BlueCross BlueShield Federal Employee Program

XOLAIR
(omalizumab)

Pre - PA Allowance

None

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following **AND** submission of medical records (e.g., chart notes, laboratory values) documenting the following:

1. Moderate or severe Asthma
    a. 6 years of age or older
    b. Positive skin prick test or RAST response to at least one common allergen
    c. Inadequate control of asthma symptoms after a minimum of 3 months of compliant use with greater than or equal to 50% adherence with **ONE** of the following within the past 6 months:
        i. Inhaled corticosteroids & long acting $beta_2$ agonist
        ii. Inhaled corticosteroids & long acting muscarinic antagonist
    d. Baseline serum IgE level ≥ 30 IU/mL
    e. **NO** dual therapy with another monoclonal antibody for the treatment of asthma or COPD (see Appendix 2)

2. Chronic rhinosinusitis with nasal polyps (CRSwNP)
    a. 18 years of age or older
    b. Inadequate response, intolerance, or contraindication to a 3-month trial of **TWO** nasal corticosteroid sprays (i.e., mometasone, fluticasone, budesonide, or triamcinolone)
    c. Baseline serum IgE level ≥ 30 IU/mL
    d. Used as add-on maintenance treatment
    e. **NO** dual therapy with another monoclonal antibody for the treatment of CRSwNP (see Appendix 3)

3. IgE-mediated food allergy
    a. 1 year of age or older
    b. Used for the reduction of allergic reactions that may occur with accidental exposure to one or more foods
    c. Patient is allergic to peanut **AND** at least two other foods (e.g., milk, egg, wheat, cashew, hazelnut, or walnut) with positive food specific IgE ≥ 6 kUA/L for each
    d. Baseline serum IgE level ≥ 30 IU/mL
    e. Used in conjunction with food allergen avoidance
    f. **NOT** for emergency treatment of allergic reactions, including

anaphylaxis

4. Chronic spontaneous urticaria (CSU)
    a. 12 years of age or older
    b. Symptomatic after at least **TWO** previous trials of H1-antihistamines
    c. Baseline urticaria activity score (UAS) (e.g., *https://www.mdcalc.com/urticaria-activity-score-uas*)
    d. **NO** dual therapy with another monoclonal antibody for the treatment of CSU (see Appendix 4)

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following **AND** submission of medical records (e.g., chart notes, laboratory values) documenting the following:

1. Asthma
    a. 6 years of age or older
    b. Decreased exacerbations **OR** improvement in symptoms
    c. Decreased utilization of rescue medications
    d. **NO** dual therapy with another monoclonal antibody for the treatment of asthma or COPD (see Appendix 2)
    e. **NO** interruption in therapy 1 year or greater **OR** interruption lasting 1 year or more requires re-testing with a serum IgE level ≥ 30 IU/mL

2. Chronic rhinosinusitis with nasal polyps (CRSwNP)
    a. 18 years of age or older
    b. **NO** interruption in therapy 1 year or greater **OR** interruption lasting 1 year or more requires re-testing with a serum IgE level ≥ 30 IU/mL
    c. Used as add-on maintenance treatment
    d. Improvement in sino-nasal symptoms
    e. **NO** dual therapy with another monoclonal antibody for the treatment of CRSwNP (see Appendix 3)

3. IgE-mediated food allergy

a. 1 year of age or older
b. Used for the reduction of allergic reactions that may occur with accidental exposure to one or more foods
c. **NO** interruption in therapy 1 year or greater **OR** interruption lasting 1 year or more requires re-testing with a serum IgE level ≥ 30 IU/mL
d. Used in conjunction with food allergy avoidance
e. **NOT** for emergency treatment of allergic reactions, including anaphylaxis

4. Chronic spontaneous urticaria (CSU)
    a. 12 years of age or older
    b. Decrease in urticaria activity score (UAS), such as improvement in pruritic wheals, hives, and itching (e.g., *https://www.mdcalc.com/urticaria-activity-score-uas*)
    c. **NO** dual therapy with another monoclonal antibody for the treatment of CSU (see Appendix 4)

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Prior – Approval *Renewal* Limits

Same as above

Appendix 1 – Xolair Dosing

Table 1. Subcutaneous XOLAIR Doses Every 2 or 4 Weeks* for Patients 12 Years of Age and Older with Asthma

Pretreatment Serum IgE (IU/mL)	Dosing Freq.	Body Weight			
		30–60 kg	>60–70 kg	>70–90 kg	>90–150 kg
		Dose (mg)			
≥30–100	Every 4 weeks	150	150	150	300
>100–200		300	300	300	225
>200–300		300	225	225	300
>300–400	Every 2 weeks	225	225	300	Insufficient Data to Recommend a Dose
>400–500		300	300	375	
>500–600		300	375	Insufficient Data to Recommend a Dose	
>600–700		375	Insufficient Data to Recommend a Dose		

*Dosing frequency:

- ■ Subcutaneous doses to be administered every 4 weeks
- □ Subcutaneous doses to be administered every 2 weeks

Table 2. Subcutaneous XOLAIR Doses Every 2 or 4 Weeks* for Pediatric Patients with Asthma Who Begin XOLAIR Between the Ages of 6 to <12 Years

Pre-treatment Serum IgE (IU/mL)	Dosing Freq.	Body Weight									
		20-25 kg	>25-30 kg	>30-40 kg	>40-50 kg	>50-60 kg	>60-70 kg	>70-80 kg	>80-90 kg	>90-125 kg	>125-150 kg
		Dose (mg)									
30-100	Every 4 weeks	75	75	75	150	150	150	150	150	300	300
>100-200		150	150	150	300	300	300	300	300	225	300
>200-300		150	150	225	300	300	225	225	225	300	375
>300-400		225	225	300	225	225	225	300	300	Insufficient Data to Recommend a Dose	
>400-500		225	300	225	225	300	300	375	375		
>500-600		300	300	225	300	300	375	Insufficient Data to Recommend a Dose			
>600-700		300	225	225	300	375	Insufficient Data to Recommend a Dose				
>700-800	Every 2 weeks	225	225	300	375	Insufficient Data to Recommend a Dose					
>800-900		225	225	300	375						
>900-1000		225	300	375	Insufficient Data to Recommend a Dose						
>1000-1100		225	300	375							
>1100-1200		300	300	Insufficient Data to Recommend a Dose							
>1200-1300		300	375	Insufficient Data to Recommend a Dose							

*Dosing frequency:

- ■ Subcutaneous doses to be administered every 4 weeks
- □ Subcutaneous doses to be administered every 2 weeks

XOLAIR (omalizumab)

Table 3. Subcutaneous XOLAIR Doses Every 2 or 4 Weeks* for Adult Patients with CRSwNP

Pretreatment Serum IgE (IU/mL)	Dosing Freq.	Body Weight							
		>30-40 kg	>40-50 kg	>50-60 kg	>60-70 kg	>70-80 kg	>80-90 kg	>90-125 kg	> 125-150 kg
		Dose (mg)							
30 - 100	Every 4 Weeks	75	150	150	150	150	150	300	300
>100 - 200		150	300	300	300	300	300	450	600
>200 - 300		225	300	300	450	450	450	600	375
>300 - 400		300	450	450	450	600	600	450	525
>400 - 500		450	450	600	600	375	375	525	600
>500 - 600		450	600	600	375	450	450	600	
>600 - 700		450	600	375	450	450	525		
>700 - 800	Every 2 Weeks	300	375	450	450	525	600		
>800 - 900		300	375	450	525	600			
>900 - 1000		375	450	525	600				
>1000 - 1100		375	450	600					
>1100 - 1200		450	525	600					
>1200 - 1300		450	525						
>1300 - 1500		525	600						

Insufficient Data to Recommend a Dose

*Dosing frequency:

- Subcutaneous doses to be administered every 4 weeks
- Subcutaneous doses to be administered every 2 weeks

Table 4. Subcutaneous XOLAIR Doses Every 2 or 4 Weeks* for Adult and Pediatric Patients 1 Year of Age and Older with IgE-Mediated Food Allergy

Pretreatment Serum IgE (IU/mL)	Dosing Freq.	Body Weight (kg)												
		≥10-12	>12-15	>15-20	>20-25	>25-30	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90 - 125	>125 - 150
		Dose (mg)												
≥30 - 100	Every 4 Weeks	75	75	75	75	75	75	150	150	150	150	150	300	300
>100 - 200		75	75	75	150	150	150	300	300	300	300	300	450	600
>200 - 300		75	75	150	150	150	225	300	300	450	450	450	600	375
>300 - 400		150	150	150	225	225	300	450	450	450	600	600	450	525
>400 - 500		150	150	225	225	300	450	450	600	600	375	375	525	600
>500 - 600		150	150	225	300	300	450	600	600	375	450	450	600	
>600 - 700		150	150	225	300	225	450	600	375	450	450	525		
>700 - 800	Every 2 Weeks	150	150	150	225	225	300	375	450	450	525	600		
>800 - 900		150	150	150	225	225	300	375	450	525	600			
>900 - 1000		150	150	225	225	300	375	450	525	600				
>1000 - 1100		150	150	225	225	300	375	450	600					
>1100 - 1200		150	150	225	300	300	450	525	600					
>1200 - 1300		150	225	225	300	375	450	525						
>1300 - 1500		150	225	300	300	375	525	600						
>1500 - 1850			225	300	375	450	600							

Insufficient data to Recommend a Dose

*Dosing frequency:

- ☐ Subcutaneous doses to be administered every 4 weeks
- ☐ Subcutaneous doses to be administered every 2 weeks

Appendix 2 - List of Monoclonal Antibodies for Asthma or COPD

Generic Name	Brand Name
benralizumab	Fasenra
dupilumab	Dupixent
mepolizumab	Nucala
omalizumab	Xolair
reslizumab	Cinqair
tezepelumab-ekko	Tezspire

Appendix 3 - List of Monoclonal Antibodies for CRSwNP

Generic Name	Brand Name
dupilumab	Dupixent
mepolizumab	Nucala
omalizumab	Xolair

Appendix 4 - List of Monoclonal Antibodies for CSU

Generic Name	Brand Name

XOLAIR (omalizumab)

dupilumab	Dupixent
omalizumab	Xolair