



INLAND EMPIRE HEALTH PLAN

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the IEHP Pharmacy and Therapeutics Subcommittee.

Drug: Xolair (omalizumab)

Class: Biologic

Formulary medication: N/A

Effective Date: May 2004, updated January 2006, August 2008, August 2009

Policy/Criteria:

1. Patient has moderate to severe persistent asthma defined by NAEPP.
 - a. By symptoms:
 - i. Moderate Persistent: Daily day symptoms/ >1 night per week night symptoms
 - ii. Severe persistent: Continual day symptoms/ Frequent night symptoms
 - b. By PEF or FEV1:
 - i. Moderate Persistent: >60%-<80% day/ >30% night
 - ii. Severe persistent: <60% day/ >30% night
2. Member is on optimal therapy per NAEPP guideline:
 - a. ICS (inhaled corticosteroid) + Long acting inhaled beta2-agonists
 - b. Compliant on therapy according to refills record for the past 6 months.
 - c. Member is symptomatic with above therapies. (i.e. hospitalized despite multidrug asthma therapy)
3. Prescribed by Allergist or Pulmonologist.
4. For patients who are dependent on oral steroid.
5. Have had adverse effects from corticosteroids.
6. Serum IgE test within range of 30-700IU/mL.
7. Member is 12 years or older.

8. Positive skin tests or *in vitro* reactivity to common aeroallergen.
9. Initial therapy may be authorized up to a period of 6 months.
10. Extended authorization (up to 6 months) may be granted if efficacy is documented (stable asthma control) and recent lab (IgE) work is provided.

Clinical Justification:

1. Efficacy and dosing of omalizumab in patients with IgE levels above 700 have not been established.
2. Clinical trials did not show significant differences between the exacerbation rates, the median decrease in ICS dose was about 10% more in omalizumab treated group versus placebo.¹⁻⁷
3. The effect of omalizumab on FEV1 or PEF was very minimal across all trials. ¹⁻⁷
4. Hospitalization rate was 0.26 per 100 patient-years with omalizumab vs 3.42 per 100 patient-years with placebo (P=<.01). Although the analysis favored omalizumab group, there were not significant differences between the groups.¹⁻⁷

Reference:

1. Holgate S, Bousquet J, Wenzel S, et al. Omalizumab improves disease control in patients at high risk of serious asthma related morbidity and mortality. *Am J Respir Crit Care Med* 2002;165:A187.
2. Milgrom H, Fick R, su J, et al. Treatment of allergic asthma with monoclonal anti-IgE antibody. *N Engl J Med* 1999;341:1966-1973.
3. Milgrom H, Berger W, Nayak A, et al. Treatment of childhood asthma with anti-immunoglobulin E antibody. *Pediatrics* 2001;108:E36.
4. Finn A, Gross G, van Bavel J, et al. Omalizumab improves asthma-related quality of life in patients with severe allergic asthma. *J Allergy Clin Immunol* 2003; 111: 278-84.
5. Soler M, Matz J, Townley R, et al. The anti-IgE antibody omalizumab reduces exacerbations and steroid requirement in allergic asthmatics. *Eur Respir J* 2001; 18: 254-61.
6. Busse W, Corren J, Lanier BQ, et al. Omalizumab, anti-IgE recombinant humanized monoclonal antibody, for the treatment of severe allergic rhinitis. *J Allergy Clin Immunol* 2001; 108:184-90.
7. Corren J, Casale T, Deniz Y, et al. Omalizumab, a recombinant humanized anti-IgE antibody, reduces asthma-related emergency room visits and hospitalizations in patients with allergic asthma. *J Allergy Clin Immunol* 2003; 111: 87-90.