Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	May 8, 2018 June 14, 2019; September 29, 2020; September 28, 2021; June 16, 2022, August 9, 2022

NUCALA® (mepolizumab)

LENGTH OF AUTHORIZATION: Initial: SIX MONTHS
Continuation: ONE YEAR

INITIAL REVIEW CRITERIA:

Specific Review Criteria for Maintenance Treatment of Severe Asthma

- Patient is 6 years of age or older.
- Verified diagnosis of severe persistent asthma; must be an eosinophilic phenotype.
- Must have a blood eosinophil count of ≥ 150 cells/mcL within the past six weeks while on oral corticosteroid or ≥ 300 cells/mcL within the past year (submit documentation).
- Must have adherence to optimized medication therapy regimen, yet uncontrolled:
  - Hospitalization for asthma within the past year; OR
  - Two occurrences in the past year requiring systemic corticosteroids (oral or parenteral) to control exacerbations of asthma; OR
  - Daily use of oral corticosteroids with inability to taper off the medication
- Trial of high dose inhaled corticosteroids and one of the following:
  - Inhaled long acting beta 2-agonist
  - theophylline
  - leukotriene receptor antagonist
- Trial of preferred monoclonal antibodies for the treatment of asthma (Dupixent®, Fasenra® and Xolair®).

Specific Review Criteria for Eosinophilic Granulomatosis with Polyangiitis

- Patient is 18 years of age or older.
- Verified diagnosis of eosinophilic granulomatosis with polyangiitis.
- Must have an adequate trial of a minimum of three months of the following, with an inadequate response or significant side effects/toxicity to therapy:
  - Corticosteroids; AND
  - An immunosuppressant such as azathioprine or methotrexate

Specific Review Criteria for Hypereosinophilic Syndrome (HES)

- Patient is 12 years of age or older.
- Verified diagnosis of HES for ≥ 6 months without an identifiable non-hematologic secondary cause.
- Patient has history of at least 2 HES flares (HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy) within the past 12 months.
- Must have a blood eosinophil count of ≥ 1,000 cells/mcL.

- Must be on stable HES therapy for 4 weeks prior to treatment (chronic or episodic oral corticosteroids, immunosuppressive, or cytotoxic therapy).

Specific Review Criteria for Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

- Patient is 18 years of age or older.
- Verified diagnosis of CRSwNP including:
    - Nasal obstructive symptoms with a visual analog scale (VAS) score of > 5 out of a maximum score of 10; **AND**
    - Endoscopic bilateral nasal polyp score (NPS) of ≥ 5 out of 8 with NPS ≥ 2 in each nasal cavity.
- Must have an adequate trial of a minimum of two months of nasal corticosteroids, with an inadequate response or significant side effects/toxicity to therapy.
- Patient will continue nasal corticosteroid therapy while receiving Nucala®.

CONTINUATION OF THERAPY:

Severe Asthma

- Patient has met initial review requirements.
- Improvement of asthma while on current regimen including Nucala® through:
    - A reduction in the frequency or severity of symptoms or exacerbations; OR
    - A reduction in the daily maintenance oral corticosteroid dose; OR
    - A reduction in the number of rescued medications; OR
    - A reduction in the number of hospitalizations or emergency room visits

Eosinophilic Granulomatosis with Polyangiitis

- Patient has met initial review requirements.
- Patient has seen a response to therapy by the following:
    - Reduction in frequency of relapses; OR
    - No active vasculitis; OR
    - A reduction in the dose of daily oral corticosteroids

HES

- Patient has met initial review requirements.
- Patient has seen a response to therapy (e.g. reduction in HES flares).

CRSwNP

- Patient has met initial review criteria.

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- Patient has seen a response to therapy (e.g., reduction in VAS score and NPS, improvement in symptomology, and reduction in requirement for systemic steroid).

DOSING AND ADMINISTRATION:

- Available as:
  - 40 mg/0.4 mL, single-dose prefilled syringe
  - 100 mg/mL, single-dose, prefilled autoinjector
  - 100 mg/ml, single-dose prefilled syringe
  - 100 mg single-dose vial for reconstitution
- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/