A Public Entity
Inland Empire Health Plan

Drug Class Prior Authorization Criteria
Nucala (mepolizumab)

Line of Business: Medicaid
P & T Approval Date: February 19, 2020 **Effective Date:** April 1, 2020

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:	*Severe asthma: Add-on maintenance treatment in patients with an eosinophilic phenotype (*Subject to review by a Clinical Pharmacist)
Exclusion Criteria:	N/A
Required Medical Information:	Must meet all of the following requirements: a. Diagnosis confirmed by "1" of the following laboratory results: i. Blood eosinophil counts greater than or equal to 150 cells/uL at the initiation of therapy ii. Blood eosinophil counts greater than or equal to 300 cells/uL in the past 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 previous year ii. Hospitalization due to asthma exacerbation iii. Forced expiratory volume in one second (FEV_1) less than 80% predicted
Age Restrictions:	Must be 6 years of age or older
Prescriber Restrictions:	Allergist, Immunologist or Pulmonologist

Other Criteria:	Reauthorization criteria: Must meet "1" of the following requirements: a. Confirmed stability or no disease progression b. Recent claim within 180 days of request

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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 per cubic millimeter ii. The presence of two or more criteria that are typical of eosinophilic granulomatosis with polyangiitis (i.e., histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation; neuropathy; pulmonary infiltrates; sinonasal abnormality; cardiomyopathy; glomerulonephritis; alveolar hemorrhage; palpable purpura; or antineutrophil cytoplasmic antibody [ANCA] positivity) b. Concurrently on stable dose of oral corticosteroids (i.e., prednisone or prednisolone)
Age Restrictions:	Must be 18 years of age or older
Prescriber Restrictions:	Allergist, Immunologist or Pulmonologist
Other Criteria:	Reauthorization criteria: Must meet "1" of the following requirements: a. Confirmed stability or no disease progression b. Recent claim within 180 days of request

References:

1. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2018. http://www.ginasthma.org. Accessed February 15th, 2019
2. Nucala (mepolizumab) [package insert]. Philadelphia, PA. GlaxoSmithKline. 2017.
3. 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**
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