UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2238-6
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, 9/2022, 7/2023, 10/2023
Effective Date	1/1/2024

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 maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)].

-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 (resilizumab), Fasenra (benralizumab)]
iii. Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

-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) 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

-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** maximally dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta$_2$ agonist (LABA) [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

-OR-

ii. Combination therapy including **both** of the following:

- **One** maximally dosed (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 (resilizumab), Fasenra (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 maintennce medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)].

-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)]
(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 (resilizumab), Fasenra (benralizumab)]

iii. Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

-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 (resilizumab), 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)

-AND-

(2) 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)]
(c) Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

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 (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
ii. Anti-interleukin-4 therapy [e.g., Dupixent (dupilumab)]
iii. Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

-OR-

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

(a) Diagnosis of nasal polyps

-AND-

(b) **Two or more** of the following symptoms for longer than 12 weeks duration:

i. Nasal mucopurulent discharge
ii. Nasal obstruction, blockage, or congestion
iii. Facial pain, pressure, and/or fullness
iv. Reduction or loss of sense of smell

-AND-

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

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

-AND-

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

i. Patient has been unable to obtain symptom relief after trial of **both** of the following:
- Intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)^

-AND-

- **One** other therapy used in the management of nasal polyps [i.e., nasal saline irrigations. antileukotriene agents (e.g., montelukast, zafirlukast, zileuton)]

-OR-

ii. Patient has required systemic corticosteroids (e.g., prednisone, methylprednisolone) for nasal polyps in the previous 2 years

-OR-

iii. Patient has required prior sinus surgery

-AND-

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

-AND-

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

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

-AND-

(g) 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-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
(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.; August 2023.
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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.
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6. Holguin F, Cardet JC, Chung KF, Diver S, Ferreira DS, Fitzpatrick A, Gaga M, Kellermeyer L, Khurana S, Knight S, McDonald VM, Morgan RL, Ortega VE, Rigau D, Subbarao P, Tonia T, Adcock IM, Bleecker ER, Brightling C, Boulet LP, Cabana M, Castro M, Chanez P, Custovic A, Djukanovic R, Frey U, Frankemölle B, Gibson P, Hamerlijnck D, Jarjour N, Konno S, Shen H, Vitary C, Bush A. Management of severe asthma: a European Respiratory Society/American Thoracic Society guideline. Eur Respir J. 2020 Jan 2;55(1):1900588. doi: 10.1183/13993003.00588-2019. PMID: 31558662
7. Rank MA, Chu DK, Bognanni A, et al. The Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis. J Allergy Clin Immunol. 2023;151(2):386-398. doi:10.1016/j.jaci.2022.10.026

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.

9/2022	Updated coverage criteria for nasal polyps to more closely align with label which does not specify laterality of nasal polyps and includes inadequate response to intranasal corticosteroids. Updated references.
7/2023	Updated coverage criteria for severe asthma to align with GINA & ERS/ATS guidelines. Added/updated examples of ICS-containing maintenance medications and removed coverage for patients currently dependent on maintenance therapy with oral corticosteroids. Updated references.
10/2023	Annual review. Removed prescriber requirement for initial authorizations for patients established on therapy under UHC medical prior authorization. Added requirement patient is not receiving Xolair with other similar treatments for chronic urticaria reauthorization.