Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 141.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Nucala (mepolizumab)

I. Policy:
Nucala vial (mepolizumab)

II. Purpose/Objective:
To provide a policy of coverage regarding Nucala vial (mepolizumab)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Nucala (mepolizumab) is an interleukin-5 antagonist (immunoglobulin G1 [IgG1] kappa). IL-5 is the major cytokine responsible for the growth and differentiation, recruitment, activation, and survival of eosinophils (a cell type associated with inflammation and (an important component of the pathogenesis of asthma). Mepolizumab, by inhibiting interleukin-5 signaling, reduces the production and survival of eosinophils; however, the mechanism of mepolizumab action in asthma has not been definitively established.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Nucala (mepolizumab) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when all of the following criteria are met:

Severe Eosinophilic Asthma

- Documentation of patient age ≥ 6 years **AND**
- Medical record documentation of a diagnosis of severe eosinophilic asthma AND that Nucala is being used as add-on maintenance treatment **AND**
- Prescription written by an allergist or pulmonologist **AND**
- Medical record documentation of a blood eosinophil count of either ≥ 300 cells/mcL during the 12-month period before screening and/or ≥ 150 cells/mcL within 3 months of the start of therapy **AND**
- Medical record documentation of:
    - Intolerance to or not well controlled or very poorly controlled symptoms* despite at least a 3 month trial of: high-dose inhaled corticosteroids and/or oral systemic corticosteroids plus a long-acting beta agonist **OR**
    - Two or more exacerbations in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care visits, or hospitalization) despite current therapy with high-dose inhaled corticosteroids plus a long-acting beta agonist **AND**
- Insured individual must be adherent with current therapeutic regimen and must demonstrate appropriate inhaler technique **AND**
- Known environmental triggers within the member's control have been eliminated **AND**
- Medical record documentation that the medication will not be used in combination with another biologic medication indicated for asthma treatment (e.g. Fasenra (benralizumab), Cinqair (reslizumab), Dupixent (dupilumab), Xolair (omalizumab), Tezspire (tezepelumab))

*****Measures of disease severity

Measure	Not Well Controlled	Very Poorly Controlled
Symptoms	> 2 days per week	Throughout the day
Nighttime awakenings	1-3x/week	≥ 4x/week
Interference with normal activity	Some limitation	Extremely limited
SABA use for symptom control (not to prevent exercise-induced bronchospasm)	> 2 days/week	Several times per day
FEV1 (% predicted) or peak flow (% personal best)	60-80%	< 60%
Asthma Control Test (ACT) Score	16-19	≤ 15

Eosinophilic Granulomatosis (EGPA)

- Prescription written by an allergist/immunologist, pulmonologist, and/or rheumatologist **AND**
- Medical record documentation that patient is ≥18 years of age **AND**
- Medical record documentation of eosinophilic granulomatosis (EGPA) confirmed by biopsy evidence of vasculitis AND at least four (4) of the following criteria:
    - Asthma (a history of wheezing or the finding of diffuse high-pitched wheezes on expiration)
    - Eosinophilia (blood eosinophil level of ≥10% or ≥1500 cells/microL on differential white blood cell count)
    - Mononeuropathy (including multiplex) or polyneuropathy
    - Migratory or transient pulmonary opacities detected radiographically
    - Paranasal sinus abnormality
    - Biopsy containing a blood vessel showing the accumulation of eosinophils in extravascular areas

  AND

- Medical record documentation of a therapeutic failure on, contraindication to, or intolerance to systemic glucocorticoid therapy AND at least one immunosuppressant therapy (cyclophosphamide, azathioprine, methotrexate) **AND**
- Medical record documentation that the medication will not be used in combination with Fasenra (benralizumab), Cinqair (reslizumab), Dupixent (dupilumab), Xolair (omalizumab), or Tezspire (tezepelumab)

Hypereosinophilic syndrome (HES)

- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of hypereosinophilic syndrome (HES) for greater than or equal to 6 months **AND**
- Medical record documentation that member has been evaluated for and does NOT have an identifiable non-hematologic secondary cause* or FIP1 like 1-platelet derived growth factor receptor (FIP1L1-PDGFRα) kinase-positive hypereosinophilic syndrome (HES) **AND**
- Medical record documentation of a blood eosinophil count of 1,000 cells/mcL or higher **AND**
- Medical record documentation of at least two hypereosinophilic syndrome (HES) flares within the previous 12 months with a worsening of clinical symptoms of HES or increasing blood eosinophil level requiring an escalation in therapy **AND**
- Medical record documentation that member is on stable hypereosinophilic syndrome (HES) therapy including, but not limited to oral corticosteroids, immunosuppressives, or cytotoxic therapy **AND**
- Medical record documentation that the medication will not be used in combination with Fasenra (benralizumab), Cinqair (reslizumab), Dupixent (dupilumab), Xolair (omalizumab), or Tezspire (tezepelumab)

*Note: Non-hematologic secondary causes can include but are not limited to drug hypersensitivity, parasitic helminth infection, HIV infection, and non-hematologic malignancy

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

- Medical record documentation that Nucala is prescribed by or in consultation with an allergist, pulmonologist, immunologist, or otolaryngologist (ENT provider) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) **AND**
- Medical record documentation that Nucala will be used as add-on maintenance treatment **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to three (3) intranasal corticosteroids **AND**
- Medical record documentation that the medication will not be used in combination with Fasenra (benralizumab), Cinqair (reslizumab), Dupixent (dupilumab), Xolair (omalizumab), or Tezspire (tezepelumab)

QUANTITY LIMITS:
100mg vials: 1 vial (100mg) per 28 days (for eosinophilic asthma ages 12+ years or CRSwNP), 3 vials (300mg) per 28 days (for EGPA or HES)
40mg/mL Prefilled Syringes: 1 prefilled syringe (40 mg) per 28 days (for eosinophilic asthma ages 6-11 years)

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

LIMITATIONS:
Nucala is not indicated for the relief of acute bronchospasm or status asthmaticus.

Nucala (mepolizumab) will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

Severe Eosinophilic Asthma

- Documentation of patient age ≥ 6 years **AND**
- Medical record documentation of a diagnosis of severe eosinophilic asthma AND that Nucala is being used as add-on maintenance treatment **AND**
- Prescription written by an allergist or pulmonologist **AND**
- Medical record documentation of a blood eosinophil count of either ≥ 300 cells/mcL during the 12-month period before screening and/or ≥ 150 cells/mcL within 3 months of the start of therapy **AND**
- Medical record documentation of:
    - Intolerance to or not well controlled or very poorly controlled symptoms* despite at least a 3 month trial of: high-dose inhaled corticosteroids and/or oral systemic corticosteroids plus a long-acting beta agonist **OR**
    - Two or more exacerbations in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care visits, or hospitalization) despite current therapy with high-dose inhaled corticosteroids plus a long-acting beta agonist **AND**
- Medical record documentation that the medication will not be used in combination with another biologic medication indicated for asthma treatment (e.g. Fasenra (benralizumab), Cinqair (reslizumab), Dupixent (dupilumab), Xolair (omalizumab), Tezspire (Tezepelumab))

Eosinophilic Granulomatosis (EGPA)

- Prescription written by an allergist/immunologist, pulmonologist, and/or rheumatologist **AND**
- Medical record documentation that patient is ≥18 years of age **AND**
- Medical record documentation of eosinophilic granulomatosis (EGPA) confirmed by biopsy evidence of vasculitis AND at least four (4) of the following criteria:
    - Asthma (a history of wheezing or the finding of diffuse high-pitched wheezes on expiration)
    - Eosinophilia (blood eosinophil level of ≥10% or ≥1500 cells/microL on differential white blood cell count)
    - Mononeuropathy (including multiplex) or polyneuropathy
    - Migratory or transient pulmonary opacities detected radiographically
    - Paranasal sinus abnormality
    - Biopsy containing a blood vessel showing the accumulation of eosinophils in extravascular areas

AND

- For nonsevere disease:
    - Medical record documentation of use in combination with, or of a therapeutic failure on, contraindication to, or intolerance to systemic glucocorticoid therapy **OR**
- For severe* disease:
    - Medical record documentation of a therapeutic failure on, contraindication to, or intolerance to systemic glucocorticoid therapy AND at least one immunosuppressant therapy (e.g. cyclophosphamide, rituximab)

AND

- Medical record documentation that the medication will not be used in combination with Fasenra (benralizumab), Cinqair (reslizumab), Dupixent (dupilumab), Xolair (omalizumab), or Tezspire (tezepelumab)

*note: Severe disease is defined by the American College of Rheumatology (ACR) guidelines as: Vasculitis with life- or organ-threatening manifestations (e.g., alveolar hemorrhage, glomerulonephritis, central nervous system vasculitis, mononeuritis multiplex, cardiac involvement, mesenteric ischemia, limb/digit ischemia)

Hypereosinophilic syndrome (HES)

- Medical record documentation of age greater than or equal to 12 years **AND**
- Medical record documentation of a diagnosis of hypereosinophilic syndrome (HES) for greater than or equal to 6 months **AND**
- Medical record documentation that member has been evaluated for and does NOT have an identifiable non-hematologic secondary cause* or FIP1 like 1-platelet derived growth factor receptor (FIP1L1-PDGFRα) kinase-positive hypereosinophilic syndrome (HES) **AND**
- Medical record documentation of a blood eosinophil count of 1,000 cells/mcL or higher **AND**

- Medical record documentation of at least two hypereosinophilic syndrome (HES) flares within the previous 12 months with a worsening of clinical symptoms of HES or increasing blood eosinophil level requiring an escalation in therapy **AND**
- Medical record documentation that member is on stable hypereosinophilic syndrome (HES) therapy including, but not limited to oral corticosteroids, immunosuppressives, or cytotoxic therapy **AND**
- Medical record documentation that the medication will not be used in combination with Fasenra (benralizumab), Cinqair (reslizumab), Dupixent (dupilumab), Xolair (omalizumab), or Tezspire (tezepelumab)

*Note: Non-hematologic secondary causes can include but are not limited to drug hypersensitivity, parasitic helminth infection, HIV infection, and non-hematologic malignancy

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

- Medical record documentation that Nucala is prescribed by or in consultation with an allergist, pulmonologist, immunologist, or otolaryngologist (ENT provider) **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) **AND**
- Medical record documentation that Nucala will be used as add-on maintenance treatment **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to two (2) intranasal corticosteroids **AND**
- Medical record documentation that the medication will not be used in combination with Fasenra (benralizumab), Cinqair (reslizumab), Dupixent (dupilumab), Xolair (omalizumab), or Tezspire (tezepelumab)

QUANTITY LIMITS:
100mg vials: 1 vial (100mg) per 28 days (for eosinophilic asthma ages 12+ years or CRSwNP), 3 vials (300mg) per 28 days (for EGPA or HES)
40mg/mL Prefilled Syringes: 1 prefilled syringe (40 mg) per 28 days (for eosinophilic asthma ages 6-11 years)

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

LIMITATIONS:
Nucala is not indicated for the relief of acute bronchospasm or status asthmaticus.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Nucala [prescribing information]. Philadelphia, PA: GlaxoSmithKline LLC; January 2022.
2. Global Strategy for Asthma Management and Prevention. Global Initiative for Asthma. 2023 July [cited 2023 Dec 26]. Available from: https://ginasthma.org/2023-gina-main-report/
3. Chung SA, Langford CA, Abril A, et al. 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Antineutrophil Cytoplasmic Antibody–Associated Vasculitis. American College of Rheumatology (ACR). Arthritis & Rheumatology; 2021; 0(0):1-8 [cited 2023 Dec 26]. Available from: https://www.vasculitisfoundation.org/2021-acr-vf-gpa-mpa-egpa-guidelines/

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 3/15/2016

Revised: 5/15/18 (EGPA added), 11/19/19 (age for asthma, vials), 3/16/21 (HES), 12/24/21 (CRSwNP), 5/17/22 (concomitant asthma biologics verbiage), 6/24/22 (QL update), 5/11/23 (CRSwNP prescriber [see 3/2022 P&T], Medicaid business segment), 12/30/23 (references added), 6/3/24 (LOB carve out, added Tezspire and therapeutic duplication per Dec 2023 P&T)

Reviewed: 2/28/17, 1/24/18, 4/22/19, 11/16/20

MA UM Committee approval: 12/31/23, 8/30/24