Department:	Pharmacy Management	**Original Approval:**	12/14/2016
Policy #:	PM141	**Last Approval:**	06/14/2018
Title:	Omalizumab (Xolair®) injection for subcutaneous use		
Approved By:	UM Committee		

REQUIRED CLINICAL DOCUMENTATION FOR REVIEW

Documentation required to determine medical necessity for Omalizumab (Xolair) for subcutaneous use: History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service: -Diagnosis -Age - Prescribed by or in consultation with an allergist, immunologist, dermatologist or pulmonologist -Labs/diagnostics - Medication list (current and past) to include start and end dates of previous trials for all asthma, urticaria or rhinitis therapies.

BACKGROUND

Asthma is a common chronic inflammatory disease of the airways. For most patients asthma is well controlled with inhaled therapy but for those with severe asthma it can be associated with substantial morbidity, mortality, and economic effects.

Xolair is a recombinant humanized immunoglobulin G (IgG)1κ monoclonal antibody which selectively binds to human immunoglobulin E (IgE), thus inhibiting IgE from binding to the surface of mast cells and basophils (at the high-affinity IgE receptor [FcεRI]), and resulting in a decrease of mediators released in the allergic response.1 Xolair treatment also reduces the number of FcεRI receptors on basophils in atopic patients. Xolair is indicated for use in patients aged ≥ 6 years with moderate to severe persistent asthma and who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. Xolair decreases the incidence of asthma exacerbations in these patients. Safety and efficacy of Xolair in pediatric patients with asthma aged < 6 years have not been established. Doses and dosing frequency in asthma are determined by serum total IgE level (which is measured before the start of therapy) and the patient's body weight. Xolair is also indicated for the treatment of adults and adolescents (aged ≥ 12 years) with chronic idiopathic urticaria (CIU) who remain symptomatic despite H1 antihistamine treatment.

Dosing in patients with CIU does not depend on serum IgE (free or total) or on body weight. In CIU, Xolair binds to IgE and lowers free IgE levels; subsequently, FcεRI on cells down-regulate. How these effects of Xolair result in an improvement in CIU symptoms is not known.

Xolair is **not indicated** for the following conditions:

- Treatment of other allergic conditions or other forms of urticaria

- Acute bronchospasm or status asthmaticus

DEFINITIONS

Enter all definitions here.

INDICATIONS/CRITERIA

Coverage of Xolair is recommended in those who meet one of the following criteria:

FDA-Approved Indications

MediCAID Members	Follow WA HCA Antiasthmatic Monoclonal Antibodies Medical Policy no.44.60.30-1. Continue to clinical criteria below.
MediCARE Members	Follow criteria from MCG 22nd Ed: ACG: A-0315 (AC) ***Step-utilization of Part D drugs not required.***

1. Asthma in Patients with Moderate to Severe Persistent Disease.[1]

A) Initial Therapy. Approve for 12 months if the patient meets all of the following criteria:

- **i.** Greater than or equal to (≥) 6 years of age
- **ii.** History of failure (remains symptomatic after 6 weeks), contraindication or intolerance to medium- to high-dose inhaled corticosteroids (ICS)
- **iii.** Positive skin test or in vitro reactivity to a perennial aeroallergen
- **iv.** Uncontrolled or inadequately controlled severe asthma is defined by at least **ONE** of the following:
    a. FEV_1 less than (<) 80% predicted
    b. Two or more bursts of systemic corticosteroids in the previous 12 months
    c. Poor symptom control (e.g., ACQ score consistently greater than 1.5 or ACT score consistently less than 20)
- **v.** Pre-treatment serum IgE level between 30 and 1500 IU/mL
- **vi.** NOT to be used in combination with other monoclonal antibodies (e.g. benralizumab, mepolizumab, reslizumab)
- **vii.** Prescribed by or in consultation with a specialist in allergy, pulmonology, or immunology

Patients Continuing Xolair Therapy. Clinical documentation of disease stability or improvement compared to baseline measures.

Approve for 12 months Dosage and quantity limits

B) Asthma: 375mg every 2 weeks; 2.5 vials per 14-day supply (5 vials per 28-day supply)

Xolair is indicated for use in patients aged ≥ 6 years 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.[1] Xolair is not indicated for acute bronchospasm or

status asthmaticus. Doses and dosing frequency are determined by serum total IgE level (which is measured before the start of therapy) and the patient's body weight. Based on the prescribing information for Xolair, an IgE level of ≥ 30 IU/mL is required to calculate a dose. In addition, most of the clinical studies used a baseline IgE level of ≥ 30 IU/mL for inclusion.[1-922,24] Serum total IgE levels increase during Xolair therapy due to formation of Xolair:IgE complexes and remain elevated for up to one year after Xolair is stopped. The 2014 ERS/ATS guidelines for the definition, evaluation, and treatment of severe asthma suggest a trial of Xolair may be considered when a patient's total serum IgE level is ≥ 30 IU/mL and < 700 IU/mL (in addition to other qualifiers).[11] The 2016 GINA guidelines also reference this IgE level requirement for a trial of Xolair therapy.[10] The GINA guidelines and the 2007 NAEPP guidelines indicate that inhaled corticosteroids plus a LABA are the recommended controller medications for asthma patients prior to the potential addition of Xolair.[10,12] The ERS/ATS guidelines reference the GINA guidelines for these therapy recommendations.[11] The following agents are noted as alternatives to LABA therapy according to the GINA guidelines: sustained-release theophylline, tiotropium, or a LTRA (e.g., montelukast).[10] However, tiotropium is not indicated in patients < 12 years of age at this time, and therefore is not recommended in guidelines.[10] If a patient is uncontrolled despite optimal therapy with the previously listed agents, the GINA guidelines support referral to a specialized physician for further investigation and consideration of additional therapies, such as Xolair.

In regard to assessing current clinical control (preferably over 4 weeks), the GINA guidelines state that uncontrolled asthma is demonstrated by at least three of the following: daytime symptoms more than twice per week, any limitation of activities, any nocturnal symptoms/awakening, or the need for reliever/rescue treatment more than twice per week. The NAEPP guidelines recommend patient referral to an asthma specialist for consultation or co-management if the patient is having difficulty achieving or maintaining control of asthma, if immunotherapy or Xolair are considered, or if the patient has had an exacerbation requiring hospitalization.[12] Following initiation of Xolair therapy, the ERS/ATS guidelines also recommend a physician assessment of treatment response, taking into consideration asthma control, exacerbations, unscheduled healthcare utilization, and patient quality of life.11 These guidelines note that if a patient has not responded within 4 months of initiating treatment, further Xolair therapy is unlikely to be beneficial. The ERS/ATS guidelines define uncontrolled asthma in patients ≥ 6 years of age, as asthma that meets one of the following four criteria: poor symptom control; frequent severe exacerbations (two or more requiring systemic corticosteroids per year); serious exacerbations (one hospitalization in the previous year); or airflow limitation (FEV1 < 80% of predicted in the setting of reduced FEV1/FVC). Additionally, patients may also have severe asthma if their asthma worsens upon tapering of corticosteroids (high-dose ICSs or systemic corticosteroids). In the professional opinion of specialist physicians reviewing the data, we have adopted the seasonal aeroallergens listed in the criteria above (Criterion 1, A, iv).

2. Chronic Idiopathic Urticaria (Chronic Spontaneous Urticaria).[1]

	Per WA HCA Antiasthmatic Monoclonal Antibodies Medical Policy no.44.60.30-1. Continue to clinical criteria below.
	Follow criteria from MCG 22nd Ed: ACG: A-0315 (AC).

A) Initial Therapy. Approve for 12 months if the patient meets all of the following criteria):

1. Greater than or equal to (≥) 12 years of age
2. History of failure, contraindication or intolerance to H1 antihistamine therapy
3. NOT to be used in combination with other monoclonal antibodies (e.g. benralizumab, mepolizumab, reslizumab)

i. 4. Prescribed by or in consultation with a specialist in allergy, pulmonology, or immunology

B. Patients Continuing Xolair Therapy. Clinical documentation of disease stability or improvement compared to baseline measures.

Dosage and quantity limits:
Urticaria: 300mg every 4 weeks; 2 vial per 28-day supply

Xolair is indicated for the treatment of adults and adolescents aged ≥ 12 years with CIU who remain symptomatic despite H1 antihistamine treatment.[1] Dosing in patients with CIU does not depend on serum IgE (free or total) or on body weight. Xolair is not indicated for other forms of urticaria. In studies and guidelines, patients with chronic urticaria are generally defined as those having symptoms (e.g., pruritus and hives) for > 3 days per week for > 6 consecutive weeks despite treatment with an H1 antihistamine.[16-19] Guidelines recommend non-sedating (second-generation) H1 antihistamines at standard daily doses as first-line therapy for CIU.[19-21] In patients who do not respond adequately to standard doses of non- sedating H1 antihistamines, the dosage should be increased up to four times the standard dose. Adding a second non-sedating antihistamine, an H2 antagonist, a LTRA, or a 1st generation antihistamine to be taken at bedtime may be considered for patients with refractory CIU despite non-sedating H1 antihistamine therapy. If the patient still has poorly controlled symptoms, treatment with hydroxyzine or doxepin may be considered as part of step-up therapy. Patients with refractory chronic urticaria despite treatment with the previously listed therapies for 1 to 4 weeks may consider alternative therapies, such as Xolair or cyclosporine. For any drug therapy, it is recommended to temporarily discontinue the drug to check for spontaneous remission.[20] Adequate controlled clinical studies have not been conducted in patients less than 12 years of age with CIU.[1] In the professional opinion of specialist physicians reviewing the data, we have adopted this criterion.

SPECIAL CONSIDERATIONS

None.

LIMITATIONS/EXCLUSIONS

Please refer to a product line's certificate of coverage for benefit limitations and exclusions for these services:

PRODUCT LINE	LINK TO CERTIFICATE OF COVERAGE
MEDICARE ADVANTAGE	http://healthfirst.chpw.org/for-members/resource-library/handbooks-and-guides
WASHINGTON APPLE HEALTH	http://chpw.org/our-plans/apple-health/
INTEGRATED MANAGED CARE	http://chpw.org/our-plans/apple-health/

Citations & References

CFR		
WAC	WAC 284-43-2050	
RCW		
Contract Citation	☒ WAH	
	☒ IMC	
	☒ MA	
Other Requirements		
NCQA Elements		
References	1. Xolair® subcutaneous injection [prescribing information]. South San Francisco, CA and East Hanover, NJ: Genentech, Inc. and Novartis Pharmaceuticals Corporation; May 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. 3. Finn A, Gross G, van Bavel J, et al. Omalizumab improves asthma-related quality of life in patients with severe allergic asthma. *J Allergy Clin Immunol.* 2003;111(2):278-284. 4. Lanier BQ, Corren J, Lumry W, et al. Omalizumab is effective in the long-term control of severe allergic asthma. *Ann Allergy Asthma Immunol.* 2003;91:154-159. 5. Bousquet J, Wenzel S, Holgate S, et al. Predicting response to omalizumab, an anti-IgE antibody, in patients with allergic asthma. *Chest.* 2004;125(4):1378-1386. 6. Solèr M, Matz J, Townley R, et al. The anti-IgE antibody omalizumab reduces exacerbations and steroid requirement in allergic asthmatics. *Eur Respir J.* 2001;18:254- 261. 7. Buhl R, Solèr M, Matz J, et al. Omalizumab provides long-term control in patients with moderate-to-severe allergic asthma. *Eur Respir J.* 2002;20:73-78. 8. Buhl R, Hanf G, Solèr M, et al. The anti-IgE antibody omalizumab improves asthma-related quality of life in patients with allergic asthma. *Eur Respir J.* 2002;20:1088-1094.	

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Revision History

Revision Date	Revision Description	Revision Made By
12/14/2016	NEW	Sophia Yun, PharmD
02/24/2017	Approval	MMLT
11/25/2017	Clarification of criteria based on product line	Sonya Ou, PharmD
12/21/2017	Approval	MMLT
03/09/2018	Reassigned from UM to Pharmacy	Cindy Bush
05/04/2018	Transferred to new template	Cindy Bush
05/16/2018	Selected revisions	Catherine Vu, PharmD
06/07/2018	Revised to HCA Policy	Jennifer Farley, PharmD
06/14/2018	Approval	UM Committee