MetroPlus Health Plan

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**IMMUNOMODULATORS**
BRAND NAME/(generic)	**XOLAIR (omalizumab)**
Type: Initial Prior Authorization	

Effective Date:
Review Date:

FDA-APPROVED INDICATIONS

A. Allergic asthma
Xolair is indicated for patients with Moderate to severe persistent asthma in 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 corticosteroid

Limitations of use: Xolair is not indicated for acute bronchospasm or status asthmaticus.

B. Chronic idiopathic urticaria
Xolair is indicated for Chronic idiopathic urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment

Limitations of use: Xolair is Not indicated for other allergic conditions or other forms of urticaria

MECHANISM OF ACTION

Xolair inhibits the binding of IgE to the high-affinity IgE receptor (FcεRI) on the surface of mast cells and basophils. Reduction in surface-bound IgE on FcεRI-bearing cells limits the degree of release of mediators of the allergic response. Treatment with Xolair also reduces the number of FcεRI receptors on basophils in atopic patients.

COVERAGE CRITERIA

A. Asthma
Authorization will be granted for 12 months when all the following criteria are met:

- Member is 6 years of age or older

AND

- Patient has a confirmed diagnosis consistent with severe asthma as defined by any of the following (documentation **MUST** be submitted):
  - Experiences asthma symptoms frequently throughout the day
  - Has nighttime awakenings ≥ 7 times per week
  - Uses short-acting beta-2-agonist (SABA) for symptom control several times per day
  - Symptoms extremely interferes with normal activity
  - Lung function is defined as FEV_1 < 60% predicted; FEV1/FVC reduced > 5%*

AND

- Patient has documented adherence to asthma medications at optimized doses for sufficient treatment length. Medication adherence is defined as > 80% PDC, **MUST** be confirmed by paid claim or chart documentation *:
  - 12 months of high-dose Inhaled corticosteroid (ICS) given in combination with a minimum of 3 months of controller medication (either a long acting $beta_2$-agonist [LABA], or a leukotriene receptor antagonist (LTRA), or sustained-release theophylline), unless the patient is intolerant of or has a known contraindication to these agents; **OR**

- 6 months of ICS with daily oral glucocorticoids given in combination with a minimum of 3 months of controller medication (either a LABA, or LTRA, or theophylline), unless the patient is intolerant of or has a known contraindication to these agents

AND

- Total serum IgE count of at least 30IU/mL

AND

- Dose is within approved FDA dosing:

Table 1. Subcutaneous Xolair Doses Every 4 Weeks for Patients 12 Years of Age and Older with Asthma

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

Table 2. Subcutaneous Xolair Doses Every 2 Weeks for Patients 12 Years of Age and Older with Asthma

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

Table 3. Subcutaneous Xolair Doses Every 2 or 4 Weeks* for Pediatric Patients with Asthma Who Begin Xolair Between the Ages of 6 to <12 Years

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	DO NOT DOSE	
>400-500		225	300	225	225	300	300	375	375		
>500-600		300	300	225	300	300	375	DO NOT DOSE			
>600-700		300	225	225	300	375	DO NOT DOSE				
>700-800	Every 2 weeks	225	225	300	375	DO NOT DOSE					
>800-900		225	225	300	375						
>900-1000		225	300	375	DO NOT DOSE						
>1000-1100		225	300	375							
>1100-1200		300	300	DO NOT DOSE							
>1200-1300		300	375								

*Dosing frequency:

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

B. <u>Chronic Idiopathic Urticaria</u>

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

- Member is 12 years of age or older.

AND

- Member has been evaluated for other causes of urticaria, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis).

AND

- Member has experienced a spontaneous onset of wheals, angioedema, or both, for at least 6 weeks.

AND

- Member has tried/failed or has history of contradiction or intolerance of ALL of the following regimen for at least 4 weeks each*:
    a. At least two second generation H1-antihistamines [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]; AND
    b. Titrate at least two second generation H1-antihistamine to FOUR times normal dose.
    c. A combination: One second generation H1-antihistamine and One of the following:
        i. A Different second generation H1-antihistamine
        ii. At least TWO first generation H1-antihistamine: [e.g., Benadryl (diphenhydramine), Chlor-Trimeton (chlorpheniramine), Vistaril (hydroxyzine)]
        iii. At least TWO H2-antihistamine [e.g., Pepcid (famotidine), Tagamet HB (cimetidine), Zantac (ranitidine)]
        iv. Leukotriene modifier [e.g., Singulair (montelukast)]

AND

- Patient does not have the following contraindication/health condition:
    a. Known hypersensitivity to Xolair or any of its excipients

AND

XOLAIR dosing is in accordance with the FDA approved dosing schedule:

- Asthma: Xolair 75 to 375 mg SC every 2 or 4 weeks. Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg).

- Chronic Idiopathic Urticaria: Xolair 150 or 300 mg SC every 4 weeks. Dosing in CIU is not dependent on serum IgE level or body weight.

Approved x 6 months

Renewal Request:

- All initial conditions of coverage have been met

AND

- Documented improvement of the condition

AND

- The patient did not experience any adverse effects while on Xolair therapy:

Approved x 12 months

REFERENCES

1. Xolair [package insert]. South San Francisco, CA: Genentech, Inc.; July 2018.
2. Busse W, Corren J, Lanier BQ, et al. Omalizumab, anti-IgE recombinant humanized monoclonal antibody, for the treatment of severe allergic asthma. J Allergy Clin Immunol. 2001;108(2):184-190. doi:10.1067/mai.2001.117880.
3. Saini SS, Bindslev-Jensen C, Maurer M, et al. Efficacy and safety of omalizumab in patients with chronic idiopathic/spontaneous urticaria who remain symptomatic on H1 antihistamines: a randomized, placebo-controlled study [published correction appears in J Invest Dermatol. 2015;135(3):925. doi:10.1038/jid.2014.512]. J Invest Dermatol. 2015;135(1):67-75. doi:10.1038/jid.2014.306.
4. Zuberbier T. The EAACI/GA²LEN/EDF/WAO guideline for the definition, classification, diagnosis and management of urticaria. *Allergy* 2017 Dec; DOI: 10.1111/all.13397
5. Exploring the Effects of Omalizumab in Allergic Asthma An Analysis of Biomarkers in the EXTRA Study. https://www.atsjournals.org/doi/full/10.1164/rccm.201208-1414OC?url_ver=Z39.88 2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub%3Dpubmed