Iowa Medicaid
IOWA HHS

**FAX Completed Form To**
1 (800) 574-2515

**Provider Help Desk**
1 (877) 776-1567

**Request for Prior Authorization**

# OMALIZUMAB (XOLAIR)

(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. Requests for omalizumab (Xolair) lyophilized powder for reconstitution will not be considered through the pharmacy benefit. Payment for omalizumab (Xolair) prefilled syringe will be considered for FDA approved and compendia indications under the following conditions:

1. Patient meets the FDA approved age; and
2. 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
3. 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
4. Dose follows the FDA approved dosing for indication; and
5. Prescriber is an allergist, dermatologist, immunologist, otolaryngologist or pulmonologist; and
6. Patient has access to an epinephrine injection to treat allergic reactions that may occur after administration of omalizumab (Xolair); and
7. Prescriber and dispensing pharmacy will educate patient on proper storage and administration. Improperly stored medications will not be replaced.

Moderate to Severe Persistent Asthma:

1. Patient has a diagnosis of moderate to severe persistent asthma for at least one year, and
2. Pretreatment IgE level is within the following range:
   a. Adults and adolescent patients 12 years of age or older- 30 IU/mL to 700 IU/mL; or
   b. Pediatric patients 6 to less than 12 years of age- 30 IU/mL to 1300 IU/mL; and
3. Patient's weight is within the following range:
   a. Adults and adolescent patients 12 years of age or older- 30 kg to 150 kg; or
   b. Pediatric patients 6 to less than 12 years of age- 20 kg to 150 kg; and
4. History of positive skin or RAST test to a perennial aeroallergen; and
5. Patient is currently using a high dose inhaled corticosteroid, long-acting beta-agonist, AND leukotriene receptor antagonist, and is compliant with therapy and asthma symptoms are not adequately controlled after at least three (3) months of therapy; and
6. Is dosed according to manufacturer labeling based on pretreatment serum IgE and body weight. 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.

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, long-acting beta-agonist, and leukotriene receptor antagonist.

<u>Chronic Idiopathic Urticaria:</u>

1. Patient has a diagnosis of moderate to severe chronic urticaria; and
2. Patient has documentation of a trial and therapy failure with at least one preferred second- generation antihistamine, one of which must be cetirizine at a dose up to 20mg per day; and

3. Patient has documentation of a trial and therapy failure with at least one preferred first-generation antihistamine; and
4. Patient has documentation of a trial and therapy failure with at least one preferred potent H1 receptor antagonist (hydroxyzine and/or doxepin); and
5. Patient has documentation of a trial and therapy failure with a preferred leukotriene receptor antagonist in combination with a first- or second- generation antihistamine.

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.

Nasal Polyps:

1. Patient has a diagnosis of nasal polyps; and
2. Pretreatment IgE level is within the following range:
   a. Adults and adolescent patients 12 years of age or older- 30 IU/mL to 1500 IU/mL; and
3. Patient's weight is within the following range:
   a. Adults and adolescent patients 12 years of age or older- 30 kg to 150 kg; and
4. Patient has documentation of an adequate trial and inadequate response with at least two nasal corticosteroids at a maximally tolerated dose; and
5. Will be used concomitantly with a nasal corticosteroid; and
6. Is dosed according to manufacturer labeling based on pretreatment serum IgE and body weight. 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.

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

**Preferred**

☐ Xolair prefilled syringe

| 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

**Moderate to Severe Persistent Asthma:**

**Date of diagnosis:** _____

**Inhaled Corticosteroid trial:** Drug Name: _____ Strength: _____ Instructions: _____

Trial dates: _____

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**Inhaled Long-Acting Beta-Agonist trial:** Drug Name: _____Strength: _____ Instructions: _____

Trial dates: _____

**Leukotriene Receptor Antagonist trial:** Drug Name: _____ Strength: _____ Instructions: _____

Trial dates: _____

Medical or contraindication reason to override trial requirements: _____

**Pretreatment IgE level**: _____ Date Obtained: _____

**Patient's Weight (kg):** _____ Date Obtained: _____

**Is Xolair being dosed according to manufacturer labeling based on pretreatment serum IgE and body weight:** ☐ Yes ☐ No

**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: _____

**<u>Moderate to Severe Chronic Idiopathic Urticaria:</u>**

**Preferred Second-Generation Antihistamine trial:** Drug Name: _____ Strength: _____
Dosing Instructions: _____Trial dates: _____

**Preferred First-Generation Antihistamine trial:** Drug Name: _____Strength: _____
Dosing Instructions: _____ Trial dates: _____

**Preferred Potent H1 receptor antagonist trial:** Drug Name: _____Strength: _____
Dosing Instructions: _____ Trial dates: _____

**Preferred Leukotriene Receptor Antagonist in combination with a preferred first-or second- generation antihistamine:**

**Preferred Leukotriene Receptor Antagonist trial**: Drug Name: _____Strength: _____
Dosing Instructions: _____ Trial dates: _____

**Preferred First-or Second-Generation Antihistamine trial**: Drug Name: _____Strength: _____
Dosing Instructions: _____ Trial dates: _____

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

Please describe: _____

**Nasal Polyps:**

**Pretreatment IgE level**: _____ Date Obtained: _____

**Patient's Weight (kg):** _____ Date Obtained: _____

**Nasal Corticosteroid Trials:**

**Trial 1:** Drug Name: _____ Strength: _____
Dosing Instructions: _____ Trial dates: _____

**Trial 2:** Drug Name: _____ Strength: _____
Dosing Instructions: _____ Trial dates: _____

**Will omalizumab be used concurrently with a nasal corticosteroid?** ☐ Yes Drug Name: _____ ☐ No

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**Is Xolair being dosed according to manufacturer labeling based on pretreatment serum IgE and body weight:** ☐
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

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 Human Services, that the member continues to be eligible for Medicaid.*