



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Xolair

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Effective Date: 8/19/2024

Last Review Date: 7/23/2024

Applies to: New Jersey

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. IgE-mediated food allergy

Xolair is indicated for the reduction of allergic reactions (Type 1), including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy.

Xolair is to be used in conjunction with food-allergen avoidance.

Limitations of use: Xolair is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

3. Chronic rhinosinusitis with Nasal polyps (CRSwNP)

Xolair is indicated for add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids..

B. **Compensial 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.

Prescriber Specialties

- A. CRSwNP: allergist/immunologist or otolaryngologist
- B. IgE-mediated food allergy: allergist/immunologist
- C. Chronic spontaneous urticaria: allergist/immunologist or dermatologist
- D. Immune checkpoint inhibitor-related toxicity: dermatologist, hematologist, or oncologist



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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. IgE-mediated food allergy:

1. Initial Requests: Chart notes, medical record documentation, or laboratory tests showing the following (if applicable):
 - i. Pre-treatment allergen specific IgE level
 - ii. Skin-prick test wheal diameter
 - iii. Pre-treatment serum IgE level
 - iv. Positive result of a physician controlled oral food challenge
 - v. History of a systemic reaction to a food
2. Continuation Requests: Chart notes or medical record documentation supporting positive response to therapy (e.g., decrease in hypersensitivity to food-allergen).

C. CRSwNP:

1. Initial Requests:
 - i. Chart notes or medical record documentation showing nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) details (e.g., polyps 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 including drug, dose, frequency and duration. 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

D. Immune checkpoint inhibitor-related toxicity

Initial requests: Member's chart or medical record showing pre-treatment IgE level



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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)

Prescriber Specialties:

This medication must be prescribed by or in consultation with ONE of the following:

- E. CRSwNP: allergist/immunologist or otolaryngologist
- F. IgE-mediated food allergy: allergist/immunologist
- G. Chronic spontaneous urticaria: allergist/immunologist or dermatologist
- H. Immune checkpoint inhibitor-related toxicity: dermatologist, hematologist or oncologist

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 H₁ 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) in the past year.

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:



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- 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. IgE-mediated food allergy

Authorization of 6 months may be granted for the reduction of IgE-mediated food allergy reactions when all of the following criteria are met:

1. Member is 1 year of age or older.
2. IgE-mediated food allergy has been confirmed by either of the following:
 - i. Pre-treatment allergen specific IgE level greater than or equal to 6 IU/mL
 - ii. Skin-prick test (SPC) with wheal diameter greater than or equal to 4 mm
3. Member has either of the following:
 - i. A positive physician controlled oral food challenge (e.g., moderate to severe skin, respiratory, or gastrointestinal [GI] symptoms)
 - ii. History of a systemic reaction to a food
4. Member has a pre-treatment serum IgE level greater than or equal to 30 IU/mL.
5. Member will continue to follow a food-allergen avoidance diet

D. Immune checkpoint inhibitor-related toxicity

Authorization of 6 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

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



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- 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. **IgE-mediated food allergy**

Authorization of 12 months may be granted for the reduction of IgE-mediated food allergy reactions when ALL the following criteria are met:

1. Member is 1 year of age or older.
2. Member has achieved or maintained a positive clinical response to therapy as evidenced by a decrease in hypersensitivity (e.g., moderate to severe skin, respiratory or GI symptoms) to food-allergen.
3. Member will continue to maintain a food-allergen avoidance diet.

D. **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:

2022 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:



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1. spindle-shaped in dense and diffuse mast cell infiltrates in bone marrow or other extracutaneous organ(s)
2. Activating KIT point mutation(s) at codon 816 or in other critical regions of KIT in the bone marrow or other extracutaneous organ(s)
3. Mast cells in bone marrow, blood, or other extracutaneous organs aberrantly express one or more of the following antigens: CD2, CD25, CD30
4. Baseline serum tryptase concentration greater than 20 ng/mL in the absence of a myeloid associated hematologic neoplasm (AHN). In the case of a known hereditary alpha-tryptasemia (HαT), the tryptase level should be adjusted.

Approval Duration and Quantity Restrictions:

- Initial Approval:
 - Chronic Spontaneous Urticaria: 6 months
 - IgE-mediated food allergy: 6 months
 - CRSwNP: 6 months
 - Immune Checkpoint Inhibitor-related toxicities: 6 months
 - Systemic Mastocytosis: 12 months
- Renewal Approval: 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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