# Nucala® (mepolizumab)

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## Definition

Nucala® is an interleukin-5 antagonist monoclonal antibody (IgG1 kappa) indicated for add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype. NUCALA is also indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA). The drug is administered as a subcutaneous (SC) injection.

## Related Medical Guidelines

Off-Label Use of FDA-Approved Drugs and Biologicals
Xolair® (omalizumab)

## Dosing and Administration

Nucala Package Insert

## Guideline

**Criterion A or B must be met.**

**A.** Nucala is considered medically necessary for members ≥ 6 years of age for the treatment of severe eosinophilic asthma when **all** of the following criteria are met:

1. Prescribed by an asthma specialist (e.g., allergist, immunologist, pulmonologist)
2. Pre-treatment eosinophilic asthma phenotype of either:
    a. ≥ 150 cells/mcL at screening within 6 weeks prior to initiation of therapy
    b. ≥ 300 cells/mcL within prior 12 months

Note: Alternate eosinophilia causes should be ruled out [i.e., hypereosinophilic syndromes, neoplastic disease and known or suspected parasitic infection])

**Underlying conditions or triggers for asthma/pulmonary disease optimally managed**

3. Clinical documentation of poor asthma control or recurrent exacerbations requiring additional treatment is received:
    a. Additional medical treatment may include any of the following: treatment with oral corticosteroids, emergency department visits, hospitalizations, or frequent office visits
    b. Poor asthma control may include but is not limited to clinical documentation of limitation in activities of daily living, nighttime awakening or dyspnea
    c. Recurrent exacerbation is defined as ≥ 2 acute exacerbations in a 12 month period
4. Symptoms inadequately controlled; either:
    a. 12 months of high-dose inhaled corticosteroid (ICS) given in combination with a minimum of 3 months of controller medication (either a long-acting beta2-agonist, or leukotriene receptor antagonist, or theophylline), unless member is intolerant of, or has a medical contraindication to these agents; or
    b. 6 months of ICS with daily oral glucocorticoids given in combination with a minimum of 3 months of controller medication (either a long-acting beta2-agonist, or leukotriene receptor antagonist, or theophylline), unless member is intolerant of, or has a medical contraindication to these agents

**B.** Nucala is considered medically necessary for adult patients with eosinophilic granulomatosis with polyangiitis when member has all of the following criteria features:

1. Asthma
2. Eosinophilia [>10% on differential WBC count]
3. Mononeuropathy
4. Transient pulmonary infiltrates on chest X-rays
5. Paranasal sinus abnormalities
6. Biopsy containing a blood vessel with extravascular eosinophils
7. Symptoms inadequately controlled by corticosteroids (prednisone or methylprednisone) AND immunosuppressive therapies (ex: azathioprine, mycophenolate mofetil, methotrexate, cyclophosphamide, or rituximab).
8. Age 18 or older

**Authorization**

1. Initial authorization period of 6 months
2. Renewal
    a. For treatment of severe eosinophilic asthma, renewal may be provided every 12 months for members not receiving an alternate IL-5 inhibitor and is predicated upon clinical documentation demonstrating a sustained positive therapeutic response, as evidenced by ≥ 1 of the following:
        i. Increase in Forced Expiratory Volume (FEV1) from pretreatment baseline
        ii. ICS dosing reduction
        iii. Reduction in oral corticosteroid use frequency
        iv. Reduction in asthma exacerbations (e.g., decreased frequency of emergency room/urgent care visits)

v. Reduction in asthma symptoms (e.g., chest tightness, coughing, shortness of breath or nocturnal awakenings)

b. For treatment of eosinophilic granulomatosis with polyangiitis, renewal may be provided every 12 months.

### Limitations/Exclusions

Nucala is considered investigational when used for all other conditions, including, but not limited to **any**:

1. Severe allergic asthma (without documentation of severe eosinophilia)
2. Use in combination with other anti-asthma monoclonal antibodies, including omalizumab (Xolair) or reslizumab (Cinqair) (for asthma or any indication)
3. Allergic bronchopulmonary aspergillosis (ABPA)
4. Atopic dermatitis
5. Chronic obstructive pulmonary disease (COPD)
6. Eosinophilic esophagitis (EE)
7. Hypereosinophilic syndrome (HES, "hyper-E")
8. Nasal polyposis

### Revision History

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| **09/19/2019** | Addition of covered use for the add-on maintenance treatment of patients 6 years and older with severe asthma with an eosinophilic phenotype. |
| **06/21/2019** | Addition of EGPA indication to description; added adult age restriction for EGPA to match FDA label |
| **01/12/2018** | Addition of covered use for eosinophilic granulomatosis with polyangiitis. |

### Applicable Procedure Codes

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| J2182 | Injection, mepolizumab, 1 mg |

### Applicable Diagnosis Codes

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| J45.50 | Severe persistent asthma, uncomplicated |
| J45.51 | Severe persistent asthma with (acute) exacerbation |
| J45.52 | Severe persistent asthma with status asthmaticus |
| J82 | Pulmonary eosinophilia, not elsewhere classified |
| M30.1 | Polyarteritis with lung involvement [Churg-Strauss] |

### References

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