MOLINA HEALTHCARE

Iowa Health Link Hawki

Request for Prior Authorization
OMALIZUMAB (XOLAIR)

FAX Completed Form To
1 (877) 733-3195
Provider Help Desk
1 (844) 236-1464

(PLEASE PRINT – ACCURACY IS IMPORTANT)

IA Medicaid Member ID #	Patient name	DOB
Patient address		
Provider NPI	Prescriber name	Phone
Prescriber address		Fax
Pharmacy name	Address	Phone
Prescriber must complete all information above. It must be legible, correct, and complete or form will be returned.		
Pharmacy NPI	Pharmacy fax	NDC

Prior authorization (PA) is required for omalizumab (Xolair) prefilled syringe and autoinjector. Requests for omalizumab (Xolair) lyophilized powder for reconstitution will not be considered through the pharmacy benefit. Request must adhere to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations. Payment for omalizumab (Xolair) prefilled syringe and autoinjector will be considered when patient has an FDA approved or compendia indication under the following conditions:

1. **Therapy will be initiated in a healthcare setting, under the guidance of a healthcare provider, where the patient can be closely observed for anaphylaxis and safety of therapy has been established after a minimum of 3 doses of omalizumab; and**
2. **The healthcare provider has determined self-administration with omalizumab is appropriate based on careful assessment of risk for anaphylaxis and mitigation strategies, as outlined in the label; and**
3. **Prescriber is an allergist, dermatologist, immunologist, otolaryngologist or pulmonologist; and**
4. **For a diagnosis of asthma, chronic rhinosinusitis with nasal polyps, IgE-mediated food allergy, and any other FDA approved diagnosis where dosing is dependent on serum IgE level and body weight, the pretreatment IgE level and body weight in kilograms (kg), is provided. Note: according to the label, there is insufficient data to recommend a dose for certain pretreatment serum IgE levels and body weight. PA requests will be denied in these instances; and**
5. **Patient has access to an epinephrine injection to treat allergic reactions that may occur after administration of omalizumab (Xolair); and**
6. **Prescriber and dispensing pharmacy will educate patient on proper storage and administration. Improperly stored medications will not be replaced.**

<u>Moderate to Severe Persistent Asthma:</u>

1. **Patient has a diagnosis of moderate to severe persistent asthma for at least one year, and**
2. **Patient has a history of positive skin or RAST test to a perennial aeroallergen; and**
3. **Symptoms are inadequately controlled with documentation of current treatment with a high dose inhaled corticosteroid (ICS) given in combination with a controller medication (e.g.long-acting beta$_2$-agonist [LABA] or a leukotriene receptor antagonist [LTRA]), for a minimum of three (3) consecutive months of therapy. Patient must be compliant with therapy, based on pharmacy claims.**

If the criteria for coverage are met, the initial authorization will be given for 16 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to omalizumab (Xolair) therapy and for patients who do not continue concurrent use with a high dose inhaled corticosteroid and controller medication (as defined above).

<u>Chronic Spontaneous Urticaria:</u>

1. **Patient has a diagnosis of moderate to severe chronic spontaneous urticaria; and**
2. **Patient has documentation of an adequate trial and therapy failure with a preferred second- generation H1 receptor antihistamine for at least two weeks.**

If criteria for coverage are met, the initial authorization will be given for 12 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to omalizumab (Xolair) therapy.

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Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):

1. **Patient has a diagnosis of chronic rhinosinusitis with nasal polyps; and**
2. **Patient has documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:**
    a. **Nasal corticosteroid spray; and**
    b. **Oral corticosteroid; and**
3. **Will be used as an add on maintenance treatment.**

If criteria for coverage are met, the initial authorization will be given for 24 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to omalizumab (Xolair) therapy and for patients who do not continue concurrent use with a nasal corticosteroid.

IgE Mediated Food Allergy:

1. **Medication is being prescribed for the reduction of allergic reactions (Type 1) that may occur with accidental exposure to one or more foods in a patient that has an IgE-mediated food allergy; and**
2. **Diagnosis is confirmed by a skin prick test or in vitro test (attach results); and**
3. **Will be used in conjunction with food allergen avoidance.**

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Preferred

☐ Xolair prefilled syringe ☐ Xolair autoinjector

Strength	Dosage Instructions	Quantity	Days Supply
_____	_____	_____	_____

Diagnosis: _____

Was therapy initiated in a healthcare setting, under the guidance of a healthcare provider for a minimum of 3 doses? ☐ Yes Date dose 1: _____ Date dose 2: _____ Date dose 3: _____ ☐ No

Has healthcare provider determined self-administration is appropriate based on careful assessment of risk for anaphylaxis and mitigation strategies, as outlined in the label? ☐ Yes ☐ No

Prescriber Specialty: ☐ Allergist ☐ Dermatologist ☐ Immunologist ☐ Otolaryngologist ☐ Pulmonologist

☐ Other (specify): _____

Patient has access to epinephrine injection: ☐ Yes ☐ No

Has patient been educated on proper storage and administration? ☐ Yes ☐ No

Pretreatment IgE level: _____Date Obtained: _____

Patient's Weight (kg):_____Date Obtained: _____

Moderate to Severe Persistent Asthma:

Date of diagnosis: _____

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Document concurrent treatment of ICS given in combination with a controller medication:

Inhaled Corticosteroid trial: Drug Name:_____Strength:_____Instructions: _____
Trial dates: _____

Inhaled LABA trial: Drug Name: _____Strength:_____Instructions: _____
Trial dates: _____

LTRA trial: Drug Name:_____Strength:_____Instructions: _____
Trial dates: _____
Medical or contraindication reason to override trial requirements: _____

History of positive skin or RAST test to a perennial aeroallergen: ☐ Yes ☐ No Date Performed: _____

For Renewals Only:
Has patient shown adequate response to Xolair® therapy? ☐ Yes ☐ No
Please describe: _____

Is patient continuing use with a high dose inhaled corticosteroid and controller medication? ☐ Yes ☐ No

Moderate to Severe Chronic Spontaneous Urticaria:

Preferred Second-Generation H1 receptor Antihistamine trial: Drug Name:_____Strength: _____
Dosing Instructions:_____Trial dates: _____

For Renewals Only: Has patient shown adequate response to Xolair® therapy? ☐ Yes ☐ No
Please describe: _____

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):

Nasal Corticosteroid Spray Trial:

Drug Name:_____Strength: _____
Dosing Instructions:_____Trial dates: _____

Oral Corticosteroid Trial:

Drug Name:_____Strength: _____
Dosing Instructions:_____Trial dates: _____

Will omalizumab be used as an add on maintenance treatment? ☐ Yes ☐ No

For Renewals Only: Has patient shown adequate response to Xolair® therapy? ☐ Yes ☐ No
Please describe: _____

Is patient currently using a nasal corticosteroid? ☐ Yes ☐ No

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IgE Mediated Food Allergy:

Is medication being prescribed for the reduction of Type 1 allergic reactions that may occur with accidental exposure to one or more foods in a patient that has an IgE-mediated food allergy? ☐ Yes ☐ No

Is diagnosis confirmed by a skin prick test or in vitro test? ☐ Yes (attach results) ☐ No

Will requested medication be used in conjunction with food allergen avoidance? ☐ Yes ☐ No

Medical or contraindication reason to override trial requirements: _____
_____

Attach lab results and other documentation as necessary.

Prescriber signature (Must match prescriber listed above.)	Date of submission

IMPORTANT NOTE: *In evaluating requests for prior authorization, the consultant will consider the treatment from the standpoint of medical necessity only. If approval of this request is granted, this does not indicate that the member continues to be eligible for Medicaid. It is the responsibility of the provider who initiates the request for prior authorization to establish by inspection of the member's Medicaid eligibility card and, if necessary, by contact with the county Department of Health and Human Services, that the member continues to be eligible for Medicaid.*