Updated: 11/2018
PARP Approved: 11/2018

Prior Authorization Criteria

Xolair (omalizumab)

All requests for Xolair (omalizumab) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Coverage may be provided with a diagnosis of moderate to severe persistent asthma and the following criteria is met:

- The member is 6 years of age or older
- Must be prescribed by, or in consultation with, a pulmonologist, allergist or immunologist
- The member has a diagnosis of moderate to severe persistent asthma
- The member must have one of the following:
    - The member has a baseline $FEV_1 < 80\%$
    - Required systemic (oral or parenteral) corticosteroids to control asthma exacerbations ≥ 2 times in the past year
    - Required hospitalization due to an asthma exacerbation within the past year
    - Exacerbations return when the dose of inhaled/and or systemic corticosteroids are lowered
    - Symptoms occurring > 2 days a week
    - Nighttime awakenings occurring more than once a week
    - Some limitation with normal activity
    - Use of rescue medications (short-acting inhaled beta-2 agonists) > 2 days a week
- Documentation the member had at least a three month consecutive trial of combination therapy that included a medium- or high-dose inhaled corticosteroid PLUS another controller medication (e.g., long-acting beta-2 agonist, leukotriene receptor antagonist, theophylline) prior to initiating therapy with Xolair.
- The member has a positive skin test or in vitro reactivity (radioallergosorbent test [RAST]) to a perennial aeroallergen;
- The member weighs between 30 kg to 150 kg if the member is ≥12 years or the member weighs between 20 kg and 150 kg if the member is age 6 to <12 years
- Member has a serum total IgE level, measured before the start of treatment, of ≥30 IU/mL and ≤ 700 IU/mL in members age ≥12 years or ≥30 IU/mL and ≤1300 IU/mL in members age 6 to <12 years
- Documentation that adjunctive therapies (inhaled corticosteroids, long-acting beta-2 agonist, leukotriene receptor antagonist, theophylline) have been used within the past 2 months.
    - Adjunctive therapies must be verified by pharmacy claims
    - If pharmacy claims do not confirm fills within the previous 2 months, the request will be denied
        - If enrollment is less than 3 months, provider attestation that member is receiving adjunctive therapy is sufficient
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines.

- **Initial Duration of Approval:** 6 months

- **Reauthorization criteria**
    - Documentation the member had a positive clinical response or stabilization as demonstrated by one of the following:
        - An increase in the member's FEV_1
        - A decreased need for systemic corticosteroids
        - A decrease in the number of asthma related hospitalizations
        - A reduction in reported asthma-related symptoms
    - Documentation the prescribed dose and dosing frequency of Xolair remain appropriate for the current weight of the member
    - Adjunctive therapies (inhaled corticosteroids, long-acting beta-2 agonist, leukotriene receptor antagonist, theophylline) must be consistently filled per pharmacy claims history
        - If pharmacy claims do not confirm fills within the previous 2 months, the request will be denied
- **Reauthorization Duration of approval:** 12 months

Coverage may be provided with a diagnosis of chronic idiopathic urticaria and the following criteria is met:

- The member is at least 12 years of age
- Must be prescribed by, or in consultation with, an allergist, immunologist, or dermatologist
- Must have a documented history of urticaria for a period of at least 3 months
- Must have documented therapeutic failure despite adherence with a four-week trial of, or history of contraindication or intolerance to, a second-generation H1 antihistamine at the maximum tolerated dose
- Must have documented therapeutic failure despite adherence with a four-week trial of, or history of contraindication or intolerance to, at least one of the following medications in combination with a second-generation H1 antihistamine.
    - Leukotriene receptor antagonist (LTRA)
    - H2 antihistamine
    - First-generation H1 antihistamine
    - Addition of another second-generation H1 antihistamine
- Dosing does not exceed 300 mg administered subcutaneously every 4 weeks
- **Initial Duration of Approval:** 3 months
- **Reauthorization criteria for chronic idiopathic urticaria**
    - Documentation that demonstrates the member is tolerating and responding (e.g., documented improvement in condition) to Xolair.
    - The dose of Xolair must not exceed 300mg every 4 weeks.
- **Reauthorization Duration of approval:** 6 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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XOLAIR (omalizumab)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis (include ICD-10 code):_____

ASTHMA DIAGNOSIS

Does the patient have a confirmed diagnosis of moderate to severe persistent asthma? ☐ Yes ☐ No

Baseline FEV_1 _____ Date taken:

Has the member had any of the following:

- ☐ Baseline $FEV_1 < 80\%$
- ☐ Required systemic (oral or parenteral) corticosteroids to control asthma exacerbations ≥ 2 times in the past year
- ☐ Had an asthma related hospitalization
- ☐ Unable to lower member dose of high dose inhaled steroids or systemic corticosteroids

Does the member have a positive skin test or in vitro reactivity (RAST test) to a perennial aeroallergen? ☐ Yes ☐ No

Pretreatment serum IgE Level: **Test Date:**

Are the member's symptoms inadequately controlled despite adherence with at least a 3 month trial on combination therapy that includes a medium- or high-dose inhaled corticosteroid PLUS another controller medication (e.g., long-acting beta-2 agonist, leukotriene receptor antagonist)?

☐ Yes ☐ No *If yes, please list the drugs in previous therapy section below.*

Is Xolair being used as adjunctive therapy ☐ Yes ☐ No

***** Continued on next page *****

Gateway Health

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XOLAIR (omalizumab)
PRIOR AUTHORIZATION FORM (CONTINUED)– PAGE 2 of 2

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PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

MEDICAL HISTORY (Complete for ALL requests)

CHRONIC IDIOPATHIC URTICARIA DIAGNOSIS

Does the patient have a documented history of urticaria for a period of at least 3 months? ☐ Yes ☐ No

Was an evaluation conducted to rule out other causes of urticaria? ☐ Yes ☐ No

Does the patient have a documented failure, contraindication, or intolerance to at least a 4-week trial of a second-generation H_1 antihistamine at the maximum tolerated dose?
☐ Yes, *please list the drugs in previous therapy section below* ☐ No

Does the patient have a documented failure, contraindication, or intolerance to at least a 4-week trial of any of the following medications in combination with a second-generation H_1 antihistamine? ☐ Yes ☐ No
Please check all that apply and list the drug(s) in the adjunctive therapy section below.
☐ Leukotriene receptor antagonist (LTRA) ☐ H_2 antihistamine
☐ First-generation H_1 antihistamine ☐ Addition of another second-generation H_1 antihistamine

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

ASTHMA DIAGNOSIS

Has the patient tolerated and responded to treatment with Xolair? ☐ Yes ☐ No
Please describe response:_____

Has the member had any of the following:
☐ An increase in FEV_1 (Please provide current FEV_1 and date) _____
☐ A decrease in the need for systemic corticosteroids
☐ A decrease in the number of asthma related hospitalizations

Has the patient's weight changed requiring a dose adjustment? ☐ **Yes** ☐ **No**
Please provide the members current asthma regimen:
_____

CHRONIC IDIOPATHIC URTICARIA DIAGNOSIS

Has the patient tolerated and responded to treatment with Xolair? ☐ Yes ☐ No
Please describe response: _____

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date