Reference number(s)
1656-A

Specialty Guideline Management
Xolair-Omlyclo

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Xolair	omalizumab
Omlyclo	omalizumab-igec

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.

FDA-Approved Indications[1,2]

Asthma

Indicated for adult and pediatric 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

Not indicated for the relief of acute bronchospasm or status asthmaticus.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

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.

IgE-Mediated Food Allergy

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.

To be used in conjunction with food allergen avoidance.

Limitations of use

Not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

Chronic Spontaneous Urticaria (CSU)

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

Not indicated for treatment of other forms of urticaria.

Compendial Uses[11]

- Immune checkpoint inhibitor-related toxicities
- Systemic mastocytosis

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

Documentation

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

Asthma

Initial requests

- Chart notes or medical record documentation showing pretreatment IgE level (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.

Continuation requests

Chart notes or medical record documentation supporting improvement in asthma control.

CRSwNP

Initial requests

- Chart notes or medical record documentation showing nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) details (e.g., location, size), Meltzer Clinical Score, or endoscopic nasal polyp score (NPS) (where applicable).
- 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.

Continuation requests

Chart notes or medical record documentation supporting positive response to therapy.

IgE-Mediated Food Allergy

Initial requests

Chart notes, medical record documentation, or laboratory tests showing the following (where applicable):

- Pretreatment allergen-specific IgE level
- Positive skin-prick test (SPT)
- Pretreatment serum IgE level
- Positive result of a physician controlled oral food challenge
- History of a systemic reaction to a food

Continuation requests

Chart notes or medical record documentation supporting positive response to therapy (e.g., reduction or absence of hypersensitivity to food allergen).

Chronic Spontaneous Urticaria (CSU)

Initial requests

Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy.

Continuation requests

Chart notes or medical record documentation supporting positive response to therapy.

Immune Checkpoint Inhibitor-Related Toxicity

Initial requests

Chart notes or medical record documentation showing pretreatment IgE level.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Systemic Mastocytosis

Initial requests

- Chart notes or medical record documentation supporting diagnosis of systemic mastocytosis.
- Chart notes, medical record documentation, or claims history supporting previous medications tried (where applicable).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

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

- Asthma: allergist/immunologist or pulmonologist
- CRSwNP: allergist/immunologist or otolaryngologist
- IgE-mediated food allergy: allergist/immunologist
- Chronic spontaneous urticaria: allergist/immunologist or dermatologist
- Immune checkpoint inhibitor-related toxicity: dermatologist, hematologist, or oncologist
- Systemic mastocytosis: allergist/immunologist, dermatologist, hematologist, or oncologist

Coverage Criteria

Asthma[1-6,13]

Authorization of 6 months may be granted for members 6 years of age or older who have previously received a biologic drug (e.g., Nucala, Cinqair) indicated for asthma in the past 12 months. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid [ICS] and additional controller) in combination with the requested medication.

Authorization of 6 months may be granted for treatment of moderate-to-severe asthma when all of the following criteria are met:

- Member is 6 years of age or older.
- Member has a positive skin test or in vitro reactivity to at least one perennial aeroallergen.
- Member has a pretreatment IgE level greater than or equal to 30 IU/mL.
- Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past 12 months:
    - Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment

  - One or more asthma exacerbation(s) resulting in hospitalization or emergency medical care visit(s)
  - Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)
- Member has inadequate asthma control despite adherence to current treatment with both of the following medications at optimized doses:
  - Medium-to-high-dose ICS (see Appendix A and B)
  - Additional controller (i.e., long acting beta2-agonist [LABA], long-acting muscarinic antagonist [LAMA], leukotriene modifier, or sustained-release theophylline)
- Member will continue to use maintenance asthma treatments (e.g., ICS and additional controller) in combination with the requested medication.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)[1,2,9,10,14-17]

Authorization of 6 months may be granted for members 18 years of age and older who have previously received a biologic drug (e.g., Dupixent, Nucala) indicated for chronic rhinosinusitis with nasal polyps (CRSwNP) in the past 12 months. Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

Authorization of 6 months may be granted for treatment of CRSwNP when all of the following criteria are met:

- Member is 18 years of age or older.
- Member has bilateral nasal polyposis and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 4 weeks unless contraindicated or not tolerated.
- Member has a pretreatment IgE level greater than or equal to 30 IU/mL.
- Member 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
- Member has 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
- Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

IgE-Mediated Food Allergy[1,2,18,19]

Authorization of 12 months may be granted for members 1 year of age or older for the reduction of IgE-mediated food allergy reactions when all of the following criteria are met:

- IgE-mediated food allergy has been confirmed by either of the following:
  - Pretreatment food allergen-specific IgE level
  - Skin-prick test (SPT)
- Member 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
- Member has a pretreatment serum IgE level greater than or equal to 30 IU/mL.
- Member will continue to follow a food-allergen avoidance diet.

Chronic Spontaneous Urticaria (CSU)[1,2,7,8]

Authorization of 12 months may be granted for members 12 years of age or older who have previously received a biologic drug (e.g., Dupixent) indicated for chronic spontaneous urticaria in the past 12 months.

Authorization of 12 months may be granted for treatment of chronic spontaneous urticaria in members 12 years of age or older when all of the following criteria are met:

- Member has been evaluated for other causes of wheals (hives) and/or angioedema, including bradykinin-related angioedema (e.g., angiotensin-converting-enzyme [ACE]-inhibitor induced angioedema, hereditary angioedema) and interleukin-1-associated urticarial syndromes (e.g., auto-inflammatory disorders, urticarial vasculitis).
- Member remains symptomatic despite treatment with up-dosing (in accordance with EAACI/GA2LEN/EuroGuiDerm/APAAACI guidelines) of a second-generation H1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine) for at least 2 weeks.
- Member has experienced a spontaneous onset of wheals (hives), angioedema, or both, for at least 6 weeks.

Immune Checkpoint Inhibitor-Related Toxicity[11,20]

Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when both of the following criteria are met:

- The member has a refractory case of immunotherapy-related related moderate (G2) or severe (G3) pruritus with no response to gabapentinoids in one month.
- The member has elevated IgE levels.

Systemic Mastocytosis[11,12]

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

- 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 C).
- The requested medication 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:
        - H1 blockers and 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 tolerance while on venom immunotherapy.

Continuation of Therapy

Asthma[1,2]

Authorization of 12 months may be granted for treatment of moderate-to-severe asthma when all of the following criteria are met:

- Member is 6 years of age or older.
- Asthma control has improved on the requested medication as demonstrated by at least one of the following:
    - A reduction in the frequency and/or severity of symptoms and exacerbations
    - A reduction or discontinuation in the daily maintenance oral corticosteroid dose
- Member will continue to use maintenance asthma treatments (e.g., ICS and additional controller) in combination with the requested medication.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)[1,2,9,10,14-17]

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

- Member is 18 years of age or older.
- Member has achieved or maintained a positive clinical response with the requested medication as evidenced by improvement in signs and symptoms of CRSwNP (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sino-nasal inflammation, hyposmia and/or facial pressure or pain or reduction in corticosteroid use).
- Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

IgE-Mediated Food Allergy[1,2,18,19]

Authorization of 12 months may be granted for members 1 year of age or older for the reduction of IgE-mediated food allergy reactions when all of the following criteria are met:

- Member has achieved or maintained a positive clinical response to therapy as evidenced by a reduction or absence of hypersensitivity (e.g., moderate to severe skin, respiratory or GI symptoms) to food-allergen.
- Member will continue to maintain a food-allergen avoidance diet.

Chronic Spontaneous Urticaria[1,2,7,8]

Authorization of 12 months may be granted for treatment of chronic spontaneous urticaria in members 12 years of age or older, when the member has experienced a positive clinical response (e.g., improved symptoms, decrease in weekly urticaria activity score [UAS7]) since initiation of therapy).

Immune Checkpoint Inhibitor-Related Toxicity and Systemic Mastocytosis[11,12,20]

Authorization of 12 months may be granted for treatment of refractory immune checkpoint inhibitor-related moderate (G2) or severe (G3) pruritus or systemic mastocytosis when the member achieves or maintains a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Other

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

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.

Appendix

Appendix A: Examples of Medium- and High-Dose ICS (Alone or in Combination with LABA) for Adults and Adolescents (12 Years and Older)[4]

Drug	Dosage Form	Medium-Dose Total Daily Dose	High-Dose Total Daily Dose
Beclomethasone dipropionate	Pressurized metered-dose inhaler (pMDI), standard particle size hydrofluoroalkane propellant (HFA)	>500-1000 mcg	>1000 mcg
Beclomethasone dipropionate	Dry-powder inhaler (DPI) or pMDI, extra-fine particle size HFA	>200-400 mcg	>400 mcg
Budesonide	DPI or pMDI, standard particle size HFA	>400-800 mcg	>800 mcg
Ciclesonide	pMDI, extra-fine particle size HFA	>160-320 mcg	>320 mcg
Fluticasone furoate	DPI	100-200 mcg	200 mcg
Fluticasone propionate	DPI or pMDI, standard particle size HFA	>250-500 mcg	>500 mcg
Mometasone furoate	DPI or pMDI, standard particle size HFA	200-400 mcg	>400 mcg

Appendix B: Examples of Medium- and High-Dose ICS (Alone or in Combination with LABA) for Children 6 to 11 Years[4]

Drug	Dosage Form	Medium-Dose Total Daily Dose	High-Dose Total Daily Dose
Beclomethasone dipropionate	pMDI, standard particle size HFA	>200-400 mcg	>400 mcg
Beclomethasone dipropionate	pMDI, extra-fine particle size HFA	>100-200 mcg	>200 mcg
Budesonide	DPI or pMDI, standard particle size HFA	>200-400 mcg	>400 mcg
Budesonide	Nebules	>500-1000 mcg	>1000 mcg
Ciclesonide	pMDI, extra-fine particle size HFA	>80-160 mcg	>160 mcg
Fluticasone furoate	DPI	50 mcg	Not applicable
Fluticasone propionate	DPI or pMDI, standard particle size HFA	>100-200 mcg	>200 mcg
Mometasone furoate	pMDI, standard particle size HFA	100 mcg	200 mcg

Appendix C: World Health Organization (WHO) Diagnostic Criteria for Systemic Mastocytosis[13]

- 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 organ(s)
- Minor Criteria:
  - Atypical mast cell morphology, including spindle shape or immature morphology, present in greater than 25% of all mast cells on bone marrow smears or in other extracutaneous organ(s)
  - Mast cells aberrantly express one or more of the following antigens: CD2, CD25, CD30
  - KIT p.D816V mutation or other activating KIT mutation(s) detected in peripheral blood, bone marrow, or other extracutaneous organ(s)
  - Baseline serum tryptase concentration of greater than 20 ng/mL in the absence of an associated myeloid neoplasm; in the case of a known HαT, the tryptase level could be adjusted

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