SENTARA COMMUNITY PLAN
(MEDICAID)

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:** _____

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:** _____

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 medical 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 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			

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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):**

- Asthma that remains uncontrolled despite optimized treatment with high-dose ICS-LABA
- Asthma that requires high-dose ICS-LABA to prevent it from being uncontrolled
- 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	Insufficient Data to Recommend a Dose				
>1200 - 1300		450	525						
>1300 - 1500		525	600						

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					
>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

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 Specialty Pharmacy - PropriumRx

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.*