AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Xolair	Page:	1 of 6
Effective Date:	1/19/2024	Last Review Date:	12/2023
Applies to:	☐Illinois ☒New Jersey ☐Pennsylvania Kids	☐Florida ☐Maryland ☐Virginia	☐Michigan ☐Florida Kids ☐Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Xolair under the patient's prescription drug benefit.

Description:

A. FDA-Approved Indications

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

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

2. Chronic rhinosinusitis with 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. Immune checkpoint inhibitor-related toxicities
   2. Systemic mastocytosis

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

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.

For all indications:
Member will not use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Applicable Drug List:

Xolair

Policy/Guideline:

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

A. CSU:
   1. Initial Requests: Member's chart or medical record documentation, or claims history supporting previous medications tried showing an inadequate treatment response to a second-generation H1 antihistamine
   2. Continuation Requests: Chart notes or medical record documentation supporting response to therapy

B. Nasal polyps:
   1. Initial Requests:
      i. Member's chart or medical record showing nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) details (e.g., location, size), or Meltzer Clinical Score or endoscopic nasal polyp score (NPS) (where applicable).
      ii. Chart notes, medical record documentation, or claims history supporting previous medications tried. If therapy is not advisable, documentation of clinical reason to avoid therapy.
   2. Continuation Requests: Chart notes or medical record documentation supporting response to therapy

C. Immune checkpoint inhibitor-related toxicity
   Initial requests: Member's chart or medical record showing pre-treatment IgE level

D. 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)

Prescriber Specialties:
This medication must be prescribed by or in consultation with ONE of the following:
A. Chronic spontaneous urticaria: allergist/immunologist or dermatologist
B. Nasal polyps: allergist/immunologist or otolaryngologist

Criteria for Initial Approval:

A. Chronic spontaneous urticaria
Authorization of 6 months may be granted for treatment of chronic spontaneous urticaria when ALL the following criteria are met:
1. Member is 12 years of age or older.
2. Member remains symptomatic despite treatment with up-dosing (in accordance with EAACI/GA²LEN/EDF/WAO guidelines) of 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.

B. Chronic rhinosinusitis with nasal polyps (CRSwNP)

Authorization of 6 months may be granted for adult members who have previously received a biologic drug indicated for chronic rhinosinusitis with nasal polyps (CRSwNP).

OR

Authorization of 6 months may be granted for treatment of nasal polyps when ALL the following criteria are met:

1. Member is 18 years of age or older.
2. Member has bilateral nasal polyps and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 2 months unless contraindicated or not tolerated.
3. Member has one of the following:
   i. A bilateral nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril
   ii. Meltzer Clinical Score of 2 or higher in both nostrils
   iii. A total endoscopic nasal polyp score (NPS) of at least 5 with a minimum score of 2 for each nostril
4. Member has nasal blockage plus one additional symptom:
   i. Rhinorrhea (anterior/posterior); or
   ii. Reduction or loss of smell; or
   iii. Facial pain or pressure
5. Member will continue to use a daily intranasal corticosteroid while being treated with Xolair, unless contraindicated or not tolerated.

C. Immune checkpoint inhibitor-related toxicity

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

D. Systemic mastocytosis

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

Criteria for Continuation of Therapy:

A. Chronic spontaneous urticaria
Authorization of 12 months may be granted for continuation of treatment of chronic spontaneous urticaria when ALL 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.

B. Chronic rhinosinusitis with nasal polyps (CRSwNP)
Authorization of 12 months may be granted for continuation of treatment of nasal polyps when ALL 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, sinonasal inflammation, hyposmia and/or facial pressure or pain or reduction in corticosteroid use).
3. Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

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

Appendix:
2017 WHO Diagnostic Criteria for Systemic Mastocytosis
A. Major Criteria:

1. 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 the infiltrate are spindle-shaped or have atypical morphology, or 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)

Approval Duration and Quantity Restrictions:

Approval:

- Initial approval:
  - Asthma: 6 months
  - Chronic Spontaneous Urticaria: 6 – 12 months
  - Nasal Polyps: 6 – 12 months
  - Immune Checkpoint Inhibitor-related toxicities: 30 days
  - Systemic Mastocytosis: 12 months
- Continuation: 12 months

Quantity Level Limit:

- Xolair 150 mg vial: 8 vials per 28 days
- Xolair 75 mg single-dose prefilled syringe: 2 syringes per 28 days
- Xolair 150 mg single-dose prefilled syringe: 8 syringes per 28 days

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