UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1358-6
Program	Prior Authorization/Notification
Medications	*Xolair® (omalizumab) *This program applies to the prefilled syringe for subcutaneous use formulation
P&T Approval Date	6/2021, 11/2021, 11/2022, 7/2023, 10/2023, 4/2024
Effective Date	7/1/2024

1. Background:

Xolair (omalizumab) is an anti-IgE antibody indicated for:

- Moderate to severe persistent 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
- Chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment
- IgE-mediated food allergy in adult and pediatric patients aged 1 year and older for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. To be used in conjunction with food allergen avoidance
- Chronic spontaneous urticaria (CSU) 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 or status asthmaticus.
- Xolair is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.
- Xolair is not indicated for other forms of urticaria.

2. Coverage Criteria[a]:

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 medical benefit prior authorization

-AND-

(b) Documentation of positive clinical response to Xolair therapy

-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 therapy [e.g., Tezspire (tezepelumab)]

-OR-

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

(a) Diagnosis of moderate to severe persistent asthma

-AND-

(b) Patient has a positive skin test or in vitro reactivity to a perennial aeroallergen.

-AND-

(c) Symptoms inadequately controlled with inhaled corticosteroids [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 therapy [e.g., Tezspire (tezepelumab)]

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Xolair therapy

-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.

B. Chronic Urticaria

1. **Initial Authorization**

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

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

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

-AND-

(b) Documentation of positive clinical response to Xolair therapy

-OR-

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

(a) Diagnosis of chronic urticaria

-AND-

(b) Patient remains symptomatic despite H1 antihistamine treatment [e.g., cetirizine (Zyrtec), fexofenadine (Allegra), loratadine (Claritin)].

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Xolair** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Xolair therapy

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 medical benefit prior authorization

-AND-

(b) Documentation of positive clinical response to Xolair therapy

-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 nasal polyps

-AND-

(b) Patient has had inadequate response to nasal corticosteroids [e.g., fluticasone (Flonase), budesonide (Rhinocort), mometasone (Nasonex)]

-AND-

(c) Patient continues current maintenance therapy.

-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)]

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Xolair therapy

-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.

D. IgE-Medicated Food Allergy

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 IgE-mediated food allergy under an active UnitedHealthcare medical benefit prior authorization

-AND-

(b) Documentation of positive clinical response to Xolair therapy

-AND-

(c) Xolair will be used in conjunction with food allergen avoidance

-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 IgE-mediated food allergy

-AND-

(b) Patient is aged ≥ 1 year

-AND-

(c) Xolair will be used in conjunction with food allergen avoidance.

-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)]

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) Xolair will be used in conjunction with food allergen avoidance.

-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.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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.
- Medical Necessity may be in place.

4. References:

1. Xolair® [package insert]. South San Francisco, CA: Genentech USA, Inc. February 2024.

Program	Prior Authorization/Notification - Xolair (omalizumab)
Change Control	
6/2021	New program.
11/2021	Added coverage criteria for patients established on therapy under UnitedHealthcare medical benefit.
11/2022	Annual review with no changes to coverage criteria. Added state mandate footnote. Updated background and reference.
7/2023	Within the Asthma section, updated examples of maintenance therapy and added Tezspire to list of agents that should not be used in combination with Xolair. Updated reference.
10/2023	Annual review. Updated list of agents that should not be used in combination with Xolair. Updated reference.
4/2024	Added criteria for new indication, IgE-mediated food allergy. Updated background and references.