

Reference number(s)
1655-A

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.

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

- 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).

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 notes or medical record showing pretreatment blood eosinophil count, dependance 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:
 - i. Member's chart notes or medical record showing pretreatment blood eosinophil count.
 - 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 EGPA control.
- C. HES:
1. For initial requests:
 - i. FIP1L1-PDGFR α fusion gene test results.
 - ii. Member's chart notes 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 notes or medical record showing nasal endoscopy, anterior rhinoscopy, or computed tomography details (e.g., location, size), or Meltzer Clinical Score or endoscopic nasal polyps score (NPS) (where applicable).
 - 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. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:

- A. Asthma: allergist/immunologist or pulmonologist
- B. Chronic rhinosinusitis with nasal polyposis: allergist/immunologist or otolaryngologist

IV. CRITERIA FOR INITIAL APPROVAL

A. Asthma

1. Authorization of 6 months may be granted for members 6 years of age or older who have previously received a biologic drug (e.g., Dupixent, Cinqair) indicated for asthma.
2. Authorization of 6 months may be granted for treatment of severe asthma when all of the following criteria are met:
 - i. Member is 6 years of age or older.
 - ii. Member meets either of the following criteria:
 - a. Member has a baseline blood eosinophil count of at least 150 cells per microliter
 - b. Member is dependent on systemic corticosteroids
 - iii. Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
 - a. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment.
 - b. One or more asthma exacerbation resulting in hospitalization or emergency medical care visit.
 - c. Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma).
 - iv. Member has inadequate asthma control despite current treatment with both of the following medications at optimized doses:
 - a. High-dose inhaled corticosteroid
 - b. Additional controller (i.e., long acting beta₂-agonist, long acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)

- v. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

B. Eosinophilic granulomatosis with polyangiitis (EGPA)

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 is currently taking oral corticosteroids, unless contraindicated or not tolerated.
4. 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
 - iv. Sino-nasal abnormality
 - v. Cardiomyopathy (established by echocardiography or magnetic resonance imaging)
 - vi. Glomerulonephritis (hematuria, red cell casts, proteinuria)
 - vii. Alveolar hemorrhage (by bronchoalveolar lavage)
 - viii. Palpable purpura
 - ix. Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinase 3)
5. Member has had at least one relapse (i.e., requiring increase in oral corticosteroids dose, initiation/increased dose of immunosuppressive therapy or hospitalization) within 2 years prior to starting treatment with the requested medication 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 the requested medication 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

1. Authorization of 6 months may be granted for adult members who have previously received a biologic drug (e.g., Dupixent, Xolair) indicated for CRSwNP.
2. Authorization of 6 months may be granted for treatment of chronic rhinosinusitis with nasal polyps when all of the following criteria are met:
 - i. Member is 18 years of age or older.
 - ii. Member has bilateral nasal polyposis and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 2 months unless contraindicated or not tolerated
 - iii. The member has CRSwNP despite one of the following:
 - a. Prior sino-nasal surgery
 - b. Prior treatment with systemic corticosteroids within the last two years was ineffective, unless contraindicated or not tolerated

- iv. Member has one of the following:
 - a. A bilateral nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril
 - b. Meltzer Clinical Score of 2 or higher in both nostrils
 - c. A total endoscopic nasal polyp score (NPS) of at least 5 with a minimum score of 2 for each nostril
- v. Member has symptoms of nasal blockage, congestion, or obstruction plus one of the following additional symptoms:
 - a. Rhinorrhea (anterior/posterior)
 - b. Reduction or loss of smell
 - c. Facial pain or pressure
- vi. Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

V. CONTINUATION OF THERAPY

A. Asthma

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

1. Member is 6 years of age or older.
2. Asthma control has improved on the requested medication 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 dose
3. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

B. Eosinophilic granulomatosis with polyangiitis (EGPA)

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 the requested medication as demonstrated by any of the following:
 - i. A reduction in the frequency of relapses
 - ii. A reduction in the daily oral corticosteroid dose
 - 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 the requested medication.
3. Member will not use the requested medication 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 when all of the following are met:

1. Member is 18 years of age or older.
2. Member has achieved or maintained a positive clinical response with the requested medication as evidenced by improvement in signs and symptoms of CRSwNP (e.g., improvement in nasal

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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).

3. Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

VI. OTHER

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

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.

VII. REFERENCES

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