Reference number(s)
2063-A

STANDARD MEDICARE PART B MANAGEMENT

NUCALA (mepolizumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Maintenance Treatment of Severe Asthma
   Nucala is an interleukin-5 antagonist monoclonal antibody (IgG1 kappa) indicated for add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype.

   Limitations of Use: Not for relief of acute bronchospasm or status asthmaticus

2. Eosinophilic Granulomatosis with Polyangiitis
   Nucala is indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

3. Hypereosinophilic Syndrome
   Nucala is indicated for the treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥6 months without an identifiable non-hematologic secondary cause.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

A. Eosinophilic asthma
Authorization of 12 months may be granted for treatment of eosinophilic asthma when all of the following criteria are met:

1. Member has a baseline blood eosinophil count of at least 150 cells per microliter.
2. Member has a history of severe asthma despite current treatment with both of the following medications at optimized doses, unless the member has a clinical reason to avoid these therapies:
   a. Inhaled corticosteroid
   b. Additional controller (long acting beta$_2$-agonist, leukotriene modifier, or sustained release theophylline)

B. Eosinophilic Granulomatosis with Polyangiitis
Authorization of 12 months may be granted for treatment of eosinophilic granulomatosis with polyangiitis in members with a history or the presence of an eosinophil count of more than 1000 cells per microliter or a blood eosinophil level of greater than 10%.

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C. Hypereosinophilic Syndrome (HES)

Authorization of 12 months may be granted for treatment of hypereosinophilic syndrome (HES) when all of the following criteria are met:

1. Member does not have either of the following:
   a. HES secondary to a non-hematologic cause (e.g., drug hypersensitivity, parasitic helminth infection, [human immunodeficiency virus] HIV infection, non-hematologic malignancy)
   b. FIP1L1-PDGFRA kinase-positive HES
2. Member has a history or presence of a blood eosinophil count of at least 1000 cells per microliter.
3. Member has been on a stable dose of HES therapy (e.g., oral corticosteroid, immunosuppressive, and/or cytotoxic therapy).
4. Member has had HES for at least 6 months.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

A. The member is currently receiving therapy with Nucala.
B. Nucala is being used to treat an indication enumerated in Section II.
C. The member is receiving benefit from therapy.

IV. REFERENCES

1. Nucala [package insert]. Research Triangle Park, NC: GlaxoSmithKline; September 2020.
2. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2019 update. Available at: https://ginasthma.org/reports/. Accessed March 5, 2020.
3. Ortega HG, Liu MC, Pavord ID, et al. Mepolizumab treatment in patients with severe eosinophilic asthma. *N Engl J Med*. 2014;371:1198-1207.
4. National Institutes of Health. National Asthma Education and Prevention Program Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma - Full Report 2007. Bethesda, MD: National Heart Lung and Blood Institute; August 2007. Available at: https://www.ncbi.nlm.nih.gov/books/NBK7232/pdf/Bookshelf_NBK7232.pdf. Accessed March 6, 2020.
5. Wechsler ME, Akuthota P, Jayne D, et al. Mepolizumab or placebo for eosinophilic granulomatosis with polyangiitis. *N Engl J Med*. 2017:18;376(20):1921-1932.

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