

EVH Clinical Guideline 5036.CC for Omalizumab Products

Guideline Number: EVH_CG_5036.CC	<u>Applicable Codes</u>	
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STATEMENT

General Information

- *It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity and approval by the Medical Policy Committee.*
- *If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.*

Purpose

The purpose of this guideline is to define the prior authorization process for the omalizumab products.

Scope

This guideline applies to all practitioners who are involved in providing the requested drug. This guideline is specific to the Health Plan's medical benefit.

Special Note

Additional uses are included in this policy based on being supported by one or more compendia (e.g., Merative Micromedex®, UpToDate® Lexidrug™, Elsevier Clinical Pharmacology).

INITIAL REVIEW CRITERIA

The request must meet all of the criteria listed under the diagnosis-specific sections below.

Asthma

- Member is 6 years or older
- Must be prescribed by, or in consultation with, an allergist, an immunologist, or a pulmonologist
- Must have chart documentation supporting a diagnosis of moderate-to-severe persistent asthma
- Must have a baseline IgE level >30 IU/mL
- Documentation of current weight
- Documentation of a positive skin test or *in vitro* testing [i.e., a blood test for allergen specific IgE antibodies such as the radioallergosorbent test (RAST)] for one or more perennial aeroallergens (e.g., house dust mite, animal dander, cockroach, feathers, mold spores)

- Must have inadequate asthma control despite current treatment with both of the following medications at optimized doses:
 - Medium-to-high dose inhaled corticosteroid
 - Additional controller medication (i.e., long-acting beta agonist, long-acting muscarinic antagonist, leukotriene receptor antagonist, or sustained release theophylline)
- Documentation asthma symptoms have not been adequately controlled by the above medication therapy regimen, defined by one of the following:
 - Hospitalization or emergency visit for asthma in the past year
 - Requirement for systemic (oral, parenteral) corticosteroids to control exacerbations of asthma on TWO occurrences in the past year
 - Poor symptom control (e.g., frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)
- Must have documentation or attestation from the provider of the following:
 - Will not be used with another biologic or targeted synthetic drug for asthma, such as Nucala (mepolizumab) or Cinqair (reslizumab)
 - The member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with omalizumab
- Must be requested at a dose that falls within the recommended dosing guidelines within the manufacturer's package insert, based on IgE level and weight

Chronic Urticaria

- Age 12 years or older
- Prescribed by an allergist, immunologist, or dermatologist
- Must have chart documentation showing at least a 6-week history of spontaneous wheals (hives), angioedema, or both
- Must provide a baseline Urticaria Activity Score (UAS7) score (to evaluate improvement on follow-up) OR documentation of number of wheals/hives and description of itch severity
- Must provide documentation, or an attestation from the provider, that other causes of urticaria ruled out (such as autoinflammatory disorder, urticarial vasculitis, exposure causes)
- Must be symptomatic despite treatment for at least 2 weeks with a second-generation H₁ antihistamine at 4x the standard dose (or at the maximally tolerated dose)
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

IgE-mediated Food Allergy

- Age 1 year or older

- Prescribed by or in consultation with an allergist or immunologist
- Must have a diagnosis of IgE-mediated food allergy, with documentation showing ONE of the following:
 - Pre-treatment allergen-specific IgE level ≥ 6 IU/mL
 - Skin-prick test (SPC) with wheal diameter ≥ 4 mm
- Must have chart note documentation showing ONE of the following:
 - 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
- Must have a baseline IgE level >30 IU/mL
- Must have documentation or an attestation from the provider that the member will continue to follow a food-allergen avoidance diet
- Must be requested at a dose that falls within the recommended dosing guidelines within the manufacturer's package insert, based on IgE level and weight

Immune Checkpoint Inhibitor-Related Toxicity (*off-label supported indication*)

- Must have refractory immune-therapy related severe (G3) pruritis
- Must have elevated IgE levels

Nasal Polyps

- Age 18 years or older
- Prescribed by an allergist, immunologist, or otolaryngologist (ENT)
- Must have a diagnosis of bilateral nasal polyps with documentation of at least ONE of the following:
 - 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
 - Total endoscopic nasal polyp score (NPS) of at least 5 with a minimum score of 2 for each nostril
- Must have documentation showing symptoms of nasal blockage, congestion, or obstruction plus ONE additional symptom below:
 - Rhinorrhea (anterior/posterior)
 - Reduction or loss of smell
 - Facial pain or pressure

- Documentation of an adequate trial of nasal corticosteroids for at least 4 weeks with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies
- Must have documentation or attestation from the provider of the following:
 - That the requested medication will not be used with another biologic or targeted synthetic drug for nasal polyps, such as Nucala (mepolizumab)
 - That the requested medication will be used as an add-on maintenance treatment (e.g., nasal corticosteroids)
- Must be requested at a dose that falls within the recommended dosing guidelines within the manufacturer's package insert, based on IgE level and weight

Systemic Mastocytosis (*off-label supported indication*)

- Age 1 year or older
- Must have a diagnosis of systemic mastocytosis, as evidenced by one of the following (see **Appendix 1** for diagnostic criteria):
 - At least ONE major and ONE minor diagnostic criterion **OR**
 - At least THREE minor diagnostic criteria
- Medication must be used in at least one 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 all of the following:
 - H1 blockers
 - H2 blockers.
 - 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

REAUTHORIZATION CRITERIA

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at one-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy including all the following:

Asthma

- Documentation indicating the member has a reduction in the frequency and/or severity

of symptoms and exacerbations **OR** a reduction in the daily maintenance oral corticosteroid dose

- Must have documentation or attestation from the provider of the following:
 - Will not be used with another biologic or targeted synthetic drug for asthma, such as Nucala (mepolizumab) or Cinqair (reslizumab)
 - Member must continue to use maintenance asthma treatments (e.g., inhaled corticosteroids) in combination with omalizumab
- Must be requested at a dose that falls within the recommended dosing guidelines within the manufacturer's package insert, based on IgE level and weight

Chronic Urticaria

- Must submit recent documentation showing a positive clinical response to the requested medication by a decrease in urticaria activity score (UAS7) or decreased number of wheals/hives and severity of itching
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

Food allergy

- Must submit recent documentation showing a positive clinical response to the requested medication by a decrease in food allergy symptoms (e.g., moderate-to-severe skin reaction, respiratory or GI symptoms)
- Member must continue to maintain a food-allergen avoidance diet
- Must be requested at a dose that falls within the recommended dosing guidelines within the manufacturer's package insert, based on IgE level and weight

Immune Checkpoint Inhibitor-Related Toxicities (*off-label supported indication*)

- All reauthorization requests must meet initial authorization criteria

Nasal Polyps

- Must submit recent documentation showing a positive clinical response to the requested medication by a decrease in nasal polyp score (NPS) and/or associated symptoms (sense of smell, postnasal drip, runny nose, etc.)
- Must have documentation or attestation from the provider of the following:
 - That the requested medication will not be used with another biologic or targeted synthetic drug for nasal polyps, such as Nucala (mepolizumab)
 - Member must continue to use a daily intranasal corticosteroid in combination with omalizumab, unless contraindicated or not tolerated

- Must be requested at a dose that falls within the recommended dosing guidelines within the manufacturer's package insert, based on IgE level and weight

Systemic Mastocytosis (*off-label supported indication*)

- All reauthorization requests must meet initial authorization criteria

APPROVAL DURATIONS

Initial Authorization	Up to one year
Reauthorization	Same as initial

APPENDICES

Appendix 1 - 2017 WHO Diagnostic Criteria for Systemic Mastocytosis

Major Criteria	Minor 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	• 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 • Detection of an activating point mutation at codon 816 of KIT in the bone marrow, blood, or another extracutaneous organ • Mast cells in bone marrow, blood, or other extracutaneous organs express CD25, with or without CD2, in addition to normal mast cell markers • Serum total tryptase persistently greater than 20 ng/mL (unless there is an associated myeloid neoplasm, in which case this parameter is not valid)

CODING AND STANDARDS

Codes

Code	Brand	Description
J2357	Xolair	Injection, omalizumab, 5mg
Q5154	Omlyclo	Injection, omalizumab-igec (omlyclo), biosimilar, 5 mg

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☐	Commercial
☐	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

BACKGROUND

The purpose of this policy is to define the prior authorization process for Xolair (omalizumab), an anti-IgE antibody indicated for the for the treatment of:

- Moderate to severe persistent asthma in adults and pediatric patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids
- Chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment
- IgE-mediated food allergy in adult and pediatric patients aged 1 year and older for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. To be used in conjunction with food allergen avoidance
- Chronic spontaneous urticaria (CSU) in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment

Definitions

Severe Asthma – As defined by the European Respiratory Society (ERS)/American Thoracic Society (ATS), severe asthma is “asthma that requires treatment with high dose inhaled corticosteroids [...] plus a second controller (and/or systemic corticosteroids) to prevent it from becoming ‘uncontrolled’ or which remains ‘uncontrolled’ despite this therapy”.

POLICY HISTORY

Date	Summary
July 2026	- Added Omlyclo - Updated dosing criteria for initial and reauthorization criteria for all indications - Updated the prerequisite medication requirements for both Asthma and Chronic Urticaria indications - Updated the initial criteria for Asthma
August 2025	- Addition of three new indications - food allergy, immune checkpoint inhibitor-related toxicities, & systemic mastocytosis - Updated prerequisite requirement for idiopathic urticaria - Addition of diagnostic criteria for nasal polyps
April 2023	- Updated initial authorization duration to 1 year and drug prerequisite trials for chronic urticaria. Removed requirements involving confirming adherence via PDC. - Updated prerequisite requirement for asthma to ONE plus high dose inhaled corticosteroid.
March 2022	Initial Review

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Administrative Services Medical Policy Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

Evolent Clinical Guidelines are comprehensive and inclusive of various procedural applications for each service type. Our guidelines may be used to supplement Medicare criteria when such criteria is not fully established. When Medicare criteria is determined to not be fully established, we only reference the relevant portion of the corresponding Evolent Clinical Guideline that is applicable to the specific service or item requested in order to determine medical necessity.

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