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**

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**

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**

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**

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. Has member received long-acting beta agonist (LABA) therapy? **Yes or No**
- **If Yes**, please provide drug name______________________________________
  - Dates filled within the past several months ____
- **If No,** Can member try LABA therapy instead? **Yes** or **No**
  - **If Yes**: Please notify the pharmacy of the change
  - **If No**, please provide clinical reason____

P. Has member received Leukotriene modifier (e.g., montelukast or zafirlukast)? **Yes** or **No**
- **If Yes**, please provide drug name______________________________________
  - Dates filled within the past several months ____
- **If No**, Can member try Leukotriene modifier therapy instead? **Yes or No**
  - **If yes**: Please notify the pharmacy of the change
  - **If No,** please provide clinical reason____

Q. Has member received Long-acting muscarinic antagonist (LAMA)? **Yes** or **No**
- **If Yes**, please provide drug name____
  - Dates filled within the past several months ____
- **If No**, Can member try LAMA therapy instead? **Yes** or **No**
  - **If yes**: Please notify the pharmacy of the change
  - **If No,** please provide clinical reason____

R. Has member received Theophylline? **Yes or No**
- **If yes**, please provide drug name____
  - Dates filled within the past several months ____
- **If No**, Can member try Theophylline therapy 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: _____________

Physician office's signature*______________________________ Print Name_____________________________

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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**

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.

____

□ **Other diagnosis:______________________________**

Physician office's signature*______________________________ Print Name_____________________________

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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**

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)]? □ **Yes** □ **No**
□ Allergic Asthma □ Allergies and Asthma □ Asthma □ Allergies	1. What is the member's current weight? __________lbs Date Taken: _____________ __________ kg 2. What was the member's pre-treatment IgE level (IU/ml)? ___________________ 3. How has the member responded to therapy compared to baseline? (Please select all that apply) □ Reduction of number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to asthma exacerbations □ Reduction in the dose of inhaled/oral corticosteroids required to control the patient's asthma □ Reduction in use of rescue medication □ Increase in pulmonary function tests (e.g., Forced Expiratory Volume from baseline) □ Decrease in symptoms and asthma exacerbations □ None of the above **- If None of the above**, please provide any additional clinical information pertaining to the request. ____ 4. Does the member currently smoke? **Yes or No** 5. Will the member be using any other biologic drug (e.g., Nucala, Cinqair, Fasenra, Dupixent, etc.) with Xolair? **Yes or No** - **If yes,** please provide drug name and diagnosis/diagnoses it is being used to treat ____
□ Nasal Polyps	1. How has the member responded to therapy compared to baseline? (Please select all that apply) □ Improvement from baseline in nasal blockage/congestion (e.g., decrease in nasal congestion score) □ Improvement in endoscopic nasal polyps score

Physician office's signature*________________________________ Print Name________________________________

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	□ 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 □ Decrease in nasal corticosteroid use □ None of the above **- If None of the above**, please provide any additional clinical information pertaining to the request. ____ 2. Will the member be using Omalizumab (Xolair) as add-on to maintenance treatment? **Yes or No**
□ Other diagnosis ____________________	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**