CLINICAL MEDICAL POLICY	
Policy Name:	Xolair® (Omalizumab)
Policy Number:	MP-051-MD-PA
Approved By:	Medical Management
Provider Notice Date:	07/01/2017
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Revision Date:	N/A
Products:	Pennsylvania Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 9

DISCLAIMER

Gateway Health℠ (Gateway) medical policy is intended to serve only as a general reference resource regarding payment and coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Gateway Health℠ provides coverage under the medical surgical benefits of the Company's Medicaid products for medically necessary Xolair (omalizumab) subcutaneous injections.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

DEFINITIONS

Prior Authorization Review Panel – A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

IgE – Immunoglobulin E (IgE) is an antibody in the human immune system that plays a critical role in the allergic process

Xolair – A monoclonal antibody that directs its action specifically against Immunoglobulin E (IgE). Xolair is a subcutaneous injection that should be administered only in a health care setting by health care providers prepared to manage anaphylaxis that can be life-threatening.

PROCEDURES

1. Xolair is considered medically necessary as a subcutaneous injection for:
    A. The treatment of moderate to severe persistent asthma when the patient meets all of the following criteria:
        1) The patient is at least 6 years of age; AND
        2) Must be prescribed by, or in consultation with, a pulmonologist, allergist, or immunologist; AND
        3) The patient has a confirmed diagnosis of moderate to severe persistent asthma; AND
        4) Patient's symptoms are inadequately controlled despite adherence with at least a three-month trial of combination therapy that includes a medium- or high-dose inhaled corticosteroid PLUS another controller medication (e.g., long-acting beta-2 agonist, leukotriene receptor antagonist, theophylline). See Attachment C Appendix I for examples of asthma therapies and Appendix II for comparative daily dosages for inhaled corticosteroids; AND
        5) The patient has a positive skin test or in vitro reactivity (radioallergosorbent test [RAST]) to a perennial aeroallergen; AND
        6) The patient weighs between 20 kg and 150 kg; AND
        7) Patient has a serum total IgE level, measured before the start of treatment, of ≥ 30 IU/mL and ≤ 700 IU/mL in patients age ≥ 12 years or ≤ 1300 IU/mL in patients aged 6 to < 12 years; AND
        8) The prescribed dose and dosing frequency of Xolair is in accordance with FDA-approved labeling based on the patient's pretreatment serum IgE levels and body weight. See Attachment C Appendix III for dosing charts from the Xolair package insert.

    B. The treatment of chronic idiopathic urticaria when the patient meets all of the following criteria:
        1) The patient is at least 12 years of age; AND
        2) Must be prescribed by, or in consultation with, an allergist, immunologist, or dermatologist; AND
        3) Must have a documented history of urticaria for a period of at least 3 months; AND
        4) An evaluation has been conducted to rule out other causes of urticaria; AND
        5) Must have documented therapeutic failure despite adherence with a four-week trial of, or history of contraindication or intolerance to, a second-generation H1 antihistamine at the maximum tolerated dose; AND
        6) Must have documented therapeutic failure despite adherence with a four-week trial of, or history of contraindication or intolerance to, at least one of the following medications in combination with a second-generation H1 antihistamine. See Attachment C Appendix IV for examples of therapies for chronic idiopathic urticaria; AND
        7) Dosing does not exceed 300 mg administered subcutaneously every 4 weeks.

2. Contraindications
   Severe hypersensitivity reaction to Xolair or any ingredient of Xolair.

3. When the Xolair is not covered
   Xolair is not covered for conditions other than those listed above because the scientific evidence has not been established.

   Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis (es) for which it is prescribed. These requests will be reviewed on a case-by-case basis to determine medical necessity.

   When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

4. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Gateway Health℠ at any time pursuant to the terms of your provider agreement.

5. Place of Service
   The place of service for the administration of Xolair is outpatient.

GOVERNING BODIES APPROVAL

On June 20, 2003, the U.S. Food and Drug Administration (FDA) approved Xolair (omalizumab) for the treatment of adults and adolescents (12 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. On July 6, 2016, the FDA expanded Xolair approval for the management of moderate to severe persistent asthma to patients 6 years of age and older. Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus. Xolair is not indicated for treatment of other allergic conditions. For moderate to severe persistent asthma, Xolair is administered by subcutaneous injection every 2 or 4 weeks. Xolair dosage and dosing frequency are determined based on total serum IgE concentrations and body weight prior to therapy. Xolair dosage should be adjusted accordingly for significant changes in body weight during treatment.

On March 21, 2014, the FDA approved Xolair (omalizumab) for the treatment of chronic idiopathic urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment. Xolair is not indicated for treatment of other forms of urticaria. For chronic idiopathic urticaria, Xolair is administered by subcutaneous injection every 4 weeks. Dosing of Xolair in chronic idiopathic urticaria patients is not dependent on serum IgE (free or total) level or body weight

CODING REQUIREMENTS

Procedure Codes

HCPCS Code	Description
J2357	Injection, omalizumab, 5 MG

Diagnosis Codes

ICD-10 Codes	Description
J45.40	Moderate persistent asthma, uncomplicated
J45.41	Moderate persistent asthma with (acute) exacerbation
J45.50	Severe persistent asthma, uncomplicated
J45.51	Severe persistent asthma with (acute) exacerbation
L50.0	Allergic urticaria
L50.1	Idiopathic urticaria

REIMBURSEMENT

Participating facilities will be reimbursed per their Gateway Health℠ contract.

POLICY SOURCE(S)

Xolair [package insert]. Genentech, Inc., South San Francisco, CA; July 2016.

National Asthma Education and Prevention Program (NAEPP). Guidelines for the diagnosis and management of asthma. Expert Panel Report 3. Bethesda, MD: National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI); July 2007.

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Saini SS, Bindslev-Jensen C, Maurer M, et al. Efficacy and safety of omalizumab in members with chronic idiopathic/spontaneous urticaria who remain symptomatic on H1 antihistamines: a randomized placebo controlled study. J Invest Dermatol. 2015; 135(1):67-75.

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Kaplan A, Ledford D, Ashby M, et al. Omalizumab in members with symptomatic chronic idiopathic/spontaneous urticarial despite standard combination therapy. J Allergy Clin Immunol. 2013; 132(1):101-109.

Guillén-Aguinaga S, Jáuregui Presa I, Aguinaga-Ontoso E, et al. Updosing nonsedating antihistamines in members with chronic spontaneous urticarial: a systematic review and meta-analysis. Br J Dermatol. 2016; 175(6):1153-1165.

Schaefer P, Urticaria: evaluation and treatment. Am Fam Physician. 2011; 83(9):1078-1084.

Powell RJ, Leech SC, Till S, et al. BSACI guideline for the management of chronic urticarial and angioedema. Clin Exp Allergy. 2015; 45(3):547-65.

Khan DA. Chronic urticaria: treatment of refractory symptoms. In: UpToDate, Feldweg AM, UpToDate, Waltham, MA. (Accessed on January 17, 2017).

OTHER REFERENCES

Therapy Examples and Dosing Tables

Appendix I

Inhaled Corticosteroids	Beclometasone dipropionate (QVAR) Budesonide DPI (Pulmicort Flexhaler) Budesonide nebules (Pulmicort Respules) Ciclesonide (Alvesco) Flunisolide (Aerospan) Fluticasone furoate (Arnuity Ellipta) Fluticasone propionate (Flovent Diskus) Fluticasone propionate (Flovent HFA) Mometasone furoate (Asmanex Twisthaler) Mometasone furoate (Asmanex HFA)
Combination Long-Acting Bronchodilator and Corticosteroid	Budesonide/formoterol (Symbicort) Fluticasone/salmeterol (Advair Diskus) Fluticasone/salmeterol (Advair HFA) Fluticasone/vilanterol (Breo Ellipta) Mometasone/formoterol (Dulera)
Leukotriene receptor antagonist (LTRA)	Montelukast (Singulair) Zafirlukast (Accolate)

**List not all inclusive*
Key- **HFA**: hydrofluoroalkane propellant metered dose inhaler; **DPI**: dry powder inhaler

Appendix II

Estimated Comparative Daily Doses for Inhaled Glucocorticoids in Adolescents and Adults			
Adults and Adolescents (12 years of age and older)			
Drug	**Daily dose (mcg)**		
	Low	**Medium**	**High**
Beclomethasone dipropionate HFA 40 or 80 mcg/puff	80-240 mcg	> 240-480 mcg	> 480 mcg
Budesonide DPI 90, 180, or 200 mcg/inhalation	180-600 mcg	> 600-1,200 mcg	> 1,200 mcg
Flunisolide HFA 80 mcg/puff	320 mcg	> 320-640 mcg	> 640 mcg
Fluticasone propionate DPI 50, 100, 250 mcg/inhalation	100-300 mcg	> 300-500 mcg	> 500 mcg
Fluticasone propionate HFA 44, 110, 220 mcg/puff	88-264 mcg	> 264-440 mcg	> 440 mcg
Mometasone furoate HFA 200 mcg/inhalation	200 mcg	400 mcg	> 400 mcg
Mometasone furoate DPI 110 or 220 mcg/inhalation	110-220 mcg	> 220-440 mcg	> 440 mcg
* *List not all inclusive* **Key**- **HFA**: hydrofluoroalkane propellant metered dose inhaler; **DPI**: dry powder inhaler			

Estimated Comparative Daily Doses for Inhaled Glucocorticoids in Children			
Children 5-11 years of age			
Drug	**Daily dose (mcg)**		
	Low	**Medium**	**High**
Beclomethasone dipropionate HFA 40 or 80 mcg/puff	80-160 mcg	> 160-320 mcg	> 320 mcg
Budesonide DPI 90, 180, or 200 mcg/inhalation	180-400 mcg	> 400-800 mcg	> 800 mcg
Budesonide inhaled Inhalation suspension for nebulization (child dose)	0.5 mg	1.0 mg	2.0 mg
Flunisolide HFA 80 mcg/puff	160 mcg	320 mcg	≥ 640 mcg
Fluticasone propionate DPI 50, 100, 250 mcg/inhalation	100-200 mcg	> 200-400 mcg	> 400 mcg
Fluticasone propionate HFA 44, 110, 220 mcg/puff	88-176 mcg	> 176-352 mcg	> 352 mcg
Mometasone furoate DPI 110 or 220 mcg/inhalation	110 mcg	≥ 220 - < 440	≥ 440 mcg
* *List not all inclusive* **Key**- **HFA**: hydrofluoroalkane propellant metered dose inhaler; **DPI**: dry powder inhaler			

Appendix III: Xolair Dosing Charts (per package insert)

Adult and adolescent patients 12 years of age and older: Initiate dosing according to Table 1 or 2.

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		
> 300–400 IU/mL	SEE TABLE 2			
> 400–500 IU/mL				
> 500–600 IU/mL				

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			
> 100–200 IU/mL				225 mg
> 200–300 IU/mL		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	
> 500–600 IU/mL	300 mg	375 mg	DO NOT DOSE	
> 600–700 IU/mL	375 mg	DO NOT DOSE		

Pediatric patients 6 to <12 years of age: Initiate dosing according to Table 3.

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

DO NOT DOSE

*Dosing frequency:

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

Appendix IV

First-generation H1 antihistamine	Chlorpheniramine (Chlor-Trimeton) Cyproheptadine (Periactin) Diphenhydramine (Benadryl) Hydroxyzine (Atarax, Vistaril)
Second-generation H1 antihistamine	Cetirizine (Zyrtec) Desloratadine (Clarinex) Fexofenadine (Allegra) Levocetirizine (Xyzal) Loratadine (Claritin)
Leukotriene receptor antagonist (LTRA)	Montelukast (Singulair) Zafirlukast (Accolate)
H2 antihistamine	Cimetidine (Tagamet) Famotidine (Pepcid) Ranitidine (Zantac)
* *List not all inclusive*	

Policy History

Date	
06/06/2017	Initial policy developed
06/21/2017	QI/UM Committee approval
08/01/2017	Provider effective date