

Policy Key: Omalizumab (Xolair)

TriWest Clinical Operations – TRICARE West

SCOPE

This Policy Key provides criteria to be used during medical necessity review for the use of Intravenous (IV) Omalizumab (Xolair).

NOT COVERED

Any of the following indications because effectiveness has not been established: [3]

- Allergic broncho-pulmonary aspergillosis
- Allergic rhinitis
- Atopic dermatitis
- Aquagenic urticaria
- Atopic eczema
- Bullous pemphigoid
- Cholinergic urticaria and urticaria of other known causes
- Chronic autoimmune urticaria
- Coronavirus 2 (SARS-CoV-2, COVID-19)
- Cutaneous mastocytosis
- Eosinophilic esophagitis
- Eosinophilic gastroenteritis
- Eosinophilic granulomatosis with polyangiitis (formerly Churg-Strauss syndrome)
- Eosinophilic pneumonia
- Inhibition of respiratory reaction during aspirin desensitization in individuals with aspirin exacerbated respiratory disease
- Initial therapy for allergic asthma
- Insulin allergy
- Latex allergy
- Non-allergic (non-atopic) asthma
- Subcutaneous immunotherapy, adjunct
- Urticarial vasculitis
- Use as an adjunct in allergen immunotherapy
- Vibratory angioedema

COVERAGE CRITERIA

General Information

- Authorizations may be approved for 365 days unless otherwise specified.
- Pharmaceutical agents supplied by physicians and other appropriate clinicians, and pharmaceutical agents provided in support of home health care (e.g., home infusion therapy) are processed under the medical benefit. [1]
- If preauthorized, pharmaceutical agents (e.g., injectables) not appropriate for self-administration may be obtained through the TRICARE Pharmacy benefit and administered by the physician, other appropriate clinician, or in the home if it is an appropriate setting. [1]

Asthma [3]

Initial Request

- **Initial Level of Review** may approve if ordered by or in consultation with an allergist/immunologist or pulmonologist and meets **one** of the following:
 - 6 years of age or older who have previously received a biologic drug (e.g., Nucala, Cinqair) indicated for asthma in the past year or
 - Treatment of moderate-to-severe asthma when **all** of the following criteria are met:
 - 6 years of age or older
 - A positive skin test or in vitro reactivity to at least one perennial aeroallergen
 - A pre-treatment IgE level greater than or equal to 30 IU/mL
 - uncontrolled asthma as demonstrated by experiencing at least **one** of the following within the past year:
 1. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment
 2. One or more asthma exacerbation resulting in hospitalization or emergency medical care visit
 3. Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)
 - Inadequate asthma control despite current treatment with **all** of the following medications at optimized doses:
 - Medium-to-high-dose inhaled corticosteroid
 - Additional controller (i.e., long acting beta2-agonist, long acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
 - Continued use of maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Xolair

Continuation of Therapy

- **Initial Level of Review** may approve if meets ALL the following:
 - 6 years of age or older
 - Asthma control has improved on Xolair treatment as demonstrated by at least **one** of the following:
 - A reduction in the frequency and/or severity of symptoms and exacerbations
 - A reduction in the daily maintenance oral corticosteroid dose

- Continued use of maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Xolair

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) [3]

Initial Request

- **Initial Level of Review** may approve when ordered by or in consultation with an allergist/immunologist or otolaryngologist and meets **ALL** the following:
 - 18 years of age or older and have previously received a biologic drug (e.g., Nucala, Dupixent) indicated for CRSwNP in the past year
 - Bilateral nasal polyps and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 2 months unless contraindicated or not tolerated
 - Beneficiary has **one** of the following:
 - 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;
 - Meltzer Clinical Score of 2 or higher in both nostrils
 - A total endoscopic nasal polyp score (NPS) of at least 5 with a minimum score of 2 for each nostril
 - Symptoms of nasal blockage, congestion, or obstruction plus **one** of the following additional symptoms:
 - Rhinorrhea (anterior/posterior)
 - Reduction or loss of smell
 - Facial pain or pressure
 - Continued use of a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated

Continuation of Therapy

- **Initial Level of Review** may approve if meets **ALL** the following:
 - 18 years of age or older
 - Experienced a positive 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
 - Continued use of a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated

Chronic spontaneous urticaria [2,3]

Initial Request

- **Initial Level of Review** may approve when ordered by or in consultation with an allergist/immunologist or dermatologist and meets **ALL** the following:

- 12 years of age or older
- 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
- Evaluated for other causes of urticaria, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis)
- Experienced a spontaneous onset of wheals (hives), angioedema, or both, for at least 6 weeks

Continuation of Therapy

- **Initial Level of Review** may approve if meets **Both** the following:
 - 12 years of age or older
 - Experienced a positive response (e.g., improved symptoms, decrease in weekly urticaria activity score [UAS7]) since initiation of therapy

IgE-Mediated Food Allergy [3]

Initial Request

- **Initial Level of Review** may approve when ordered by or in consultation with an allergist/immunologist and meets **ALL** the following:
 - 1 year of age or older
 - Diagnosis of IgE-mediated food allergy has been confirmed by either of the following:
 - Pre-treatment allergen-specific IgE level greater than or equal to 6 IU/mL
 - Skin-prick test (SPC) with wheal diameter greater than or equal to 4 mm
 - Beneficiary has **either** of the following:
 - A positive physician-controlled oral food challenge (e.g., moderate to severe skin, respiratory, or gastrointestinal [GI] symptoms)
 - History of a systemic reaction to a food
 - A pre-treatment serum IgE level greater than or equal to 30 IU/mL
 - Will continue to follow a food-allergen avoidance diet

Continuation of Therapy

- **Initial Level of Review** may approve if meets **ALL** the following:
 - 1 year of age or older
 - 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
 - Will continue to maintain a food-allergen avoidance diet

Immune Checkpoint Inhibitor-Related Toxicity [3]

Initial Request

- **Initial Level of Review** may approve when ordered by or in consultation with a dermatologist, hematologist, or oncologist and meets **Both** of the following:
 - A refractory case of immune-therapy related severe pruritus(G3) based on the following grading of pruritus scale:
 - G1: Mild or localized
 - G2: Moderate. Intense or widespread; intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); limiting activities of daily living (ADLs)
 - G3: Severe. Intense or widespread; constant; limiting self-care ADLs or sleep
 - Elevated IgE levels

Continuation of Therapy

- **Initial Level of Review** may approve if continues to meet the criteria for initial therapy.

Systemic Mastocytosis [3]

Initial Request

- **Initial Level of Review** may approve if meets Both the following:
 - 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 A below)
 - Will be used in **any** of the following treatment settings:
 - Used as stepwise prophylactic treatment for chronic mast cell mediator-related cardiovascular and pulmonary symptoms when the member has tried **both** of the following:
 1. H1 blockers and H2 blockers
 2. Corticosteroids
 - Used for prevention of recurrent unprovoked anaphylaxis
 - Used for prevention of hymenoptera or food-induced anaphylaxis, with negative specific IgE or negative skin test
 - Used to improve tolerability of venom immunotherapy

Continuation of Therapy

- **Initial Level of Review** may approve if continues to meet the criteria for initial therapy.

Appendix A: 2022 WHO Diagnostic Criteria for Systemic Mastocytosis

- 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
- Minor Criteria:
 - Greater than 25% of all mast cells are atypical cells (type 1 or type II) on bone marrow smears or are spindle-shaped in dense and diffuse mast cell infiltrates in bone marrow or other extracutaneous organ(s)
 - Activating KIT point mutation(s) at codon 816 or in other critical regions of KIT in the bone marrow or other extracutaneous organ(s)
 - Mast cells in bone marrow, blood, or other extracutaneous organs aberrantly express one or more of the following antigens: CD2, CD25, CD30
 - 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

DEFINITIONS

NA

CODES

HCPCS J2357

REFERENCES

[1] TRICARE Policy Manual 6010.63-M, April 2021, Change 20 (October 2, 2024), Chapter 8, Section 9.1, Pharmacy Benefits Program, https://manuals.health.mil/pages/DisplayManualHtmlFile/2024-09-20/AsOf/TPT5/C8S9_1.html

[2] TRICARE Policy Manual 6010.63-M, April 2021, Change 20 (October 2, 2024), Chapter 7, Section 2.7, Hydration, Therapeutic, Prophylactic, And Diagnostic Injections And Infusions, https://manuals.health.mil/pages/DisplayManualHtmlFile/2024-10-02/AsOf/TPT5/C7S2_7.html

[3] Aetna. (n.d.). Clinical policy bulletin: Omalizumab (Xolair). Retrieved July 23, 2025, from https://www.aetna.com/cpb/medical/data/600_699/0670.html

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