I. Medication Description

Omalizumab inhibits the binding of IgE to the high-affinity IgE receptor (FcεRI) on the surface of mast cells and basophils. Reduction in surface-bound IgE on FcεRI-bearing cells limits the degree of release of mediators of the allergic response. Treatment with Xolair also reduces the number of FcεRI receptors on basophils in atopic patients. Omalizumab binds to IgE and lowers free IgE levels. Subsequently, IgE receptors (FcεRI) on cells down-regulate. The mechanism by which these effects of omalizumab result in an improvement of CIU symptoms is unknown.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Xolair is covered for the treatment of the following:

- Allergic Asthma (moderate to severe, persistent disease) when the following criteria are met:
  - Treatment is prescribed by either an allergist/immunologist or pulmonologist AND
  - Member must be at least 6 years old AND
  - Member must not weigh > 150 kg AND
  - A positive skin test or invitro reactivity (such as radioallergosorbent test, RAST) to a perennial aeroallergen (such as pollen, mold, dust mites, or pet dander) has been documented AND
  - One of the following:
    - If member is 6 to 11 years of age: baseline serum IgE is between 30 IU/mL and 1300 IU/mL
    - If member is 12 years of age or older: baseline serum IgE is between 30 IU/mL and 700 IU/mL
  - Symptoms are inadequately controlled with compliant treatment of moderate to high dose inhaled and/or oral corticosteroids AND
    - Combination therapy such as a leukotriene modifier (Singulair, Zyflo, Accolate, etc.) OR
    - Theophylline OR
    - Long acting beta-agonist (Serevent, Advair, etc.) AND
  - Member has inadequately controlled allergic asthma as defined below:
    - 2 or more ER visits needed due to acute asthma exacerbation in the previous 12 months OR
2 or more courses of short pulse corticosteroids (oral or IV) needed in the previous 12 months

- Chronic Idiopathic Urticaria when the following criteria are met:
  - Treatment is prescribed by either an allergist or dermatologist AND
  - Specific diagnosis of chronic idiopathic disease has been confirmed AND
  - Member must be at least 12 years old AND
  - Symptoms persist despite the following interventions:
    - Second-generation antihistamine usage AND
    - One or more of the following:
      - Dose advancement of a 2\textsuperscript{nd}-generation antihistamine
      - Addition of a different 2\textsuperscript{nd}-generation antihistamine
      - H\textsubscript{2}-antagonist usage
      - Leukotriene receptor antagonist usage
      - 1\textsuperscript{st}-generation antihistamine (at bedtime) AND
    - Dose advancement of a potent antihistamine (e.g. doxepin or hydroxyzine) as tolerated

IV. Quantity Limits

- Allergic Asthma: Coverage is provided for up to six 150mg vials every 30 days for the life of the authorization.
- Chronic Idiopathic Urticaria: Coverage is provided for up to two 150mg vials every 30 days for the life of the authorization.

V. Coverage Duration

- Allergic Asthma: Coverage is granted for 12 months and may be renewed.
- Chronic Idiopathic Urticaria: Coverage is provided initially for 6 months and may be renewed in up to 12 month intervals.

VI. Coverage Renewal Criteria

- Coverage for the treatment of allergic asthma can be renewed based upon the following criteria:
  - Continued clinical benefit as evidenced by reductions in asthma exacerbations from baseline AND
  - An absence of unacceptable toxicity is noted.
- Coverage for the treatment of chronic idiopathic urticaria can be renewed based upon the following criteria:
  - Continued clinical benefit as evidenced by signs and symptoms of disease AND
  - It is documented that continuation of therapy is medically necessary AND
  - An absence of unacceptable toxicity is noted.
VII. Billing/Coding Information

- J2357 – 1 billable unit is 5mg
- Pertinent diagnoses:
  - Extrinsic Asthma – J45.20-J45.22
  - Idiopathic Urticaria – L50.1
- Available as sterile powder in a single-use 5ml vial; each vial delivers 150mg of Xolair upon reconstitution.

VIII. Summary of Policy Changes

- 6/1/11: Change in coverage duration to 12 months; Change in baseline serum IgE level needed to treat; Change in coverage age to ≥ 12 years of age (Based on approved indications); Addition of renewal criteria; Addition of Warnings/Precautions; Addition of Coding/Billing information
- 6/15/12: No changes
- 3/15/13: removed smoking status as criterion for coverage
- 3/15/14: no policy changes
- 9/15/14: new indication of chronic idiopathic urticaria added to policy
- 3/15/15: no policy changes
- 7/1/15: formulary distinctions made
- 3/15/16: no policy changes
- 1/1/18: updated coverage criteria

IX. References

1. Up-to-date Online, retrieved October 2015.
3. Facts and Comparisons Online, retrieved October 2010

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.