	225	300	
>400-500	300	300	375	
>500-600	300	375		
>600-700	375			

Duration of Therapy: Indefinite

Criteria for use: (bullet points below are all inclusive unless otherwise noted)

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient’s medical records
- If approved, initial approval will be for 6 months
- Clinically documented severe persistent asthma for greater than 1 year: reversible airflow obstruction, bronchial hyperactivity (challenged), FEV1 > 40% to <80% of predicted normal pre-inhaled steroids
- Ruled out co-morbidities that can cause asthma exacerbation: sinusitis, GERD, allergic rhinitis, OTC and Rx medications
- Ruled out non-asthma diagnoses: hyperventilation, laryngeal dysfunction, panic disorder
- Clinically documented IgE levels between 30-700 IU/ml
- Clinically documented specific allergic sensitivity: positive skin testing or RAST, in vitro testing to at least one perennial aeroallergen
- Failed/intolerant to oral corticosteroids

- Failed/intolerant to inhaled corticosteroids, long acting beta-2 agonists, leukotriene modifiers, and theophylline
- Failed/ intolerant to combination therapies: high dose inhaled steroids, long acting beta-agonists, antileukotrienes, theophylline
- Patient's asthma must be inadequately controlled using oral inhaled corticosteroids at maximum doses for at least 3 months. (Inadequate control on inhaled corticosteroids is demonstrated by hospitalization for asthma and requirement for systemic (oral or parenteral) corticosteroids to control exacerbations of asthma.)
- Patient must be educated and evaluated to insure that proper self-administration technique is being used when administering asthma medications
- Ages 12 and older
- Must have a consult by a pulmonary specialist
- Must forward baseline pulmonary function tests (including PEF, FEV1) and asthma severity (ie, Asthma Control Test result)
- Patient must be compliant on previous and current asthma therapy
- Patient must not be a current smoker
 - If patient is a current smoker, expectation is that the patient will stop smoking. Patient must be actively receiving a smoking cessation treatment.

Contraindications:

- Patients who have experienced a severe hypersensitivity reaction to Xolair.

Not approved if:

- Persistent smoking
- Above criteria not met
- Patient has any contraindications to the use of Xolair
- Patient is not compliant with their current asthma therapy

Criteria for continuation of therapy:

- Must forward clinical notes from the patient's medical records documenting the patient's current condition (including patient's response to Xolair treatment, patient's current asthma severity (ie, Asthma Control Test result) and any asthma exacerbations or hospitalizations).
- Must forward current pulmonary function tests (including PEF, FEV1)
- Must have evidence of reversible disease: > 12% improvement in FEV1 with at least a 200ml increase or >20% improvement in PEF
- Must have evidence of improvement on PFT's
- Must have evidence of stabilization or improvement in asthma severity (ie, Asthma Control Test result)
- Must have evidence of decreased steroid requirements
- Patient must be compliant with current therapy
- Must be a non-smoker

Note:

Asthma Control Test score:

19 or below – asthma may not be well controlled

20 or above – asthma may be well controlled

Rationale

The intent of the criteria is to ensure that patients follow selection elements noted in labeling.

Xolair is indicated for adults and adolescents (12 years of age or 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. Safety and efficacy have not been established in other allergic conditions.

Xolair has been shown to decrease the incidence of asthma exacerbations in these patients. Xolair has been shown to be beneficial as adjunctive therapy in patients whose symptoms are inadequately controlled despite the regular use of maximum dose inhaled corticosteroids. Xolair is to be prescribed as prophylactic therapy for allergy-induced asthma. Xolair is to be used in conjunction with other agents in the management of moderate to severe persistent asthma, but never as monotherapy.

Xolair has shown to be effective against allergy-induced asthma only. Allergy tests are required to identify patients who may be candidates for Xolair therapy. The FDA advisory committee defines having allergic asthma as testing positive to at least one perennial aeroallergen according to either a skin test (e.g. prick/puncture test, intracutaneous test) or a blood test (e.g. RAST) and having an IgE level between 30 and 700 IU/ml.

Xolair was evaluated in several clinical studies for safety and efficacy. Dosing was based on body weight and baseline serum IgE concentration. All patients are required to have a baseline IgE between 30 and 700 IU/ml and body weight not more than 150 kg. Xolair does not offer any benefit and should not be used in patients with IgE levels < 30 IU/ml. If the IgE level is > 700 IU/ml the maximum dose is 375 mg every 4 weeks.

Xolair has not been shown to alleviate asthma exacerbations acutely and should not be used for the treatment of acute bronchospasm or status asthmaticus. Patients should have a short-acting beta2-agonist available for rescue therapy.

Current guidelines for the management of asthma recommend patients with moderate to severe persistent asthma use either an oral inhaled corticosteroid at maximum dose plus a long acting inhaled beta2-agonist, or an oral inhaled corticosteroid plus a leukotriene modifier as alternative treatment. A leukotriene modifier can be added on to the standard regimen of an inhaled corticosteroid and a long acting beta2-agonist if needed, particularly in patients with recurring severe exacerbations.

Note: Total IgE levels are elevated during treatment and remain elevated for up to one year after the discontinuation of treatment. Therefore re-testing of IgE levels during Xolair treatment cannot be used as a guide for dose determination. Dose determination after treatment interruptions lasting less than 1 year should be based on serum IgE levels obtained at initial dose determination. Total serum IgE levels may only be re-tested for dose determination if treatment of Xolair has been interrupted for one year or more.

P&T Approval: _____ Date: _____