



coordinated care™

Antiasthmatic Monoclonal Antibodies – Anti-IgE Antibodies

WA.PHAR.29 Antiasthmatic Monoclonal Antibodies Anti IgE Antibodies

Related medical policies: Antiasthmatic Monoclonal Antibodies – IL-5 Antagonists (Medical policy no. 44.60.40)

Background:

Asthma is a common chronic inflammatory disease of the airways. For most patients asthma is well controlled with inhaled therapy but for those with severe asthma it can be associated with substantial morbidity, mortality, and economic effects.

Medical necessity

Drug	Medical Necessity
omalizumab (XOLAIR®)	<p>Omalizumab may be considered medically necessary when used for ONE of the following:</p> <ul style="list-style-type: none"> • Severe persistent allergic asthma in patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids. • Chronic idiopathic urticaria in patients 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
omalizumab (XOLAIR®)	<p><u>Moderate to severe persistent allergic asthma</u></p> <ol style="list-style-type: none"> 1. Greater than or equal to (\geq) 6 years of age 2. History of failure (remains symptomatic after 6 weeks), contraindication or intolerance to medium- to high-dose inhaled corticosteroids (ICS) 3. Positive skin test or in vitro reactivity to a perennial aeroallergen 4. Uncontrolled or inadequately controlled severe asthma is defined by at least ONE of the following: <ol style="list-style-type: none"> a. FEV₁ less than (<) 80% predicted b. Two or more bursts of systemic corticosteroids in the previous 12 months c. Poor symptom control (e.g., ACQ score consistently greater than 1.5 or ACT score consistently less than 20) 5. Pre-treatment serum IgE level between 30 and 1500 IU/mL 6. NOT to be used in combination with other monoclonal antibodies (e.g. benralizumab, mepolizumab, reslizumab)

	<p>7. Prescribed by or in consultation with a specialist in allergy, pulmonology, or immunology</p> <p>Approve for 12 months</p>
	<p>Criteria (Reauthorization)</p> <p>Clinical documentation of disease stability or improvement compared to baseline measures.</p> <p>Approve for 12 months</p>
	<p><u>Chronic idiopathic urticaria</u></p> <ol style="list-style-type: none"> Greater than or equal to (\geq) 12 years of age History of failure, contraindication or intolerance to H1 antihistamine therapy NOT to be used in combination with other monoclonal antibodies (e.g. benralizumab, mepolizumab, reslizumab) Prescribed by or in consultation with a specialist in allergy, pulmonology, or immunology <p>Approve for 12 months</p>
	<p>Criteria (Reauthorization)</p> <p>Clinical documentation of disease stability or improvement compared to baseline measures.</p> <p>Approve for 12 months</p>

Dosage and quantity limits

Drug Name	Dose and Quantity Limits
omalizumab (XOLAIR®)	<ul style="list-style-type: none"> Asthma: 375mg every 2 weeks; 2.5 vials per 14-day supply (5 vials per 28-day supply) Urticaria: 300mg every 4 weeks; 2 vial per 28-day supply

Coding:

HCPCS Code	Description
J2357	Injection, omalizumab, 5 mg

References

- Product Information: FASENRA™ subcutaneous injection, benralizumab subcutaneous injection. AstraZeneca Pharmaceuticals LP (per manufacturer), Wilmington, DE, 2017.
- Product Information: NUCALA® subcutaneous injection, mepolizumab subcutaneous injection. GlaxoSmithKline LLC (per manufacturer), Philadelphia, PA, 2017
- Product Information: XOLAIR® subcutaneous injection powder, omalizumab subcutaneous injection powder. Genentech Inc (per manufacturer), South San Francisco, CA, 2016.

4. Product Information: CINQAIR® intravenous injection, reslizumab intravenous injection. Teva Pharmaceuticals (per manufacturer), Frazer, PA, 2016.
5. Vaglio A, Buzio C, Zwerina J. Eosinophilic granulomatosis with polyangiitis (Churg-Strauss): state of the art. *Allergy* (2013) 68:261–73. doi:10.1111/all.12088
6. Seo, P. Eosinophilic Granulomatosis with Polyangiitis: Challenges and Opportunities. *JACI*, (2016) Volume 4 , Issue 3 , 520–521.
7. Nair P. Anti-interleukin-5 monoclonal antibody to treat severe eosinophilic asthma. *N Engl J Med*. 2014;371(13):1249-1251.
8. Gotlib J. World Health Organization-defined eosinophilic disorders: 2015 update on diagnosis, risk stratification, and management. *Am J Hematol*. 2015;90(11):1077-1089.
9. Centers for Disease Control and Prevention (CDC). CDC National Health Interview Survey 2013. Atlanta, GA: CDC; 2013. Available at: <http://www.cdc.gov/asthma/nhis/2013/table3-1.htm>. Accessed November 11, 2015.
10. Nair P. Anti-interleukin-5 monoclonal antibody to treat severe eosinophilic asthma. *N Engl J Med*. 2014;371(13):1249-1251.
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