AETNA BETTER HEALTH® Coverage Policy/Guideline					
Name:	Nucala			Page:	1 of 8
Effective Date:	2/1/2024			Last Review Date:	11/29/2023
Applies to:	☐Illinois ☐New Jersey ☒Pennsylvania Kids	☐Florida ☒Maryland ☐Virginia		☐ Michigan ☒ Florida Kids ☒ Kentucky PRMD	

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Nucala under the patient's prescription drug benefit.

Description:

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).

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.

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

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

Applicable Drug List:

Nucala

Policy/Guideline:

Criteria for Initial Approval:

Severe Eosinophilic Phenotype Asthma

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

1. Asthma

i. Member is unable to take Dupixent and Xolair for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval
ii. Member's chart or medical record showing pretreatment blood eosinophil count, dependance on systemic corticosteroids if applicable.

iii. Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.

2. Eosinophilic granulomatosis with polyangiitis

i. Member's chart or medical record showing pretreatment blood eosinophil count.

3. Hypereosinophilic syndrome (HES)

i. FIP1L1-PDGFRA fusion gene test results.

ii. Member's chart or medical record showing pretreatment blood eosinophil count.

4. Chronic rhinosinusitis with nasal polyps

i. Member is unable to take Dupixent and Xolair for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval

ii. Member's chart 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).

iii. Chart notes, medical record documentation, or claims history supporting previous medications tried. If therapy is not advisable, documentation of clinical reason to avoid therapy.

B. Nucala must be prescribed by or in consultation with ONE of the following:

i. Asthma: allergist/immunologist or pulmonologist

ii. Chronic rhinosinusitis with nasal polyposis: allergist/immunologist or otolaryngologist

C. Authorization may be granted for treatment of asthma when all the following criteria are met:

1. Asthma

i. Member has previously received a biologic drug indicated for asthma

a. Requests will require that the patient is unable to take Dupixent and Xolair for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

b. Member is 6 years of age or older

c. Member will not use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication

OR

ii. Member is 6 years of age or older.

iii. 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

iv. 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).

v. 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 beta$_2$-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)

vi. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Nucala.

vii. Member will not use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication

2. Eosinophilic granulomatosis with polyangiitis

i. Member is 18 years of age or older.

ii. 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%.

iii. 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 proteinase 3)

iv. 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

3. Hypereosinophilic syndrome (HES)

i. Member is 12 years of age or older.
ii. 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
iii. Member has a history or presence of a blood eosinophil count of at least 1000 cells per microliter.
iv. Member will not use Nucala as monotherapy.
v. Member has been on a stable dose of HES therapy (e.g., oral corticosteroid, immunosuppressive, and/or cytotoxic therapy).
vi. Member has had HES for at least 6 months.
vii. Member has experienced at least two HES flares within the past 12 months

4. Chronic rhinosinusitis with nasal polyps

i. Member has previously received a biologic drug indicated for chronic rhinosinusitis with nasal polyps
   a. Requests will require that the patient is unable to take Dupixent and Xolair for the given diagnosis due to a trial and inadequate

treatment response or intolerance, or a contraindication. Documentation is required for approval.

b. Member will not use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication

OR

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; and

iii. The member has CRSwNP despite one of the following:
   a. Prior sino-nasal surgery; or
   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 nasal blockage plus one additional symptom:
   a. Rhinorrhea (anterior/posterior); or
   b. Reduction or loss of smell; or
   c. Facial pain or pressure

vi. Member will continue to use a daily intranasal corticosteroid while being treated with Nucala, unless contraindicated or not tolerated.

vii. Member will not use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication

Criteria for Continuation of Therapy:

Severe Eosinophilic Phenotype Asthma

A. Submission of the following information is necessary for the prior authorization review:

1. Asthma:

i. Chart notes or medical record documentation supporting improvement in asthma control.
ii. Member is 6 years of age or older.
iii. 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
iv. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Nucala.
v. Member will not use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication

2. Eosinophilic granulomatosis with polyangiitis

i. Chart notes or medical record documentation supporting improvement in EGPA control
ii. Member is 18 years of age or older.
iii. 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

3. Hypereosinophilic syndrome (HES)

i. Chart notes or medical record documentation supporting improvement in HES control.
ii. Member is 12 years of age or older.
iii. Member has experienced a reduction in HES flares since starting treatment with Nucala.
iv. Member will not use Nucala as monotherapy.

4. Chronic rhinosinusitis with nasal polyps

i. Chart notes or medical record documentation supporting positive clinical response.
ii. Member is 18 years of age or older.
iii. Member has achieved or maintained 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).

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

v. Member will not use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication

Approval Duration and Quantity Restrictions:

Initial Approval

- Asthma: 6 months
- Chronic rhinosinusitis with nasal polyps: 6 months
- Eosinophilic granulomatosis with polyangiitis: 12 months
- Hypereosinophilic syndrome (HES): 12 months

Renewal Approval: 12 months

Quantity Level Limit:

- Nucala 100 mg single-dose vial: 3 vials per 28 days
- Nucala 100 mg/mL single-dose prefilled safety syringe: 3 syringes per 28 days
- Nucala 100 mg/mL single-dose prefilled autoinjector: 3 autoinjector's per 28 days
- Nucala 40mg/0.4mL, single-dose prefilled syringe: 1 syringe per 28 days

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