SENTARA HEALTH PLANS

MEDICAL 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 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Xolair® (omalizumab) **(J2357) (Medical)**

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:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

***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.**

- **Maximum Units (per dose and over time)**
  - Allergic Asthma: 90 billable units every 14 days
  - Nasal Polyps: 120 billable units every 14 days
  - All other indications: 60 billable units every 28 days

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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 Health Plans pharmacy 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)**

❑ DIAGNOSIS: 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	Insufficient data to Recommend a Dose				
>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							

- ❑ 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

- ❑ 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 (check applicable box(es) below):

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

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.*

***Approved by Pharmacy and Therapeutic Committee:** ~~3/31/2009; 3/21/2024;~~ **5/23/2024**
REVISED/UPDATED/REFORMATTED: ~~9/9/2011; 5/2/2012; 7/25/2012; 8/28/2012; 4/29/2014; 5/28/2014; 6/3/2014; 6/16/2014; 8/18/2014; 10/31/204; 4/3/2015; 5/22/2015;12/29/2015; 1/29/2016; 8/19/2016; 9/22/2016; 12/11/2016; 6/27/2017; 7/24/2017; 12/31/2018; 3/23/2019; 4/19/2019; 5/2/2019; 7/8/2019; 9/18/2019; 10/31/2019; 12/23/2021; 5/9/2022; 6/16/2022; 4/29/2024;~~ **6/6/2024**