

## Request for Prior Authorization OMALIZUMAB (XOLAIR)

FAX Completed Form To 1 (800) 574-2515 Provider Help Desk 1 (877) 776-1567

(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. 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 will be considered under the following conditions:

- 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.

#### **Moderate to Severe Persistent Asthma:**

- 1. Patient has a diagnosis of moderate to severe persistent asthma for at least one year, and
- 2. Patient has a Patient has a history of positive skin or RAST test to a perennial aeroallergen; and
- 3. 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.

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.

#### **Chronic Idiopathic Urticaria:**

- 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.

470-4279 (Rev. 1/25) Page 1 of 4

## Request for Prior Authorization OMALIZUMAB (XOLAIR)

(PLEASE PRINT - ACCURACY IS IMPORTANT)

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. Patient has documentation of an adequate trial and inadequate response with at least two nasal corticosteroids at a maximally tolerated dose; and
- 3. Will be used concurrently with a nasal corticosteroid.

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				
Strength	Dosage Instructions		Quantity	Days Supply
	healthcare setting, under the g se 1: Date dose 2:			
	etermined self-administration i nitigation strategies, as outline			sment of
Prescriber Specialty:	Allergist	Immunologist   C	tolaryngologist [	☐ Pulmonologist
Other (specify):				
Patient has access to epir	nephrine injection: Yes	] No		
Has patient been educated	d on proper storage and admin	stration?  Yes	☐ No	
Pretreatment IgE level:	Date Obtained:			
Patient's Weight (kg):	Date Obtained:			
Moderate to Severe Persis	stent Asthma:			
Date of diagnosis:				
Inhaled Corticosteroid tria	al: Drug Name:	Strength:	Instruction	าร:
Trial dates:				

470-4279 (Rev. 1/25) Page 2 of 4

# Request for Prior Authorization OMALIZUMAB (XOLAIR) (PLEASE PRINT – ACCURACY IS IMPORTANT)

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 requirem	nents:	
History of positive skin or RAST test to a perennial aero	pallergen: Yes No	Date Performed:
For Renewals Only: Has patient shown adequate respo	nse to Xolair <sup>®</sup> therapy? <b></b>	] Yes
Please describe:		
Moderate to Severe Chronic Idiopathic Urticaria:		
Preferred Second-Generation Antihistamine trial: Drug Dosing Instructions:Tri	Name:	Strength:
Dosing instructionsnii	ai uales.	-
<b>Preferred First-Generation Antihistamine trial:</b> Drug Nar Dosing Instructions:Tria	ne:Str al dates:	rength:
The		
		onath:
Preferred Potent H1 receptor antagonist trial: Drug Nam Dosing Instructions:Tria	ne:Stre	
Preferred Potent H1 receptor antagonist trial: Drug Nam Dosing Instructions:Tria Preferred Leukotriene Receptor Antagonist in combina	ne:Stre	
Preferred Potent H1 receptor antagonist trial: Drug Nam Dosing Instructions:  Preferred Leukotriene Receptor Antagonist in combina antihistamine:  Preferred Leukotriene Receptor Antagonist trial: Drug N	tion with a preferred first-o	or second- generation Strength:
Preferred Potent H1 receptor antagonist trial: Drug Nam Dosing Instructions:Tria  Preferred Leukotriene Receptor Antagonist in combina antihistamine:  Preferred Leukotriene Receptor Antagonist trial: Drug N Dosing Instructions:Tria  Preferred First-or Second-Generation Antihistamine tria	tion with a preferred first-outline:Street  tion with a preferred first-outline:Street  al dates:Street	or second- generation  Strength: Strength:
Preferred Potent H1 receptor antagonist trial: Drug Nam Dosing Instructions:Tria  Preferred Leukotriene Receptor Antagonist in combina antihistamine:  Preferred Leukotriene Receptor Antagonist trial: Drug N Dosing Instructions:Tria  Preferred First-or Second-Generation Antihistamine tria Dosing Instructions:Tria	al: Drug Name:al dates:	or second- generation  Strength:  Strength:
Preferred Potent H1 receptor antagonist trial: Drug Nam Dosing Instructions:Trial  Preferred Leukotriene Receptor Antagonist in combina antihistamine:  Preferred Leukotriene Receptor Antagonist trial: Drug Nosing Instructions:Trial  Preferred First-or Second-Generation Antihistamine trial Dosing Instructions:Trial  For Renewals Only: Has patient shown adequate response.	tion with a preferred first-on with a prefer	or second- generation  Strength:  Strength:
Preferred Potent H1 receptor antagonist trial: Drug Nam Dosing Instructions:Trial  Preferred Leukotriene Receptor Antagonist in combina antihistamine:  Preferred Leukotriene Receptor Antagonist trial: Drug N Dosing Instructions:Trial  Preferred First-or Second-Generation Antihistamine trial Dosing Instructions:Trial  For Renewals Only: Has patient shown adequate response describe:	tion with a preferred first-on with a prefer	or second- generation  Strength:  Strength:
Preferred Potent H1 receptor antagonist trial: Drug Nam Dosing Instructions: Trial  Preferred Leukotriene Receptor Antagonist in combina antihistamine:  Preferred Leukotriene Receptor Antagonist trial: Drug Nosing Instructions: Trial  Preferred First-or Second-Generation Antihistamine trial Dosing Instructions: Trial  For Renewals Only: Has patient shown adequate response describe: Nasal Polyps:	tion with a preferred first-on with a prefer	or second- generation  Strength:  Strength:
Preferred Potent H1 receptor antagonist trial: Drug Nam Dosing Instructions:Trial  Preferred Leukotriene Receptor Antagonist in combina antihistamine:  Preferred Leukotriene Receptor Antagonist trial: Drug Nosing Instructions:Trial  Preferred First-or Second-Generation Antihistamine trial Dosing Instructions:Trial  For Renewals Only: Has patient shown adequate responses describe:	tion with a preferred first-ordane:  al dates:  Iame:  al dates:  al: Drug Name:  al dates:  Inse to Xolair® therapy?	or second- generation  Strength:  Strength:
Preferred Potent H1 receptor antagonist trial: Drug Nam Dosing Instructions:Trial  Preferred Leukotriene Receptor Antagonist in combina antihistamine:  Preferred Leukotriene Receptor Antagonist trial: Drug Nosing Instructions:Trial  Preferred First-or Second-Generation Antihistamine trial Dosing Instructions:Trial  For Renewals Only: Has patient shown adequate response describe:	tion with a preferred first-ordane:  al dates:  Iame:  al dates:  al: Drug Name:  al dates:  Inse to Xolair® therapy?	or second- generation  Strength:  Strength:
Preferred Potent H1 receptor antagonist trial: Drug Nam Dosing Instructions:Trial  Preferred Leukotriene Receptor Antagonist in combina antihistamine:  Preferred Leukotriene Receptor Antagonist trial: Drug N Dosing Instructions:Trial  Preferred First-or Second-Generation Antihistamine trial Dosing Instructions:Trial  For Renewals Only: Has patient shown adequate response.	tion with a preferred first-ordane:  al dates:  lame:  al dates:  al: Drug Name:  al dates:  mse to Xolair® therapy?	or second- generation  Strength:  Strength:

Page 3 of 4 470-4279 (Rev. 1/25)

## Request for Prior Authorization OMALIZUMAB (XOLAIR)

(PLEASE PRINT - ACCURACY IS IMPORTANT)

For Renewals Only: Has patient shown adequate response to Xolair® therapy?   Yes No				
Please describe:				
Is patient currently using a nasal corticosteroid?  Yes No				
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.

470-4279 (Rev. 1/25) Page 4 of 4