Reference number(s)
2063-A

STANDARD MEDICARE PART B 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

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.

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

2. Eosinophilic Granulomatosis with Polyangiitis
   Nucala is indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

3. Hypereosinophilic Syndrome
   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.

4. Chronic rhinosinusitis with nasal polyps (CRSwNP)
   Nucala is indicated as add-on maintenance treatment of adult patients 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP)

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

A. Asthma:
   1. For initial requests:
      i. Member's chart or medical record showing pretreatment blood eosinophil count, dependance on inhaled 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-PDGFRA 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. Eosinophilic asthma

Authorization of 12 months may be granted for treatment of eosinophilic asthma when all of the following criteria are met:
1. Member is 6 years of age or older.
2. Member has a baseline blood eosinophil count of at least 150 cells per microliter.
3. Member has a history of severe asthma despite current treatment with both of the following medications at optimized doses, unless the member has a clinical reason to avoid these therapies:
   a. Inhaled corticosteroid
   b. Additional controller (long acting beta$_2$-agonist, leukotriene modifier, or sustained release theophylline)

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 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%.
2. Member is 18 years of age or older.

C. Hypereosinophilic Syndrome (HES)

Authorization of 12 months may be granted for treatment of hypereosinophilic syndrome (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 has been on a stable dose of HES therapy (e.g., oral corticosteroid, immunosuppressive, and/or cytotoxic therapy).
5. Member has had HES for at least 6 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; and
3. Member has a bilateral nasal endoscopy or anterior rhinoscopy showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril
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

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

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. The member is currently receiving therapy with Nucala.
3. Nucala is being used to treat an indication enumerated in Section III.
4. The member is receiving benefit from therapy as defined by reduction in the frequency and/or severity of symptoms and exacerbations.

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. The member is currently receiving therapy with Nucala.
3. Nucala is being used to treat an indication enumerated in Section III.
4. The member is receiving benefit from therapy as defined by reduction in the frequency and/or severity of symptoms and exacerbations.

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. The member is currently receiving therapy with Nucala.
3. Nucala is being used to treat an indication enumerated in Section III.
4. The member is receiving benefit from therapy as defined by reduction in the frequency and/or severity of symptoms and exacerbations.

D. Chronic rhinosinusitis with nasal polyps (CRSwNP)

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

1. Member is 18 years of age or older.
2. The member is currently receiving therapy with Nucala.
3. Nucala is being used to treat an indication enumerated in Section III.
4. The member is receiving benefit from therapy as defined by achieving or maintaining a 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. REFERENCES

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