Xolair® (omalizumab) Injectable Medication Precertification Request

(All fields must be completed and legible for precertification review.)

Aetna Precertification Notification
Phone: 1-866-752-7021 (TTY: 711)
FAX: 1-888-267-3277
For Medicare Advantage Part B:
Please Use Medicare Request Form

Please indicate: ☐ **Start of treatment:** Start date ____/____/____ ☐ **Continuation of therapy:** Date of last treatment ____/____/____

Precertification Requested By: _____ Phone: _____ Fax: _____

A. PATIENT INFORMATION

First Name:	Last Name:	DOB:	
Address:	City:	State:	ZIP:
Home Phone:	Work Phone:	Cell Phone:	E-mail:
Patient Current Weight: ____ lbs or ____ kgs Patient Height: ____ inches or ____ cms		Allergies:	

B. INSURANCE INFORMATION

Aetna Member ID #: _____
Group #: _____
Insured:

Does patient have other coverage? ☐ Yes ☐ No
If yes, provide ID#: _____ Carrier Name: _____
Insured:

Medicare: ☐ Yes ☐ No If yes, provide ID #: _____ **Medicaid**: ☐ Yes ☐ No If yes, provide ID #: _____

C. PRESCRIBER INFORMATION

First Name:	Last Name:	*(Check one):* ☐ M.D. ☐ D.O. ☐ N.P. ☐ P.A.			
Address:	City:	State:	ZIP:		
Phone:	Fax:	St Lic #:	NPI #:	DEA #:	UPIN:
Provider E-mail:	Office Contact Name:	Phone:			

Specialty *(Check one):* ☐ **Allergist** ☐ **Pulmonologist** ☐ **ENT** ☐ **Pediatrician** ☐ **Primary Care** ☐ **Other:** _____

D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

Place of Administration:
☐ Self-administered ☐ Physician's Office
☐ Outpatient Infusion Center Phone: _____
Center Name: _____
☐ Home Infusion Center Phone: _____
Agency Name: _____
☐ Administration code(s) (CPT): _____
Address: _____

Dispensing Provider/Pharmacy: *(Patient selected choice)*
☐ Physician's Office ☐ Retail Pharmacy
☐ Specialty Pharmacy ☐ Other: _____
Name: _____
Address: _____
Phone: _____ Fax: _____
TIN: _____ PIN: _____

E. PRODUCT INFORMATION

Request is for: Xolair (omalizumab) Dose: _____ **Frequency:** _____

F. DIAGNOSIS INFORMATION - Please indicate primary ICD code and specify any other where applicable.

Primary ICD Code: _____ **Secondary ICD Code:** _____ **Other ICD Code:** _____

G. CLINICAL INFORMATION - Required clinical information must be completed in its entirety for all precertification requests.

For All Requests (clinical documentation required):

☐ Yes ☐ No Is this infusion request in an outpatient hospital setting?

→ ☐ Yes ☐ No Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (e.g., acetaminophen, steroids, diphenhydramine, fluids, or other pre-medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion?

☐ Yes ☐ No Does the patient have significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver?

→ Please provide a description of the behavioral issue or impairment: _____

☐ Yes ☐ No Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may limit the patient's ability to tolerate a large volume or load or predispose the patient to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment?

→ Please provide a description of the condition:
☐ Cardiovascular: _____
☐ Respiratory: _____
☐ Renal: _____
☐ Other: _____

Will the requested drug be used concomitantly with any other biologic (e.g., Adbry, Humira, Nucala), or targeted synthetic drug (e.g., Rinvoq, Olumiant, Otezla, Xeljanz) for the same indication?

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G. CLINICAL INFORMATION *(Continued)* - Required clinical information must be completed for ALL precertification requests.

For Initiation Requests (clinical documentation required):

Asthma

Please indicate the patient's pre-treatment IgE level (IU/mL): _____

☐ Yes ☐ No Is the medication prescribed by or in consultation with an allergist, immunologist, or pulmonologist?

☐ Yes ☐ No Has the patient previously received another biologic drug (e.g., Cinqair, Nucala) indicated for asthma?

☐ Yes ☐ No Does the patient have uncontrolled asthma as demonstrated by experiencing two or more asthma exacerbations requiring oral or injectable corticosteroid treatment within the past year?

→ ☐ Yes ☐ No Does the patient have uncontrolled asthma as demonstrated by experiencing one or more asthma exacerbation resulting in hospitalization or emergency medical care visit within the past year?

→ ☐ Yes ☐ No Does the patient have uncontrolled asthma as demonstrated by experiencing poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma) within the past year?

☐ Yes ☐ No Prior to receiving the requested medication, did the patient have inadequate asthma control despite current treatment with a medium-to-high dose inhaled corticosteroid and additional controller (i.e., long acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained release theophylline) at optimized doses?

☐ Yes ☐ No Does the patient have a positive skin test or in vitro reactivity to at least 1 perennial aeroallergen?

☐ Yes ☐ No Will the patient continue to use maintenance asthma treatments (i.e., inhaled corticosteroids, additional controller) in combination with the requested medication?

Chronic spontaneous urticaria (CSU)

Please indicate how long the patient had a spontaneous onset of wheals and/or angioedema (in weeks): _____

☐ Yes ☐ No Is the medication prescribed by or in consultation with an allergist/immunologist or dermatologist?

☐ Yes ☐ No Does the patient remain symptomatic despite treatment with up-dosing (in accordance with EAACI/GA2LEN/EDF/WAO guidelines) a second-generation H1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine) for at least 2 weeks?

☐ Yes ☐ No Has the patient been evaluated for other causes of urticaria, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis)?

Immune checkpoint inhibitor-related toxicity

☐ Yes ☐ No Does the patient have a refractory case of immune-therapy related severe (G3) pruritus?

☐ Yes ☐ No Does the patient have elevated IgE levels?

Chronic rhinosinusitis with nasal polyps (CRSwNP)

☐ Yes ☐ No Is the medication prescribed by or in consultation with an allergist/immunologist or otolaryngologist?

☐ Yes ☐ No Has the patient previously received another biologic drug (e.g., Nucala, Dupixent) indicated for CRSwNP?

→ ☐ Yes ☐ No Does the patient have bilateral nasal polyps and chronic symptoms of sinusitis?

☐ Yes ☐ No Has the patient had intranasal corticosteroid treatment for at least 2 months?

→ ☐ Yes ☐ No Are intranasal corticosteroids contraindicated or not tolerated?

☐ Yes ☐ No Has the patient had a bilateral nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril?

→ ☐ Yes ☐ No Has the patient had a Meltzer Clinical Score of 2 or higher in both nostrils?

→ ☐ Yes ☐ No Has the patient had a total endoscopic nasal polyps score (NPS) of at least 5 with a minimum score of 2 for each nostril?

☐ Yes ☐ No Does the patient have symptoms of nasal blockage, congestion, or obstruction?

☐ Yes ☐ No Does the patient have rhinorrhea (anterior/posterior), reduction or loss of smell, or facial pain or pressure?

☐ Yes ☐ No Will the patient be using a daily intranasal corticosteroid while being treated with the requested medication?

→ ☐ Yes ☐ No Are intranasal corticosteroids contraindicated or not tolerated?

Systemic mastocytosis

☐ Yes ☐ No Does the patient have a major and at least one minor diagnostic criterion for systemic mastocytosis present?

→ ☐ Yes ☐ No Does the patient have three or more minor diagnostic criteria present for systemic mastocytosis?

☐ Yes ☐ No Is the requested medication being prescribed as a step-wise prophylactic treatment for chronic mast cell mediator-related cardiovascular and pulmonary symptoms?

→ ☐ Yes ☐ No Is the requested medication being prescribed for prevention of recurrent unprovoked anaphylaxis?

→ ☐ Yes ☐ No Is the requested medication being prescribed for prevention of hymenoptera or food-induced anaphylaxis?

→ ☐ Yes ☐ No Is the requested medication being prescribed to improve tolerability of venom immunotherapy?

☐ Yes ☐ No Has the patient tried both of the following: 1) H1 blockers and H2 blockers AND 2) corticosteroids?

☐ Yes ☐ No Does the patient have negative specific IgE or a negative skin test?

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G. CLINICAL INFORMATION *(continued)* – Required clinical information must be completed in its entirety for all precertification requests.

For Continuation Requests (clinical documentation required):

☐ Yes ☐ No Is the patient currently receiving the requested medication through samples or a manufacturer's patient assistance program?

Asthma

☐ Yes ☐ No Is the medication prescribed by or in consultation with an allergist, immunologist, or pulmonologist?

☐ Yes ☐ No Has the patient's asthma control improved on the requested medication therapy as demonstrated by a reduction in the frequency and/or severity of symptoms and exacerbations?

☐ Yes ☐ No Has the patient's asthma control improved on the requested medication therapy as demonstrated by a reduction in the daily maintenance oral corticosteroid dose?

☐ Yes ☐ No Will the patient continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication?

Chronic spontaneous urticaria (CSU)

☐ Yes ☐ No Is the medication prescribed by or in consultation with an allergist/immunologist or dermatologist?

☐ Yes ☐ No Has the patient experienced a response (e.g., improved symptoms, decrease in weekly urticaria activity score [UAS7]) since initiation of therapy?

Chronic rhinosinusitis with nasal polyps (CRSwNP)

☐ Yes ☐ No Is the medication prescribed by or in consultation with an allergist/immunologist or otolaryngologist?

☐ Yes ☐ No Has the patient experienced a response as evidenced by improvement in signs and symptoms (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sinonasal inflammation, hyposmia and/or facial pressure or pain, or reduction in corticosteroid use)?

☐ Yes ☐ No Will the patient continue to use a daily intranasal corticosteroid while being treated with the requested medication?

→ ☐ Yes ☐ No Are intranasal corticosteroids contraindicated or not tolerated?

H. ACKNOWLEDGEMENT

Request Completed By *(Signature Required):* _____ **Date:** ____/____/____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

The plan may request additional information or clarification, if needed, to evaluate requests.