UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Xolair

Program	Prior Authorization
Medication	Xolair (omalizumab)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	3/2008
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

1. Background:

Xolair is approved by the U.S. Food and Drug Administration (FDA) for use in adults and adolescents 6 years of age and older, who have moderate to severe persistent asthma and a positive skin test or *in vitro* reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. Xolair is not indicated for acute bronchospasm or status asthmaticus. Xolair is also approved for chronic idiopathic urticaria in adults and adolescents (12 years of age and above) who remain symptomatic despite H_1 antihistamine treatment. It is not indicated for other allergic conditions or other forms of urticaria. Because of the risk of anaphylaxis, healthcare providers administering Xolair should observe patients closely for an appropriate period of time and be prepared to manage anaphylaxis that can be life-threatening.

Xolair contains a black boxed warning for anaphylaxis. See full prescribing information for additional details.

2. Coverage Criteria:

A. <u>Asthma</u>

1. **<u>Initial Authorization</u>**

   a. **Xolair** will be approved when all of the following criteria are met:

      (1) Diagnosis of moderate or severe asthma

-AND-

(2) Classification of asthma as uncontrolled or inadequately controlled as defined by at least one of the following:

(a) Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20)

-OR-

(b) Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months

-OR-

(c) Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)

-OR-

(d) Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80% predicted [in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal])

-OR-

(e) Patient is currently dependent on oral corticosteroids for the treatment of asthma

-AND-

(3) **One** of the following:

(a) Baseline (pre-omalizumab treatment) serum total IgE level greater than or equal to 30 IU/mL and less than or equal to 1500 IU/mL

-OR-

(b) Patient is currently dependent on oral corticosteroids for the treatment of asthma

-AND-

(4) Positive skin test or in vitro reactivity to a perennial aeroallergen

-AND-

(5) Used in combination with **one** of the following:

(a) One maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2-agonist (LABA) product [e.g., fluticasone propionate/salmeterol (AirDuo/Advair®), budesonide/formoterol (Symbicort®)]

-OR-

(b) Combination therapy including **both** of the following:

i. One high-dose (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco®), mometasone furoate (Asmanex®), beclomethasone dipropionate (QVAR®)]

-AND-

ii. One additional asthma controller medication [e.g., LABA - olodaterol (Striverdi®) or indacaterol (Arcapta®); leukotriene receptor antagonist – montelukast (Singulair®); theophylline]

-AND-

(6) Patient is not receiving Xolair in combination with **any** of the following:

(a) Anti-interleukin 4 therapy [e.g. Dupixent (dupilumab)]
(b) Anti-interleukin 5 therapy [e.g. Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

-AND-

(7) Xolair dosing for moderate to severe persistent asthma is in accordance with the United States Food and Drug Administration approved labeling

-AND-

(8) Prescribed by or in consultation with an allergist/immunologist or pulmonologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Xolair** will be approved when **all** of the following criteria are met:

(1) Documentation of positive clinical response as demonstrated by at least one of the following: reduction in frequency of exacerbations, decreased utilization of rescue medications, increase in percent predicted FEV1 from pretreatment baseline, reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing)

-AND-

(2) Used in combination with an ICS-containing controller medication

-AND-

(3) Patient is not receiving Xolair in combination with **any** of the following:

(a) Anti-interleukin 4 therapy [e.g. Dupixent (dupilumab)]
(b) Anti-interleukin 5 therapy [e.g. Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

-AND-

(4) Xolair dosing for moderate to severe persistent asthma is in accordance with the United States Food and Drug Administration approved labeling

-AND-

(5) Prescribed by or in consultation with allergist/immunologist or pulmonologist

Authorization will be issued for 12 months.

B. Chronic Idiopathic Urticaria

1. **Initial Authorization**

a. **Xolair** will be approved when all of the following criteria are met:

(1) Diagnosis of chronic idiopathic urticaria

-AND-

(2) **One** of the following:

(a) Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to, two H1-antihistamines [e.g., Allegra (fexofenadine), Benadryl (diphenhydramine), Claritin (loratadine)]*

-OR-

(b) Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to **both** of the following taken in combination:

i. Second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]

-AND-

ii. **One** of the following:

a. Different second generation H1-antihistamine [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)]
b. First generation H1-antihistamine [e.g., Benadryl (diphenhydramine), Chlor-Trimeton (chlorpheniramine), Vistaril (hydroxyzine)]*
c. H2-antihistamine [e.g., Pepcid (famotidine), Tagamet HB (cimetidine), Zantac (ranitidine)]
d. Leukotriene modifier [e.g., Singulair (montelukast)]

-AND-

(3) Xolair dosing for chronic idiopathic urticaria is in accordance with the United States Food and Drug Administration approved labeling

-AND-

(4) Prescribed by or in consultation with an allergist/immunologist or dermatologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Xolair** will be approved when all of the following criteria are met:

(1) Documentation of positive clinical response (e.g., reduction in exacerbations, itch severity, hives)

-AND-

(2) Xolair dosing for chronic idiopathic urticaria is in accordance with the United States Food and Drug Administration approved labeling

-AND-

(3) Prescribed by or in consultation with allergist/immunologist or dermatologist

Authorization will be issued for 12 months.

*Note: Patients 65 years of age and older in whom first generation H1-antihistamines are considered high risk medications to be avoided (e.g., Beers criteria, HEDIS) should be directed to try alternatives that are not considered high risk.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

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15. FDA Drug Safety Communication. FDA approves label changes for asthma drug Xolair (omalizumab), including describing slightly higher risk of heart and brain adverse events. Updated September 26, 2014. Available at http://www.fda.gov/Drugs/DrugSafety/ucm414911.htm. Accessed May 16, 2016.
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17. Sampson HA. A phase II, randomized, double-blind, parallel-group, placebo-controlled oral food challenge trial of Xolair® (omalizumab) in peanut allergy (TOPS). *J Allergy Clin Immunol*. 2007;119 (Supp 1):s117. Abstract.
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Program	Program type – Prior Authorization
Change Control	
Date	Change
3/10/2008	New policy
3/11/2008	Diagnosis list updated per instructions from Coding and Integrity.
4/16/2009	Policy format updated. Approved by National Pharmacy & Therapeutics Committee 2/12/2009. Policy 2008D0033A archived
8/24/2009	Added in vitro reactivity to criteria for allergen response
12/30/2009	Added ICD-9s 493.00, 493.10, and 493.90. Removed ICD-9 495.9
4/1/2010	Policy updated per annual review, approved by National Pharmacy & Therapeutics Committee on 03/09/2010. Policy 2009D0033B archived.
6/7/2011	Policy updated per annual review, approved by National Pharmacy and Therapeutics Committee on 3/8/2011. Created an Additional Information section within the Coverage Rationale to address the IgE level upon which dosing is calculated. Added acute bronchospasm and status asthmaticus to the list of unproven uses. Added Benefits Consideration section. Updated Clinical Evidence. Removed deleted CPT codes 90769 and 90772. Moved 493.01, 493.11, 493.21 and 493.91 to unproven codes. Added 519.11 to unproven codes. Updated references. Policy 2010D0033C archived.
8/1/2011	Clarified drug policy. Moved IgE level to proven indication under coverage rationale. Removed “to support medical necessity review where applicable” from Additional Information. Moved Additional Information section to under proven indications. Removed all unproven ICD-9 codes from the policy because

	standard policy format is to list only proven ICD-9 codes [477.0, 477.1, 477.2, 477.8, 477.9, 493.01, 493.11, 493.21, 493.91, 519.11, 691.0, 691.8, 692.9, V15.01].
4/1/2012	Policy updated per annual review, approved by National Pharmacy and Therapeutics Committee on 2/21/2012. Added chronic urticaria to list of unproven uses. Updated Clinical Evidence. Policy 2011D0033D archived.
9/1/2012	Added list of applicable ICD-10 codes (preview draft) in preparation for the transition from ICD-9 to ICD-10 medical coding on 10/01/14.
4/1/2013	Policy updated per annual review, approved by National Pharmacy and Therapeutics Committee on 2/19/2013. Added medical necessity criteria. Updated Clinical Evidence. Policy 2012D0033E archived.
7/1/2013	Policy revised to include proven indication for chronic urticaria. Updated Benefits Consideration, Clinical Evidence, U.S. FDA, and References. Approved by the National Pharmacy and Therapeutics Committee on 5/21/2013. Policy 2013D0033F archived.
9/1/2014	Policy revised per annual review. Expanded IgE level requirement for asthma and clarified medical necessity criteria. Added new criteria for asthma in children age 6 < 12 years of age. Updated chronic urticaria requirement to include symptomatic despite H1 antihistamine treatment. Updated Clinical Evidence, U.S. FDA, and References. Added codes 708.0, 708.1 & 708.9. Approved by the National Pharmacy and Therapeutics Committee on 7/8/2014. Policy 2013D0033G archived.
8/1/2015	Annual review. Minor formatting revisions (removed 'refer to benefit considerations for specific state guidance') but no changes to clinical criteria in Coverage Rationale. Updated Benefits, Clinical Evidence and References. Approved by the National Pharmacy and Therapeutics Committee on 5/20/2015. Policy 2014D0033H archived.
10/1/2015	Updated policy with minor formatting changes. Updated Applicable Codes for ICD-10 transition. Policy 2015D0033I archived.
2/1/2016	Removed 708.9, 493.92 and J45.901. Added L50.0 & L50.1. Policy 2015D0033J archived.
5/2016	Annual review. Transitioned policy to new template. Added background. Removed age criteria. Updated coverage criteria for classification of uncontrolled asthma and combination controller therapy to align with GINA guidelines. Updated examples of ICS/LABA to preferred products. Minor change to coverage rationale to specify failure of maximally dosed (age-appropriate) combination ICS/LABA product. Added

	reauthorization/continuation of care criteria. Updated clinical evidence and CMS statement. Updated formatting and references.
3/2017	Updated policy template. Added authorization durations.
8/2018	Annual review. Minor revisions to clinical criteria to align with medical policy. Added Fasenra as a medication not to be used with Xolair in asthma section. Updated references.
12/2018	Updated background to align with medical policy. Revised criteria regarding combination therapy due to recent Dupixent approval for asthma.
7/2019	Revised coverage rationale to include oral corticosteroid dependent asthma to align with medical benefit policy. Updated references.
9/2020	Annual review. No changes to clinical criteria. Updated references. Added Additional Clinical Rules section.