Nucala (mepolizumab)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Nucala (mepolizumab) drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines, and clinical studies. The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1) Maintenance Treatment of Severe Asthma
   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.
2) Eosinophilic Granulomatosis with Polyangiitis
   Nucala is indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
3) Hypereosinophilic syndrome (HES)
   Nucala is indicated for the treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non-hematologic secondary cause.

Limitations of Use:

- Not for relief of acute bronchospasm or status asthmaticus

POLICY

Documentation

Submission of the following information is necessary to initiate the prior authorization review (initial requests only):

A. Asthma: Member's chart or medical record showing baseline blood eosinophil count, if applicable
B. EGPA: Member's chart or medical record showing blood eosinophil count or level as noted in section B.2. below
C. HES:
    1. FIP1L1-PDGFRA fusion gene test results
    2. Member's chart or medical record showing blood eosinophil count as noted in section C.3 below

Criteria for Initial Approval

A. Asthma

Authorization of 6 months may be granted for treatment of severe asthma with an eosinophilic phenotype when ALL of the following criteria are met:

1. Member is 6 years of age or older.
2. Member meets either of the following criteria:
    a) Member has a baseline blood eosinophil count of at least 150 cells per microliter; or
    b) Member is dependent on systemic corticosteroids
3. Member has severe asthma as defined by, inadequate asthma control (e.g., hospitalization or emergency medical care visit within the past year) despite current treatment with both of the following medications at optimized doses.
    a) Inhaled corticosteroid
    b) Additional controller (long acting beta2-agonist, leukotriene modifier, or sustained-release theophylline)
4. Member will not use Nucala as monotherapy
5. Member will not use Nucala concomitantly with other biologics (e.g., Cinqair, Dupixent, Fasenra, Xolair)

B. Eosinophilic Granulomatosis with Polyangiitis

Authorization of 12 months may be granted for treatment of eosinophilic granulomatosis with polyangiitis when all of the following criteria are met:

1. Member is 18 years of age or older
2. Member has a history or the presence of an eosinophil count of more than 1000 cells per microliter or a blood eosinophil level of greater than 10%
3. Member has at least two of the following disease characteristics of EGPA:
    a) Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
    b) Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)
    c) Pulmonary infiltrates, non-fixed; sino-nasal abnormality
    d) Cardiomyopathy (established by echocardiography or magnetic resonance imaging)
    e) Glomerulonephritis (hematuria, red cell casts, proteinuria)
    f) Alveolar hemorrhage (by bronchoalveolar lavage)
    g) Palpable purpura
    h) Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinease 3)
4. Member has had at least one relapse (requiring increase in oral corticosteroids dose, initiation/increased dose of immunosuppressive therapy or hospitalization) within 2 years prior to starting treatment with Nucala or has a refractory disease.

C. Hypereosinophilic syndrome (HES)

Authorization of 12 months may be granted for treatment of HES when all of the following criteria are met:

1. Member is 12 years of age or older
2. Member does not have either of the following:
   a) HES secondary to a non-hematologic cause (e.g., drug hypersensitivity, parasitic helminth infection, [human immunodeficiency virus] HIV infection, non-hematologic malignancy)
   b) FIP1L1-PDGFRA kinase-positive HES
3. Member has a history or presence of a blood eosinophil count of at least 1000 cells per microliter
4. Member will not use Nucala as monotherapy
5. Member has been on a stable dose of HES therapy (e.g., oral corticosteroid, immunosuppressive, and/or cytotoxic therapy).
6. Member has had HES for at least 6 months
7. Member has experienced at least two HES flares within the past 12 months

Continuation of Therapy

A. Asthma

Authorization of 12 months may be granted for continuation of treatment of severe asthma with an eosinophilic phenotype when all of the following criteria are met:

1. Member is 6 years of age or older.
2. Asthma control has improved on Nucala treatment as demonstrated by at least one of the following:
   a). A reduction in the frequency and/or severity of symptoms and exacerbations
   b). A reduction in the daily maintenance oral corticosteroid dose
3. Member will not use Nucala as monotherapy
4. Member will not use Nucala concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Xolair)

B. Eosinophilic Granulomatosis with Polyangiitis

Authorization of 12 months may be granted for continuation of treatment of eosinophilic granulomatosis with polyangiitis when all of the following criteria are met:

1. Member is 18 years of age or older.
2. Member has beneficial response to treatment with Nucala as demonstrated by any of the following:
   a). A reduction in the frequency of relapses, or
   b). A reduction in the daily oral corticosteroid dose, or
   c). No active vasculitis

C. Hypereosinophilic syndrome (HES)

Authorization of 12 months may be granted for continuation of treatment of HES when all of the following criteria are met:

1. Member is 12 years of age or older.
2. Member has experienced a reduction in HES flares since starting treatment with Nucala
3. Member will not use Nucala as monotherapy

Nucala is considered **not medically necessary** for members who do not meet the criteria set forth above.

Other

Note: If the member is a current smoker or vaper, they should be counseled on the harmful effects of smoking and vaping on pulmonary conditions and available smoking and vaping cessation options.

Quantity Limits Apply

- Eosinophilic Granulomatosis with Polyangitis: 300 mg per 28 days
- Eospinophilic Asthma: 100 mg per 28 days
- Hypereosinophilic syndrome (HES): 300 mg per 28 days

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J2182 Injection, Mepolizumab, 1mg

REFERENCES

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POLICY HISTORY

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