SmartHealth Ascension

Mepolizumab

(Nucala®) J2182

Mepolizumab (Nucala®) may be authorized when the following criteria are met:

Severe Asthma:

- Individuals aged 6 years or older with severe eosinophilic asthma, defined as:
  - blood eosinophils greater than or equal to 150 cells/mcl within the previous 6 weeks; **OR**
  - history of blood eosinophils greater than or equal to 300 cells/mcl; **AND**
- Severe asthma uncontrolled by high dosage inhaled corticosteroids; **AND**
- Continued use of an inhaled corticosteroid; **AND**
- Another controller therapy (for example, long-acting beta-agonist, leukotriene receptor); **AND**
- Dosing for severe asthma in patients
  - Age 12 years and older is 100 mg administered subcutaneously once every 4 weeks; **OR**
  - Age 6-11 years is 40 mg administered subcutaneously once every 4 weeks.

Exclusion criteria:

- Pediatric individuals (< age 6);
- Hypersensitivity to mepolizumab or any component of the formulation;
- Not for the relief of acute bronchospasm or status asthmaticus;
- Individuals with known parasitic (helminth) infections;
- Will not be used in combination with another antiasthmatic monoclonal antibody (for example, Cinqair, Fasenra, Xolair);
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.

Initial authorization is up to 12 months.

Continuation requests may be approved if there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage

NUCALA® is an interleukin-5 (IL-5) antagonist monoclonal antibody (IgG1 kappa) indicated for:

- Add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.
- The treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

Developed by: Medical Specialty Prior Authorization Team, April 2022
Approved by: Ambulatory Care Expert Review Panel, April 2022; Therapeutic Affinity Group, May 2022

- Add-on maintenance treatment of adult patients 18 years and older with chronic rhinosinusitis with nasal polyps
- Treatment of adult and pediatric patients aged 12 years and older with HES for ≥ 6 months without an identifiable non-hematologic secondary cause.

Limitations of use: Not for relief of acute bronchospasm or status asthmaticus.

References:

Ascension. (2022, January). *Medical Specialty Respiratory Drug Review for SmartHealth: SBAR*. Ascension TAG INITIATIVES - PSWP.

Ascension. (2022, January 21). *Mepolizumab (Nucala®) Criteria for Use*. Ascension TAG INITIATIVES - PSWP.

Nucala® (mepolizumab) label. (2019, June). Accessdata.fda.gov. Retrieved April 23, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761122s000lbl.pdf

Nucala® (mepolizumab) [prescribing information] Philadelphia, PA: GlaxoSmithKline; 10/2021

Pavord I, Korn S, Haworth P, *et al*. Mepolizumab for severe eosinophilic asthma (DREAM): a multicentre, double-blind, placebo-controlled trial. *Lancet* 2012;380:651-659

Criteria History/ Revision Information:

Date	Summary of Changes
January 2022	Medical Specialty Respiratory Drug Review for SmartHealth SBAR developed by Ambulatory Care Expert REview Panel
January 2022	Approved by Ambulatory Care Steering Committee
February 2022	Approved by Therapeutic Affinity Group
April 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
May 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.