PriorityHealth

Medicare Part B Step Therapy Form

Fax completed form to: 877 974-4411 toll free, or 616 942-8206

This form applies to: ☒ **Medicare Part B**

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 Provider: _____ Prov. Phone: _____ Prov. Fax: _____

Provider Address: _____

Provider NPI: _____ Contact Name: _____

Provider Signature: _____ Date: _____

Product and Billing Information

☐ New request ☐ Continuation request - **Original therapy start date**: _____

Drug product: ☐ Xolair vial

☐ Xolair prefilled syringe

Patient Dosing Information:

Date of last dose (if applicable): _____ **Total doses/cycles/duration requested:** _____

Date of next dose (if applicable) _____ **Height:** _____ **Weight:** _____ **BSA:** _____

Dose: _____ **Dose Frequency**: _____

Place of Administration:

☐ Patient self-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: _____NPI: _____ Fax:_____

ICD-10 Diagnosis Code(s): _____

HCPCS Code: _____

All fields must be complete and legible for review. Your office will receive a response via fax.

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No changes made since 01/2021
Last reviewed 01/2021

Precertification Requirements

NOTE: Step therapy (trial with the below listed drug(s)) is only applicable to members who are enrolled in a Medicare Advantage Prescription Drug (MAPD) plan.

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

1. Must be used for a medically accepted indication*
2. For asthma:
    - Must first try 1 high-dose ICS/LABA inhaler in combination with 1 other asthma controller drug (e.g., Spiriva)
    - Must provide patient's current weight and baseline IgE level
3. For chronic urticaria, must meet 1 of the following:
    - Must first try two H1 antihistamines OR
    - Must first try one H1 antihistamine and either H2 antihistamines, oral steroids, or leukotriene modifiers
4. For nasal polyps:
    - Must first try inhaled corticosteroids
    - Must provide patient's current weight and baseline IgE level

Additional Precertification Requirements and Resources

A. National and Local Coverage Determination/Article (NCD, LCD, and LCA) Criteria

Priority Health applies Medicare NCD, LCD, and LCA criteria for Part B drugs. The following apply to Xolair: **N/A**

B. Medically accepted indication*

If no NCD, LCD, or LCA criteria are available for the state in which the member is receiving the services, the medication will be reviewed for a medically accepted indication, as defined in the Medicare Benefit Policy Manual Chapter 15 § 50:

A medically accepted indication for a drug or biologic that is not a part of an anti-cancer regimen is a use that is:

- approved by the Food and Drug Administration. (That is, the Food and Drug Administration has approved the drug for the diagnosis or condition for which it is being prescribed.)
- — *or* — *supported* by certain references, taking into consideration the major drug compendia (e.g. American Hospital Formulary Service-Drug Information, Micromedex DrugDex, Lexi-Drugs), authoritative medical literature, and/or accepted standards of medical practice.

Precertification Documentation

A. What condition is this drug being requested for?

☐ Asthma, moderate to severe, with positive skin test or in vitro reactivity to a perennial aeroallergen

1. Has the patient tried 1 high-dose ICS/LABA with 1 other asthma controller drug (e.g., Spiriva)?

☐ Yes

☐ No. **Are you asking for an exception to this requirement?**

☐ Yes. ***Rationale for exception***: _____

☐ No

2. What is the patient's current weight? _____ (kg) Date: _____

3. What is the patient's baseline IgE level? _____ (IU/mL) Date: _____

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☐ Chronic idiopathic urticaria

1. **Has the patient tried two H1 antihistamines (e.g., diphenhydramine, cetirizine, hydroxyzine)?**
   - ☐ Yes
   - ☐ No
2. **Has the patient tried one H1 antihistamine AND either H2 antihistamines (e.g., famotidine, ranitidine), oral steroids, or leukotriene modifiers (e.g., montelukast)?**
   - ☐ Yes
   - ☐ No. **Are you asking for an exception to this requirement?**
     - ☐ Yes. ***Rationale for exception***: _____
     - ☐ No

☐ Nasal polyps, as an add-on maintenance treatment

1. **Has the patient inhaled corticosteroids?**
   - ☐ Yes
   - ☐ No. **Are you asking for an exception to this requirement?**
     - ☐ Yes. ***Rationale for exception***: _____
     - ☐ No
2. **What is the patient's current weight? _____ (kg) Date: _____**
3. **What is the patient's baseline IgE level? _____ (IU/mL) Date: _____**

☐ Other: _____

Rationale for Other use: _____

Additional information

Note: When criteria are met, coverage duration is up to 2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.

Priority Health Medicare Exception Request *(exceptions to the above criteria)*

Do you believe one or more of the prior authorization requirements should be waived? ☐ Yes ☐ No
If yes, you must provide a statement explaining the medical reason why the exception should be approved.

Would Xolair likely be the most effective option for this patient?
☐ No
☐ Yes, because: _____

_____

_____

If the patient is currently using Xolair, would changing the patient's current regimen likely result in adverse effects for the patient?
☐ No
☐ Yes, because: _____

_____

_____

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