Antiasthmatic Monoclonal Antibodies – IL-5 Antagonists

WA.PHAR.30 Antiasthmatic Monoclonal Antibodies IL 5 Antagonists

Effective Date: May 1, 2020

Related medical policies:

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

Note: New-to-market drugs are non-preferred and subject to this class/category prior authorization (PA) criteria. Non-preferred agents in this class/category, require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class/category documentation of inadequate response to ONE preferred agent is needed.

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
mepolizumab (NUCALA®)	**Mepolizumab** may be considered medically necessary when: • 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
benralizumab (FASENRA®) reslizumab (CINQAIR®)	**Benralizumab** and **reslizumab** may be considered medically necessary when: • Used as an add-on maintenance treatment with severe asthma with eosinophilic phenotype. **Note:** Non-preferred products require trial of preferred product with the same indication

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
Severe asthma with an eosinophilic phenotype FDA-approved medications: • mepolizumab (NUCALA®) • benralizumab (FASENRA®) • reslizumab (CINQAIR®)	1. Documentation of blood eosinophil count (in the absence of other potential causes of eosinophilia) of **ONE** of the following: a. Greater than or equal to (≥) 150 cells/µL in prior 6 weeks; **OR** b. Greater than or equal to (≥) 300 cells/µL in prior 12 months; **AND** 2. Severe asthma as defined by at least **ONE** of the following: a. FEV_1 less than (<) 80% predicted; **OR** b. Two or more bursts of systemic corticosteroids in the previous 12 months; **OR** c. frequent (at least twice per year) additional medical treatment such as: emergency department (ED) visits, hospitalizations, or unplanned (sick) office visits; **OR** d. Documentation of functional impairment due to poor asthma control or exacerbations: (e.g. activities of daily living (ADLs), nighttime awakening, or dyspnea); **AND** 3. Poor symptom control (e.g., ACQ score consistently greater than 1.5 or ACT score consistently less than 20); **AND** 4. History of failure (remains symptomatic after 6 weeks), contraindication or intolerance to high-dose inhaled corticosteroid in combination with additional controller(s); **AND** 5. Used in combination with additional asthma controller medications; **AND** 6. Combination use with any of the following monoclonal antibodies is not considered medically necessary a. Anti-interleukin 5 therapy [e.g., mepolizumab, resilizumab, benralizumab]; **OR** b. Anti-IgE therapy [e.g., omalizumab]; **OR** c. Anti-interleukin 4 therapy [e.g., dupilumab]; **AND** 7. Age limits: a. Mepolizumab: greater than or equal to (≥) 6 years of age; **OR** b. Benralizumab: greater than or equal to (≥) 12 years of age; **OR** c. Raslizumab: greater than or equal to (≥) 18 years of age; **AND** 8. Prescribed by or in consultation with a specialist in allergy, pulmonology, or immunology If ALL criteria are met, the request may be approved for 12 months
	Criteria (Reauthorization)
	1. Clinical documentation of disease improvement compared to baseline measures (e.g., reduced missed days from work or school, improved FEV_1, ACQ or ACT scores, or decrease in burst of systemic corticosteroids)

	If ALL criteria are met, the request may be approved for 12 months
Eosinophilic granulomatosis with polyangiitis (EGPA) FDA-approved medications: • mepolizumab (NUCALA®)	1. Symptoms that include **FOUR** of the following a. Documentation of blood eosinophil count (in the absence of other potential causes of eosinophilia) greater than 10% eosinophils on the differential leukocyte count; b. Biopsy showing white blood cells present outside blood vessels (extravascular eosinophils); **OR** c. Migratory spots or lesions on a radiologic test (pulmonary infiltrates); **OR** d. Paranasal sinus abnormality; **OR** e. Mononeuropathy (including multiplex) or polyneuropathy; **OR** f. Asthma (a history of wheezing or the finding of diffuse high pitched wheezes on expiration); **AND** 2. Clinical documentation that the patient has a history of EGPA for at least 6 months with a history of relapsing or refractory disease to maximally tolerated inhaled or oral corticosteroid within the past 90 days, unless not tolerated or contraindicated; **AND** 3. Treatment with an oral DMARD (such as azathioprine, cyclophosphamide or methotrexate) in the past 90 days has been ineffective, not tolerated, or all oral DMARDs are contraindicated; **AND** 4. Prescribed by or in consultation with a specialist in allergy, , , pulmonology, or rheumatology; **AND** 5. Greater than or equal to (≥) 12 years of age: **AND** 6. Combination use with any of the following monoclonal antibodies is not considered medically necessary a. Anti-interleukin 5 therapy [e.g., mepolizumab, resilizumab, benralizumab] b. Anti-IgE therapy [e.g., omalizumab] c. Anti-interleukin 4 therapy [e.g., dupilumab] If ALL criteria are met, the request may be approved for 12 months
	Criteria (Reauthorization)
	1. Clinical documentation of disease stability or improvement compared to baseline measures as demonstrated by at least one of the following a. Reduction in the frequency and/or severity of relapses; **OR** b. Reduction or discontinuation of doses of corticosteroids and/or immunosuppressant; **OR** c. Disease remission; **OR** d. Reduction in severity or frequency of EGPA-related symptoms; **AND**

	2. Combination use with any of the following monoclonal antibodies is not considered medically necessary: a. Anti-interleukin 5 therapy [e.g., mepolizumab, resilizumab, benralizumab] b. Anti-IgE therapy [e.g., omalizumab] c. Anti-interleukin 4 therapy [e.g., dupilumab] If ALL criteria are met, the request may be approved for 12 months

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
reslizumab (CINQAIR®)	• 3mg/kg every 4 weeks

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.
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History

Date	Action and Summary of Changes
01/27/2020	General formatting updates and updated footnote date to January 27, 2020
01/13/2020	Changed effective date to May 1, 2020
12/10/2019	Updated definition of severe asthma. Removed cardiology and hematology specialty from EGPA criteria.
10/11/2019	Updated preferred/non-preferred status
10/03/2019	General formatting updates; added the note at the top.
07/07/2019	Clinical criteria update for diagnosis of severe asthma with an eosinophilic phenotype AND diagnosis of EGPA
02/21/2018	New Policy