

Prior Authorization Form

Xolair®



Fax this form to: 1-800-424-3260

A fax cover sheet is not required.

Instructions: Please fill out all applicable sections on all pages completely and legibly. Attach any additional documentation that is important for the review (e.g., chart notes or lab data, to support the prior authorization). Information contained in this form is Protected Health Information under HIPAA.

NON-URGENT EXIGENT CIRCUMSTANCES

MEMBER INFORMATION

Member's Last Name:

Grid for Member's Last Name

Member's First Name:

Grid for Member's First Name

Member's Identification Number:

Grid for Member's Identification Number

Date of Birth:

Grid for Date of Birth (MM-DD-YYYY)

Member's Address:

Grid for Member's Address

City:

Grid for City

State:

Grid for State

ZIP:

Grid for ZIP

PRESCRIBER INFORMATION

Prescriber's Last Name:

Grid for Prescriber's Last Name

Prescriber's First Name:

Grid for Prescriber's First Name

Prescriber's Specialty:

Email Address:

National Provider Identifier (NPI) Number:

Grid for NPI Number

DEA Number:

Grid for DEA Number

Office Phone Number:

Grid for Office Phone Number (XXX-XXX-XXXX)

Office Fax Number:

Grid for Office Fax Number (XXX-XXX-XXXX)

CLINICAL CRITERIA

1. What is the member's diagnosis?

- Moderate to severe persistent allergic asthma
Chronic idiopathic urticaria
Management of immune checkpoint inhibitor-related toxicity
Systemic mastocytosis
Other:

(Form continued on next page.)

Member's Last Name:

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Member's First Name:

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For Diagnosis of Moderate to Severe Persistent Allergic Asthma:

2. What is the member's weight? _____
3. Does the member have a positive skin test or in vitro reactivity to a perennial allergen?
 Yes No
4. What is the member's pre-treatment serum total immunoglobulin E (IgE) level: _____
5. Does the member continue to have documented ongoing symptoms of moderate-to-severe asthma with a minimum trial on a previous combination therapy including medium- or high-dosed inhaled corticosteroids plus another controller medication such as a long acting beta-2 agonist or leukotriene receptor agonist?
 Yes No
 If **Yes**, provide details:

6. Will the requested medication be used in combination with any other monoclonal antibody?
 Yes No
 If **Yes**, provide details:

For Diagnosis of Chronic Idiopathic Urticaria:

1. Has the underlying cause of the member's condition been ruled out and is not considered to be any other allergic condition or form of urticaria?
 Yes No
2. Is the member avoiding triggers?
 Yes No
3. Will the requested medication be used in combination with any other monoclonal antibody?
 Yes No
4. What is the member's baseline score and clinical evaluation tool used?

5. Did the member have an inadequate response to at least a one-month trial on previous therapy with scheduled dosing on any of the following? (Check all that apply.)
 - Second generation H1-antihistamine product (e.g., cetirizine, fexofenadine, hydroxyzine, diphenhydramine)
 - 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)
 - Add-on therapy with cyclosporine
 - Add-on therapy with an H2-antagonist (e.g., ranitidine)
 - Add-on therapy with another H1-antihistamine

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Member's Last Name:

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Member's First Name:

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For Diagnosis of Management of Immune Checkpoint Inhibitor-Related Toxicity:

1. Will the requested medication be used in combination with any other monoclonal antibody?

Yes No

2. Has the member been receiving therapy with an immune checkpoint inhibitor?

Yes No

If **Yes**, provide details:

3. Does the member have an increased serum IgE level above the upper limit of normal of the laboratory reference value?

Yes No

If **Yes**, provide details:

For Diagnosis of Systemic Mastocytosis:

1. Will the requested medication be used in combination with any other monoclonal antibody?

Yes No

2. What condition is this medication is being prescribed to prevent? (Check all that apply.)

Chronic mast-cell-mediator-related cardiovascular (e.g., pre-syncope, tachycardia) symptoms not controlled by conventional therapy such as H1 or H2 blockers or corticosteroids

Pulmonary symptoms (e.g., wheezing, throat-swelling) not controlled by conventional therapy such as H1 or H2 blockers or corticosteroids

3. Is the requested medication being used to improve tolerance while on immunotherapy (i.e. venom immunotherapy [VIT])?

Yes No

For Any Other Diagnosis for which This Medication Is Being Prescribed:

1. What is the clinical rationale for use of Xolair® for the provided diagnosis?

Renewal Requests:

1. Has the member experienced any unacceptable toxicity from the drug?

Yes No

2. What is the member's current weight? _____

(Form continued on next page.)

Member's Last Name:

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Member's First Name:

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For Diagnosis of Moderate to Severe Persistent Allergic Asthma:

1. Has the treatment with Xolair® resulted in clinical improvement as documented by any of the following? (Check all that apply.)

- Decreased utilization of rescue medications
- Decreased frequency of exacerbations
- Improvement in lung function (increase in % predicted FEV1 or PEF) from pre-treatment baseline
- Decreased frequency of exacerbations

2. Has a reduction in reported symptoms (decrease in asthma score) been evidenced by decrease in frequency or magnitude of any of the following symptoms? (Check all that apply.)

- Asthma attacks
- Chest tightness or heaviness
- Coughing or clearing throat
- Difficulty taking breath or breathing out
- Shortness of breath
- Tiredness
- Sleep disturbance/night awakening/ symptoms upon awakening
- Wheezing/heavy breathing/fighting for air

3. Is the member periodically checked to reassess the need for continued therapy based upon the member's disease severity and level of asthma control?

- Yes
- No

For Diagnosis of Moderate to Severe Persistent Allergic Asthma:

1. Has the treatment with Xolair® resulted in clinical improvement as documented improvement from baseline using any of the following clinical evaluation tools? (Check all that apply.)

- Urticaria Activity Score (UAS7)
- Angioedema Activity Score (AAS)
- Dermatology for Life Quality Index (DLQI)
- Angioedema Quality of Life (AE-QoL)
- Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL)

Please submit current documentation of any of the above tools used to document improvement from baseline.

For Diagnosis of Systemic Mastocytosis:

1. Has the treatment with Xolair® resulted in clinical improvement as indicated by improvement in signs and symptoms compared to baseline or a decreased frequency of exacerbations?

- Yes
- No

Note: Requests for a diagnosis of management of immune checkpoint inhibitor related toxicity are not renewable.

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Member's Last Name:

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Member's First Name:

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Prescriber Signature (Required)

Date

(By signature, the Physician confirms the above information is accurate and verifiable by patient records.)

Fax this form to: 1-800-424-3260

Mail requests to:

Magellan Rx Management Prior Authorization Program

c/o Magellan Health, Inc.

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Phoenix, AZ 85034

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