ALASKA MEDICAID
Prior Authorization Criteria

Xolair® (omalizumab)

FDA INDICATIONS AND USAGE[1]

Xolair® is indicated to treat moderate to severe persistent asthma, age 6 years and older, who have had a positive skin test or in vitro reactivity to perennial aeroallergen and those symptoms are inadequately controlled with inhaled corticosteroids. It is also indicated for the treatment of chronic idiopathic urticaria, age 12 years and older, who remain symptomatic despite H1 antihistamine treatment.

APPROVAL CRITERIA[1,2,4]

Moderate to Severe Asthma

1. Patient is 6 years of age or older **AND;**
2. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist **AND;**
3. Patient is not being treated for acute bronchospasm or status asthmaticus **AND;**
4. Patient has a positive skin test or in vitro testing (I.E. for allergen specific IgE antibodies) and/or one or more seasonal aeroallergens **AND;**
5. Baseline IgE level is ≥ 30 IU/mL **AND;**
6. Patent's asthma symptoms have not been adequately controlled for at least three months while being treated with a corticosteroid combination with a long acting beta agonist, leukotriene modifier, theophylline, or an oral corticosteroid.

Chronic Idiopathic Urticaria[1,3]

1. Patient is 12 years of age or older **AND;**
2. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist **AND;**
3. Patient has had urticaria for at least 6 weeks with symptoms present on 3 or more days a week while taking a non-sedating antihistamine titrated to a maximum dose **AND;**
4. Patient has tried and fail or has an intolerance to a combination of leukotriene modifier, plus a non-sedating anti-histamine for at least 2 months.

DENIAL CRITERIA[1,2,3,4]

1. Patient has failed to meet approval criteria **OR;**
2. Patient is currently using an anti-interleukin 4 or 5 inhibitor.

CAUTIONS[1]

- Xolair should be administered in a healthcare setting that is prepared for anaphylaxis.
- Malignancies have been observed with use.
- Xolair should be stopped of patient develops symptoms similar to serum sickness.
- Patients should be monitored for eosinophilic conditions especially upon reduction of oral steroids.

DURATION OF APPROVAL

- Approval: Up to 3 months
- Reauthorization: Up to 12 months

QUANTITY LIMITS

- For Asthma = 3-150 mg vials, Max dose 375 mg
- For Urticaria = 2 -150mg vials, Max dose 300mg

REFERENCES / FOOTNOTES:

1. Xolair® subcutaneous injection [prescribing information]. South San Francisco, CA and East Hanover, NJ: Genentech, Inc. and Novartis Pharmaceuticals Corporation; July 2016.
2. Busse W, Corren J, Lanier BQ, et al. Omalizumab, anti-IgE recombinant humanized monoclonal antibody, for the treatment of severe allergic asthma. J Allergy Clinical Immunology. 2001;108(2):184-190.
3. Nam YH, Kim JH, Jun HJ, et al. Effects of omalizumab treatment in patients with refractory chronic urticaria. Allergy Asthma Immunology Res. 2012;4:357-361.
4. Global Initiative for Asthma. Global strategy for asthma management and prevention. Updated 2019. Available at: http://www.ginasthma.org. Accessed on: February 26, 2020.