Clinical Policy: Mepolizumab (Nucala)

Reference Number: PA.CP.PHAR.200
Effective Date: 01/18
Last Review Date: 04/17

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for mepolizumab (Nucala®).

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness that Nucala is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Severe Asthma (must meet all):

1. Prescribed by a pulmonologist or allergist;
2. Age ≥ 12 years;
3. Diagnosis of asthma with absolute blood eosinophil count ≥150 cells/mcL;
4. If current smoking history, referred for smoking cessation;
5. Member has experienced at least two exacerbations requiring oral/systemic corticosteroid treatment, urgent care visit or hospital admission, within the last 12 months, despite adherent use of controller therapy (i.e., high dose inhaled corticosteroid [ICS] plus either a long acting beta-2 agonist [LABA] or leukotriene modifier [LTRA] if LABA contraindication/intolerance);
6. Nucala is prescribed concomitantly with an ICS plus either an LABA or LTRA;
7. Prescribed dose does not exceed 100 mg every 4 weeks.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PHAR.57 Global Biopharm Policy

II. Continued Approval

A. Severe Asthma (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Demonstrated adherence to asthma controller therapy that includes an ICS plus either an LABA or LTRA;
3. Member is responding positively to therapy (e.g.: reduction in exacerbations or corticosteroid dose, improvement in forced expiratory volume$_1$ over one second) since baseline; reduction in the use of rescue therapy);
4. Prescribed dose does not exceed 100 mg every 4 weeks.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PHAR.57 - Global Biopharm Policy**.**

Background

Description/Mechanism of Action:

Mepolizumab is a humanized interleukin-5 (IL-5) antagonist monoclonal antibody. Mepolizumab is produced by recombinant DNA technology in Chinese hamster ovary cells. Mepolizumab binds to IL-5 with a dissociation constant of 100 pM, inhibiting the bioactivity of IL-5 by blocking its binding to the alpha chain of the IL-5 receptor complex expressed on the eosinophil cell surface. By inhibiting IL-5 signaling, it reduces the production and survival of eosinophils; however, the mechanism of mepolizumab action in asthma has not been definitively established.

Formulations:

Nucala: 100-mg single-dose vial of lyophilized powder for reconstitution.

FDA Approved Indications:

Nucala is an IL-5 antagonist monoclonal antibody/subcutaneous injectable formulation indicated for:

- Add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

Limitations of use:

- Nucala is not indicated for treatment of other eosinophilic conditions.
- Nucala is not indicated for the relief of acute bronchospasm or status asthmaticus.

Appendices

Appendix A: Abbreviation Key

ICS: inhaled corticosteroid
IL: interleukin
LABA: long acting beta-2 agonist
LTRA: leukotriene modifier

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J2182	Injection, mepolizumab, 1 mg

Reviews, Revisions, and Approvals	Date	Approval Date

References

1. Nucala prescribing information. Irvine, CA: Philadelphia, PA: GlaxoSmithKline LLC; February 2017. Available at http://www.nucala.com. Accessed March 21, 2017.
2. National Asthma Education and Prevention Program: Expert panel report III: Guidelines for the diagnosis and management of asthma. Bethesda, MD: National Heart, Lung, and Blood Institute, 2007. (NIH publication no. 08-4051). Available at http://www.nhlbi.nih.gov/health-pro/guidelines/current/asthma-guidelines. Accessed March 21, 2017.
3. Wenzel S. Treatment of severe asthma in adolescents and adults. In: UpToDate, Waltham, MA: Wolters Kluwer Health; 2017. Available at uptodate.com. Accessed March 21, 2017.