

# OMALIZUMAB



Included Products: Xolair (omalizumab)

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Severe Asthma			
Initial Criteria		If yes	If no
1.	Is Xolair being requested by a pulmonologist or immunologist?	Continue to #2.	Do not approve.
2.	Is the member $\geq 6$ years?	Continue to #3.	Do not approve.
3.	Does the member have a diagnosis of moderate to severe persistent asthma?	Continue to #4.	Do not approve.
4.	Is the member a current smoker?	Do not approve.	Continue to #5.
5.	Does the member have a positive skin test or RAST to a perennial aeroallergen?	Continue to #6.	Do not approve.
6.	Is the member's baseline IgE serum level within FDA label? a. Age 6-11: 30-1,300 IU/mL Age 12 and up: 30-700 IU/mL	Continue to #7.	Do not approve.
7.	Have the provider and member taken all steps to reduce and maximally manage environmental allergens and other triggers (e.g., tobacco smoke, dust mites, pets, molds, occupational exposures, GERD)?	Continue to #8.	Do not approve.
8.	Has the member failed the following agents including as combination therapy? a. High dose inhaled corticosteroid with a long acting beta agonist (such as AirDuo, Advair, or Symbicort) b. Long acting muscarinic antagonist (such as Spiriva) Leukotriene inhibitor (such as montelukast)	Continue to #9.	Do not approve.
9.	Does the member have a history of compliance with asthma medications?	Continue to #10.	Do not approve.

10.	In the past year has the member had frequent asthma exacerbations resulting in repeated use of health care services, such as urgent care or ED visits or hospitalization?	Continue to #11.	Do not approve.
11.	Approve for 6 months.		
<b>Renewal Criteria</b>		<b>If yes</b>	<b>If no</b>
1.	Has the member had a reduction in asthma exacerbations necessitating frequent office visits, ED / urgent care visits, hospitalizations, oral steroids and demonstrated sustained clinical improvement from baseline while on Xolair?	Continue to #2.	Do not approve.
2.	Approve for 12 months.		

<b>Nasal Polyps</b>			
<b>Initial Criteria</b>		<b>If yes</b>	<b>If no</b>
1.	Is the request from an allergist or ENT?	Continue to #2.	Do not approve.
2.	Does the member have recurrent nasal polyps after multiple prior sinus surgeries within the past 2 years?	Continue to #3.	Do not approve.
3.	Has the member failed all the following? a. At least 2 prior intranasal corticosteroids b. Sinuva	Continue to #4.	Do not approve.
4.	Is the member currently adherent to a nasal corticosteroid and is Xolair intended to be adjunctive therapy?	Continue to #5.	Do not approve.
5.	Is the member at risk of another sinus surgery?	Continue to #6.	Do not approve.
6.	Is there a statement why sinus surgery is not medically appropriate?	Continue to #7.	Do not approve.
7.	Consult with a medical director for approval.		
<b>Renewal Criteria</b>		<b>If yes</b>	<b>If no</b>
1.	Has the member had a clinically significant improvement in symptoms and reduced risk of needing surgery?		Do not approve.
2.	Approve for 6 months.		

<b>Chronic Idiopathic Urticaria</b>		
<b>Initial Criteria</b>	<b>If yes</b>	<b>If no</b>

1.	Is the member's current age <21 years?	Evaluate for medical necessity and appropriateness.	Deny. Chronic idiopathic urticaria is not an OHP funded condition.
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<b>Peanut Allergy</b>			
<b>Initial Criteria</b>		<b>If yes</b>	<b>If no</b>
1.	Is Xolair being prescribed by, or in consultation with an allergist or immunologist?	Continue to #2	Deny, guideline note 203 not met.
2.	Does the member have a history of serious peanut allergy with anaphylaxis?	Continue to #3	Deny, guideline note 203 not met.
3.	Does the member have a diagnosis of peanut allergy confirmed with an IgE or skin-prick test?	Continue to #4	Deny, guideline note 203 not met.
4.	Has the member had a baseline eliciting dose of allergy symptoms on double-blind, placebo-controlled food challenge (DBPCFC) test?	Continue to #5	Deny, guideline note 203 not met.
5.	Has the member failed Palforzia?	Approve for 6 months.	Deny, criteria not met.