



# Antiasthmatic Monoclonal Antibodies – IL-5 Antagonists

## WA.PHAR.30 Antiasthmatic Monoclonal Antibodies IL 5 Antagonists

### Related medical policies:

- **Antiasthmatic Monoclonal Antibodies – Anti-IgE Antibodies (WA.PHAR.29 Antiasthmatic Monoclonal Antibodies Anti IgE Antibodies)**

### 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®)	<b>Benralizumab, reslizumab</b> may be considered medically necessary when: <ul style="list-style-type: none"> <li>• Used as an add-on maintenance treatment with severe asthma with eosinophilic phenotype.</li> </ul>
mepolizumab (NUCALA®)	<b>Mepolizumab</b> may be considered medically necessary when: <ul style="list-style-type: none"> <li>• Used as an add-on maintenance treatment with severe asthma with eosinophilic phenotype.</li> <li>• Used for the treatment of eosinophilic granulomatosis with polyangiitis (EGPA) in adult patients</li> </ul>

### Clinical policy:

Drug	Clinical Criteria (Initial Approval)
benralizumab (FASENRA®) mepolizumab (NUCALA®) reslizumab (CINQAIR®)	<u>Diagnosis of severe asthma with an eosinophilic phenotype</u> <ol style="list-style-type: none"> <li>1. Documentation of blood eosinophil count (in the absence of other potential causes of eosinophilia) of <b>ONE</b> of the following:               <ol style="list-style-type: none"> <li>a. Greater than or equal to (<math>\geq</math>) 150 cells/<math>\mu</math>L in prior 6 weeks</li> <li>b. Greater than or equal to (<math>\geq</math>) 300 cells/<math>\mu</math>L in prior 12 months</li> </ol> </li> <li>2. Uncontrolled or inadequately controlled severe asthma is defined by at least <b>ONE</b> of the following:               <ol style="list-style-type: none"> <li>a. FEV<sub>1</sub> less than (&lt;) 80% predicted</li> <li>b. Two or more bursts of systemic corticosteroids in the previous 12 months</li> <li>c. Poor symptom control (e.g., ACQ score consistently greater than 1.5 or ACT score consistently less than 20)</li> </ol> </li> </ol>

	<ol style="list-style-type: none"> <li>3. History of failure (remains symptomatic after 6 weeks), contraindication or intolerance to high-dose inhaled corticosteroid in combination with additional controller(s)</li> <li>4. Used in combination with additional asthma controller medications</li> <li>5. NOT used in combination with other monoclonal antibodies for the treatment of asthma (e.g. mepolizumab, reslizumab, benralizumab, omalizumab)</li> <li>6. Age limits:             <ol style="list-style-type: none"> <li>a. Benralizumab, mepolizumab: greater than or equal to (<math>\geq</math>) 12 years of age</li> <li>b. Raslizumab: greater than or equal to (<math>\geq</math>) 18 years of age</li> </ol> </li> <li>7. Prescribed by or in consultation with a specialist in allergy, pulmonology, or immunology</li> </ol> <p><b>Approve for 12 months</b></p> <p style="background-color: #0070C0; color: white; text-align: center;"><b>Criteria (Reauthorization)</b></p> <p>Clinical documentation of disease stability or improvement compared to baseline measures.</p> <p><b>Approve for 12 months</b></p>
mepolizumab (NUCALA®) only	<p><u>Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA)</u></p> <ol style="list-style-type: none"> <li>1. Symptoms that include <b>TWO</b> of the following             <ol style="list-style-type: none"> <li>a. Documentation of blood eosinophil count (in the absence of other potential causes of eosinophilia) of <b>ONE</b> of the following:                 <ol style="list-style-type: none"> <li>i. Greater than or equal to (<math>\geq</math>) 150 cells/<math>\mu</math>L in prior 6 weeks</li> <li>ii. Greater than or equal to (<math>\geq</math>) 300 cells/<math>\mu</math>L in prior 12 months</li> </ol> </li> <li>b. White blood cells present outside blood vessels (extravascular eosinophils)</li> <li>c. Migratory spots or lesions on a chest X-ray (pulmonary infiltrates)</li> <li>d. Sinus problems (acute or chronic sinusitis)</li> <li>e. Damage to one or more nerve groups (mononeuropathy or polyneuropathy)</li> </ol> </li> <li>2. History of failure, contraindication or intolerance to <b>ONE</b> of the following:             <ol style="list-style-type: none"> <li>a. Oral corticosteroids</li> <li>b. Inhaled corticosteroids</li> <li>c. Immunosuppressants (e.g. cyclophosphamide, azathioprine, methotrexate)</li> </ol> </li> <li>3. Less than or equal to (<math>\leq</math>) 300mg every 4 weeks</li> <li>4. Prescribed by or in consultation with a specialist in allergy, cardiology, hematology, pulmonology, or rheumatology</li> <li>5. Greater than or equal to (<math>\geq</math>) 12 years of age</li> </ol>

	<p>6. <b>NOT</b> to be used in combination with other antiasthmatic – monoclonal antibodies (e.g. benralizumab, omalizumab, reslizumab)</p> <p><b>Approve for 12 months</b></p>
	<p><b>Criteria (Reauthorization)</b></p> <p>Clinical documentation of disease stability or improvement compared to baseline measures.</p> <p><b>Approve for 12 months</b></p>

### Dosage and quantity limits

Drug Name	Dose and Quantity Limits
benralizumab (FASENRA®)	<ul style="list-style-type: none"> <li>30mg (1 syringe) every 4 weeks x3 doses, then 30mg (1 syringe) every 8 weeks</li> </ul>
mepolizumab (NUCALA®)	<ul style="list-style-type: none"> <li>Asthma: 100mg every 4 weeks; 1 vial per 28-day supply</li> <li>EGPA: 300mg every 4 weeks; 3 vials per 28-day supply</li> </ul>
Reslizumab (CINQAIR®)	<ul style="list-style-type: none"> <li>3mg/kg every 4 weeks</li> </ul>

### Coding:

HCPCS Code	Description
J2182	Injection, mepolizumab, 1mg
J2786	Injection, reslizumab, 1mg

### 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.
10. Nair P. Anti-interleukin-5 monoclonal antibody to treat severe eosinophilic asthma. *N Engl J Med*. 2014;371(13):1249-1251.

11. Gotlib J. World Health Organization-defined eosinophilic disorders: 2015 update on diagnosis, risk stratification, and management. *Am J Hematol.* 2015;90(11):1077-1089.
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13. Nair P. Anti-interleukin-5 monoclonal antibody to treat severe eosinophilic asthma. *N Engl J Med.* 2014;371(13):1249-1251.
14. Gotlib J. World Health Organization-defined eosinophilic disorders: 2015 update on diagnosis, risk stratification, and management. *Am J Hematol.* 2015;90(11):1077-1089.
15. 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.