

mepolizumab (NUCALA)

Diagnosis Considered for Coverage:

- Eosinophilic granulomatosis with polyangiitis (EGPA)
- Severe eosinophilic asthma
- Hypereosinophilic syndrome (HES)
- Chronic rhinosinusitis with nasal polyps (CRSwNP)

Coverage Criteria:

For diagnosis of eosinophilic granulomatosis with polyangiitis:

INITIAL REQUEST

- Home self-injectables are under the pharmacy benefit, **and**
- Patient is at least 18 years old, **and**
- Prescribed by or in consultation with an immunologist, **and**
- Patient has relapsing or refractory disease despite treatment with oral corticosteroid (e.g. prednisone, prednisolone) OR immunosuppressive therapy (e.g. azathioprine, methotrexate, mycophenolic acid), **and**
- Dose does not exceed FDA label maximum.

Coverage Duration: 6 months

REAUTHORIZATION

- Home self-injectables are under the pharmacy benefit, **and**
- Provider attestation that patient is responding to Nucala, **and**
- Dose does not exceed FDA label maximum.

Coverage Duration: 1 year

For diagnosis of severe eosinophilic asthma:

INITIAL REQUEST

- Home self-injectables are under the pharmacy benefit, **and**
- Patient is at least 6 years old, **and**
- Prescribed by or in consultation with a pulmonologist, allergist, or immunologist, **and**
- Eosinophil blood count of ≥ 150 cells/ μ L within last 6 weeks or ≥ 300 cells/ μ L within the last 12 months, **and**
- Asthma symptoms remain uncontrolled despite 3 months of treatment with a high-dose inhaled corticosteroid (ICS) in combination with long-acting beta agonist (LABA) or leukotriene receptor antagonists (e.g.

montelukast, zafirlukast, zileuton), **and**

- Patient is not receiving this medication in combination with another biologic medication indicated for asthma treatment (e.g. Cinqair, Dupixent, Fasenra, Xolair, Tezspire), **and**
- Dose does not exceed FDA label maximum, **and**
- Meets ONE of the following within the past year:
 - One or more acute asthma attacks requiring emergency care, or
 - One or more acute inpatient visits where asthma was the principal diagnosis, or
 - Use of chronic systemic steroids due to severe asthma OR two or more acute asthma exacerbations requiring oral systemic steroids

Coverage Duration: 6 months

REAUTHORIZATION

- Home self-injectables are under the pharmacy benefit, **and**
- Patient is not receiving this medication in combination with another biologic medication indicated for asthma treatment (e.g. Cinqair, Dupixent, Nucala, Xolair, Tezspire), **and**
- Dose does not exceed FDA label maximum. , **and**
- Provider attestation that asthma symptoms have improved or controlled while on Nucala.

Coverage Duration: length of benefit

For diagnosis of hypereosinophilic syndrome (HES):

- Home self-injectables are under the pharmacy benefit, **and**
- Prescribed by or in consultation with an allergist or immunologist, **and**
- Patient is negative for FIP1-like 1-platelet derived growth factor receptor (FIP1L1-PDGFR) gene mutation, **and**
- Inadequate response to oral corticosteroids (e.g. prednisone) or hydroxyurea, **and**
- Dose does not exceed FDA label maximum.

Coverage Duration: length of benefit

For diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP):

- Home self-injectables are under the pharmacy benefit, **and**
- Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist, **and**
- Provider attestation that patient has nasal polyps, **and**

- Patient is at least 18 years old, **and**
- Inadequate response, intolerable side effect, or contraindication to an intranasal glucocorticoid **and**
- Dose does not exceed FDA label maximum.

Coverage Duration: length of benefit

Coverage Duration: see coverage criteria

References:

1. Prescribing Information. Nucala. GlaxoSmithKline Inc. 2022
2. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention (2021 Update). Available from: www.ginasthma.org.
3. Expert Panel Working Group of the National Heart, Lung, and Blood Institute (NHLBI) administered and coordinated National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC), Cloutier MM, Baptist AP, et al. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. J Allergy Clin Immunol 2020; 146:1217.

Effective Date: 8/31/2022