Generic Name: Omalizumab

Therapeutic Class or Brand Name: Xolair®

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 4460306000

Preferred: N/A

Non-preferred: N/A

Date of Origin: 7/27/2015

Date Last Reviewed / Revised: 1/17/2020

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 the following (based on patient's age and weight):
   a) Ages 12 years and older:
      (1) > 90 kg to 150 kg: 300 IU/ml.
      (2) > 70 kg to 90 kg: 500 IU/ml.
      (3) > 60 kg to 70 kg: 600 IU/ml.
      (4) > 30 kg to 60 kg: 700 IU/ml.
   b) Ages 6 years to 12 years:
      (1) > 90 kg to 150 kg: 300 IU/ml.
      (2) > 70 kg to 90 kg: 500 IU/ml.
      (3) > 60 kg to 70 kg: 600 IU/ml.
      (4) > 50 kg to 60 kg: 700 IU/ml.
      (5) > 40 kg to 50 kg: 900 IU/ml.
      (6) > 30 kg to 40 kg: 1,100 IU/ml.
      (7) 20 kg to 30 kg: 1,300 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.

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.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
1/17/2020	1. **Deleted** "https://regence.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/Cambia/Program_Summaries/dru538reg.pdf," "http://www.tuftshealthplan.com/providers/pdf/pharmacy_criteria/xolair.pdf," http://www.connecticare.com/provider/PDFs/Pharmacy/Xolair.pdf" "http://ahca.myflorida.com/Medicaid/Prescribed_Drug/drug_criteria_pdf/Xolair_Criteria.pdf" **under References.**
1/17/2020	1. **Deleted** "http://blue.regence.com/trgmedpol/drugs/dru087.pdf." (link no longer active) and **Added** "https://regence.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/Cambia/Program_Summaries/dru538reg.pdf." **under References.**
1/4/2018	1. **Changed** "I. A. 3. Documentation of pre-treatment serum IgE level of at least 30 IU/mL but not greater than 700 IU/mL" **to** "I. A. 3. Documentation of pre-treatment serum IgE level of at least 30 IU/mL but not greater than the following (based on patient's age and weight): a. Ages 12 years and older: i. > 90 kg to 150 kg: 300 IU/ml; ii. > 70 kg to 90 kg: 500 IU/ml; iii. > 60 kg to 70 kg: 600 IU/ml; iv. > 30 kg to 60 kg: 700 IU/ml; b. Ages 6 years to 12 years: i. > 90 kg to 150 kg: 300 IU/ml; ii. > 70 kg to 90 kg: 500 IU/ml; iii. > 60 kg to 70 kg: 600 IU/ml; iv. > 50 kg to 60 kg: 700 IU/ml; v. > 40 kg to 50 kg: 900 IU/ml; vi. > 30 kg to 40 kg: 1,100 IU/ml; 20 kg to 30 kg: 1,300 IU/ml" **under Prior Authorization Criteria**.
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**.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.