Member Name: _____ Member ID: _____ Member DOB: _____

Drug Name: _____ Strength: _____ Directions: _____

Physician Name: _____ Physician Phone #: _____ Specialty: _____

Physician Fax #: _____ Pharmacy Name: _____Pharmacy Phone: _____

# Horizon NJ Health

## *Omalizumab (Xolair) – Medical Necessity Request*

## **Complete page 1 and 2 for New/Initial requests**

1. What is the prescriber's specialty managing the medication?
   □ Allergy □ Pulmonology □ Dermatology □ Otolaryngologist/ENT □ Other: _____

2. Is the medication being administered in a healthcare setting by a healthcare provider? **Yes** or **No**
   a. **If No**:
   - Will the member have received at least 3 doses under the guidance of a healthcare provider with no hypersensitivity reactions before self-administration? **Yes** or **No**

## Diagnosis

□ **Urticaria**

A. Is the urticaria chronic (continuously or intermittently present for at least 6 weeks)? **Yes** or **No**

B. Is the urticaria idiopathic (of unknown cause)? **Yes** or **No**

C. Will completion and documentation of baseline evaluation of disease activity, quality-of-life instruments, and/or disease control monitoring tools be used to determine if member is achieving efficacy for continuation of therapy [i.e., Urticaria Activity Score (UAS7), Chronic Urticaria Quality-of-Life Questionnaire (CU-Q2oL), angioedema activity score (AAS), Angioedema Quality of Life (AE-QoL) score, and/or Urticaria Control Test (UCT)]? **Yes or No**

D. Is the member symptomatic or refractory after trial of a second-generation $H_1$- antihistamine? **Yes or No**
   a. Please provide the drug name that was tried: _____

□ **Allergic Asthma, Allergies, Asthma, and/or dual diagnosis of Asthma and Allergies**

A. Does the member have asthma? **Yes or No**
   a. **If Yes:**
      - Is the asthma allergic? **Yes or No**
      - Does the member have allergies: **Yes or No**

B. Please indicate the severity of the asthma: □ mild □ moderate □ severe

C. Is the Asthma persistent? **Yes or No**

D. Has the member received Xolair within the past year? **Yes or No**

E. What is the member's current weight? _____lbs Date Taken: _____
   _____ kg

F. What was the member's pre-treatment IgE level (IU/ml)? _____ Date Taken: _____

G. Has the member had a positive skin test or in vitro reactivity to a perennial aeroallergen (e.g. prick/puncture test, intracutaneous test, RAST)? **Yes or No**

H. Does the member currently smoke? **Yes or No**

I. Has the member experienced ≥2 exacerbations requiring oral corticosteroids within the past 12 months? **Yes or No**

***Continue to Page 2***

**Physician office's signature*_____ Print Name_____**
***Form must be completed and signed by physician or licensed representative from the physician's office**

Member Name: _____ Member ID: _____ Member DOB: _____

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Physician Name: _____ Physician Phone #: _____ Specialty: _____

Physician Fax #: _____ Pharmacy Name: _____Pharmacy Phone: _____

J. Has the member had serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within past 12 months? **Yes or No**

K. Does the member have a baseline Forced Expiratory Volume (FEV1) that is less than 80% of the predicted after bronchodilator use? **Yes or No**

L. Does the member's controlled asthma get worse when the dose of inhaled or systemic corticosteroids are tapered? **Yes or No**

M. Will the member be using any other biologic drug [e.g., omalizumab (Xolair), Reslizumab (Cinqair), Mepolizumab (Nucala), Benralizumab (Fasenra)] with Xolair? **Yes or No**
   a. **If Yes,** please provide the drug name and diagnosis it is being used to treat _____

N. Has member received a medium-high dose inhaled corticosteroid? **Yes** or **No**
   - **If Yes**: Please provide drug name and strength _____
     Directions_____
     Dates filled within the past several months_____
   - **If No**, Can member try a medium-high dose inhaled corticosteroid instead? **Yes** or **No**
     - **If Yes**: Please notify the pharmacy of the change
     - **If No**: Please provide clinical reason_____
       - Can the member try a low-dose inhaled corticosteroid instead? **Yes or No**
         - **If Yes:** Please notify the pharmacy of the change
         - **If No:** Please provide clinical reason why member can not use any inhaled corticosteroids _____

O. Is the member currently being treated with an additional controller medication (e.g., Long-acting beta-2 agonist (LABA), Leukotriene receptor antagonist (LTRA), Long-acting muscarinic antagonist (LAMA), etc.)? **Yes** or **No**
   - **If Yes**, Please provide drug name_____
     - Dates filled within the past several months _____
   - **If No,** Can member try a controller medication instead? **Yes** or **No**
     - **If Yes**: Please notify the pharmacy of the change
     - **If No**, please provide clinical reason_____

□ **Nasal Polyps**

A. Has the member received Xolair within the past year? **Yes or No**

B. What is the member's current weight? _____lbs Date Taken: _____
   _____ kg

C. What was the member's pre-treatment IgE level (IU/ml)? _____ Date Taken: _____

D. Will the member be using Omalizumab (Xolair) as add-on to maintenance treatment? **Yes or No**

E. Does the member have ongoing symptoms of nasal congestion, blockage, or obstruction with moderate to severe symptom severity and has another symptom such as loss of smell, rhinorrhea (anterior/posterior)? **Yes or No**

***Continue to Page 3***

**Physician office's signature*_____ Print Name_____**
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Member Name: _____ Member ID: _____ Member DOB: _____

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Physician Name: _____ Physician Phone #: _____ Specialty: _____

Physician Fax #: _____ Pharmacy Name: _____Pharmacy Phone: _____

F. Has the member tried nasal corticosteroids?
   □ Yes:
      - Did the member have an inadequate response or intolerance to nasal corticosteroid? **Yes or No**
   □ No: Can the member try nasal corticosteroids instead?
      □ Yes: Please notify the pharmacy of the change and return the form.
      □ No: Please provide the clinical reason why a nasal corticosteroids cannot be tried.

G. Will the member be using any other biologic drug [e.g., Mepolizumab (Nucala), Dupilumab (Dupixent)] with Xolair? **Yes or No**
   a. **If Yes,** please provide the drug name and diagnosis it is being used to treat:_____
      _____

□ **Other diagnosis:**_____

**Physician office's signature*_____ Print Name_____**
***Form must be completed and signed by physician or licensed representative from the physician's office**

Member Name: _____ Member ID: _____ Member DOB: _____

Drug Name: _____ Strength: _____ Directions: _____

Physician Name: _____ Physician Phone #: _____ Specialty: _____

Physician Fax #: _____ Pharmacy Name: _____Pharmacy Phone: _____

****Complete page 3 only for Subsequent/Renewal requests****

1. Is the medication being administered in a healthcare setting by a healthcare provider? **Yes or No**
   a. If No:
      - Has the member received at least 3 doses under guidance of a healthcare provider with no hypersensitivity reactions before self-administration? **Yes** or **No**

2. What is the diagnosis? **(please CHECK the member's diagnosis AND then answer the additional questions)**

| Diagnosis | Additional Questions |
|---|---|
| □ Chronic Idiopathic Urticaria | Does the member have documented efficacy of omalizumab of improved symptoms compared to baseline based on disease activity, quality-of-life instruments, and/or disease control monitoring tools used to determine if member is achieving efficacy for continuation of therapy [i.e., Urticaria Activity Score (UAS7), Chronic Urticaria Quality-of-Life Questionnaire (CU-Q2oL), angioedema activity score (AAS), Angioedema Quality of Life (AE-QoL) score, and/or Urticaria Control Test (UCT)]?<br>□ **Yes** □ **No** |
| □ Allergic Asthma<br>□ Allergies and Asthma<br>□ Asthma<br>□ Allergies | 1. What is the member's current weight?<br>_____lbs Date Taken: _____<br>_____ kg<br>2. What was the member's pre-treatment IgE level (IU/ml)? _____<br>3. How has the member responded to therapy compared to baseline? (Please select <u>all</u> that apply)<br>□ Reduction in number of hospitalizations, need for mechanical ventilation, emergency room visits, or unscheduled visits to healthcare provider due to asthma exacerbations<br>□ Reduction in the dose of inhaled/oral corticosteroids required to control the patient's asthma<br>□ Reduction in use of rescue medication<br>□ Increase in pulmonary function tests (e.g., Forced Expiratory Volume from baseline)<br>□ Decrease in symptoms and asthma exacerbations<br>□ None of the above<br>- **If None of the above**, please provide any additional clinical information pertaining to the request.<br>_____<br>4. Does the member currently smoke? **Yes or No**<br>5. Will the member be using any other biologic drug (e.g., Nucala, Cinqair, Fasenra, Dupixent, etc.) with Xolair? **Yes or No**<br>- **If yes,** please provide drug name and diagnosis/diagnoses it is being used to treat<br>_____ |

**Physician office's signature*_____ Print Name_____**
***Form must be completed and signed by physician or licensed representative from the physician's office**

Member Name: _____ Member ID: _____ Member DOB: _____

Drug Name: _____ Strength: _____ Directions: _____

Physician Name: _____ Physician Phone #: _____ Specialty: _____

Physician Fax #: _____ Pharmacy Name: _____Pharmacy Phone: _____

| | |
|---|---|
| □ Nasal Polyps | 1. How has the member responded to therapy compared to baseline? (Please select <u>all</u> that apply)<br>□ Improvement from baseline in nasal blockage/congestion (e.g., decrease in nasal congestion score)<br>□ Improvement in endoscopic nasal polyps score<br>□ Improvement in one or more of the following symptoms from baseline: nasal discharge (anterior/posterior nasal drip, runny nose) and/or reduction or loss of smell<br>□ Decrease in nasal corticosteroid use<br>□ None of the above<br>**- If None of the above**, please provide any additional clinical information pertaining to the request.<br>_____<br>2. Will the member be using Omalizumab (Xolair) as add-on to maintenance treatment? **Yes or No**<br>3. Will the member be using any other biologic drug [[e.g., Mepolizumab (Nucala), Dupilumab (Dupixent)] with Xolair? **Yes or No**<br>- **If Yes,** please provide the drug name and diagnosis it is being used to treat<br>_____ |
| □ Other diagnosis<br>_____ | Please provide any additional clinical information pertaining to the request. |

**Physician office's signature*_____ Print Name_____**
***Form must be completed and signed by physician or licensed representative from the physician's office**