

Antiasthmatic – monoclonal antibodies

Medical policy no. 44.60.00-1

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. Asthma has been divided into subtypes, some of which are associated with elevated eosinophil levels (a marker of inflammation) in both the blood and airways.

Medical necessity

Drug	Medical Necessity
benralizumab (FASENRA®) reslizumab (CINQAIR®)	Benralizumab, reslizumab may be considered medically necessary when: Used as an add-on maintenance treatment with severe asthma with eosinophilic phenotype.
mepolizumab (NUCALA®)	Mepolizumab may be considered medically necessary when: <ul style="list-style-type: none"> Used as an add-on maintenance treatment with severe asthma with eosinophilic phenotype. Used for the treatment of eosinophilic granulomatosis with polyangiitis (EGPA) in adult patients
omalizumab (XOLAIR®)	Omalizumab may be considered medically necessary when used for ONE of the following: <ol 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)
benralizumab (FASENRA®) mepolizumab (NUCALA®) omalizumab (XOLAIR®) reslizumab (CINQAIR®)	Benralizumab, mepolizumab, reslizumab may be covered when all of the following are met: <ol style="list-style-type: none"> <u>Diagnosis of severe asthma with an eosinophilic phenotype</u> Documentation of blood eosinophil count (in the absence of other potential causes of eosinophilia) of ONE of the following: <ol style="list-style-type: none"> Greater than or equal to (\geq) 150 cells/μL in prior 6 weeks Greater than or equal to (\geq) 300 cells/μL in prior 12 months Uncontrolled or inadequately controlled severe asthma is defined by at least ONE of the following: <ol style="list-style-type: none"> FEV₁ less than (<) 80% predicted Two or more bursts of systemic corticosteroids in the previous 12 months

	<ul style="list-style-type: none"> c. Poor symptom control (e.g., ACQ score consistently greater than 1.5 or ACT score consistently less than 20) 4. History of failure (remains symptomatic after 6 weeks), contraindication or intolerance to high-dose inhaled corticosteroid in combination with additional controller(s) 5. Used in combination with additional asthma controller medications 6. NOT used in combination with other monoclonal antibodies for the treatment of asthma (e.g. mepolizumab, reslizumab, benralizumab, omalizumab) 7. Age limits: <ul style="list-style-type: none"> a. Benralizumab, mepolizumab: greater than or equal to (\geq) 12 years of age b. Raslizumab: greater than or equal to (\geq) 18 years of age 8. Prescribed by or in consultation with a specialist in allergy, pulmonology, or immunology <p>Approve for 12 months</p>
	<p>Mepolizumab may be covered when all of the following are met:</p> <ul style="list-style-type: none"> 1. <u>Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA)</u> 2. Greater than or equal to (\geq) 12 years of age 3. Symptoms that include TWO of the following <ul style="list-style-type: none"> a. Documentation of blood eosinophil count (in the absence of other potential causes of eosinophilia) of ONE of the following: <ul style="list-style-type: none"> i. Greater than or equal to (\geq) 150 cells/μL in prior 6 weeks ii. Greater than or equal to (\geq) 300 cells/μL in prior 12 months b. White blood cells present outside blood vessels (extravascular eosinophils) c. Migratory spots or lesions on a chest X-ray (pulmonary infiltrates) d. Sinus problems (acute or chronic sinusitis) e. Damage to one or more nerve groups (mononeuropathy or polyneuropathy) 4. History of failure, contraindication or intolerance to ONE of the following: <ul style="list-style-type: none"> a. Oral corticosteroids b. Inhaled corticosteroids c. Immunosuppressants (e.g. cyclophosphamide, azathioprine, methotrexate) 5. Less than or equal to (\leq) 300mg every 4 weeks 6. NOT to be used in combination with other monoclonal antibodies (e.g. benralizumab, omalizumab, reslizumab) 7. Prescribed by or in consultation with a specialist in allergy, cardiology, hematology, pulmonology, or rheumatology <p>Approve for 12 months</p>
	<p>Omalizumab may be covered when all of the following are met:</p> <ul style="list-style-type: none"> 1. Diagnosis of ONE of the following: <ul style="list-style-type: none"> a. <u>Moderate to severe persistent allergic asthma</u>

	<ul style="list-style-type: none"> i. Greater than or equal to (\geq) 6 years of age ii. History of failure (remains symptomatic after 6 weeks), contraindication or intolerance to medium- to high-dose inhaled corticosteroids (ICS) iii. Positive skin test or in vitro reactivity to a perennial aeroallergen iv. Symptoms inadequately controlled with inhaled corticosteroids v. FEV₁ is less than (<) 80% predicted vi. Pre-treatment serum IgE level between 30 and 1500 IU/mL <p>b. <u>Chronic idiopathic urticaria</u></p> <ul style="list-style-type: none"> i. Greater than or equal to (\geq) 12 years of age ii. History of failure, contraindication or intolerance to H1 antihistamine therapy <p>2. NOT to be used in combination with other monoclonal antibodies (e.g. benralizumab, mepolizumab, reslizumab)</p> <p>3. Prescribed by or in consultation with a specialist in allergy, pulmonology, or immunology</p> <p>Approve for 12 months</p>
	Criteria (Reauthorization)
	<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
benralizumab (FASENRA®)	30mg (1 syringe) every 4 weeks x3 doses, then 30mg (1 syringe) every 8 weeks
mepolizumab (NUCALA®)	Asthma: 100mg every 4 weeks; 1 vial per 28-day supply EGPA: 300mg every 4 weeks; 3 vials per 28-day supply
omalizumab (XOLAIR®)	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
Reslizumab (CINQAIR®)	3mg/kg every 4 weeks

Coding:

HCPCS Code	Description
J2182	Injection, mepolizumab, 1mg
J2357	Injection, omalizumab, 5 mg
J2786	Injection, reslizumab, 1mg

ICD-10 Code	Description
J45.50	Severe persistent asthma, uncomplicated
J45.51	Severe persistent asthma with (acute) exacerbation
J45.52	Severe persistent asthma with status asthmaticus

J82	Pulmonary eosinophilia, not elsewhere classified
L50.1	Idiopathic urticaria
M30.1	Polyarteritis with lung involvement [Churg-Strauss]
M31.30	Granulomatosis with polyangiitis

References

1. Product Information: FASENRA™ subcutaneous injection, benralizumab subcutaneous injection. AstraZeneca Pharmaceuticals LP (per manufacturer), Wilmington, DE, 2017.
2. Product Information: NUCALA® subcutaneous injection, mepolizumab subcutaneous injection. GlaxoSmithKline LLC (per manufacturer), Philadelphia, PA, 2017
3. 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.
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