

AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Xolair[®] (omalizumab) (self-administered) (Pharmacy)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight (if applicable): _____ Date weight obtained: _____

Quantity Limits: 1 syringe/auto-injector/vial per 28 days

- 75 mg/0.5 mL auto-injector
- 75 mg/0.5 mL prefilled syringe
- 150 mg/1 mL auto-injector
- 150 mg/1 mL prefilled syringe
- 150 mg/1.2 mL powder vial
- 300 mg/2 mL auto-injector
- 300 mg/2 mL prefilled syringe

*The Health Plan considers the use of concomitant therapy with Cinqair[®], Dupixent[®], Fasentra[®], Nucala[®], Tezspire[™] and Xolair[®] to be experimental and investigational. Safety and efficacy of these combinations have **NOT** been established and will **NOT** be permitted. In the event a member has an active Cinqair[®], Dupixent[®], Fasentra[®], Nucala[®] or Tezspire[™] authorization on file, all subsequent requests for Xolair[®] will **NOT** be approved.

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- DIAGNOSIS: Moderate to Severe Persistent Asthma** – with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms are inadequately controlled with inhaled corticosteroids.

Initial Authorization: 12 months

Recommended Dosage: Maximum dosages will be based on a member weight of 150 kg.

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	4 weeks	300	300	300	225
>200–300	weeks	300	225	225	300
>300–400	Every 2 weeks	225	225	300	
>400–500	2 weeks	300	300	375	
>500–600	weeks	300	375	Insufficient Data to Recommend a Dose	
>600–700		375	Insufficient Data to Recommend a Dose		

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		
>400-500		225	300	225	225	300	300	375	375		
>500-600	Every 2 weeks	300	300	225	300	300	375				
>600-700		300	225	225	300	375					
>700-800		225	225	300	375						
>800-900		225	225	300	375						
>900-1000		225	300	375							
>1000-1100		225	300	375	Insufficient Data to Recommend a Dose						
>1100-1200		300	300								
>1200-1300	300	375									

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- Prescribed by or in consultation with an allergist, immunologist or pulmonologist
- Has the member been approved for Xolair[®] previously through AvMed Health Plans medical department?
 - Yes
 - No
- Member is currently being treated with **ONE** of the following unless there is a contraindication or intolerance to these medications and must be compliant on therapy **for at least 90 consecutive days** within a year of request (**verified by pharmacy paid claims**):
 - High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) **AND** an additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline)
 - One maximally dosed combination ICS/LABA product (e.g., Advair[®] (fluticasone propionate/salmeterol), Dulera[®] (mometasone/formoterol), Symbicort[®] (budesonide/formoterol))
- Member must meet **ONE** of the following:
 - Member is ≥ 6 and < 12 years of age with a pre-treatment IgE level of 30-1300
 - Member is ≥ 12 years of age with a pre-treatment IgE level of 30-700

IgE level: _____ **Test Date:** _____
- Member has experienced **ONE** of the following (check box that applies):
 - ONE (1)** or more exacerbations requiring additional medical treatment (e.g., oral corticosteroids, emergency department, urgent care visits or hospitalizations within the past 12 months)
 - Any prior intubation for an asthma exacerbation

Diagnosis: Moderate-to-Severe Persistent Asthma

Reauthorization: 12 months

- Member has experienced a sustained positive clinical response to Xolair[®] therapy as demonstrated by at least **ONE** of the following (**check all that apply**):
 - Increase in percent predicted Forced Expiratory Volume (FEV1) from baseline (pre-treatment)
 - Reduction in the dose of inhaled corticosteroids required to control asthma
 - Reduction in the use of oral corticosteroids to treat/prevent exacerbation
 - Reduction in asthma symptoms such as chest tightness, coughing, shortness of breath or nocturnal awakenings
- Member is currently being treated with **ONE** of the following unless there is a contraindication or intolerance to these medications (**verified by pharmacy paid claims**):
 - High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) **AND** an additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline)
 - One maximally dosed combination ICS/LABA product (e.g., Advair[®] (fluticasone propionate/salmeterol), Dulera[®] (mometasone/formoterol), Symbicort[®] (budesonide/formoterol))

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❑ DIAGNOSIS: Chronic Spontaneous Urticaria

Initial Authorization: 12 months

Recommended Dosage: 150 mg or 300 mg by subcutaneous injection every 4 weeks

- ❑ Prescribed by or in consultation with an allergist or pulmonologist
- ❑ Member is ≥ 12 years of age
- ❑ Member has had a confirmed diagnosis of chronic spontaneous urticaria for at least 6 weeks with or without angioedema
- ❑ Member has failed **ONE (1)** of the following H1 antihistamines at 4 times the initial dose for at least 4 weeks:

❑ levocetirizine 10 mg – 20 mg QD	❑ desloratadine 10 – 20 mg QD	❑ fexofenadine 120 mg – 240 mg BID
❑ cetirizine 20 mg – 40 mg QD	❑ loratadine 20 mg – 40 mg QD	

- ❑ Member has remained symptomatic despite treatment with **ALL** the following therapies (**verified by pharmacy paid claims**):
 - ❑ Hydroxyzine 10 mg – 25 mg taken daily
 - ❑ Leukotriene Antagonist for at least 4 weeks (e.g., montelukast, zafirlukast)
 - ❑ H2 antihistamine, for treatment of acute exacerbations, for at least 5 days (e.g., famotidine, cimetidine)

❑ Diagnosis: Chronic Spontaneous Urticaria

Reauthorization: 12 months

- ❑ Members disease status has been re-evaluated since the last authorization to confirm the members condition warrants continued treatment (**chart notes must be submitted for documentation**)
- ❑ Provider has submitted chart notes documenting the members symptoms have improved (e.g., a decrease in the number of hives, a decrease in the size of hives, and improvement of itching)
- ❑ Symptoms returned when the Xolair® dose was tapered or withheld beyond the next dosing interval (**chart notes must be submitted for documentation supporting tapering of dose and/or withholding of therapy beyond the next dosing interval to see if symptoms return**)

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❑ DIAGNOSIS: Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Initial Authorization: 12 months

Recommended Dosage:

Pretreatment Serum IgE (IU/mL)	Dosing Freq.	Bodyweight								
		>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	Insufficient Data to Recommend a Dose					
>1200 - 1300		450	525		Insufficient Data to Recommend a Dose					
>1300 - 1500		525	600	Insufficient Data to Recommend a Dose						

- ❑ Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist
- ❑ Pre-treatment IgE level of 30-1500: _____ Test Date: _____
- ❑ Member is 18 years of age or older
- ❑ Member has a **diagnosis of CRSwNP** confirmed by the American Academy of Otolaryngology- Head and Neck Surgery Clinical Practice Guideline (Update): Adult Sinusitis (AAO-HNSF 2015)/American Academy of Allergy Asthma & Immunology (AAAAI) with **ONE** of the following clinical procedures:
 - ❑ Anterior rhinoscopy
 - ❑ Nasal endoscopy
 - ❑ Computed tomography (CT)

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- ❑ Member has a documented diagnosis of chronic rhinosinusitis defined by at least 12 weeks of the following:
 - ❑ Mucosal inflammation **AND** at least **TWO** of the following:
 - ❑ Decreased sense of smell
 - ❑ Facial pressure, pain, fullness
 - ❑ Mucopurulent drainage
 - ❑ Nasal obstruction
- ❑ Member has tried and failed intranasal corticosteroids **for at least 30 consecutive days** within a year of request (**verified by pharmacy paid claims**)
- ❑ Member is requesting Xolair[®] (omalizumab) as add-on therapy to maintenance intranasal corticosteroids (**verified by pharmacy paid claims**)

❑ Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
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<u>Reauthorization: 12 months</u>
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- ❑ Member has experienced a positive clinical response to Xolair[®] therapy (e.g., reduced nasal polyp size, improved nasal congestion, reduced sinus opacification, decreased sino-nasal symptoms, improved sense of smell, reduction in use of oral corticosteroids)
- ❑ Member has been compliant on Xolair[®] therapy and continues to receive therapy with an intranasal corticosteroid (**verified by pharmacy paid claims**)

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❑ DIAGNOSIS: Immunoglobulin (Ig) E-Mediated Food Allergy

Initial Authorization: 12 months

Recommended Dosage:

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	Insufficient data to Recommend a Dose				
>1200 - 1300		150	225	225	300	375	450	525		Insufficient data to Recommend a Dose				
>1300 - 1500		150	225	300	300	375	525	600		Insufficient data to Recommend a Dose				
>1500 - 1850			225	300	375	450	600		Insufficient data to Recommend a Dose					

- ❑ Member is ≥ 1 year of age
- ❑ Prescribed by or in consultation with an allergist or immunologist
- ❑ Member has a baseline immunoglobulin (Ig)E level ≥ 30 IU/mL - **Note: “Baseline” is defined as prior to receiving any treatment with Xolair® or another monoclonal antibody therapy that may lower IgE levels (e.g., Dupixent® [dupilumab subcutaneous injection], Tezspire™ [tezepelumab-ekko subcutaneous injection]).**
- ❑ Member must meet **BOTH** of the following:
 - ❑ Member has a positive skin prick test response to one or more foods
 - ❑ Member has a positive in vitro test (i.e., a blood test) for IgE to one or more foods

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- Provider attests member has a history of an allergic reaction to a food that met **ALL** the following:
 - Member demonstrated signs and symptoms of a significant systemic allergic reaction (e.g., hives, swelling, wheezing, hypotension, and gastrointestinal symptoms)
 - Reaction occurred within a short period of time following a known ingestion of the food
 - Prescriber deemed this reaction significant enough to require a prescription for an epinephrine auto-injector (e.g., EpiPen, EpiPen Jr., Auvi-Q, and generic epinephrine auto-injectors)
- Member has been prescribed an epinephrine auto-injector
- Provider attests Xolair[®] will be used in conjunction with a food allergen-avoidant diet
- Medication will **NOT** be used in conjunction with Palforzia[®] or oral immunotherapy (OIT)

DIAGNOSIS: Immunoglobulin (Ig) E-Mediated Food Allergy

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- Member is compliant with Xolair[®] therapy
- Provider attests Xolair[®] will continue to be used in conjunction with a food allergen-avoidant diet
- Member has been prescribed an epinephrine auto-injector

Medication being provided by a Specialty Pharmacy – Proprium Rx

*****Use of samples to initiate therapy does not meet step-edit/ preauthorization criteria*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****