XOLAIR® (OMALIZUMAB)
Preauthorization Request
(Preauthorization is not a guarantee of payment)

SECTION I – General Information

Today's Date: / /	☐ New request
Fax completed form to:**1-866-805-4150 toll free**	☐ Re-Authorization

Level of Urgency:

Standard Request (Routine Care)—Care/treatment that is not emergent, urgent, or preventive in nature.

Expedited Request—Care/treatment that is emergent or the application of the timeframe for making Standard/Routine or nonlife-threatening care determinations:

- Could seriously jeopardize the life, health, or safety of the member or others, due to the member's psychological state, or
- In the opinion of the practitioner with knowledge of the member's medical or behavioral condition, would subject the member to adverse health consequences without the care or treatment that is the subject of the request.

For Expedited Request, Please Explain:

SECTION II – Member Information

Patients Name:	Member ID:	**Patient Information**: DOB:__/__/__ Sex: Age: Weight: ☐ lbs. ☐ Kg Will the patient self-administer the requested medication? ☐ Yes ☐ No
Patients Address:	Is CBC primary payer: ☐ Yes ☐ No	

Plan Type:

☐ PPO ☐ POS ☐ KHPC ☐ CHIP (aka Capital Cares 4Kids)

☐ Traditional ☐ Comprehensive ☐ Special Care ☐ Other* _____

NOTE: For all Medicare Advantage products, please contact Prime Therapeutics at https://www.covermymeds.com/main or via phone at 1-866-260-0452.

SECTION III – Provider Information Required

Requesting Provider Name: **Address**:	**Requesting Provider CBC #**_____ **NPI #** _____
Telephone #:	Secure Fax #:

Capital

Office Contact Name:	Office Contact Telephone #:
Is the Rendering/Servicing provider different? ☐ No ☐ Yes – Complete rendering provider information below.	
Rendering Provider Name: **Address**: **Telephone:**	**Rendering Provider CBC #**_____ **NPI #** _____
Site of Service: ☐ MD Office ☐ Home Health ☐ Non-hospital affiliated, outpatient infusion center ☐ Hospital affiliated, outpatient infusion center ☐ Other: Specify _____ **Please refer to MP 3.016 for Site of Service requirements.*	**Check all that apply and include all applicable documentation:** ☐ There are contraindications to a less intensive site of care. ☐ A less intensive site of care is not appropriate for the patient's condition. ☐ Patient is being treated with a drug that cannot be administered in a less intensive site of care concurrently. ☐ Less intensive site of care is not available. **Please include all applicable documentation.*

SECTION IV – Preauthorization Requirements and Clinical Criteria

Is the prescriber a specialist in the area of the patient's diagnosis or has the prescriber consulted with a specialist in the area of the patient's diagnosis?
☐ Yes Specialty: _____ ☐ No

☐ New to therapy ☐ Continuing therapy*: Initial start __/__/__ ☐ Reinitiating therapy: Last treatment __/__/__ *Please include documentation for changes in dose.	**Route of Administration:** ☐ Intravenous (IV) ☐ Injection (Sub Q or IM) ☐ Oral (PO) or Enteral ☐ Other: Specify _____
HCPC Code(s):	**Diagnosis Code(s)**:
Medication requested:	**Indication:**

Does the patient have late stage metastatic disease? ☐ Yes ☐ No
For patients with late stage metastatic disease (Stage IV), please refer to MP 2.373 Step Therapy Treatment in Cancer, Including Treatments for Stage Four, Advanced Metastatic Cancer and Severe Related Health Conditions for additional guidance.

Type of drug requested: ☐ Brand name ☐ Generic ☐ Biosimilar ☐ Other: Specify _____

Initial start date of therapy: __/__/__	Anticipated date of **next administration:** __/__/__
Dosing period for request: Start Date: __/__/__ End Date __/__/__	**Dosing Information:** Dose: Strength: Frequency: Quantity requested per month:

<u>Attach documentation demonstrating the medical necessity of the requested drug.</u> Please list all reasons for selecting the requested medication, strength, dosing schedule, and quantity over alternatives (e.g., contraindications, allergies, history of adverse drug reactions to alternatives, lower dose has been tried, information supporting dose over FDA max.)

Has the patient had **medical testing** completed for use of this drug? (labs, imaging) ☐ Yes ☐ No Results:_____
Is drug being requested for an "**off label" indication**? ☐ Yes ☐ No If yes, please see Medical Policy 2.103 and include any applicable documentation.
Please list any previous medications that were **tried and failed**. Include reason for discontinuation (intolerance, hypersensitivity, inadequate response etc.). Please attach documentation. Drug(s) and strength: Documentation of failure:
☐ **Xolair® (omalizumab)**

Patient is at least 18 years of age (unless otherwise specified below) □ Yes □ No

Will not be used in combination with another anti-IL4 or anti-IL5 monoclonal antibody (e.g., benralizumab mepolizumab, reslizumab, dupilumab, etc.) □ Yes □ No

COMPLETE BELOW FOR RELEVANT DIAGNOSIS

Moderate-to-severe persistent allergic asthma

Patient is at least 6 years of age□ Yes □ No

Will not be used for treatment of acute bronchospasm, status asthmaticus, or allergic conditions (other than indicated) □ Yes □ No

Patient has a positive skin test or in vitro reactivity to a perennial aero-allergen □ Yes □ No

Patient must weigh between 20 kg (44 lbs.) and 150 kg (330 lbs.); □ Yes □ No

Patient has a serum total IgE level, measured before the start of treatment, of either: (see below)

≥ 30 IU/mL and ≤ 700 IU/mL in patients age ≥ 12 years □ Yes □ No

≥ 30 IU/mL and ≤ 1300 IU/mL in patients age 6 to <12 years □ Yes □ No

Patient has documented ongoing symptoms of moderate-to-severe asthma* with a minimum (3) month trial on previous combination therapy including medium- or high-dose inhaled corticosteroids PLUS another controller medication (e.g., long-acting beta-2 agonist, leukotriene receptor antagonist, theophylline, etc.) □ Yes □ No

Baseline measurement of at least one of the following for assessment of clinical status (see below)

Use of systemic corticosteroids □ Yes □ No

Use of inhaled corticosteroids □ Yes □ No

Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition □ Yes □ No

Forced expiratory volume in 1 second (FEV1) □ Yes □ No

Chronic Idiopathic Urticaria/Chronic Spontaneous Urticaria (CIU/CSU)

Patient is at least 12 years of age □ Yes □ No

The underlying cause of the patient's condition is NOT considered to be any other allergic condition(s) or other form(s) of urticarial □ Yes □ No

Patient is avoiding triggers (e.g., NSAIDs, etc.) □ Yes □ No

Documented baseline score from an objective clinical evaluation tool, such as: urticarial activity score (UAS7), angioedema activity score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life (AE-QoL), or Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL) □ Yes □ No

Patient had an inadequate response to a one or more month trial on previous therapy with scheduled dosing of a second-generation H1-antihistamine product □ Yes □ No

Patient had an inadequate response to a one or more month trial on previous therapy with scheduled dosing of at least one of the following (see below)

Up-dosing/dose advancement (up to 4-fold) of a second generation H1-antihistamine□ Yes □ No

Add-on therapy with a leukotriene antagonist (e.g., montelukast, zafirlukast, etc.) □ Yes □ No

Add-on therapy with another H1-antihistamine □ Yes □ No

Add-on therapy with a H2-antagonist (e.g. ranitidine, etc.) □ Yes □ No

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Patient has bilateral symptomatic sino-nasal polyposis with symptoms lasting at least 8 weeks□ Yes □ No

Patient has failed at least 8 weeks of daily intranasal corticosteroid therapy□ Yes □ No

Patient has at least four (4) of the following indicators for biologic treatment [Note: Patients with a history of sino-nasal surgery are only required to have at least three (3) of the indicators] (see below)

Patient has evidence of type 2 inflammation (i.e., biological biomarkers indicating immune dysregulation and epithelial barrier dysfunction) □ Yes □ No

Patient has required two or more short courses of systemic corticosteroids within the previous year□ Yes □ No

Disease significantly impairs the patient's quality of life□ Yes □ No

Patient has experienced significant loss of smell□ Yes □ No

Patient has a comorbid diagnosis of asthma□ Yes □ No

Does patient have any of the following: (see below)

Antrochoanal polyps□ Yes □ No

Nasal septal deviation that would occlude at least one nostril□ Yes □ No

Disease with lack of signs of type 2 inflammation□ Yes □ No

Cystic fibrosis□ Yes □ No

Mucoceles□ Yes □ No

Other causes of nasal congestion/obstruction have been ruled out (e.g., acute sinusitis, nasal infection or upper respiratory infection, rhinitis medicamentosa, tumors, infections, granulomatosis, etc.) □ Yes □ No

Physician has assessed baseline disease severity utilizing an objective measure/tool□ Yes □ No

Therapy will be used in combination with intranasal corticosteroids unless not able to tolerate or is contraindicated □ Yes □ No

Management of Immune Checkpoint Inhibitor-Related Toxicity

Patient has been receiving therapy with an immune checkpoint inhibitor (e.g. nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, ipilimumab, etc.) □ Yes □ No

Patient has refractory and severe (i.e., grade 3: intense or widespread, constant, limiting self-care activities of daily living or sleep) pruritis □ Yes □ No

Patient has an increased serum IgE level above the upper limit of normal of the laboratory reference value □ Yes □ No

Systemic Mastocytosis

Used for the prevention of one of the following (see below)

Chronic mast cell mediator-related cardiovascular (e.g., pre-syncope, tachycardia, etc.) or pulmonary (e.g., wheezing, throat-swelling, etc.) symptoms insufficiently controlled by conventional therapy (e.g., H1 or H2 blockers or corticosteroids) □ Yes □ No

Unprovoked anaphylaxis □ Yes □ No

Hymenoptera or food-induced anaphylaxis in patients with a negative test for specific □ Yes □ No

IgE antibodies or a negative skin test □ Yes □ No

Used to improve tolerance while on immunotherapy (i.e., venom immunotherapy [VIT]) □ Yes □ No

Renewal Criteria:

Patient continues to meet the universal and other indication-specific relevant criteria identified in section III □ Yes □ No

Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: symptoms of anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema), malignancy, symptoms similar to serum sickness (fever, arthralgia, and rash), parasitic (helminth) infection, eosinophilic conditions (e.g. vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy, especially upon reduction of oral corticosteroids), etc. □ Yes □ No

Moderate-to-severe persistent allergic asthma

Patient weighs between 20 kg (44 lbs.) and 150 kg (330 lbs.) □ Yes □ No

Improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following (see below):

- □ Use of systemic corticosteroids
- □ Two-fold or greater decrease in inhaled corticosteroid use for at least 3 days
- □ Hospitalizations
- □ ER visits
- □ Unscheduled visits to healthcare provider

Improvement from baseline in forced expiratory volume in 1 second (FEV1) □ Yes □ No

Chronic Idiopathic Urticaria/Chronic Spontaneous Urticaria (CIU/CSU)

Treatment has resulted in clinical improvement as documented by improvement from baseline using objective clinical evaluation tools such as the urticaria activity score (UAS7), angioedema activity score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life (AE-QoL), or Chronic Urticaria Quality of Life Questionnaire(CU-Q2oL) □ Yes □ No

Submitted current UAS7, AAS, DLQI, AE-QoL, or Cu-Q2oL was recorded within the past 3-6 months. □ Yes □ No

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Disease response as indicated by improvement in signs and symptoms compared to baseline in one or more of the following: nasal/obstruction symptoms, improvement of sinus opacifications as assessed by CT-scans and/or an improvement on a disease activity scoring tool (e.g., nasal polyposis score (NPS), nasal congestion (NC) symptom severity score, sinonasal outcome test-22 (SNOT-22), etc.); □ Yes □ No

Patient had an improvement in at least one (1) of the following response criteria (see below)

- Reduction in nasal polyp size □ Yes □ No
- Reduction in need for systemic corticosteroids □ Yes □ No
- Improvement in quality of life □ Yes □ No
- Improvement in sense of smell □ Yes □ No
- Reduction of impact of comorbidities □ Yes □ No

Systemic Mastocytosis

Disease response as indicated by improvement in signs and symptoms compared to baseline or a decreased frequency of exacerbations □ Yes □ No

Please use a separate form for each drug.

To fill out form type or write using blue or black ink

Please fax this form to: 1-866-805-4150

Telephone: 1-800-471-2242

Prior authorization is not a guarantee of payment; benefits and eligibility will apply at the time of claim adjudication.

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