PRIOR AUTHORIZATION CRITERIA

BRAND NAME (generic)	XOLAIR (omalizumab)	
Status: CVS/caremark Criteria		***MDC***
Type: Initial Prior Authorization		***Ref # 473-A***

FDA-APPROVED INDICATIONS[1]

Allergic Asthma

Xolair is indicated for patients 6 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.

Chronic Idiopathic Urticaria (CIU)

Xolair is indicated for the treatment of adults and adolescents 12 years of age and older with chronic idiopathic urticaria who remain symptomatic despite H1 antihistamine treatment.

Limitations of Use:
- Xolair is not indicated for treatment of other allergic conditions or other forms of urticaria
- Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus

CRITERIA FOR APPROVAL

1	Is Xolair being requested for the treatment of moderate to severe persistent allergic asthma? [If no, skip to question 9.]	Yes	No
2	Is the patient currently receiving treatment with Xolair for allergic asthma? [If no, skip to question 4.]	Yes	No
3	Has the asthma control improved since initiation of Xolair therapy? [If yes, skip to question 8.] [If no, no further questions.]	Yes	No
4	Did the patient test positive (by skin or blood test) to at least one perennial aeroallergen? [If no, no further questions.]	Yes	No
5	Does the patient have a baseline immunoglobulin E (IgE) level greater than or equal to 30 IU per mL? [If no, no further questions.]	Yes	No
6	Does the patient have inadequate asthma control despite treatment with both of the following medications at optimized doses: 1) inhaled corticosteroid, AND 2) additional controller (long acting beta$_2$-agonist, leukotriene modifier, or sustained-release theophylline)? [If yes, skip to question 8.]	Yes	No
7	Did the patient have an intolerance or contraindication to all of these therapies? [If no, no further questions.]	Yes	No
8	Is the patient 6 years of age or older? [No further questions.]	Yes	No

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9	Is Xolair being requested for the treatment of chronic idiopathic urticaria (CIU)? [If no, no further questions.]	Yes	No
10	Is the patient currently receiving treatment with Xolair for chronic idiopathic urticaria (CIU)? [If no, skip to question 12.]	Yes	No
11	Has the patient experienced a response (e.g., improved symptoms) since initiation of therapy? [If yes, skip to question 14.] [If no, no further questions.]	Yes	No
12	Has the patient been evaluated for other causes of urticaria, including bradykinin-related angioedema and IL-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis)? [If no, no further questions.]	Yes	No
13	Has the patient experienced a spontaneous onset of wheals, angioedema, or both, for at least six (6) weeks? [If no, no further questions.]	Yes	No
14	Is the patient 12 years of age or older? [No further questions.]	Yes	No

Guidelines for Approval					
Duration of Approval: 12 months					
Set 1: Asthma - Initial		**Set 2:** Asthma – intolerance/CI to LABA/ LT modifier/ theophylline, initial		**Set 3:** Asthma - Renewal	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
1	2	1	2	1	None
4		4	6	2	
5		5		3	
6		7		8	
8		8			
Duration of Approval: 6 months		**Duration of Approval: 12 months**			
Set 4: CIU – Initial		**Set 5:** CIU – Renewal			
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**		
9	1	9	1		
12	10	10			
13		11			
14		14			

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Internal Use Only – Mapping Instructions		
	Yes	**No**
1.	Go to 2	Go to 9
2.	Go to 3	Go to 4
3.	Go to 8	Deny
4.	Go to 5	Deny
5.	Go to 6	Deny
6.	Go to 8	Go to 7
7.	Go to 8	Deny
8.	Approve, 12 months	Deny
9.	Go to 10	Deny
10.	Go to 11	Go to 12
11.	Go to 14	Deny
12.	Go to 13	Deny
13.	Go to 14	Deny
14.	Approve 6 months for initial CIU, 12 months for renewal	Deny

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

REFERENCES

1. Xolair [package insert]. South San Francisco, CA: Genentech, Inc.; June 2017.
2. National Institutes of Health. *National Asthma Education and Prevention Program Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma - Full Report 2007*. Bethesda, MD: National Heart Lung and Blood Institute; August 2007. http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.pdf. Accessed March 2, 2017.
3. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2017 update. http://ginasthma.org/2017-gina-report-global-strategy-for-asthma-management-and-prevention/. Accessed March 2, 2017.
4. Strunk RC, Bloomberg GR. Omalizumab for asthma. *N Engl J Med*. 2006;354(25):2689-2695.
5. Maurer M, Rosen K, Hsieh HJ, et al. Omalizumab for the treatment of chronic idiopathic or spontaneous urticaria. *N Engl J Med*. 2013;368(10):924-935.
6. Zuberbier T, Asero R, Bindslev-Jensen C, et al. *EAACI/GA²LEN/EDF/WAO guideline for the definition, classification, diagnosis, and management of urticaria: the 2013 revision and update*. Allergy 2014;69:868-887.
7. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado. Available at http://www.micromedexsolutions.com. Accessed March 2, 2017.

DOCUMENT HISTORY

Written by:	Specialty Clinical Development (TG) 12/2009
Revised:	KR 10/2011 (CMS), LD 09/2012 (CMS), LD 06/2013 (CMS); AS 03/2014 (added new indication), KW 09/2014 (CMS), PK 08/2015 (CMS); KF 06/2016 (CMS), ST 07/2016 (label update – asthma age), 09/2016 (Per CMS - CIU: added immunologist, removed moderate to severe, added intol or CI for antihistamine; Asthma: added intol or CI for all prereq meds, removed specific examples of improvement for cont of tx), LP 07/2017 (CMS)
Last Reviewed:	CDPR/ KP 12/2009, 08/2011, DHR 07/2012; DNC 05/2013, 04/2014; KRU 03/2015; LCB 07/2016, 09/2016; LMS 03/2017
External Review:	01/2010, 10/2010, 09/2011, 08/2012, 07/2013, 05/2014, 05/2015, 05/2017

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