RX.PA.037.CCH IMMUNOLOGICALS – XOLAIR [OMALIZUMAB INJECTION FOR SUBCUTANEOUS (SQ) USE]

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

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.

The drug, Xolair® (omalizumab), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all the criteria listed under the respective diagnosis:

Asthma:

Must meet all the following:

- Member is 6 years or older
- Prescribed by an allergist, an immunologist, or a pulmonologist
- Has a diagnosis of >1 year history of moderate-to-severe persistent asthma
- Has 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) AND/OR for one or more seasonal aeroallergens (grass, pollen, weeds)

- Must have tried a high dose inhaled corticosteroid (*see table 1 for ICS dosing guide*) in combination with ONE of the following:
  - Inhaled long-acting beta agonist
  - Inhaled long-acting muscarinic antagonist
  - Leukotriene receptor antagonist
  - 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
  - On daily corticosteroid with inability to taper off
- 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
- Requested dose, based on IgE level and weight, falls within the recommended dosing guidelines from the manufacturer (*see table 2 for dosing guidelines*)

Chronic Urticaria:

Must meet all the following:

- Age 12 years or older
- Prescribed by an allergist, immunologist, or dermatologist
- Has a diagnosis of chronic moderate to severe idiopathic urticaria
- Chart documentation showing at least a 6-week history of spontaneous wheals (hives), angioedema, or both
- Baseline Urticaria Activity Score (UAS7) score (to evaluate improvement on follow-up) OR documentation of number of wheals/hives and description of itch severity
- 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 H_1 antihistamine at 4x the standard dose (or at the maximally tolerated dose)
- **Dosing above 300mg every 4 weeks is not covered for a diagnosis of urticaria**

Nasal Polyps:

Must meet all the following:

- 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 TWO months 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)
- Requested dose, based on IgE level and weight, falls within the recommended dosing guidelines from the manufacturer (*see table 3 for dosing guidelines*)

IgE-mediated Food Allergy:

Must meet all the following:

- 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
- Requested dose, based on IgE level and weight, falls within the recommended dosing guidelines from the manufacturer (See table 4 for dosing guidelines)

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

Must meet all the following:

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

Systemic Mastocytosis (*off-label supported diagnosis*)

Must meet all the following:

- 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 criterion
- 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

Chronic Urticaria
- Documentation of positive clinical response to medication by a decrease in urticaria activity score (UAS7) or decreased number of wheals/hives and severity of itching

Nasal Polyps
- Documentation of positive clinical response to 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

Food allergy
- Documentation of positive clinical response to 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

Immune Checkpoint Inhibitor-Related Toxicities
- All reauthorization requests must meet initial authorization criteria

Systemic Mastocytosis
- All reauthorization requests must meet initial authorization criteria

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

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.

HCPCS Codes:

Code	Description
J2357	INJECTION, OMALIZUMAB, 5 MG

Table 1 – High daily metered doses of inhaled corticosteroids – adapted from GINA 2022 guidelines

Inhaled corticosteroid (ICS)	Total Daily ICS High dose (mcg) Ages 6 to 11 years	Total Daily ICS High dose (mcg) Ages ≥12 years
Beclometasone diproprionate (pMDI, standard particle, HFA)	>400	>1000
Beclometasone diproprionate (DPI or pMDI, extrafine particle, HFA)	>200	>400
Budesonide (DPI, or pMDI, standard particle, HFA)	>400	>800
Budesonide (nebules)	>1000	N/A
Ciclesonide (pMDI, extrafine particle, HFA)	>160	>320
Fluticasone furoate (DPI)	N/A	200
Fluticasone propionate (DPI, or pMDI, standard particle, HFA)	>200	>500
Mometasone furoate (pMDI, standard particle, HFA)	200	>400

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; pMDI: pressurized metered dose inhaler

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Table 2 – Xolair Dosing Guidelines for ASTHMA

ADMINISTRATION EVERY 2 OR 4 WEEKS

Xolair® Doses (milligrams) Administered by Subcutaneous Injection Every 2 or 4 Weeks for Adults and Adolescents (12 Years of Age and Older) with Asthma

Pretreatment Serum IgE (IU/mL)	Dosing Freq.	Body Weight			
		30–60 kg	>60–70 kg	>70–90 kg	>90–150 kg
		Dose (mg)			
≥30–100	Every 4 weeks	150	150	150	300
>100–200		300	300	300	225
>200–300		300	225	225	300
>300–400	Every 2 weeks	225	225	300	
>400–500		300	300	375	
>500–600		300	375	Insufficient Data to Recommend a Dose	
>600–700		375			

ADMINISTRATION EVERY 2 OR 4 WEEKS

Xolair® Doses (milligrams) Administered by Subcutaneous Injection Every 2 Weeks for Pediatric Patients (6 to <12 years of age) with Asthma

(SEE NEXT PAGE)

Pre-treatment Serum IgE (IU/mL)	Dosing Freq.	Body Weight									
		20-25 kg	>25-30 kg	>30-40 kg	>40-50 kg	>50-60 kg	>60-70 kg	>70-80 kg	>80-90 kg	>90-125 kg	>125-150 kg
		Dose (mg)									
30-100	Every 4 weeks	75	75	75	150	150	150	150	150	300	300
>100-200		150	150	150	300	300	300	300	300	225	300
>200-300		150	150	225	300	300	225	225	225	300	375
>300-400		225	225	300	225	225	225	300	300		
>400-500		225	300	225	225	300	300	375	375		
>500-600		300	300	225	300	300	375				
>600-700		300	225	225	300	375					
>700-800	Every 2 weeks	225	225	300	375						
>800-900		225	225	300	375						
>900-1000		225	300	375	Insufficient Data to Recommend a Dose						
>1000-1100		225	300	375							
>1100-1200		300	300								
>1200-1300		300	375								

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Table 3 – Xolair Dosing Guidelines for NASAL POLYPS

Subcutaneous XOLAIR Doses Every 2 or 4 Weeks* for Adult Patients with CRSwNP

Pretreatment Serum IgE (IU/mL)	Dosing Freq.	Body Weight							
		>30-40 kg	>40-50 kg	>50-60 kg	>60-70 kg	>70-80 kg	>80-90 kg	>90-125 kg	> 125-150 kg
		Dose (mg)							
30 - 100	Every 4 Weeks	75	150	150	150	150	150	300	300
>100 - 200		150	300	300	300	300	300	450	600
>200 - 300		225	300	300	450	450	450	600	375
>300 - 400		300	450	450	450	600	600	450	525
>400 - 500		450	450	600	600	375	375	525	600
>500 - 600		450	600	600	375	450	450	600	
>600 - 700		450	600	375	450	450	525		
>700 - 800	Every 2 Weeks	300	375	450	450	525	600		
>800 - 900		300	375	450	525	600			
>900 - 1000		375	450	525	600				
>1000 - 1100		375	450	600					
>1100 - 1200		450	525	600					
>1200 - 1300		450	525						
>1300 - 1500		525	600						

Insufficient Data to Recommend a Dose

*Dosing frequency:

- Subcutaneous doses to be administered every 4 weeks
- Subcutaneous doses to be administered every 2 weeks

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Table 4 – Xolair Dosing Guidelines for FOOD ALLERGY

ADMINISTRATION EVERY 2 or 4 WEEKS

Subcutaneous XOLAIR Doses Every 2 or 4 Weeks for Adult and Pediatric Patients 1 Year of Age and Older with IgE-Mediated Food Allergy*

Pretreatment Serum IgE (IU/mL)	Dosing Freq.	Body Weight (kg)												
		≥10-12	>12-15	>15-20	>20-25	>25-30	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90 - 125	>125 - 150
		Dose (mg)												
≥30 - 100	Every 4 Weeks	75	75	75	75	75	75	150	150	150	150	150	300	300
>100 - 200		75	75	75	150	150	150	300	300	300	300	300	450	600
>200 - 300		75	75	150	150	150	225	300	300	450	450	450	600	375
>300 - 400		150	150	150	225	225	300	450	450	450	600	600	450	525
>400 - 500		150	150	225	225	300	450	450	600	600	375	375	525	600
>500 - 600		150	150	225	300	300	450	600	600	375	450	450	600	
>600 - 700		150	150	225	300	225	450	600	375	450	450	525		
>700 - 800	Every 2 Weeks	150	150	150	225	225	300	375	450	450	525	600		
>800 - 900		150	150	150	225	225	300	375	450	525	600			
>900 - 1000		150	150	225	225	300	375	450	525	600				
>1000 - 1100		150	150	225	225	300	375	450	600	Insufficient data to Recommend a Dose				
>1100 - 1200		150	150	225	300	300	450	525	600					
>1200 - 1300		150	225	225	300	375	450	525						
>1300 - 1500		150	225	300	300	375	525	600						
>1500 - 1850			225	300	375	450	600							

*Dosing frequency:
Subcutaneous doses to be administered every 4 weeks
Subcutaneous doses to be administered every 2 weeks

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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)

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REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Initial Review	3/22
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.	04/23
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	08/2024

Record Retention

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

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