PriorityHealth

Medical prior authorization form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to: ☒ **Commercial (Traditional)** ☒ **Commercial (Individual/Optimized)**
☒ **Medicaid**

This request is: ☐ **Urgent** (life threatening) ☐ **Non-Urgent** (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

Xolair® (omalizumab)

Member

Last Name: _____ First Name: _____

ID #: _____ DOB: _____ Gender: _____

Primary Care Physician: _____

Requesting Physician: _____ Phys. Phone: _____ Phys. Fax: _____

Physician Address: _____

Physician NPI: _____ Contact Name: _____

Provider Signature: _____ Date: _____

Product and Billing Information

☐ New Request ☐ Continuation Request

Drug product: ☒ Xolair 150 mg injection

Dose:_____ **Dose Frequency**:_____

Start date: _____

Date of last dose: _____

Date of next dose: _____

Patient's weight: _____

Place of administration:
☐ Physician's office
☐ Outpatient infusion
Facility: _____ NPI:_____ Fax:_____
☐ Home infusion
Facility: _____ NPI:_____ Fax:_____

Billing:
☐ Physician to buy and bill
☐ Facility to buy and bill
☐ Specialty Pharmacy
Pharmacy:_____ NPI:_____ Fax:_____

ICD-10 Diagnosis code(s): _____

Precertification Requirements

Before this drug is covered, the patient must meet all of the following requirements:

1. **For a diagnosis of moderate to severe persistent asthma:**
   - Must be at least 6 years of age
   - Must have been compliant on all of the following therapies for at least 3 months:
     - High-dose inhaled corticosteroid (ICS)*

All fields must be complete and legible for review. Your office will receive a response via fax. No changes made since 07/2018
Last reviewed 09/2018

- Long-acting beta agonist (LABA)
- One additional asthma controller medication (e.g., leukotriene receptor antagonist, Spiriva Respimat)

- Compliant use of the above medications must not be effective as demonstrated by at least one of the following:
  - Oral or systemic steroid treatment or an increase in the current oral steroid maintenance dose
  - Hospitalization and/or ED visit
  - Increasing need for short-acting beta2-agonist
- Must have a positive skin test or in-vitro reactivity to a perennial aeroallergen **(lab results must be submitted)**
- Must be within the recommended dosing range based on current weight and baseline IgE level
- Must be using asthma inhalers properly (or provider has counseled the patient on proper inhaler technique)
- Must not currently use tobacco products
- Must not use Xolair in combination with other biologics (e.g., Fasenra, Cinqair, Nucala)

2. For a diagnosis of chronic urticaria:

- Must be age 12 or older
- Must first try two or more H1 antihistamines **-- or –**
- Must first try one H1 antihistamine and one or more of the following:
  a. H2 antihistamine,
  b. Oral corticosteroid
  c. Leukotriene modifier

For continuation when used for extrinsic asthma, patient must have met the following requirements:

1. Peak flow improvement by greater than 20%, or FEV1 improved by greater than or equal to 12%, or patient has experienced a reduction in symptoms (i.e. wheezing, shortness of breath, cough, chest tightness)
2. Decrease in the use of quick relief medications or corticosteroids (oral or inhaled)
3. Decrease in ER visits, hospitalizations, physician visits, or school/work absences due to acute asthma attacks
4. Must not currently use tobacco products
5. Must not use in combination with other biologics (e.g., Cinqair, Fasenra, or Xolair)

For continuation when used for chronic urticaria, patient must have met the following requirements:

1. Adherence to therapy and lack of adverse effects
2. Reduction in the symptom of urticaria documented by the prescriber (chart notes supporting symptom reduction must be submitted to Priority Health)

Additional Information

Allergic asthma: If criteria are met, authorization will be for 12 months.

Chronic urticaria: If criteria are met, initial authorization will be for 6 months. All subsequent authorizations will be for 12 months.

Review the *FDA-approved Dosing Guidelines for Xolair* below for coverage limitations. Dosing for chronic idiopathic urticaria is not based on IgE levels or body weight and will be limited to 150 mg or 300 mg once every 4 weeks

Note: Authorization for indications, dosing, or a route of administration not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the appropriateness of the drug, the dosing of the drug, or the route of administration to be used for the identified indication.

All fields must be complete and legible for review. Your office will receive a response via fax. No changes made since 07/2018
Last reviewed 09/2018

New request
Priority Health Precertification Documentation

A. What condition is this drug being requested for?

- ☐ chronic idiopathic urticaria (hives)
- ☐ moderate or severe persistent asthma
- ☐ Other – rationale for use: _____

Complete the following information for ALLERGIC ASTHMA:

A. Does the patient currently use tobacco products?

☐ Yes ☐ No

B. Will the patient be using Xolair in combination with another biologic (Fasenra, Cinqair, Nucala)?

☐ Yes ☐ No

C. Has the patient been compliant on a high-dose* ICS/LABA inhaler for at least 3 months?

☐ Yes ☐ No

D. Has the patient been compliant on one additional asthma controller medication for at least 3 months?

☐ Yes ☐ No

E. Please document which medications the patient has used:

Drug	Dose	Dates of Use

F. Is the patient using inhalers properly (or has proper inhaler technique been reviewed with the patient)?

☐ Yes ☐ No

G. Has compliant use of current maintenance therapy not been effective?

- ☐ Yes. *If yes, please select all that apply:*
  - ☐ Oral steroids (or an increase in current oral steroid maintenance dose) were required
  - ☐ ED visit and/or hospitalization
  - ☐ Increased need for rescue inhaler
- ☐ No

H. Did the patient have a positive skin test or in-vitro reactivity to a perennial aeroallergen?

- ☐ Yes ***(fax results)***
- ☐ No. Rationale for use: _____

I. What is the patient's IgE level prior to starting Xolair? _____ **IU/mL Date**: _____

Complete the following information for CHRONIC URTICARIA

A. Please document which medications the patient has used:

Drug	Dose	Dates of Use

All fields must be complete and legible for review. Your office will receive a response via fax. No changes made since 07/2018
Last reviewed 09/2018

PriorityHealth

Continuation request

A. What condition is this drug being requested for?

- ☐ moderate or severe persistent allergic asthma
- ☐ chronic idiopathic urticaria (hives)
- ☐ Other – the patient's condition is: _____

Complete the following information for patients with ALLERGIC ASTHMA:

A. Does the patient currently use tobacco products?

☐ Yes ☐ No

B. Will the patient be using Xolair in combination with another biologic (Fasenra, Cinqair, Nucala)?

☐ Yes ☐ No

C. Which of the following has been observed in the patient since starting Xolair?

- ☐ peak flow improved by greater than 20%
- ☐ FEV_1 improved by greater than or equal to 12%
- ☐ patient has experienced a reduction in symptoms (i.e. wheezing, shortness of breath, cough, chest tightness)
- ☐ None of the above – rationale for use: _____

D. Has there been a decrease in patient's use of quick relief and/or corticosteroid use (oral or inhaled)?

☐ Yes ☐ No – rationale for use: _____

E. Has there been a decrease in ER/hospital/ physician visits or school/work absences due to asthma attacks?

☐ Yes ☐ No – rationale for use: _____

Complete the following information for patients with CHRONIC URTICARIA:

F. Has the member been adherent to and tolerant of treatment with Xolair?

☐ Yes ☐ No – rationale for use: _____

G. Has there been a decrease in the symptom of chronic urticaria?

☐ Yes ☐ No – rationale for use: _____

H. Have chart notes supporting symptom reduction been submitted to Priority Health?

☐ Yes ☐ No – rationale for use: _____

FDA-approved Dosing Guidelines for Xolair

Source: Xolair [package insert]. South San Francisco, CA: Genentech, Inc.; 2010.

Dosing for patients 12 years of age and older

Pre-treatment Serum IgE (IU/mL)	Body Weight (kg)			
	30-60	>60-70	>70-90	>90-150
≥ 30-100	150 mg every 4 weeks	150 mg every 4 weeks	150 mg every 4 weeks	300 mg every 4 weeks
> 100-200	300 mg every 4 weeks	300 mg every 4 weeks	300 mg every 4 weeks	225 mg every 2 weeks
> 200-300	300 mg every 4 weeks	225 mg every 2 weeks	225 mg every 2 weeks	300 mg every 2 weeks
> 300-400	225 mg every 2 weeks	225 mg every 2 weeks	300 mg every 2 weeks	DO NOT DOSE
> 400-500	300 mg every 2 weeks	300 mg every 2 weeks	375 mg every 2 weeks	
> 500-600	300 mg every 2 weeks	375 mg every 2 weeks	DO NOT DOSE	
> 600-700	375 mg every 2 weeks	DO NOT DOSE		

All fields must be complete and legible for review. Your office will receive a response via fax. No changes made since 07/2018

Last reviewed 09/2018

Dosing for patients age 6 to < 12 years old

Pre-treatment Serum IgE (IU/mL)	Body Weight (kg)				
	20-25	**>25-30**	**>30-40**	**>40-50**	**>50-60**
30-100	75 mg every 4 weeks	75 mg every 4 weeks	75 mg every 4 weeks	150 mg every 4 weeks	150 mg every 4 weeks
> 100-200	150 mg every 4 weeks	150 mg every 4 weeks	150 mg every 4 weeks	300 mg every 4 weeks	300 mg every 4 weeks
> 200-300	150 mg every 4 weeks	150 mg every 4 weeks	225 mg every 4 weeks	300 mg every 4 weeks	300 mg every 4 weeks
> 300-400	225 mg every 4 weeks	225 mg every 4 weeks	300 mg every 4 weeks	225 mg every 2 weeks	225 mg every 2 weeks
> 400-500	225 mg every 4 weeks	300 mg every 4 weeks	225 mg every 2 weeks	225 mg every 2 weeks	300 mg every 2 weeks
> 500-600	300 mg every 4 weeks	300 mg every 4 weeks	225 mg every 2 weeks	300 mg every 2 weeks	300 mg every 2 weeks
> 600-700	300 mg every 4 weeks	225 mg every 2 weeks	225 mg every 2 weeks	300 mg every 2 weeks	375 mg every 2 weeks
> 700-800	225 mg every 2 weeks	225 mg every 2 weeks	300 mg every 2 weeks	375 mg every 2 weeks	
> 800-900	225 mg every 2 weeks	225 mg every 2 weeks	300 mg every 2 weeks	375 mg every 2 weeks	
> 900-1000	225 mg every 2 weeks	300 mg every 2 weeks	375 mg every 2 weeks		
> 1000-1100	225 mg every 2 weeks	300 mg every 2 weeks	375 mg every 2 weeks		
> 1100-1200	300 mg every 2 weeks	300 mg every 2 weeks		**DO NOT DOSE**	
> 1200-1300	300 mg every 2 weeks	375 mg every 2 weeks			

Pre-treatment Serum IgE (IU/mL)	Body Weight (kg)				
	>60-70	**>70-80**	**>80-90**	**>90-125**	**>125-150**
30-100	150 mg every 4 weeks	150 mg every 4 weeks	150 mg every 4 weeks	300 mg every 4 weeks	300 mg every 4 weeks
> 100-200	300 mg every 4 weeks	300 mg every 4 weeks	300 mg every 4 weeks	225 mg every 2 weeks	300 mg every 2 weeks
> 200-300	225 mg every 2 weeks	225 mg every 2 weeks	225 mg every 2 weeks	300 mg every 2 weeks	375 mg every 2 weeks
> 300-400	225 mg every 2 weeks	300 mg every 2 weeks	300 mg every 2 weeks		
> 400-500	300 mg every 2 weeks	375 mg every 2 weeks	375 mg every 2 weeks		
> 500-600	375 mg every 2 weeks				
> 600-700					
> 700-800					
> 800-900					
> 900-1000			**DO NOT DOSE**		
> 1000-1100					
> 1100-1200					
> 1200-1300					

All fields must be complete and legible for review. Your office will receive a response via fax. No changes made since 07/2018
Last reviewed 09/2018