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.
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.

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, 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: 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.

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 beta$_2$-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, 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[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 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:
   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-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.

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 dose[7]
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.

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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4. National Institutes of Health. National Asthma Education and Prevention Program Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma - Full Report 2007. Bethesda, MD: National Heart Lung and Blood Institute; August 2007. Available at: https://www.ncbi.nlm.nih.gov/books/NBK7232/pdf/Bookshel_NBK7232.pdf. Accessed March 6, 2021.
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6. Kew KM, Karner C, Mindus SM. Combination formoterol and budesonide as maintenance and reliever therapy versus combination inhaler maintenance for chronic asthma in adults and children (review). *Cochrane Database Syst Rev.* 2013;12:CD009019.
7. American Academy of Allergy, Asthma & Immunology (AAAAI) 2020 Virtual Annual Meeting. Available at: https://annualmeeting.aaaai.org/. 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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11. Yates M, Watts RA, Bajema M, et al. EULAR/ERA-EDTA recommendations for the management of ANCA-associated vasculitis. *Ann Rheum Dis*. 2016;75(9):1583-1594.
12. Gotlib J. World Health Organization-defined eosinophilic disorders: 2017 update on diagnosis, risk stratification, and management. *Am J Hematol*. 2017;92(11):1243-1259.
13. Butt NM, Lambert J, Ali S, et al. Guideline for the investigation and management of eosinophilia. *Br J Haematol*. 2017;176(4):553-572.