SENTARA COMMUNITY PLAN
(MEDICAID)

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 1-844-305-2331**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct

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:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

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

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

IgE level: _____ **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

***Sentara considers the use of concomitant therapy with Cinqair®, Dupixent®, Fasenra®, Nucala®, and Tezspire™ 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. **(Trials will be verified using pharmacy claims and/or submitted chart notes.)**

Has the member been approved for Xolair® previously through Sentara pharmacy department?

❑ Yes ❑ No

❑ **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: 6 months

Recommended Dosage: Maximum dosages will be based on a member weight of 150 kg**. Check applicable dose below:**

❑ 150mg every 4 week
❑ 225mg every 2 weeks
❑ 300mg every 2 weeks
❑ 300mg every 4 weeks
❑ 375mg every 2 weeks

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	150	150	150	300
>100–200	4	300	300	300	225
>200–300	weeks	300	225	225	300
>300–400	Every	225	225	300	
>400–500	2	300	300	375	
>500–600	weeks	300	375	Insufficient Data	
>600–700		375		to Recommend a Dose	

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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							
>1000-1100		225	300	375							
>1100-1200		300	300								
>1200-1300		300	375								

Insufficient Data to Recommend a Dose

1. Is the member 6 years of age or older? **AND**
   ❑ Yes ❑ No
2. Does the member have a diagnosis of severe asthma*? **AND**
   ❑ Yes ❑ No
3. Does the member have a positive skin test or in vitro reactivity to a perennial aeroallergen? **AND**
   ❑ Yes ❑ No
4. Does the member weigh between 20 kg (44 lbs.) and 150 kg (330 lbs.)? **AND**
   ❑ Yes ❑ No
5. Does the member have serum IgE level, measured before the start of treatment, of either:
   - ≥ 30 IU/mL and ≤ 700 IU/mL in patients age ≥ 12 years **OR**
   - ≥ 30 IU/mL and ≤ 1300 IU/mL in patients aged 6 to < 12 years **AND**

   ❑ Yes ❑ No
6. Will coadministration with another monoclonal antibody be avoided (i.e. mepolizumab, reslizumab, benralizumab, dupilumab, tezepelumab-ekko)? **AND**
   ❑ Yes ❑ No
7. Will this be used for add-on maintenance treatment in members regularly receiving **both** (unless otherwise contraindicated) of the following:
   - Medium to high dose inhale corticosteroids; **AND**
   - An additional controller medication (i.e. long-acting beta agonist, leukotriene modifier)?

   ❑ Yes ❑ No

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8. Has the member had two or more exacerbations in the previous year requiring oral or injectable corticosteroid treatment (in addition to the regular maintenance therapy defined above) **OR** one exacerbation resulting in hospitalization? **AND**
   ❑ Yes ❑ No
9. Does the member have at least one of the following for assessment of clinical status:
   - Use of systemic corticosteroids
   - Use of inhaled corticosteroids
   - Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
   - Forced expiratory volume in 1 second (FEV_1)?

   ❑ Yes ❑ No

❑ DIAGNOSIS: Moderate to Severe Persistent Asthma

Reauthorization: 12 months.

1. Has the member been assessed for toxicity? **AND**
   ❑ Yes ❑ No
2. Does the member have improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
   - Use of systemic corticosteroids
   - Hospitalizations
   - ER visits.
   - Unscheduled visits to healthcare provider
   - Improvement from baseline in forced expiratory volume in 1 second (FEV_1)?

   ❑ Yes ❑ No

***Components of severity for classifying asthma as severe may include any of the following (not all inclusive):**

- Symptoms throughout the day
- Nighttime awakenings, often 7 times per week
- SABA use for symptom control occurs several times per day.
- Extremely limited normal activities
- Lung function (percent predicted $FEV_{1)} < 60\%$.
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma.

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❑ DIAGNOSIS: Chronic Idiopathic Urticaria

Initial Authorization: 6 months

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

1. Is the member 12 years of age or older? **AND**
   ❑ Yes ❑ No
2. Is the underlying cause of the patient's condition not considered to be any other allergic condition(s) or other form(s) of urticaria? **AND**
   ❑ Yes ❑ No
3. Is the member avoiding triggers (i.e. NSAIDS, etc.)? **AND**
   ❑ Yes ❑ No
4. Documented baseline score from an objective clinical evaluation tool, such as: urticaria activity score (UAS7), angioedema activity score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life (AE-QoL), urticaria control test (UCT), angioedema control test (AECT), or Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL)? **AND**
   ❑ Yes ❑ No
5. Has the member had an inadequate response to a one or more-month trial on previous therapy with scheduled dosing of a second-generation H1-antihistamine product? **AND**
   ❑ Yes ❑ No
6. Has the member had an inadequate response to a one or more-month trial on previous therapy with scheduled dosing of at least one of the following:
   - Up-dosing/dose advancement (up to 4-fold) of a second generation H1-antihistamine
   - Add-on therapy with a leukotriene antagonist (i.e. montelukast, zafirlukast, etc.)
   - Add-on therapy with another H1-antihistamine
   - Add-on therapy with an H2-antagonist (i.e. ranitidine, famotidine, etc.)

   ❑ Yes ❑ No

❑ DIAGNOSIS: Chronic Idiopathic Urticaria.

Reauthorization: 12 months.

1. Has the member been assessed for toxicity? **AND**
   ❑ Yes ❑ No
2. Does the member have a clinical improvement as documented in an objective clinical evaluation tool? (e.g., UAS7, AAS, DLQI, AE-QoL, UCT, AECT, CU-Q2oL, etc.)?
   ❑ Yes ❑ No

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❑ **DIAGNOSIS: Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)**
Initial Authorization: 6 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					
>1200 - 1300		450	525						
>1300 - 1500		525	600						

Insufficient Data to Recommend a Dose

1. Is the member 18 years of age or older? **AND**
   ❑ Yes ❑ No
2. Has the member failed on at least 8 weeks of intranasal corticosteroid therapy? **AND**
   ❑ Yes ❑ No
3. Does the member have at least 3 of the following indicators for biologic treatment (**note**: members with a history of sino-nasal surgery are only required to have at least 3 of the indicators):
   - Member has evidence of type 2 inflammation (i.e. tissue eosinophils ≥10/hpf, blood eosinophils ≥ 150 cells/µL, or total IgE ≥ 100 IU/mL)
   - Member has required ≥ 2 courses of systemic corticosteroids per year or >3 months of low dose corticosteroids, unless contraindicated.
   - Disease significantly impairs the patient's quality of life.
   - Patient has experienced significant loss of smell.
   - Patient has a comorbid diagnosis of asthma **AND**

   ❑ Yes ❑ No

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4. Member does not have any of the following:
   - Antrochoanal polyps
   - Nasal septal deviation that would occlude at least one nostril
   - Disease with lack of signs of type 2 inflammation
   - Cystic fibrosis
   - Mucoceles **AND**

   ❑ Yes ❑ No
5. Have other causes of nasal congestion/obstruction been ruled out (e.g., acute sinusitis, nasal infection or upper respiratory infection, rhinitis medicamentosa, tumors, infections, granulomatosis)? **AND**

   ❑ Yes ❑ No
6. Has the physician assessed baseline disease severity utilizing an objective measure/tool? **AND**

   ❑ Yes ❑ No
7. Will therapy be used in combination with intranasal corticosteroids unless unable to tolerate or contraindicated? **AND**

   ❑ Yes ❑ No

❑ DIAGNOSIS: Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Reauthorization: 12 months

1. Has the member been assessed for toxicity? **AND**

   ❑ Yes ❑ No
2. Does the member have disease response as indicated by improvement in signs and symptoms compared to baseline in one or more of the following: nasal/obstruction symptoms, improvement of sinus opacifications as assessed by CT-scans and/or an improvement on a disease activity scoring tool [e.g., nasal polyposis score (NPS), nasal congestion (NC) symptom severity score, sinonasal outcome test-22 (SNOT22), etc.]? **OR**

   ❑ Yes ❑ No
3. Did the member have improvement in at least one of the following response criteria:
   - Reduction in nasal polyp size
   - Reduction in need for systemic corticosteroids
   - Improvement in quality of life
   - Improvement in sense of smell
   - Reduction of impact of comorbidities?

   ❑ Yes ❑ No

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❑ **DIAGNOSIS: IgE-Mediated Food Allergy**
Initial Authorization: 6 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							

1. Is the member 1 year of age or older? **AND**
   ❑ Yes ❑ No
2. Is the prescribing physician an allergist or immunologist or has an allergist or immunologist been consulted? **AND**
   ❑ Yes ❑ No
3. Does the member have a diagnosed food allergy as confirmed by:
   - A positive skin prick test under a drop of allergen extract **OR**
   - A positive IgE screening to identified foods? **AND**

   ❑ Yes ❑ No

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4. Will the member continue to practice allergen avoidance?
   ❑ Yes ❑ No

❑ **DIAGNOSIS: IgE-Mediated Food Allergy**
Reauthorization: 12 months.

1. Has the member been assessed for toxicity? **AND**
   ❑ Yes ❑ No
2. Is the member experiencing a clinical response and improvement as attested by the prescriber?
   ❑ Yes ❑ No

Medication being provided by:

❒ **Location/site of drug administration:**_____

NPI or DEA # of administering location:_____

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;~~ **9/30/2024**