Capital

XOLAIR® (OMALIZUMAB)
PREAUTHORIZATION REQUEST
(PREAUTHORIZATION IS NOT A GUARANTEE OF PAYMENT)

SECTION I – General information

Today's date: / /	☐ New request
Fax completed form to: **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.
- 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 Capital Blue Cross primary payer: ☐ Yes ☐ No	

Plan type:

☐ PPO ☐ POS ☐ KHPC ☐ CHIP
☐ Traditional ☐ Comprehensive ☐ Special Care ☐ Other* _____

NOTE: For all Medicare Advantage products, please contact Prime Therapeutics at www.covermymeds.com/main or via phone at 866.260.0452.

SECTION III – Provider Information Required

Requesting provider name: **Address**:	**Requesting provider Capital #**_____ **NPI #** _____

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Telephone #:	Secure fax #:
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 Capital #**_____ **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. _____
HCPCS 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:

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Attach documentation demonstrating the medical necessity of the requested drug. 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)**

Is the patient at least 18 years of age (unless otherwise specified below) ☐ Yes ☐ No

Will the patient use in combination with another anti-IL4, anti-IL5 or IgG2 lambda monoclonal antibody agents (e.g., benralizumab, mepolizumab, reslizumab, dupilumab, Tezepelumab, 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 aeroallergen ☐ Yes ☐ No

Patient weighs 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:

- ☐ ≥ 30 IU/mL and ≤ 700 IU/mL in patients age ≥ 12 years
- ☐ ≥ 30 IU/mL and ≤ 1300 IU/mL in patients aged 6 to <12 years

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:

- ☐ Use of systemic corticosteroids
- ☐ Use of inhaled corticosteroids
- ☐ Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
- ☐ Forced expiratory volume in 1 second (FEV1)

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 urticaria. □ 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:

- □ Up-dosing/dose advancement (up to 4-fold) of a second generation H1-antihistamine
- □ Add-on therapy with a leukotriene antagonist (e.g., montelukast, zafirlukast, etc.)
- □ Add-on therapy with another H1-antihistamine
- □ Add-on therapy with a H2-antagonist (e.g. ranitidine, famotidine, etc.)

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 three (3) of the following indicators for biologic treatment:

- □ Evidence of type 2 inflammation (i.e.,tissue eosinophils ≥10/hpf, blood eosinophils ≥150 cells/µl, or total IgE ≥100 IU/mL)
- □ Required ≥2 courses of systemic corticosteroids per year or >3 months of low dose corticosteroids, unless contraindicated.
- □ Disease significantly impairs patient's quality of life.
- □ Patient has experienced significant loss of smell.
- □ Patient has a comorbid diagnosis of asthma.

Does patient have any of the following:

- □ Antrochoanal polyps
- □ Nasal septal deviation that would occlude at least one nostril
- □ Disease with lack of signs of type 2 inflammation
- □ Cystic fibrosis
- □ Mucoceles

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

IgE-Mediated Food Allergic Reactions (Type1)

Patient is at least 1 year of age and is avoiding known food allergens. □ Yes □ No

Patient has at least one IgE-mediated food allergy (i.e., peanut, mik, egg, wheat, or tree nuts) confirmed by at least one of the following:

- □ Positive skin prick test (SPT) □ Yes □ No
- □ Positive food specific serum IgE □ Yes □ No

Drug will not be used for the emergency treatment of allergic reactions, including anaphylaxis. □ 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, dostarlimab, tremelimumab, nivolumab/relatlimab-rmbw, refifanlimab,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

Drug is used for the prevention of one of the following:

- □ 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)
- □ Unprovoked anaphylaxis
- □ Hymenoptera or food-induced anaphylaxis in patients with a negative test for specific IgE antibodies or a negative skin test

Drug is used to improve tolerance while on immunotherapy (i.e., venom immunotherapy (VIT). □ Yes □ No

RENEWAL CRITERIA (IF APPLICABLE, COMPLETE IN ADDITION TO ABOVE

Is there absence of unacceptable toxicity* from the drug? □ Yes □ No

**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.*

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:

- □ 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)

Patient reassessed and continued therapy is necessary for the maintenance treatment of this condition.□ Yes □ No

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

Provider has current UAS7, AAS, DLQI, AE-QoL, UCT, AECT, or Cu-Q_2oLwas recorded within the past 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:

- □ Reduction in nasal polyp size
- □ Reduction in need for systemic corticosteroids
- □ Improvement in quality of life
- □ Improvement in sense of smell
- □ Reduction of impact of comorbidities

IgE-Mediated Food Allergic Reactions (Type1)

Patient reassessed and continued therapy is necessary for the maintenance treatment of this condition. □ Yes □ No

Patient has had a reduction in allergic reaction, including anaphylaxis, and/or symptoms associated with accidental exposure of known food allergens. □ 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: 866.805.4150.

Telephone: 800.471.2242.

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

Healthcare benefit programs issued or administered by Capital Blue Cross and/or its subsidiaries, Capital Advantage Insurance Company®, Capital Advantage Assurance Company® and Keystone Health Plan® Central. Independent licensees of the Blue Cross Blue Shield Association. Communications issued by Capital Blue Cross in its capacity as administrator of programs and provider relations for all companies.