

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2022 P 2238-3
Program	Prior Authorization/Medical Necessity
Medications	*Xolair® (omalizumab) *This program applies to the prefilled syringe for subcutaneous use formulation
P&T Approval Date	6/2021, 11/2021, 2/2022
Effective Date	5/1/2022; Oxford only: 5/1/2022

1. Background:

Xolair (omalizumab) is an anti-IgE antibody indicated for the treatment of moderate to severe asthma in adults and pediatric patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids. Xolair is also indicated for add-on maintenance treatment of nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids. Xolair is also indicated for the treatment of chronic idiopathic urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.

Limitations of Use:

- Xolair is not indicated for acute bronchospasm, status asthmaticus.
- Xolair is not indicated for other allergic conditions or other forms of urticaria.

2. Coverage Criteria:

A. Asthma

1. Initial Authorization

a. Xolair will be approved based on **one** of the following criteria:

(1) **All** of the following:

(a) Patient has been established on therapy with Xolair for moderate to severe persistent asthma under an active UnitedHealthcare prior authorization

-AND-

(b) Documentation of positive clinical response to Xolair therapy as demonstrated by at least **one** of the following:

- i. Reduction in the frequency of exacerbations
- ii. Decreased utilization of rescue medications
- iii. Increase in percent predicted FEV1 from pretreatment baseline
- iv. Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

-AND-

(c) Xolair is being used in combination with an ICS-containing controller medication
-AND-

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

- i. Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
- ii. Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasentra (benralizumab)]
- iii. Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

-AND-

(e) Prescribed by **one** of the following:

- i. Allergist
- ii. Immunologist
- iii. Pulmonologist

-OR-

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

(a) Diagnosis of moderate to severe asthma

-AND-

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

- i. 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)
- ii. Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months
- iii. Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)
- iv. 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])
- v. Patient is currently dependent on oral corticosteroids for the treatment of asthma

-AND-

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

- i. Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting a baseline (pre-omalizumab treatment) serum total IgE level greater than or equal to 30 IU/mL and less than or equal to 1300 IU/mL

-OR-

- ii. Patient is currently dependent on maintenance therapy with oral corticosteroids for the treatment of asthma

-AND-

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

-AND-

- (e) Xolair will be used in combination with **one** of the following:

- i. **One** high dose (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta₂ agonist (LABA) [e.g., Advair/AirDuo Resplick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

-OR-

- ii. Combination therapy including **both** of the following:
 - **One** high-dose (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]

-AND-

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

-AND-

- (f) Patient is not receiving Xolair in combination with **any** of the following:
 - i. Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
 - ii. Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasentra (benralizumab)]
 - iii. Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

-AND-

- (g) Prescribed by **one** of the following:
 - i. Allergist
 - ii. Immunologist
 - iii. Pulmonologist

Authorization will be issued for 12 months.

2. Reauthorization

a. **Xolair** will be approved based on **all** of the following criteria:

- (1) Documentation of positive clinical response to Xolair therapy as demonstrated by at least **one** of the following:
 - (a) Reduction in the frequency of exacerbations
 - (b) Decreased utilization of rescue medications
 - (c) Increase in percent predicted FEV1 from pretreatment baseline
 - (d) Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

-AND-

- (2) Xolair is being 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 (reslizumab), Fasentra (benralizumab)]
 - (c) Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

Authorization will be issued for 12 months.

B. Chronic Urticaria

1. Initial Authorization

a. **Xolair** will be approved based on **one** of the following criteria:

- (1) **All** of the following:

- (a) Patient has been established on therapy with Xolair for chronic urticaria under an active UnitedHealthcare prior authorization

-AND-

- (b) Documentation of positive clinical response to Xolair therapy (e.g., reduction in exacerbations, itch severity, hives)

-AND-

- (c) Patient is not receiving Xolair in combination with **any** of the following:
 - i. Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
 - ii. Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasentra (benralizumab)]
 - iii. Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

-AND-

- (d) Prescribed by **one** of the following:
- i. Allergist
 - ii. Dermatologist
 - iii. Immunologist

-OR-

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

- (a) Diagnosis of chronic urticaria

-AND-

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

- i. 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-

- ii. 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^:

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

-AND-

- **One** of the following:

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

-AND-

- (c) Patient is not receiving Xolair in combination with **any** of the following:
- i. Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
 - ii. Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (reslizumab), Fasenra (benralizumab)]
 - iii. Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

-AND-

- (d) Prescribed by **one** of the following:
- i. Allergist
 - ii. Dermatologist
 - iii. Immunologist

Authorization will be issued for 12 months.

2. **Reauthorization**

- a. **Xolair** will be approved based on **all** of the following criteria:

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

Authorization will be issued for 12 months.

C. **Nasal Polyps**

1. **Initial Authorization**

- a. **Xolair** will be approved based on **one** of the following criteria:

- (1) **All** of the following:

- (a) Patient has been established on therapy with Xolair for nasal polyps under an active UnitedHealthcare prior authorization

-AND-

- (b) Documentation of positive clinical response to Xolair therapy

-AND-

- (c) Patient will continue to receive Xolair as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)

-AND-

- (d) Patient is not receiving Xolair in combination with **any** of the following:
- i. Anti-interleukin-5 therapy [e.g., Cinqair (reslizumab), Nucala (mepolizumab)]
 - ii. Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]
 - iii. Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

-AND-

(e) Prescribed by **one** of the following:

- i. Allergist
- ii. Immunologist
- iii. Otolaryngologist
- iv. Pulmonologist

-OR-

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

(a) Diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) defined by **all** of the following:

i. **Two or more** of the following symptoms for longer than 12 weeks duration:

- Nasal mucopurulent discharge
- Nasal obstruction, blockage, or congestion
- Facial pain, pressure, and/or fullness
- Reduction or loss of sense of smell

-AND-

ii. **One** of the following findings using nasal endoscopy and/or sinus computed tomography (CT):

- Purulent mucus or edema in the middle meatus or ethmoid regions
- Polyps in the nasal cavity or the middle meatus
- Radiographic imaging demonstrating mucosal thickening or partial or complete opacification of paranasal sinuses

-AND-

iii. **One** of the following:

- Presence of bilateral nasal polyposis
- Patient has previously required surgical removal of bilateral nasal polyps

-AND-

iv. **One** of the following:

- Patient has required prior sinus surgery
- Patient has required systemic corticosteroids (e.g., prednisone, methylprednisolone) for CRSwNP in the previous 2 years
- Patient has been unable to obtain symptom relief after trial of two of the following classes of agents:
 - Nasal saline irrigations
 - Intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)[^]
 - Antileukotriene agents (e.g., montelukast, zafirlukast, zileuton)

-AND-

- (b) Patient will receive Xolair as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone).

-AND-

- (c) Patient is not receiving Xolair in combination with **any** of the following:
- i. Anti-intrleukin-5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab)]
 - ii. Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]
 - iii. Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

-AND-

- (d) Prescribed by **one** of the following:
- i. Allergist
 - ii. Immunologist
 - iii. Otolaryngologist
 - iv. Pulmonologist

Authorization will be issued for 12 months.

2. **Reauthorization**

- a. **Xolair** will be approved based on **all** of the following criteria:

- (1) Documentation of positive clinical response to Xolair therapy

-AND-

- (2) Patient will continue to receive Xolair as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone).

-AND-

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

- (a) Anti-intrleukin-5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab)]
- (b) Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]
- (c) Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

Authorization will be issued for 12 months.

^Tried/failed alternative(s) are supported by FDA labeling.

3. Additional Clinical Programs:

- 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 limitations may be in place

4. References:

1. Xolair® [package insert]. South San Francisco, CA: Genentech USA, Inc. April 2021.
2. Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention - revised 20210. Accessed April 26, 2021.
3. Bernstein JA, Lang DM, Khan DA, et al. Joint Task Force on Practice Parameters (JTFPP), representing the American Academy of Allergy, Asthma & Immunology (AAAAI); the American College of Allergy, Asthma & Immunology (ACAAI); and the Joint Council of Allergy, Asthma & Immunology. Practice parameter: The diagnosis and management of acute and chronic urticaria: 2014 update. J Allerg Clin Immunol. 2014; 133(5):1270-1277.
4. Tsabouri S, Tseretopoulou X, Priftis K, et al. Omalizumab for the treatment of inadequately controlled allergic rhinitis: a systematic review and meta-analysis of randomized clinical trials. J Allergy Clin Immunol Pract. 2014; 2(3):332-40.
5. Gevaert P, Omachi TA, Corren J, et al. Efficacy and safety of omalizumab in nasal polyposis: 2 randomized phase 3 trials. J Allergy Clin Immunol. 2020; 146(3):595-605.
6. Hamilos DL, Holbrook EH. Chronic rhinosinusitis: Clinical manifestations, pathophysiology, and diagnosis. UpToDate. Waltham, MA: UpToDate Inc. <https://www.uptodate.com>. Accessed on December 21, 2021.

Program	Prior Authorization/Medical Necessity – Xolair (omalizumab)
Change Control	
6/2021	New program.
11/2021	Added coverage criteria for patients established on therapy under UnitedHealthcare medical benefit. Updated prescriber requirement for initial authorization and removed prescriber requirement for reauthorization.
2/2022	Added Tezspire to list of agents not to be used in combination with Xolair for all indications. Added a requirement that Xolair cannot be used in combination with a similar agent to the chronic urticaria criteria. Updated coverage criteria for CRSwNP. Updated references. Added footnote to support FDA labeled first line requirements.