Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Xolair® (Omalizumab)***
DEPARTMENT: **Clinical Pharmacy Services – Utilization Management**
ORIGINAL DATE: ***October 2003 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *August 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Xolair® (omalizumab).

DEFINITIONS

N/A

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, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

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

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

Asthma:

Must meet all of 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 >30IU/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 below) **FEV1 requirement may be bypassed if the requester cites compromised mobility**
- Documented history of receiving at least 3 months of combination therapy with ALL the following:
    - High dose inhaled corticosteroid **AND**
    - ONE of the following:Inhaled long acting beta agonist and/or Inhaled long acting muscarinic antagonist ANDONE of the following:
        - Leukotriene receptor antagonist
        - Theophylline
- Maximized high dose inhaled corticosteroids with long acting bronchodilator medications unless there is a documented medical reason (e.g. side effects) not to
- Documentation asthma symptoms that have not been adequately controlled despite adherence (PDC >80%) to 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 Nucala (mepolizumab) or Cinqair (reslizumab)
- Requested dose, based on IgE level and weight, falls within the recommended dosing guidelines from the manufacturer (See Table 1, Table 2, and Table 3)

Xolair® Dosing Guidelines
Table 1
ADMINISTRATION EVERY 4 WEEKS
Xolair® Doses (milligrams) Administered by Subcutaneous Injection Every 4 Weeks for Adults and Adolescents (12 Years of Age and Older) with Asthma

Pre-treatment Serum IgE (IU/mL)	**Body Weight (kg)**			
	30-60	>60-70	>70-90	>90-150
>30-100	150	150	150	300
> 100-200	300	300	300	**SEE TABLE 2**
> 200-300	300	**SEE TABLE 2**		
> 300-400	**SEE TABLE 2**			
> 400-500				
> 500-600				

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

Pre-treatment Serum IgE (IU/mL)	**Body Weight (kg)**			
	30-60	>60-70	>70-90	>90-150
>30-100	**SEE TABLE 1**			
> 100-200	**SEE TABLE 1**			225
> 200-300	**SEE TABLE 1**	225	225	300
> 300-400	225	225	300	**DO NOT DOSE**
> 400-500	300	300	375	
> 500-600	300	375	**DO NOT DOSE**	
>600-700	375	**DO NOT DOSE**		

Table 3
ADMINISTRATION EVERY 2 or 4 WEEKS
Xolair® Doses (milligrams) Administered by Subcutaneous Injection Every 2 or 4 Weeks for Pediatric Patients with Asthma Between the Ages of 6 to <12 years

Pre-treatment Serum IgE (IU/mL)	Dosing Freq	Body Weight (kg)									
		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 (light gray shading)	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 (no shading)	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								

DO NOT DOSE

Chronic Urticaria:

Must meet all of 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 TWO high-dose H1 antihistamines with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies
- Documentation of an adequate trial of ONE leukotriene antagonist with an inadequate response or significant side effects/toxicity or have a contraindication to this therapy

- Documentation of an adequate trial of ONE H2 antihistamine with an inadequate response or significant side effects/toxicity or have a contraindication to this therapy
- Documentation of an adequate trial of ONE anti-inflammatory agent (e.g., colchicine, dapsone, sulfasalazine, and hydroxychloroquine) or immunosuppressant (e.g., cyclosporine, tacrolimus, mycophenolate) with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies

Trial of immunosuppressant or anti-inflammatory agent does not apply to members ages 12 to 18Note: **Dosing above 300mg every 4 weeks is not covered for a diagnosis of urticaria**

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%

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 adherence (PDC>80%) to therapy and 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

- Confirmation of adherence (PDC>80%) to optimized asthma medication regimen including: inhaled corticosteroid, long acting beta agonist or long acting muscarinic antagonist, theophylline or leukotriene modifier
- 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

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• Asthma: Up to 6 months • Urticaria: Up to 3 months (3 doses)
Reauthorization	Up to 1 year
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.

REFERENCES

1. Xolair [package insert]. South San Francisco, CA: Genentech, Inc.; July 2010.
2. Kaplan A, Ledford D, Ashby M, et al. Omalizumab in patients with symptomatic chronic idiopathic/spontaneous urticaria despites standard combination therapy. J Allergy Clin Immunol. 2013;132:101-109.
3. Centers for Disease Control and Prevention. Asthma. Available at http://www.cdc.gov. Accessed May 16, 2016.
4. Deschildre A, Marguet C, Salleron J,et al. Add-on omalizumab in children with severe allergic asthma: a 1-year real life survey. Eur Respir J. 2013 Nov;42(5):1224-33.
5. US Department of Health and Human Services. Asthma Care Quick Reference. Diagnosing and Managing Asthma. NIH Publication No. 12-5075. Revised September 2012.
6. National Heart, Lung, and Blood Institute. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma (EPR-3) available at: www.nhlbi.nih.gov/guidelines/asthma (online).
7. Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention - revised 2017. Accessed June 16, 2017.
8. Kuehr J, Brauburger J, Zielen S, et al. Efficacy of combination treatment with anti-IgE plus specific immunotherapy in polysensitized children and adolescents with seasonal allergic rhinitis. J Allergy Clin Immunol. 2002;109(2):274-80.
9. Kopp MV Hamelmann E, Zielen S, et al. Combination of omalizumab and specific immunotherapy is superior to immunotherapy in patients with seasonal allergic rhinoconjunctivitis and co-morbid seasonal allergic asthma. Clin and Exp Allergy. 2009;39(2):271-9.
10. Maurer M, Rosen K, Hsieh H-J, et al. Omalizumab for the treatment of chronic idiopathic or spontaneous urticaria [published erratum appears in: N Engl J Med 2013 Jun 13; 368(24):2340-1] [supplementary index appears online]. N Engl J Med. 2013a. 368:924-935.4. Saini SS, Bindsley-Jensen C, Maurer M, et al. Efficacy and safety of omalizumab in H1-antihistamine-refractory
11. chronic idiopathic/spontaneous urticaria: results of a phase III randomized, double-blind, placebo-controlled trial. Ann Allergy Asthma Immunol. 2013;111 (5 suppl):A18.
12. Zuberbier T, Asero R, Bindslev-Jensen C, Walter Canonica G, et al. EAACI/GA(2)LEN/EDF/WAO guideline: management of urticaria. Allergy. 2009 Oct;64(10):1427-43. doi: 10.1111/j.1398-9995.2009.02178.x.
13. Jacqueline Eghrari-Sabet, M.D., Ellen Sher, M.D., Abhishek Kavati, Ph.D. et al. Real-world use of omalizumab in patients with chronic idiopathic/spontaneous urticaria in the United States. Allergy Asthma Proc. 2018 May-Jun; 39(3): 191–200. Published online 2018 Mar 7. doi: 10.2500/aap.2018.39.4132. PMCID: PMC5911510

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/16, 02/17, 02/18*
Criteria update	*10/16, 08/18*