MEDICATION POLICY

Generic Name: Omalizumab

Therapeutic Class or Brand Name: Xolair®

Applicable Drugs (if Therapeutic Class)**:** N/A

Date of Origin: 7/27/15 **Date Last Reviewed/Revised:** 10/8/16

GPI Code: 4460306000

Prior Authorization Criteria (may be considered medically necessary when criteria I through II are met):

I. Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis:

A. Moderate to severe persistent asthma and ALL of criteria 1 through 4 are met:

1. Documentation of a positive skin test or in vitro reactivity to a perennial aeroallergen.
2. Documentation that patient's symptoms are inadequately controlled with a high-dose inhaled corticosteroid used in combination with a long-acting inhaled beta-2 agonist.
3. Documentation of pre-treatment serum IgE level of at least 30 IU/mL but not greater than 700 IU/mL.
4. Minimum age requirement: 6 years old

B. Chronic idiopathic urticaria and ALL of criteria 1 through 5 are met:

1. Documentation that a medical evaluation has been performed to rule out other possible causes of urticaria.
2. Documentation that patient remains symptomatic with H1-antihistamine therapy taken at the maximally tolerated dose.
3. Documented trial and failure of or contraindication to an H1-antihistamine used in combination with an H2-antihistamine.
4. Documented trial and failure of or contraindication to an H1-antihistamine used in combination with a leukotriene receptor antagonist.
5. Minimum age requirement: 12 years old.

II. The prescriber is an allergist, dermatologist, immunologist, or pulmonologist.

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Exclusion Criteria:

- Treatment of other allergic conditions or other forms of urticaria.
- Treatment of acute bronchospasm or status asthmaticus.

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- Asthma: Doses up to 375 mg every 2 weeks.
- Urticaria: Doses up to 300 mg every 4 weeks.

Approval Length:

- **Authorization:** 6 months.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

Appendix:

N/A

References:

1. http://www.gene.com/download/pdf/xolair_prescribing.pdf.
2. http://www.nhlbi.nih.gov/files/docs/guidelines/asthsumm.pdf.
3. http://onlinelibrary.wiley.com/doi/10.1111/j.1398-9995.2009.02178.x/full.
4. Medi-Span.
5. http://blue.regence.com/trgmedpol/drugs/dru087.pdf.
6. http://www.tuftshealthplan.com/providers/pdf/pharmacy_criteria/xolair.pdf.
7. http://www.connecticare.com/provider/PDFs/Pharmacy/Xolair.pdf.
8. http://ahca.myflorida.com/Medicaid/Prescribed_Drug/drug_criteria_pdf/Xolair_Criteria.pdf.

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Historical Tracking Of Changes Made To Policy	
10/8/2016	1. **Changed** "I. A. Moderate to severe persistent asthma and ALL of criteria 1 through 3 are met:…B. Chronic idiopathic urticaria and ALL of criteria 1 through 4 are met:… II. Minimum age requirement: 12 years old" **to** "I. A. Moderate to severe persistent asthma and ALL of criteria 1 through 4 are met:… 4. Minimum age requirement: 6 years old…B. Chronic idiopathic urticaria and ALL of criteria 1 through 5 are met:…5. Minimum age requirement: 12 years old" **under Prior Authorization Criteria**.