Reference number(s)
1656-A

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.

A. FDA-Approved Indications[1]
   1. 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.

   2. 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.

   3. Nasal polyps
      Xolair is indicated for add-on maintenance treatment of nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.

B. Compendial Uses[1,2]
   1. Immune checkpoint inhibitor-related toxicities
   2. Systemic mastocytosis

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

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

A. Asthma:
   1. Initial Requests:
      i. Member's chart or medical record showing pre-treatment IgE level
      ii. Chart notes, medical record documentation, or claims history supporting previous medications tried
   2. Continuation requests: Chart notes or medical record documentation supporting improvement in asthma control.

B. CIU:

1. Initial Requests: Member's chart or medical record showing an inadequate treatment response to a second-generation H1 antihistamine
2. Continuation Requests: Chart notes or medical record documentation supporting response to therapy

C. Nasal polyps:
1. Initial Requests:
   i. Member's chart or medical record showing nasal endoscopy or anterior rhinoscopy details (e.g., location, size)
   ii. Chart notes, medical record documentation, or claims history supporting previous medications tried
2. Continuation Requests: Chart notes or medical record documentation supporting response to therapy

D. Immune checkpoint inhibitor-related toxicity (initial requests): Member's chart or medical record showing pre-treatment IgE level

E. Systemic mastocytosis (initial requests):
1. Chart notes or medical record documentation supporting diagnosis of systemic mastocytosis
2. Chart notes, medical record documentation, or claims history of prerequisite therapies (if applicable)

III. CRITERIA FOR INITIAL APPROVAL

A. Asthma[1-5]

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. Member has a positive skin test or in vitro reactivity to at least one perennial aeroallergen.
3. Member has a pre-treatment IgE level greater than or equal to 30 IU/mL.
4. Member has inadequate asthma control (e.g., hospitalization or emergency medical care visit within the past year) despite current treatment with both of the following medications at optimized doses:
   i. Inhaled corticosteroid
   ii. Additional controller (long acting beta$_2$-agonist, leukotriene modifier, or sustained-release theophylline)
5. Member will not use Xolair as monotherapy.
6. Member will not use Xolair concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala).

B. Chronic idiopathic urticaria[1,6-8]

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. Member remains symptomatic despite treatment with a second-generation H_1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine) for at least 2 weeks.
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).
4. Member has experienced a spontaneous onset of wheals, angioedema, or both, for at least 6 weeks.

C. Nasal polyps[1,10,11]

Authorization of 6 months may be granted for treatment of nasal polyps when all of the following criteria are met:
1. Member is 18 years of age or older.
2. Member has bilateral nasal polyposis and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 2 months unless contraindicated or not tolerated.
3. Member has bilateral nasal endoscopy or anterior rhinoscopy showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril.

4. Member has nasal blockage plus one additional symptom:
   i. Rhinorrhea (anterior/posterior); or
   ii. Reduction or loss of smell; and
5. Member will be using a daily intranasal corticosteroid while being treated with Xolair, unless contraindicated or not tolerated.

D. Immune checkpoint inhibitor-related toxicity[12]

Authorization of 1 month may be granted for treatment of immune checkpoint inhibitor-related toxicity when both of the following are met:

1. The member has a refractory case of immune-therapy related severe (G3) pruritus
2. The member has elevated IgE levels

E. Systemic mastocytosis[12]

Authorization of 12 months may be granted for the treatment of systemic mastocytosis when both of the following are met:

1. The major and at least one minor diagnostic criterion for systemic mastocytosis are present or three or more minor diagnostic criteria are present (see Appendix)
2. Xolair will be used in any of the following treatment settings:
   i. Used as stepwise prophylactic treatment for chronic mast cell mediator-related cardiovascular and pulmonary symptoms when the member has tried both of the following:
      a. H1 blockers and H2 blockers
      b. Corticosteroids
   ii. Used for prevention of recurrent unprovoked anaphylaxis
   iii. Used for prevention of hymenoptera or food-induced anaphylaxis, with negative specific IgE or negative skin test
   iv. Used to improve tolerability of venom immunotherapy

IV. CONTINUATION OF THERAPY

A. Asthma[1,9]

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

1. Member is 6 years of age or older.
2. Asthma control has improved on Xolair treatment as demonstrated by at least one of the following:
   i. A reduction in the frequency and/or severity of symptoms and exacerbations
   ii. A reduction in the daily maintenance oral corticosteroid dose[9]
3. Member will not use Xolair as monotherapy.
4. Member will not use Xolair concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala).

B. Chronic idiopathic urticaria[1,6]

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. Member has experienced a response (e.g., improved symptoms, decrease in weekly urticaria activity score [UAS7]) since initiation of therapy.

C. Nasal polyps[1,10,11]

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

1. Member is 18 years of age or older.

2. Member has experienced a response as evidenced by improvement in signs and symptoms (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, post-nasal drip).

D. Immune checkpoint inhibitor-related toxicities and systemic mastocytosis[12]
All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

V. OTHER

Note: If the member is a current smoker or vaper, they should be counseled on the harmful effects of smoking and vaping on pulmonary conditions and available smoking and vaping cessation options.

VI. APPENDIX

2017 WHO Diagnostic Criteria for Systemic Mastocytosis[13]

A. Major Criteria: multifocal, dense infiltrates of mast cells (at least 15 mast cells in aggregates) detected in sections of bone marrow and/or other extracutaneous organs
B. Minor Criteria
   1. In biopsy sections of bone marrow or other extracutaneous organs, greater than 25% of mast cells in in the infiltrate are spindle-shaped or have atypical morphology of greater than 25% of all mast cells in bone marrow aspirate smears are immature or atypical
   2. Detection of an activating point mutation at codon 816 of *KIT* in the bone marrow, blood, or another extracutaneous organ
   3. Mast cells in bone marrow, blood, or other extracutaneous organs express CD25, with or without CD2, in addition to normal mast cell markers
   4. Serum total tryptase persistently greater than 20 ng/mL (unless there is an associated myeloid neoplasm, in which case this parameter is not valid)

VII. REFERENCES

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