

ALASKA MEDICAID
Prior Authorization Criteria

FDA INDICATIONS AND USAGE¹

Xolair is an anti-IgE antibody indicated for:

- Moderate to severe persistent asthma in adults and pediatric patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids
- Chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids as add-on maintenance treatment
- IgE-mediated food allergy in adult and pediatric patients aged 1 year and older for the reduction of allergic reactions (type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. To be used in conjunction with food allergen avoidance
- Chronic spontaneous urticaria (CSU) in adults and adolescents 12 years of age 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. Patient'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.

Nasal Polyps¹

1. Patient is 18 years of age or older **AND;**
2. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist **AND;**

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3. Patient has baseline serum IgE level ≥ 30 IU/mL **AND;**
4. Patient has had inadequate response, intolerance, or contraindication to a 3-month trial of TWO nasal corticosteroid sprays **AND;**
5. Will be used as an add on maintenance therapy.

IgE-mediated food allergy⁵

1. Patient is 1 year of age or older. **AND;**
2. Prescribed by or in consultation with an allergist or immunologist **AND;**
3. Patient has the diagnosis of an IgE-mediated food allergy **AND;**
4. Baseline IgE and current weight provided

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.

CAUTIONS¹

- Xolair should be administered in a healthcare setting that is prepared for anaphylaxis.
- Malignancies have been observed with use.
- Xolair should be stopped if 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

- Up to 8 - 150mg vials per 30 days, Max dose 600mg every 2 or 4 weeks
- 2 - 75mg vial per 30 days

REFERENCES / FOOTNOTES:

1. Xolair® subcutaneous injection [prescribing information]. South San Francisco, CA and East Hanover, NJ: Genentech, Inc. and Novartis Pharmaceuticals Corporation; February 2024.
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.

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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.
5. Wood, R.A.; Togias, A.; Sicherer, S.H.; et.al. Omalizumab for the Treatment of Multiple Food Allergies. *N Engl J Med* 2024;390:889-899