Effective Date: 9/2017
Revised: 12/2018, 12/2019 Reviewed: 9/2017, 12/2018, 12/2019 Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

XOLAIR (omalizumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

A. Allergic asthma
   Xolair is indicated for patients 6 years of age and older with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.

   Limitations of use: Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus, or for treatment of other allergic conditions.

B. Chronic idiopathic urticaria (CIU)
   Xolair is indicated for the treatment of adults and adolescents 12 years of age and older with chronic idiopathic urticaria (CIU) who remain symptomatic despite H1 antihistamine treatment.

   Limitations of use: Xolair is not indicated for treatment of other forms of urticaria.

All other indications are considered experimental/investigational and are not a covered benefit.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. Asthma:
   1. Initial requests: documentation of pre-treatment IgE level, weight and components of severity that classify asthma as moderate or severe
   2. Continuation of therapy requests: documentation of weight and improved asthma control

B. CIU:
   1. Initial requests: documentation of score of objective clinical evaluation tool at baseline as noted in section III.B.5. and documentation of an inadequate treatment response to pharmacological management as noted in section III.B.6. and III.B.7. below
   2. Continuation of therapy requests: documentation of score of objective clinical evaluation tool after initiation of treatment as noted in section IV.B.4.

III. CRITERIA FOR INITIAL APPROVAL

A. Asthma

Authorization of 6 months may be granted for treatment of asthma when all of the following criteria are met:

1. Member is 6 years of age or older.
2. Xolair is prescribed by, or in consultation with, a pulmonologist or allergist/immunologist.
3. Member weighs between 20 kg (44 lbs) and 150 kg (330 lbs).
4. Member has a positive skin test or in vitro reactivity to at least one perennial aeroallergen.
5. Member has a pre-treatment IgE level of either:
   a. ≥ 30 IU/mL and ≤ 700 IU/mL in members 12 years of age and older
   b. ≥ 30 IU/mL and ≤ 1300 IU/mL in members age 6 to < 12 years
6. Member has moderate or severe asthma (see Appendix).
7. Member is adherent to current treatment with both of the following medications at optimized doses
   a. Inhaled corticosteroid
   b. Additional controller (long acting beta$_2$-agonist, leukotriene modifier, or sustained-release theophylline)
8. Member has inadequate asthma control with two or more exacerbations in the previous year requiring additional medical treatment (e.g., oral corticosteroids, emergency department or urgent care visits, or hospitalizations)
9. Member will use Xolair as add-on maintenance treatment.
10. Member will not use Xolair concomitantly with other biologics (e.g., Cinqair, Dupixent, Fasenra, Nucala).
11. Requested dose and frequency is within FDA guidelines.

B. Chronic idiopathic urticaria

Authorization of 6 months may be granted for treatment of chronic idiopathic urticaria when all of the following criteria are met:

1. Member is 12 years of age or older.
2. Xolair is prescribed by, or in consultation with, an allergist/immunologist or dermatologist.
3. Member has been evaluated for other causes of urticaria, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis), and is not considered to have any other form(s) of urticaria.
4. Member is avoiding triggers (e.g., NSAIDs, etc.)
5. Member's baseline score from an objective clinical evaluation tool, such as urticaria activity score (UAS7), angioedema activity score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life (AE-QoL), or Chronic Urticaria Quality of Life Questionnaire (CU-QoL), is provided.
6. Member has had an inadequate response to therapy with scheduled dosing of a second-generation H_1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine) for at least one month.
7. Member has had an inadequate response to previous therapy with scheduled dosing of one of the following:
   a. Updosing/dose advancement (up to 4-fold) of a second-generation H_1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine)
   b. Add-on therapy with a leukotriene antagonist (e.g., montelukast)

c. Add-on therapy with another H_1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine, diphenhydramine, hydroxyzine)
d. Add-on therapy with a H_2-antagonist (e.g., ranitidine)

8. Member has experienced a spontaneous onset of wheals, angioedema, or both, for at least 6 weeks.
9. Requested dose and frequency is within FDA guidelines.

IV. CONTINUATION OF THERAPY

A. Asthma

Authorization of 12 months may be granted for treatment of asthma when all of the following criteria are met:

1. Member is 6 years of age or older.
2. Xolair is prescribed by, or in consultation with, a pulmonologist or allergist/immunologist.
3. Member weighs between 20 kg (44 lbs) and 150 kg (330 lbs).
4. Member is tolerating treatment.
5. Asthma control has improved/stabilized on Xolair treatment from baseline as demonstrated by at least one of the following:
   a. A reduction in the frequency and/or severity of symptoms and exacerbations
   b. A reduction in the daily maintenance oral corticosteroid dose
6. Member will use Xolair as add-on maintenance treatment.
7. Member will not use Xolair concomitantly with other biologics (e.g., Cinqair, Dupixent, Fasenra, Nucala).
8. Requested dose and frequency is within FDA guidelines.

B. Chronic idiopathic urticaria

Authorization of 12 months may be granted for continuation of treatment of chronic idiopathic urticaria when all of the following criteria are met:

1. Member is 12 years of age or older.
2. Xolair is prescribed by, or in consultation with, an allergist/immunologist or dermatologist.
3. Member is tolerating treatment.
4. Member has experienced clinical improvement since initiation of Xolair therapy as documented by improvement from baseline using an objective clinical evaluation tool, such as: urticaria activity score (UAS7), angioedema activity score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life (AE-QoL), or Chronic Urticaria Quality of Life Questionnaire (CU-QoL).
5. Requested dose and frequency is within FDA guidelines.

V. QUANTITY LIMIT

1. Xolair 75mg/0.5 ml syringe - 2 syringes per 28 days
2. Xolair 150 mg/ml syringe – 4 syringes per 28 days
3. Xolair 150mg vial – 6 vials per 28 days

VI. APPENDIX

Components of Severity for Classifying Asthma as Severe may include any of the following (not all inclusive):

1. Symptoms throughout the day
2. Nighttime awakenings, often 7x/week
3. Short-acting beta agonist (SABA) use for symptom control occurs several times per day
4. Extremely limited normal activities
5. Lung function (percent predicted FEV1) <60%
6. Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

Components of Severity for Classifying Asthma as Moderate may include any of the following (not all inclusive):

1. Daily symptoms
2. Nighttime awakenings >1x/week but not nightly
3. SABA use for symptom control occurs daily
4. Some limitation to normal activities
5. Lung function (percent predicted FEV1) >60%, but <80%
6. Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to mild asthma