Xolair® (omalizumab) Injectable Medication Precertification Request

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

Aetna Precertification Notification
Phone: 1-866-752-7021
FAX: 1-888-267-3277
For Medicare Advantage Part B:
Phone: 1-866-503-0857
FAX: 1-844-268-7263

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, other pre-medications or slowing of infusion rate) 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 member's ability to tolerate a large volume or load or predispose the member 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: _____

For Initiation Requests (clinical documentation required):

Asthma

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

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

☐ Yes ☐ No Does the patient have inadequate asthma control (e.g., hospitalization or emergency medical care visit within the past year) despite current treatment with inhaled corticosteroid and additional controller (long acting beta2-agonist, leukotriene modifier, or sustained-release theophylline) at optimized doses?

☐ Yes ☐ No Will the patient receive the requested medication as monotherapy (i.e., without any other asthma medications such as inhaled corticosteroids)?

☐ Yes ☐ No Will the patient receive the requested medication concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala)?

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Patient First Name	Patient Last Name	Patient Phone	Patient DOB

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

Chronic idiopathic urticaria (CIU)

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

☐ Yes ☐ No Does the patient remain symptomatic despite treatment with 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?

Nasal polyps

☐ Yes ☐ No Does the patient have bilateral nasal polyposis 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 or anterior rhinoscopy showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril?

☐ Yes ☐ No Does the patient have nasal blockage?

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

☐ 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

Please indicate which of the following diagnostic criterion for systemic mastocytosis is present:

Major 2017 WHO Diagnostic criteria:

☐ Multifocal, dense infiltrates of mast cells (at least 15 mast cells in aggregates) detected in sections of bone marrow and/or other extracutaneous organs

Minor 2017 WHO Diagnostic criteria:

☐ In biopsy sections of bone marrow or other extracutaneous organs, greater than 25% of mast cells in in the infiltrate are spindle-shaped or have atypical morphology of greater than 25% of all mast cells in bone marrow aspirate smears are immature or atypical

☐ Detection of an activating point mutation at codon 816 of KIT in the bone marrow, blood, or another extracutaneous organ

☐ Mast cells in bone marrow, blood, or other extracutaneous organs express CD25, with or without CD2, in addition to normal mast cell markers

☐ Serum total tryptase persistently greater than 20 ng/mL (unless there is an associated myeloid neoplasm, in which case this parameter is not valid)

☐ None of the above

☐ 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 Does the patient have negative specific IgE or a negative skin test?

→ Please indicate which of the following the member has tried: ☐ H1 blockers and H2 blockers ☐ Corticosteroids ☐ None

For Continuation Requests (clinical documentation required):

☐ Yes ☐ No Is this continuation request a result of the patient receiving samples or a manufacturer's patient assistance program?

Asthma

☐ 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 receive the requested medication as monotherapy (i.e., without any other asthma medications such as inhaled corticosteroids)?

☐ Yes ☐ No Will the patient receive the requested medication concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala)?

Chronic idiopathic urticaria (CIU)

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

Nasal polyps

☐ 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, post-nasal drip)?

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.