Updated: 02/2021
DMMA Approved: 02/2021

Request for Prior Authorization for Xolair (omalizumab)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

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

Xolair (omalizumab) Prior Authorization Criteria:

For all requests for Xolair (omalizumab) all of the following criteria must be met:

- For non-preferred agents, the member has had a trial and failure of a preferred agent or submitted a clinical reason for not having a trial of a preferred agent
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines.

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

- The member is at least 6 years of age
- Must be prescribed by, or in consultation with, a pulmonologist, allergist or immunologist
- The member has a confirmed diagnosis of moderate to severe persistent asthma
- The member must have a baseline FEV1 < 80%
- The member must have one of the following:
    - 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
- Documentation the member had at least a three month consecutive trial of 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, 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
- Required medical information (baseline monitoring, ht, wt, formulary trials of previous medications, previous immunizations, caveats to the drug)
- 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
- **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 FEV1 from pretreatment baseline
    - A decreased need for systemic corticosteroids
    - A decrease in the number of asthma related hospitalizations
    - Decreased frequency of asthma exacerbations
    - Reduction in reported asthma-related symptoms, such as, but not limited to wheezing, shortness of breath, coughing, fatigue, sleep disturbance, or asthmatic symptoms upon awakening.
  - 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 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
- **Initial Duration of Approval:** 3 months
- **Reauthorization criteria**
  - Documentation that demonstrates the member is tolerating and responding (e.g., documented improvement in condition) to Xolair.
- **Reauthorization Duration of Approval:** 12 months

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Coverage may be provided with a diagnosis of nasal polyps and the following criteria is met and the following criteria is met:

- The member is at least 18 years of age
- The medication must be prescribed by or in association with an allergist, ear/nose/throat specialist, or immunologist
- Medication must be used for add-on maintenance therapy
- Must provide documentation showing the member has tried and failed (which will be verified via pharmacy claims if available) or had an intolerance or contraindication to ALL of the following:
    - 12 week trial of intranasal or oral corticosteroid
    - 1 week trial of nasal saline irrigations
    - 3 week course of antibiotics
- Member has relapsed from sinus surgery or has a contraindication to sinus surgery
- Member must have documentation of at least two of the following symptoms:
    - Nasal blockade/obstruction/congestion or nasal discharge (anterior/posterior nasal drip)
    - Facial pain/pressure
    - Reduction or loss of smell
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
    - Must provide documentation of improvement in any of the following symptoms:
        - Nasal blockade/obstruction/congestion or nasal discharge (anterior/posterior nasal drip)
        - Facial pain/pressure
        - Reduction or loss of smell
- **Reauthorization Duration of Approval:** 12 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.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

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XOLAIR (omalizumab)
PRIOR AUTHORIZATION FORM – PAGE 1 of 3

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6251 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:
Health Options 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:

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

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 ☐ Infusion Center ☐ 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

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PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 3

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MEMBER INFORMATION

Member Name:	DOB:
Health Options ID:	Member weight: _____pounds or _____kg

MEDICAL HISTORY (Complete for ALL requests)

NASAL POLYPS DIAGNOSIS

Does the member have documentation of any of the following symptoms?
☐ Nasal blockade, obstruction, congestion, or discharge (anterior/posterior nasal drip)
☐ Fascial pain/pressure
☐ Reduction or loss of smell

Does the member have documentation of trial and failure, intolerance, or contraindication to the following?
Please check all that apply and list the drug(s) in the previoust therapy section below.
☐ Sinus surgery
☐ 12 week trial of intranasal or oral corticosteroid
☐ 1 week trial of nasal saline irrigations
☐ 3 week course of antibiotics

Will Xolair be used as add-on maintenance therapy? ☐ Yes ☐ No
If yes, please list concurrent drug(s) in section below

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 current 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)

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PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 3 OF 3

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MEMBER INFORMATION

Member Name:	DOB:
Health Options ID:	Member weight: _____pounds or _____kg

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 exacerbations
☐ A decrease in the number of asthma related hospitalizations
☐ Reduction in reported asthma-related symptoms, such as, but not limited to wheezing, shortness of breath, coughing, fatigue, sleep disturbance, or asthmatic symptoms upon awakening.

CHRONIC IDIOPATHIC URTICARIA DIAGNOSIS

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

NASAL POLYPS DIAGNOSIS

Does the member have documentation of improvement in any of the following symptoms?
☐ Nasal blockade, obstruction, congestion, or discharge (anterior/posterior nasal drip)
☐ Fascial pain/pressure
☐ Reduction or loss of smell

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date