

When requesting Nucala® (mepolizumab), the individual requiring treatment must be diagnosed with the following FDA-approved indications and meet the specific coverage guidelines for the covered indications.

FDA-approved indications

- Nucala® (mepolizumab) is indicated for:
 - Add-on maintenance treatment of individuals with severe asthma having an eosinophilic phenotype
 - The treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)

Approved Off-label Compendial use

- None

Coverage Guidelines

Severe Asthma with an Eosinophilic Phenotype

The individual must meet **all** of the following criteria for approval:

- Diagnosis of severe asthma having an eosinophilic phenotype
- Requires treatment to prevent asthma from becoming uncontrolled or remaining uncontrolled despite therapy with:
 - High-dose inhaled corticosteroid plus a long-acting beta2-agonist (LABA), OR
 - Leukotriene modifier/theophylline for the previous year, OR
 - Systemic corticosteroids for ≥50% of the previous year
- Pretreatment eosinophil count ≥150 cells/mcL in peripheral blood at screening or an eosinophil count ≥300 cells/mcL during the previous year prior to initiating therapy
- Current non-smoker
- 12 years of age or older

Eosinophilic Granulomatosis with Polyangiitis

The individual must meet **all** of the following criteria for approval:

- History or presence of asthma
- A blood eosinophil level of 10% or an absolute eosinophil count of more than 1,000 cells per cubic millimeter
- Presentation of two or more criteria that define EGPA, such as:
 - o Biopsy showing evidence of EGPA
 - o Neuropathy
 - o Pulmonary infiltrates
 - o Sinonasal abnormality
 - o Cardiomyopathy

- o Glomerulonephritis
 - o Alveolar hemorrhage
 - o Palpable purpura
 - o Positive ANCA
- 12 years of age or older
- For reauthorization:
 - o The individual must meet the following criteria for renewal:
 - Reduction in relapses and/or glucocorticoid usage

Approval duration (initial and reauthorization): 12 months

Dosing Recommendations

- **Asthma:** 100 mg administered subcutaneously once every 4 weeks
- **EGPA:** 300 mg as 3 separate 100-mg injections administered subcutaneously once every 4 weeks

References

1. Nucala® prescribing information. Research Triangle Park, NC: GlaxoSmithKline: Revised December 2017.
2. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed February 2, 2018. <https://www.micromedexsolutions.com>
3. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. *Eur Respir J*. 2014;43:343-73. Accessed February 13, 2017. <https://www.ncbi.nlm.nih.gov/pubmed/24337046>
4. Ortega HG, Liu MC, Pavord ID, et al. Mepolizumab treatment in individuals with severe eosinophilic asthma. *N Engl J Med*. 2014; 371:1198-1207. Accessed February 13, 2017. <http://www.nejm.org/doi/full/10.1056/NEJMoa1403290#t=article>
5. Pavord ID, Korn S, Howarth P, et al Mepolizumab for severe eosinophilic asthma: a multicenter, double-blind, placebo-controlled trial. *Lancet*. 2012;380(9842):651-659. Accessed February 13, 2017. <https://www.ncbi.nlm.nih.gov/pubmed/22901886>
6. Wechsler, M.E, et al. Mepolizumab or placebo for eosinophilic granulomatosis with polyangiitis. *N Engl J Med*. 2017; 376: 1921-32. Accessed February 5, 2018.

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