

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.

CPT® (Current Procedural Terminology) is a registered trademark of the American Medical Association (AMA). CPT® five digit codes, nomenclature and other data are copyright 2016 American Medical Association. All Rights Reserved. No fee schedules, basic units, relative values or related listings are included in the CPT® book. AMA does not directly or indirectly practice medicine or dispense medical services. AMA assumes no liability for the data contained herein or not contained herein.