

Statement of Medical Necessity for Xolair® (omalizumab) for Asthma

Fax form to 1-844-429-7761

For questions, call 1-844-462-0022

If the following information is not complete, correct, or legible, the PA process can be delayed. **Use one form per patient please.** Information contained in this form is Protected Health Information under HIPAA and must come directly from the physician.

MEMBER INFORMATION

Member Last Name: _____

Member First Name: _____

Medicaid ID Number: _____ Date of Birth: _____

PRESCRIBER INFORMATION

Prescriber Last Name: _____

Prescriber First Name: _____

Prescriber NPI Number: _____ Prescriber Specialty: _____

Prescriber Phone: _____ Prescriber Fax: _____

DRUG INFORMATION

Drug Name: Xolair Drug Strength: _____

Compliance with all of the specific criteria listed below is a condition for payment for this drug by Summit Community Care. All information must be provided; Summit Community Care may verify through further requested documentation. The patient's drug history will be reviewed prior to approval.

1. Detailed description of diagnosis as per AHRQ National Guidelines:

2. Date diagnosed: _____

3. List daily standard controller medication(s), including prescribed dose, for the treatment of this diagnosis. The patient's Medicaid drug profile will be reviewed to assist in verification of compliance. Physician must supply documentation of compliance to daily standard controller medication(s) if supplied by means other than Medicaid (samples, third party insurance, etc.). Minimum of 6 consecutive months of compliance on daily standard controller medication(s) is required.

Drug Name: _____ Drug Dose: _____

Drug Name: _____ Drug Dose: _____

4. Is a spacer for inhaled medications used?

Yes No

If **Yes**, specify brand or type of spacer prescribed: _____

5. Symptoms and Exacerbations listed below must have occurred while patient is compliant on daily standard controller medications.

List Frequency of Symptoms: _____ Date symptoms last occurred: _____

List Frequency of Exacerbations – Number: _____ Per: _____

Patient's Name: _____

DRUG INFORMATION (CONTINUED)

Date exacerbations last occurred: _____

List Frequency of Nocturnal Symptoms – Number: _____ Per: _____

Date nocturnal symptoms last occurred: _____

6. Describe patient's level of physical activity: _____

7. FEV1 or PEF: _____ % predicted; Date measured: _____

8. Does patient have food or peanut allergy? Yes No

If Yes, describe: _____

9. List the specific perennial aeroallergen results from skin test (e.g., prick/puncture test) or blood test (e.g., RAST): _____

10. Patient's weight: _____ kg;

‡Baseline IgE Level: _____ IU/mL

‡IgE levels are not applicable for PA renewal requests.

Xolair® Dose will be based on the Xolair Dosage and Administration Dosage Chart. The chart below is a combination of the 2-week and 4-week dosage schedules, which are provided in the Xolair package insert. For full prescribing information, please refer to the Xolair package insert.

Pre-treatment Serum IgE (IU/mL)	Dosing Frequency	Body weight (kg) for patients 6 to < 12 years of age									
		20–25	> 25–30	> 30–40	> 40–50	> 50–60	> 60–70	> 70–80	> 80–90	> 90–125	> 125–150
		Dose (mg)									
≥ 30–100	Administer 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	Insufficient Data to Recommend a Dose	
> 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	Administer 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									

Pre-treatment Serum IgE (IU/mL)	Dosing Frequency	Body weight (kg) for patients ≥ 12 years of age			
		30–60	> 60–70	> 70–90	> 90–150
		Dose (mg)			
≥ 30–100	Administer every 4 weeks	150	150	150	300
> 100–200		300	300	300	225
> 200–300		300	225	225	300
> 300–400	Administer every 2 weeks	225	225	300	Insufficient Data to Recommend a Dose
> 400–500		300	300	375	
> 500–600		300	375		
> 600–700		375			

Patient's Name: _____

DRUG INFORMATION (CONTINUED)

11. Where will the medication be shipped (patient or physician)? _____

** Please provide copies of medical documentation supporting the information above, including patient's asthma management program and compliance plan.

Prescriber Signature: _____ **Date:** _____

(Prescriber's original signature required; copied, stamped, or e-signature are not allowed.
By signature, the physician confirms the above information is accurate and verifiable by patient records.)