SENTARA HEALTH PLANS

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 1-800-750-9692**. 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 Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

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

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		300	300	225	300	300	375				
>600-700		300	225	225	300	375					
>700-800	Every 2 weeks	225	225	300	375						
>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								
>1200-1300		300	375								

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- ❑ Prescribed by or in consultation with an allergist or pulmonologist
- ❑ Has the member been approved for Xolair® previously through Sentara 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:
  - ❑ Medium to 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):
  - ❑ More than > 2 exacerbations requiring additional medical treatment (e.g., an increase in oral corticosteroid dose, 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; chart notes must be submitted)**:
  - ❑ 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:
  - ❑ Medium to 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 Idiopathic 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 idiopathic 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 Idiopathic 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						
>1300 - 1500		525	600						

- ❑ 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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- ❑ Documented diagnosis of chronic rhinosinusitis defined by at least 12 weeks of the following **(chart notes must be submitted)**:
  - ❑ Mucosal inflammation **AND** at least two of the following:
    - ❑ Decreased sense of smell
    - ❑ Facial pressure, pain, fullness
    - ❑ Mucopurulent drainage
    - ❑ Nasal obstruction
- ❑ Member is currently being treated with medications in at least **two** of the following categories 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 **(chart notes documenting contraindication(s) or intolerance must be attached; trials will be verified using pharmacy claims and/or submitted chart notes)**:
  - ❑ Nasal saline irrigation
  - ❑ Intranasal corticosteroids (e.g., fluticasone, budesonide, triamcinolone)
  - ❑ Leukotriene receptor antagonists (e.g., montelukast, zafirlukast, zileuton)
- ❑ Member is refractory, ineligible, or intolerant to **ONE** of the following:
  - ❑ Systemic corticosteroids
  - ❑ Sino-nasal surgery
- ❑ Member is requesting Xolair® (omalizumab) as add-on therapy to maintenance intranasal corticosteroids
- ❑ Member has had an unsuccessful 6-month trial of Dupixent® (dupilumab) **OR** Nucala® (mepolizumab) **(verified by pharmacy paid claims)**

❑ Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Reauthorization: 12 months.

- ❑ 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) **(please submit chart notes)**
- ❑ Member has decreased utilization of oral corticosteroids **(verified by pharmacy paid claims)**
- ❑ 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					
>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

- ❑ 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.