Clinical Policy: Omalizumab (Xolair)

Reference Number: PA.CP.PHAR.01
Effective Date: 01/18
Last Review Date: 07/17

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for omalizumab (Xolair®).

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness that omalizumab is **medically necessary** when one of the following criteria are met:

I. Initial Approval Criteria

A. Moderate to Severe Persistent Asthma (must meet all):

1. Prescribed by or in consultation with an allergist or pulmonologist;
2. Age ≥ 6 years;
3. Diagnosis of moderate to severe persistent asthma;
4. Member has experienced ≥ 2 exacerbations requiring oral/systemic corticosteroid treatment, urgent care visit or hospital admission within the last 12 months despite adherent use of controller therapy (i.e., high dose inhaled corticosteroid [ICS] plus either a long acting beta-2 agonist [LABA] or leukotriene modifier [LTRA] if LABA contraindicated/intolerance);
5. Positive immunoassay or skin test to perennial aeroallergen identified to be an asthma trigger;
6. Immunoglobulin E (IgE) level ≥ 30 IU/mL;
7. If current smoking history, engaged in smoking cessation effort;
8. Xolair is prescribed concomitantly with an ICS plus either an LABA or LTRA;
9. Prescribed dose does not exceed 375 mg administered every 2 weeks (a and b):
   a. Dose is based on pre-treatment IgE level, weight, and age per Appendix B or C;
   b. Per manufacturer, dose adjustment following Appendix B or C is recommended for significant changes in body weight during treatment.

Approval duration: 6 months

B. Chronic Idiopathic Urticaria (must meet all):

1. Age ≥ 12 years;
2. Prescribed by or in consultation with a dermatologist or allergist;
3. Diagnosis of chronic idiopathic urticaria (CIU);
4. Failure of both of the following unless contraindication/intolerance (a and b):
   a. Two antihistamines (including one second generation antihistamine – e.g., cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine, ranitidine, famotidine, cimetidine) at maximum indicated doses for ≥ 4 weeks;
   b. An LTRA with an antihistamine at maximum indicated doses for ≥ 4 weeks;
5. Prescribed dose does not exceed 300 mg every 4 weeks.

Approval duration: 6 months

C. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

A. Moderate to Severe Persistent Asthma (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies ;
2. Demonstrated adherence to asthma controller therapy that includes an ICS plus either a LABA or LTRA;
3. Member is responding positively to therapy as evidenced by reduction in exacerbations or corticosteroid dose, or improvement in FEV_1 since baseline;
4. Prescribed dose does not exceed 375 mg administered every 2 weeks (a and b):
   a. Dose is based upon pre-treatment IgE level, weight, and age per Appendix B or C;
   b. Per manufacturer, dose adjustment following Appendix B or C is recommended for significant changes in body weight during treatment.

Approval duration: 12 months

B. Chronic Idiopathic Urticaria (must meet all):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Documentation supports positive response to therapy;
3. Prescribed dose does not exceed 300 mg every 4 weeks.

Approval duration: 12 months

C. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

Background

Description/Mechanism of Action:

Xolair is a recombinant DNA-derived humanized IgG1κ monoclonal antibody that selectively binds to human IgE.

Asthma: Omalizumab 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.

Chronic idiopathic urticaria: Omalizumab binds to IgE and lowers free IgE levels. Subsequently, IgE receptors (FcεRI) on cells down-regulate. The mechanism by which these effects of omalizumab result in an improvement of CIU symptoms is unknown.

Formulations:
Xolair: Reconstituted preservative free solution for subcutaneous administration: 150 mg (single-use vial).

FDA Approved Indications:
Xolair is a monoclonal antibody/subcutaneous injection indicated for:

- Moderate to severe persistent asthma
  - Patients ≥ 6 years of age 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.

  Limitations of use:
  - Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus;
  - Xolair is not indicated for treatment of other allergic conditions;
- Chronic idiopathic urticaria
  - The treatment of adults and adolescents (≥ 12 years of age) with chronic idiopathic urticaria who remain symptomatic despite H1 antihistamine treatment.

  Limitations of use:
  - Xolair is not indicated for treatment of other forms of urticaria.

Appendices

Appendix A: Abbreviation Key

CIU: chronic idiopathic urticaria
FcεRI: high-affinity IgE receptor
FEV: forced expiratory volume
ICS: inhaled corticosteroids
IgE: immunoglobulin E
IgG: immunoglobulin G
LABA: long acting beta-2 agonist
LTRA: leukotriene modifier

Appendix B: Age ≥ 12 years: Dosing based on pre-treatment IgE and body weight†

Pre-treatment serum IgE IU/mL	Dosing Frequency	Body Weight			
		30-60 kg	>60-70 kg	>70-90 kg	>90-15 kg
≥ 30-100	Every 4 weeks	150 mg	150 mg	150 mg	300 mg
> 100-200		300 mg	300 mg	300 mg	225 mg
> 200-300		300 mg	225 mg	225 mg	300 mg
> 300-400	Every 2 weeks	225 mg	225 mg	300 mg	DO NOT DOSE PER MANUFACTURER
> 400-500		300 mg	300 mg	375 mg	
> 500-600		300 mg	375 mg		
> 600-700		375 mg			

†The manufacturer recommends dose adjustments for significant body weight changes during treatment.

Appendix C: Age 6 to < 12 years: Dosing based on pre-treatment IgE and body weight†

Pre-treatment serum IgE IU/mL	Dosing Frequency	Body Weight									
		20-25 kg	>25-30 kg	>30-40 kg	>40-50 kg	>40-50 kg	>40-50 kg	>40-50 kg	>40-50 kg	>40-50 kg	>40-50 kg
≥ 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	DO NOT DOSE PER MANUFACTURER					
>800-900		225	300	375							
>900-1000		225	300	375							
>1100-1200		300	300								
>1200-1300		300	375								

†The manufacturer recommends dose adjustments for significant body weight changes during treatment.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J2357	Injection, omalizumab, 5 mg

Reviews, Revisions, and Approvals	Date	Approval Date

References

1. Xolair Prescribing Information. Irvine, CA: Spectrum Pharmaceuticals, Inc.; June 2017. Available at https://www.gene.com/download/pdf/xolair_prescribing.pdf. Accessed July 5, 2017.
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3. Wenzel S. Evaluation of severe asthma in adolescents and adults. In: UpToDate, Waltham, MA: Wolters Kluwer Health; 2017. Available at uptodate.com. Accessed July 6, 2017.
4. Wenzel S. Treatment of severe asthma in adolescents and adults. In: UpToDate, Waltham, MA: Wolters Kluwer Health; 2017. Available at uptodate.com. Accessed July 6, 2017.

5. Bernstein JA, Lang DM, Khan DA, et al. The diagnosis and management of acute and chronic urticaria: 2014 update. *J Allergy Clin Immunol*. 2014; 133(5); 1270-1277.
6. Khan DA. Chronic urticarial: Standard management and patient education. In: UpToDate, Waltham, MA: Wolters Kluwer Health; 2017. Available at uptodate.com. Accessed July 6, 2017.