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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 #:
Office Contact Name:	Office Contact Telephone #:

Is the Rendering/Servicing provider different? ☐ No ☐ Yes – Complete rendering provider information below.

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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

Prescribed in consultation with a specialist? ☐ 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:**

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:

Attach documentation demonstrating the medical nessicity 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, imagining) ☐ 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.

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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:

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Patient Diagnosis:

☐ Moderate to severe persistent asthma

☐ Chronic Idiopathic Urticaria (CIU)

☐ Chronic rhinosinusitis with nasal polyposis (CRSwNP)

☐ Other: Specify:_____

Pretreatment IgE level: _____

Is the patients age within FDA labeling for the requested indication for the requested drug or is information provided in support of using the requested drug for the patient's age? ☐ Yes ☐ No

Is the prescriber a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, pulmonologist) or has the prescriber consulted with a specialist in the area of the patient's diagnosis? ☐ Yes ☐ No

Will the requested agent be used in combination with another biologic agent for the requested indication [e.g., injectable IL-5 inhibitor (Cinqair, Fasenra, Nucala), injectable IL-4 inhibitor (Dupixent)]? ☐ Yes ☐ No

Does the patient have any FDA labeled contraindications to the requested agent? ☐ Yes ☐ No

If the patient is diagnosed with **moderate to severe persistent asthma**, answer 1-21 below.

1) Is the requested dose within the FDA labeled dose based on pre-treatment serum IgE level and the patient's body weight? ☐ Yes ☐ No
2) Has the patient's allergic asthma been confirmed by a positive skin test or in vitro reactivity test (RAST) to a perennial aeroallergen? ☐ Yes ☐ No
3) Does the patient have a history of uncontrolled asthma while on asthma control therapy? ☐ Yes ☐ No
4) Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months? ☐ Yes ☐ No
5) Has the patient had serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months? ☐ Yes ☐ No
6) Does the patient have controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered? ☐ Yes ☐ No
7) Does the patient have a baseline Forced Expiratory Volume (FEV1) that is less than 80% of predicted? ☐ Yes ☐ No
8) Is the patient currently being treated with the requested drug? ☐ Yes ☐ No
9) Is the patient currently treated with a maximally tolerated inhaled corticosteroid for at least 3-months? ☐ Yes ☐ No
10) Is the patient currently being treated (for at least 3 months) with an inhaled corticosteroid that is adequately dosed to control symptoms? ☐ Yes ☐ No
11) Is the patient currently treated with a maximally tolerated inhaled corticosteroid for at least 3-months? ☐ Yes ☐ No
12) Does the patient have an intolerance or hypersensitivity to inhaled corticosteroid therapy? ☐ Yes ☐ No
13) Does the patient have an FDA labeled contraindication to all inhaled corticosteroids? ☐ Yes ☐ No
14) Is the patient currently treated, for at least 3 months, with a long-acting beta-2 agonist (LABA)? ☐ Yes ☐ No
15) Is the patient currently treated, for at least 3 months, with a leukotriene receptor antagonist (LTRA)? ☐ Yes ☐ No
16) Is the patient currently treated, for at least 3 months, with a long-acting muscarinic antagonist (LAMA)? ☐ Yes ☐ No
17) Is the patient currently treated, for at least 3 months, with theophylline? ☐ Yes ☐ No
18) Does the patient have an intolerance or hypersensitivity to therapy with long-acting beta-2 agonists (LABA), leukotriene receptor antagonists (LTRA), long-acting muscarinic antagonists (LAMA), or Theophylline? ☐ Yes ☐ No
19) Does the patient have an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA), leukotriene receptor antagonists (LTRA), long-acting muscarinic antagonists (LAMA), AND Theophylline? ☐ Yes ☐ No
20) Will the patient continue asthma control therapy (e.g., ICS, LABA, LTRA, LAMA, theophylline) in combination with the requested drug? ☐ Yes ☐ No
21) Is the requested dose based on pre-treatment serum IgE level and the patient's body weight as defined in FDA approved labeling AND does NOT exceed 375 mg every 2 weeks? ☐ Yes ☐ No

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If the patient has a diagnosis of **chronic idiopathic urticaria (CIU)** answer 1-7 below:

1) Has the patient had hives and itching over at least 6 weeks? ☐ Yes ☐ No
2) Is the patient being treated with medications known to cause or worsen urticaria and have these drugs (e.g., NSAIDs) been reduced or discontinued or is information provided that indicates that a reduced dose or discontinuation of these drugs not appropriate? ☐ Yes ☐ No
3) Has the patient has tried and had an inadequate response to the FDA labeled maximum dose of a second-generation H-1 antihistamine (e.g., cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine) after at least a 2-week trial? ☐ Yes ☐ No
5) Has the patient has tried and had an inadequate response to a dose above the FDA labeled maximum dose (e.g., up to 4 times the FDA labeled maximum dose) of a second-generation H-1 antihistamine or is information provided indicating the patient cannot be treated with a dose above the FDA labeled maximum dose of a second-generation H-1 antihistamine? ☐ Yes ☐ No
6) Does the patient have an intolerance or hypersensitivity to second-generation H-1 antihistamine therapys or an FDA labeled contraindication to ALL second-generation H-1 antihistamines? ☐ Yes ☐ No
7) Is the requested dose is within the FDA labeled dose AND does NOT exceed 300 mg every 4 weeks? ☐ Yes ☐ N

If the patient has a diagnosis **of chronic rhinosinusitis with nasal polyposis (CRSwNP)** answer 1-5 below:

1) Was the patients diagnosis confirmed by anterior rhinoscopy or endoscopy, or computed tomography (CT) of the sinuses? ☐ Yes ☐ No
2) Has the patient tried and had an inadequate response to at least a 3-month trial of or has an intolerance or hypersensitivity to therapy with intranasal corticosteroids (e.g., fluticason, Sinuva)? ☐ Yes ☐ No
3) Does the patient have an FDA labeled contraindication or to ALL intranasal corticosteroids? ☐ Yes ☐ No
4) Will the patient continue standard maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested drug? ☐ Yes ☐ No
5) Does the patient have another FDA labeled indication or an indication supported in DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a for the requested agent AND the requested dose is within the FDA labeled dose for the requested indication? ☐ 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.