Xolair (omalizumab)/ Omlyclo(omalizumab-igce)
Prior Authorization Request Form

Caterpillar Prescription Drug Benefit
Phone: 877-228-7909 Fax: 800-424-7640

MEMBER'S LAST NAME: _____ **MEMBER'S FIRST NAME:** _____

Instructions: Please fill out all applicable sections completely and legibly. Attach any additional documentation that is important for the review (e.g., chart notes or lab data, to support the authorization request). Information contained in this form is Protected Health Information under HIPAA.

☐ **URGENT**

MEMBER INFORMATION		
LAST NAME:	**FIRST NAME:**	
PHONE NUMBER:	**DATE OF BIRTH:**	
STREET ADDRESS:		
CITY:	**STATE:**	**ZIP CODE:**
PATIENT INSURANCE ID NUMBER:		

☐ **MALE** ☐ **FEMALE** **HEIGHT (IN/CM):** _____ **WEIGHT (LB/KG):** _____ **ALLERGIES:** _____

IF YOU ARE NOT THE PATIENT OR THE PRESCRIBER, YOU WILL NEED TO SUBMIT A PHI DISCLOSURE AUTHORIZATION FORM WITH THIS REQUEST WHICH CAN BE FOUND AT THE FOLLOWING LINK: PRIMETHERAPEUTICS.COM/NOPP

PATIENT'S AUTHORIZED REPRESENTATIVE (IF APPLICABLE): _____
AUTHORIZED REPRESENTATIVE'S PHONE NUMBER: _____

PRESCRIBER INFORMATION		
LAST NAME:	**FIRST NAME:**	
PRESCRIBER SPECIALTY:	**EMAIL ADDRESS:**	
NPI NUMBER:	**DEA NUMBER:**	
PHONE NUMBER:	**FAX NUMBER:**	
STREET ADDRESS:		
CITY:	**STATE:**	**ZIP CODE:**
REQUESTER (if different than prescriber):	**OFFICE CONTACT PERSON:**	

MEDICATION OR MEDICAL DISPENSING INFORMATION			
MEDICATION NAME:			
DOSE/STRENGTH:	**FREQUENCY:**	**LENGTH OF THERAPY/REFILLS:**	**QUANTITY:**
☐ **NEW THERAPY** ☐ **RENEWAL** **IF RENEWAL:** DATE THERAPY INITIATED: DURATION OF THERAPY (SPECIFIC DATES):			

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1. HAS THE PATIENT TRIED ANY OTHER MEDICATIONS FOR THIS CONDITION? ☐ **YES** (if yes, complete below) ☐ **NO**		
MEDICATION/THERAPY (SPECIFY DRUG NAME AND DOSAGE)**:**	**DURATION OF THERAPY** (SPECIFY DATES)**:**	**RESPONSE/REASON FOR FAILURE/ALLERGY:**

2. LIST DIAGNOSES:	**ICD-10:**
☐ Chronic idiopathic urticaria(CIU) ☐ Persistent asthma ☐ Chronic rhinosinusitis with nasal polyps(CRSwNP), ☐ Other diagnosis: _____ ICD-10 Code(s):	

3. REQUIRED CLINICAL INFORMATION: PLEASE PROVIDE ALL RELEVANT CLINICAL INFORMATION TO SUPPORT A PRIOR AUTHORIZATION.

Is patient going to be using drug in a clinical trial? ☐ **Yes** ☐ **No**

Is the prescriber one of the following or in consultation with one of the following?
☐ **Yes** ☐ **No (Please provide documentation)**
□ **Allergist**
□ **Immunologist**
□ **Dermatologist**
□ **Pulmonologist**
□ **Otolaryngologist**

Has patient started branded Xolair in a prescriber's office for over 6 months? ☐ **Yes** ☐ **No Please submit documentation.**

If patient has started branded Xolair therapy in a prescriber's office, patient is required to switch to the biosimilar Omlyclo(omalizumab-igce) in the outpatient setting.

Is this request for the biosimilar Omlyclo(omalizumab-igce)? ☐ **Yes** ☐ **No**

Has patient had a 3 month trial with the biosimilar Omlyclo(omalizumab-igce)? ☐ **Yes** ☐ **No Please submit documentation.**

Does patient have an absolute contraindication to Omlyclo? ☐ **Yes** ☐ **No Please submit documentation.**
If the patient has tried the biosimilar Omlyclo, and will not be continuing it, has a U.S. FDA MedWatch Voluntary Reporting Form for adverse drug reactions (FDA Form 3500) been filed with the FDA? □ **Yes** □ **No** ***Please submit a copy of the completed FDA 3500 form.***

Is patient receiving Xolair in combination with any of the following? ☐ **Yes** ☐ **No**
□ **Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]**

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MEMBER'S LAST NAME: _____ **MEMBER'S FIRST NAME:** _____

□ **Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]**
□ **Anti-interleukin 31 therapy[e.g. Nemluvio(nemolizumab-ilto)**
□ **Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]**

Initial Reques for Chronic idiopathic urticaria(CIU) or Chronic spontaneous urticaria(CSU):

Have all other causes of urticaria(hives) such as allergies have been ruled out? ☐ Yes ☐ No (Please provide documentation)

Has patient had chronic idiopathic urticaria or chronic spontaneous urticaria for at least 6 weeks or more? ☐ Yes ☐ No (Please provide documentation)

Has patient tried and failed an antihistamine (H1 blocker) such as loratadine, cetirizine, diphenhydramine, and/or hydroxyzine? ☐ Yes ☐ No (Please provide documentation)

Has patient tried and failed a Histamine- 2 blocker such as ranitidine, famotidine, cimetidine, and/or nizatidine? ☐ Yes ☐ No (Please provide documentation)

Has patient tried a leukotriene receptor inhibitor such as montelukast and/or zafirlukast? ☐ Yes ☐ No (Please provide documentation)

Has patient had a 3-month trial of Dupixent(dupilumab)? ☐ Yes ☐ No Please provide documentation.
Does patient have an absolute contraindication to Dupixent(dupilumab)? ☐ Yes ☐ No (Please provide documentation)

Initial Request for Persistent Asthma:
Does patient have a diagnosis of moderate to severe persistent asthma? ☐ Yes ☐ No (Please provide documentation)

Has patient had asthma for at least one year? ☐ Yes ☐ No (Please provide documentation)

Does patient have a positive skin test reaction to a perennial aeroallergen? ☐ Yes ☐ No (Please provide documentation)

Does patient have a baseline plasma immunoglobulin E (IgE) level greater than or equal to 30 IU/mL and less than or equal to 1300 IU/mL? ☐ Yes ☐ No (Please provide documentation)

Is patient's classification of asthma as uncontrolled or inadequately controlled as defined by at least one of the following? ☐ Yes ☐ No (Please provide documentation)
□ **Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 month**
□ **Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)**

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□ Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80% predicted [in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal])
□ Patient is currently dependent on maintenance therapy with oral corticosteroids for the treatment of asthma

Will Xolair(omalizumab)/Omlyclo(omalizumab-igce) be used in combination with one of the following:
☐ Yes ☐ No (Please provide documentation)
□ One maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2- agonist (LABA) product [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)].
□ Combination therapy including both of the following:
□ One maximally-dosed (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco®), mometasone furoate (Asmanex®), beclomethasone dipropionate (QVAR®)];
□ One additional asthma controller medication [e.g., LABA - olodaterol (Striverdi®) or indacaterol (Arcapta®); leukotriene receptor antagonist – montelukast (Singulair®); theophylline]

<u>For new starts only</u>, has patient had a 3-month trial of Dupixent(dupilumab)? ☐ Yes ☐ No
Please provide documentation.
Does patient have an absolute contraindication to Dupixent(dupilumab)? ☐ Yes ☐ No
(Please provide documentation)

<u>Initial Request for Chronic rhinosinusitis with nasal polyps(CRSwNP):</u>

Does patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP)? ☐ Yes ☐ No (Please provide documentation)

Has patient been unable to obtain symptom relief after trial of an Intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)? ☐ Yes ☐ No (Please provide documentation)

Has patient been unable to obtain symptom relief after trial of one other therapy used in the management of nasal polyps [i.e., nasal saline irrigations. antileukotriene agents (e.g., montelukast, zafirlukast, zileuton)]? ☐ Yes ☐ No (Please provide documentation)

Has patient required systemic corticosteroids (e.g., prednisone, methylprednisolone) for CRSwNP in the previous 2 years? ☐ Yes ☐ No (Please provide documentation)

Has patient required prior sinus surgery? ☐ Yes ☐ No (Please provide documentation)

Will patient receive Xolair/Omlyclo as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)? ☐ Yes ☐ No

<u>For new starts only</u>, has patient had a 3-month trial of Dupixent(dupilumab)? ☐ Yes ☐ No
(Please provide documentation)

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Does patient have an absolute contraindication to Dupixent(dupilumab)? ☐ **Yes** ☐ **No**
(Please provide documentation)

Renewal Request:

Has patient demonstrated a reduction in severity of their disease/symptoms? ☐ **Yes** ☐ **No**
(Please provide documentation)

Is patient continuing to have clinical disease? ☐ **Yes** ☐ **No (Please provide documentation)**

Is patient receiving Xolair/Omlyclo in combination with any of the following? ☐ **Yes** ☐ **No**
□ **Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]**
□ **Anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]**
□ **Anti-interleukin 31 therapy[e.g. Nemluvio(nemolizumab-ilto)**
□ **Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]**

Are there any other comments, diagnoses, symptoms, medications tried or failed, and/or any other information the physician feels is important to this review?

_____

_____

Please note: Not all drugs/diagnosis are covered on all plans. This request may be denied unless all required information is received.

ATTESTATION: I attest the information provided is true and accurate to the best of my knowledge. I understand that the Health Plan, insurer, Medical Group or its designees may perform a routine audit and request the medical information necessary to verify the accuracy of the information reported on this form.

Prescriber Signature or Electronic I.D. Verification: _____ **Date:** _____

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FAX THIS FORM TO: 800-424-7640
MAIL REQUESTS TO: Prime Therapeutics Management Prior Authorization Program
Attn: CP-4201
P.O. Box 64811
St. Paul, MN 55164-0811
Phone: 877-228-7909

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