Drug Class Prior Authorization Criteria

Nucala (mepolizumab)

Line of Business: Medicaid
P & T Approval Date: May 5, 2023 **Effective Date:** June 2, 2023

This drug class prior authorization criteria have been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the IEHP Pharmacy and Therapeutics Subcommittee.

CRITERIA:

Covered Uses:	* Add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma and with an eosinophilic phenotype. (*Subject to review by a Clinical Pharmacist)
Exclusion Criteria:	N/A
Required Medical Information:	**Initial Coverage Criteria:** Must meet all of the following requirements: a. Diagnosis confirmed by the following laboratory results: i. Blood eosinophil counts greater than or equal to 150 cells/uL at the initiation of therapy (within 6 weeks of dosing), OR, ii. Blood eosinophil counts greater than or equal to 300 cells/uL (within 12 months) b. Documentation of inadequate control with a combination of a high-dose inhaled corticosteroid (ICS) and long-acting beta$_2$-agonist (LABA), plus an as-needed reliever therapy c. Documentation of compliance to the controller therapy for the past 6 months and that controller therapy will be continued d. Documentation of symptomatic asthma despite regular use of tried therapies, as demonstrated by "1" of the following: i. 2 or more asthma exacerbations in the past 12 months ii. Hospitalization due to asthma exacerbation iii. Forced expiratory volume in one second (FEV_1) less than 80% predicted Initial Approval Duration – 6 months
Age Restrictions:	Must be 6 years of age or older
Prescriber Restrictions:	Allergist, Immunologist, or Pulmonologist

Other Criteria:

Reauthorization criteria: Must meet all of the following requirements:

a. Must continue to meet initial coverage criteria
b. Documented improvement of asthma control demonstrated by at least "1" of the following:
    i. Reduction in frequency and/or severity of asthma symptoms and exacerbations
    ii. Reduction in the use of systemic corticosteroids
    iii. Improvement from baseline in forced expiratory volume in one second (FEV_1)

Reauthorization Approval Duration – 12 months

Covered Uses:

*****Eosinophilic granulomatosis with polyangiitis (EGPA)
(*Subject to review by a Clinical Pharmacist)

Exclusion Criteria:

N/A

Required Medical Information:

Must meet all of the following requirements:

a. Confirmed diagnosis by meeting "1" of the following:
    i. Must meet all of the following requirements:
        1. History or presence of asthma
        2. Blood eosinophil level of 10% or an absolute eosinophil count of more than 1000 cells/uL
    ii. The presence of two or more criteria that are typical of eosinophilic granulomatosis with polyangiitis such as:
        1. Histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation;
        2. Neuropathy;
        3. Pulmonary infiltrates;
        4. Sinonasal abnormality;
        5. Cardiomyopathy;
        6. Glomerulonephritis;
        7. Alveolar hemorrhage;
        8. Palpable purpura; or
        9. Antineutrophil cytoplasmic antibody [ANCA] positivity
b. Documentation of at least one relapse requiring addition or increase in oral corticosteroids or immunosuppressive therapy within 2 years prior to starting treatment of Nucala

Initial Approval Duration – 12 months

Age Restrictions: Must be 18 years of age or older

Prescriber Restrictions: Allergist, Immunologist or Pulmonologist

Other Criteria: Reauthorization criteria: Must meet all of the following requirements:

a. Must continue to meet initial coverage criteria
b. Documented improvement of asthma control on Nucala treatment demonstrated by at least "1" of the following:
    i. Reduction in the frequency and/or severity of relapses
    ii. Reduction in severity and/or frequency of the characteristics typical of EGPA symptoms
    iii. Reduction or discontinuation of doses of corticosteroid or immunosuppressive therapy
    iv. Absence of active vasculitis

Reauthorization Approval Duration – 12 months

References:

1. California Department of Health Care Services. Medi-Cal Provider Manual: Injections, Drugs I-M Policy (inject drug i-m). Accessed April 13th, 2023.
2. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 20221. http://www.ginasthma.org. Accessed March 31st, 2023.
3. Nucala (mepolizumab) [package insert]. Philadelphia, PA. GlaxoSmithKline. Revised March 2022. Accessed April 13th, 2023.
4. Masi A., Hunder G. et al. The American College of Rheumatology 1990 criteria for the classification of Churg-Strauss Syndrome (allergic granulomatosis and angiitis). Arthritis and Rheumatism. 1990;33:1094-1100

Change Control		
Date	**Change**	**RPH**
05/05/2023	• Updated Reauthorization criteria for EGPA for documentation of 1 of the following: reduction in frequency and/or severity of relapses, reduction in severity and/or frequencies typic of EGPA, and Reduction or discontinuation of doses of corticosteroid or immunosuppressive therapy, absence of active vasculitis • Removed Reauthorization requirement of recent claim within 180 days • Updated Reauthorization Duration from 6 months to 12 months	TL, SV

	• Updated References	
5/4/2022	• Updated initial coverage criteria and reauthorization criteria for Severe asthma: Add-on maintenance treatment in patients with an eosinophilic phenotype • Added approval duration for initial coverage criteria and reauthorization criteria for Severe asthma: Add-on maintenance treatment in patients with an eosinophilic phenotype	YA
02/19/2020	• Renewed with no changes	CN
11/20/2019	• Updated age restriction to 6 years and older for indication of add-on maintenance treatment in patients with an eosinophilic phenotype	CN
2/20/2019	• Added (*Subject to review by a Clinical Pharmacist) on covered uses • Changed diagnosis to covered uses for consistency • Reworded FEV1 language to be consistent with Xolair • Added criteria for documentation of inadequate control with a high dose ICS and LABA plus an as-needed reliever therapy • Added immunologist to prescriber restrictions • Reworded reauthorization criteria to state '180 days' and remove '6 months' for consistency • Added references	IK
11/29/2018	• Reformatted to align with current layout	IK
02/21/2018	• Updated indications to include Eosinophilic granulomatosis with polyangiitis and added criteria • Added clinical study for new indication: EGPA • Duration changed from 12 months to 6 months	CT