

SPECIALTY GUIDELINE MANAGEMENT

NUCALA (mepolizumab)

POLICY

I. INDICATIONS

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

- A. Nucala is indicated for add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype.
- B. Nucala is indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
- C. 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.
- D. Nucala is indicated for add-on maintenance treatment of adult patients 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP)

Limitations of Use: Not for relief of acute bronchospasm or status asthmaticus

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review :

- A. Asthma:
 1. For initial requests:
 - i. Member's chart or medical record showing pretreatment blood eosinophil count, dependence on systemic corticosteroids if applicable.
 - ii. Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.
 2. For continuation requests: Chart notes or medical record documentation supporting improvement in asthma control.
- B. EGPA:
 1. For initial requests: Member's chart or medical record showing pretreatment blood eosinophil count
 2. For continuation requests: Chart notes or medical record documentation supporting improvement in EGPA control.
- C. HES:
 1. For initial requests:
 - i. FIP1L1-PDGFR α fusion gene test results
 - ii. Member's chart or medical record showing pretreatment blood eosinophil count

2. For continuation requests: Chart notes or medical record documentation supporting improvement in HES control.
- D. CRSwNP:
1. For initial requests:
 - i. Member's chart or medical record showing nasal endoscopy or anterior rhinoscopy details (e.g., location, size).
 - ii. Chart notes, medical record documentation, or claims history supporting previous medications tried. If therapy is not advisable, documentation of clinical reason to avoid therapy.
 2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

III. CRITERIA FOR INITIAL APPROVAL

A. Asthma

Authorization of 6 months may be granted for treatment of asthma 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:
 - i. Member has a baseline blood eosinophil count of at least 150 cells per microliter; or
 - ii. Member is dependent on systemic corticosteroids
3. Member has 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:
 - i. Inhaled corticosteroid
 - ii. 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 indicated for asthma (e.g., Cinqair, Dupixent, Fasenna, 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^{8,9}:
 - i. Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
 - ii. Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)
 - iii. Pulmonary infiltrates, non-fixed; sino-nasal abnormality
 - iv. Cardiomyopathy (established by echocardiography or magnetic resonance imaging)
 - v. Glomerulonephritis (hematuria, red cell casts, proteinuria)
 - vi. Alveolar hemorrhage (by bronchoalveolar lavage)
 - vii. Palpable purpura
 - viii. Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinase 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:
 - i. HES secondary to a non-hematologic cause (e.g., drug hypersensitivity, parasitic helminth infection, [human immunodeficiency virus] HIV infection, non-hematologic malignancy)
 - ii. FIP1L1-PDGFR α 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.

D. Chronic rhinosinusitis with nasal polyps

Authorization of 6 months may be granted for treatment of chronic rhinosinusitis with nasal polyps in members 18 years of age or older when all of the following criteria are met:

1. Member has bilateral nasal polyposis and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 2 months unless contraindicated or not tolerated; and
2. The member has CRSwNP despite one of the following:
 - i. Prior sino-nasal surgery; or
 - ii. Prior treatment with systemic corticosteroids within the last two years was ineffective, unless contraindicated or not tolerated
3. Member has had a bilateral nasal endoscopy or anterior rhinoscopy showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril; and
4. Member has nasal blockage plus one additional symptom:
 - i. Rhinorrhea (anterior/posterior); or
 - ii. Reduction or loss of smell; or
 - iii. Facial pain or pressure
5. Member will be using a daily intranasal corticosteroid while being treated with Nucala, unless contraindicated or not tolerated.

IV. CONTINUATION OF THERAPY

A. Asthma

Authorization of 12 months may be granted for continuation of treatment of asthma 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:
 - i. A reduction in the frequency and/or severity of symptoms and exacerbations
 - ii. A reduction in the daily maintenance oral corticosteroid dose⁷
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:
 - i. A reduction in the frequency of relapses, or
 - ii. A reduction in the daily oral corticosteroid dose, or
 - iii. 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.

D. Chronic rhinosinusitis with nasal polyps

Authorization of 12 months may be granted for continuation of treatment of chronic rhinosinusitis with nasal polyposis in members 18 years of age or older who achieve or maintain positive clinical response to Nucala therapy as evidenced by improvement in signs and symptoms of CRSwNP (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sinonasal inflammation, hyposmia and/or facial pressure or pain or reduction in corticosteroid use).

V. 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.

VI. REFERENCES

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5. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2020 update. Available at: <https://ginasthma.org/gina-reports/>. Accessed March 5, 2021.
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9. GlaxoSmithKline. A Study to Investigate Mepolizumab in the Treatment of Eosinophilic Granulomatosis With Polyangiitis. Available from <https://clinicaltrials.gov/ct2/show/record/NCT02020889>. NLM identifier: NCT02020889. Accessed March 05, 2021.
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1655-A

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