





Fax Completed Form To 1.833.404.2392 Prescriber Help Desk 1.833.587.2012

Online covermymeds.com/main/prior-authorization-forms/

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 informa	tion above. It must be legible, correct, and co	mplete 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);
- 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.

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

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- 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
- 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.

contraindicated.				
Preferred				
Xolair prefilled	syringe			
Strength	Dosage Instruction	ons	Quantity	Days Supply
Diagnosis:				
	a healthcare setting, under the Date dose 2:			nimum of 3 doses?
	determined self-administration on strategies, as outlined in the		n careful assessmer No	nt of risk for
Prescriber Specialty: Other (specify):	Allergist Dermatologist [☐ Immunologist ☐ C	Otolaryngologist	Pulmonologist
Patient has access to epi	nephrine injection: Yes	☐ No		
Has patient been educat	ed on proper storage and admin	nistration?] No	
Moderate to Severe Per	sistent Asthma:			
Date of diagnosis:				
Inhaled Corticosteroid t	rial: Drug Name:	Strength:	Instructions:	
Trial datas:				

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illialed Long-Acting Beta-Agon	ist trial: Drug Name:	$_{}$ Strength: $_{}$	instructions:
Trial dates:			
Leukotriene Receptor Antagonis	st trial: Drug Name:	Strength:	Instructions:
Trial dates:			
Medical or contraindication reason to	o override trial requirements:		
Pretreatment IgE level:	Date Obtained:		
Patient's Weight (kg):	Date Obtained:		
ſes No 🗌	to manufacturer labeling based on protest to a perennial aeroallergen:		
For Renewals Only: Has patient	shown adequate response to Xolair®	therapy? 🗌 Ye	es 🗌 No
Please describe:			
Moderate to Severe Chronic Idio	opathic Urticaria:		
	ntihistamine trial: Drug Name: Trial dates:		Strength:
Preferred First-Generation Anti Dosing Instructions:	histamine trial: Drug Name: Trial dates:	Stren	gth:
	ntagonist trial: Drug Name: Trial dates:		rth:
Preferred Leukotriene Receptor	Antagonist in combination with a pr	eferred first-or	second- generation antihistan
	Antagonist trial: Drug Name:		ength:
Josing Instructions:	Trial dates:		
Preferred First-or Second-Gene	ration Antihistamine trial: Drug Name Trial dates: Trial dates:	:	Strength:
Preferred First-or Second-Gene Dosing Instructions:	ration Antihistamine trial: Drug Name Trial dates:	:	
Preferred First-or Second-General Dosing Instructions: For Renewals Only: Has patient	ration Antihistamine trial: Drug Name Trial dates: shown adequate response to Xolair®	: therapy?	
Preferred First-or Second-General Dosing Instructions: For Renewals Only: Has patient Please describe:	ration Antihistamine trial: Drug Name Trial dates:	: therapy?	
Preferred First-or Second-General Dosing Instructions: For Renewals Only: Has patient Please describe: Nasal Polyps:	ration Antihistamine trial: Drug Name Trial dates: shown adequate response to Xolair®	therapy? 🗌 Ye	
Preferred First-or Second-Gene Dosing Instructions: For Renewals Only: Has patient Please describe: Nasal Polyps: Pretreatment IgE level:	ration Antihistamine trial: Drug Name Trial dates: shown adequate response to Xolair® Date Obtained:	therapy?	
Preferred First-or Second-General Dosing Instructions: For Renewals Only: Has patient Please describe: Nasal Polyps: Pretreatment IgE level: Patient's Weight (kg):	ration Antihistamine trial: Drug Name Trial dates: shown adequate response to Xolair®	therapy?	
Preferred First-or Second-General Dosing Instructions:	ration Antihistamine trial: Drug Name Trial dates: shown adequate response to Xolair® Date Obtained: Date Obtained:	therapy?	
Preferred First-or Second-General Dosing Instructions:	ration Antihistamine trial: Drug Name Trial dates: shown adequate response to Xolair® Date Obtained:	:	
Preferred First-or Second-Gene Dosing Instructions: For Renewals Only: Has patient Please describe:	ration Antihistamine trial: Drug Name Trial dates: shown adequate response to Xolair® Date Obtained: Date Obtained:	:	







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Yes No	ed on pretreatment serum IgE and body weight:
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.

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