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)
- Documentation that the positive skin tested allergen(s) is an asthma trigger either from environmental exposure OR from testing OR from attempted allergen immunotherapy.

- Documentation that the patient has received immunotherapy (e.g., allergy shots) and still has clinical asthma symptoms due to allergen exposure despite immunotherapy that resulted in hospital admission or ER visit
    - Unless there is a documented medical reason for not receiving immunotherapy (e.g., severe unstable asthma or severe, systemic injection reactions)
- Documentation showing that environmental measures (e.g., air filters, pillow covers, avoidance) were attempted to avoid or minimize exposure to allergen triggers or reason (e.g., unavoidable allergen) for not trying to avoid exposure
- The patient has a documented baseline FEV1 < 80% of predicted or FEV1/FVC that has been reduced by at least 5% of normal for the patient age range (*see table 1 below*) **NOTE: FEV1 requirement may be bypassed if the requester cites compromised mobility**

TABLE 1: Normal FEV_1/FVC

Patient's	Normal
8–19 y/o	85%
20–39 y/o	80%
40–59 y/o	75%
60–80 y/o	70%

- Must have tried a high dose inhaled corticosteroid (*see table 2 below*) in combination with ONE of the following:
    - Inhaled long-acting beta agonist
    - Inhaled long-acting muscarinic antagonist
    - Leukotriene receptor antagonist
    - Theophylline

TABLE 2: 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

- Documentation asthma symptoms that have not been adequately controlled by the above medication therapy regimen, defined by one of the following:
  - Hospitalization 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
- The patient is not receiving any medication (e.g., Beta Blockers or NSAIDs) that could cause bronchospasm or cause an asthma exacerbation and if the patient is on a potential asthma inducing medication, that there is a documented medical reason for continuing that medication as well as documentation that the medication is not a cause for worsening asthma or causing any asthma symptoms
- Will not be used with another biologic drug, such as Nucala (mepolizumab) or Cinqair (reslizumab)
- Requested dose, based on IgE level and weight, falls within the recommended dosing guidelines from the manufacturer (See next page for Table 1 and Table 2)

Xolair® Dosing Guidelines
Table 1
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	150	150	150	300
>100–200	4	300	300	300	225
>200–300	weeks	300	225	225	300
>300–400	Every	225	225	300	
>400–500	2	300	300	375	
>500–600	weeks	300	375	**Insufficient Data**	
>600–700		375		**to Recommend a Dose**	

Table 2
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

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							
>1000-1100		225	300	375							
>1100-1200		300	300								
>1200-1300		300	375								

Insufficient Data to Recommend a Dose

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 a 3-month history of urticaria with presence of hives
- 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)
- Documentation of an adequate trial of ONE of the following:
    - TWO second-generation antihistamines taken at the same time

  - A second-generation antihistamine + an H2 antagonist (e.g., famotidine, cimetidine)
  - A second-generation antihistamine + a first-generation antihistamine (e.g., hydroxyzine, doxepin)
  - A second-generation antihistamine + a leukotriene antagonist (e.g., montelukast)
- Note: **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 nasal polyps
- Documentation of an adequate trial of TWO nasal corticosteroids with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies
- Must be used as an add-on maintenance treatment
- Note: **Dosing above 600mg every 2 weeks is not covered for a diagnosis of nasal polyps**

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 hospitalizations, emergency department visits, or requirement for oral or inhaled corticosteroid therapy
- Reduction in reported symptoms of asthma attacks (e.g., shortness of breath, chest tightness, tiredness, sleep disturbance, total asthma symptom score)

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.)

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial
Quantity Level Limit	
Vials	6 vials per 28 days

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

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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

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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