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Policy Number: C9704-A

Nucala (mepolizumab)

PRODUCTS AFFECTED

Nucala (mepolizumab)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of itscoverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or otherpractice that is inappropriate or excessive

DIAGNOSIS:
Severe asthma with an eosinophilic phenotype, chronic rhinosinusitis with nasal polyps, Eosinophilic granulomatosis with polyangiitis, hypereosinophilic syndrome

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federalrequirements, benefit being administered and formulary preferencing. Coverage will be determined on a case- by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

A. SEVERE ASTHMA WITH EOSINOPHILIC PHENOTYPE:
   1. Documented diagnosis of moderate to severe asthma and prescriber has ruled out COPD, acute bronchospasm, or status asthmaticus
      AND
   2. Nucala (mepolizumab) is NOT being prescribed as: (a) Monotherapy for asthma (must be prescribed as add-on maintenance to be used in combination with other medications for long-term control of asthma) AND (b) is not being prescribed as concurrent therapy with other

monoclonal antibodies used to treat asthma [i.e., Xolair (omalizumab) OR other IL-5 inhibitors [benralizumab (Fasenra), Cinqair (reslizumab) OR IL-4 agonist Dupixent (dupilumab)]

AND

3. (a) Documentation of eosinophilic phenotype or predominantly eosinophil-driven disease withblood eosinophil counts: >150 cells/microliter at initiation of therapy (within 6 weeks of request) OR > 300 cells/microliter in the prior 12 months
   OR
   (b) Member has experienced exacerbation(s) or hospitalization(s), within the last 12 months documented by any of the following:
   i. TWO (2) or more exacerbations requiring treatment with systemic corticosteroid (intramuscular, intravenous, or oral) despite the use of high-dose inhaled corticosteroids in the past 12 months OR
   ii. Two-fold increase or greater in the dose of systemic corticosteroid treatment for asthma exacerbations OR
   iii. Asthma worsens upon tapering of oral corticosteroid therapy OR
   iv. Mechanical ventilation in the past 12 months OR
   v. Poor symptom control indicated by Asthma Control Questionnaire (ACQ) score consistently greater than 1.5 or Asthma Control Test (ACT) score consistently less than 20 OR
   vi. Forced expiratory volume in 1 second (FEV1) < 80% predicted OR FEV1/forced vital capacity (FVC) < 0.80

AND

4. Symptoms inadequately controlled (as documented in criteria above) by the following adherent regimen of at least 3 months (within the past 90 days) (a) OR (b)
   a. COMBINATION THERAPY of high-dose inhaled corticosteroid (ICS) AND an asthma controller medication with or without oral corticosteroid:
      1) Maximally tolerated dose of inhaled ICS (appropriately adjusted for age), OR Documented intolerance, FDA labeled contraindication, or hypersensitivity to ICS [Appendix 2: Estimated Comparative Daily Dosages for ICS in ≥ 12 years and Adults]
      AND
      2) ONE of the following ASTHMA CONTROLLER MEDICATION (LABA, LRTA, LAMA, AND theophylline), OR documented intolerance, FDA labeled contraindication, or hypersensitivity to all these medications (LABA, LRTA, LAMA, AND theophylline)
         - Long-acting beta-2 agonist (LABA) [e.g., salmeterol (products (Serevent)formoterol (Foradil)], OR
         - Leukotriene receptor antagonist (LRTA) [e.g., montelukast (Singulair);zafirlukast (Accolate);zileuton (Zyflo)], OR
         - Long-acting muscarinic antagonist (LAMA) [e.g., tiotropium bromide inhalation spray (Spiriva, Respimat)], OR
         - Theophylline (Theo-24, Uniphyl, TheoChron ER,generics)

      OR
   b. Combination ICS/LABA at maximum recommended doses or maximally tolerated dose [i.e., fluticasone/salmeterol (Advair), mometasone/formoterol (Dulera), budesonide/formoterol (Symbicort); fluticasone/vilanterol (Breo Ellipta)]

MOLINA REVIEWER: Verify pharmacy claims for compliance with the combination therapy above in #E1 or #E2 within the last 90 days. For new members to Molina Healthcare, confirm medication use in medical chart history. Non-compliance, which can be documented by review of the prescription fill history, would not constitute therapeutic failure.

AND

5. Prescriber attestation that IF member is a smoker, the member has been counseled regarding the benefits of smoking cessation and/or connected with a program to support smoking cessation
   AND
6. Prescriber attestation that the member's underlying conditions or triggers for asthma or pulmonary disease are being maximally managed

B. EOSINOPHILIA GRANULOMATOSIS WITH POLYANGITIS (EGPA):
1. Documented diagnosis of EGPA supported by:
(a) Blood eosinophil level of at least 10% of leucocytes OR Absolute eosinophil count > 1,000 cells/µL
AND
(b) Presence of at any of the following characteristics typical of EGPA:
   i. Histopathological evidence of: Eosinophilic vasculitis, Perivascular eosinophilic infiltration, or Eosinophil- rich granulomatous inflammation
   ii. Neuropathy, mono or poly (motor deficit or nerve conductionabnormality)
   iii. Pulmonary infiltrates, non-fixe
   iv. Sino-nasal abnormality
   v. Cardiomyopathy (established by echocardiography or MRI)
   vi. Glomerulonephritis (hematuria, red cell casts, proteinuria)
   vii. Alveolar hemorrhage (by bronchoalveolar lavage)
   viii. Palpable purpura
   ix. Anti-neutrophil cytoplasmic antibody (ANCA) positiveAND
2. Prescriber attests that member has refractory disease as defined as failure to attain remission within the prior 6 months following induction treatment with standard therapy regimens [at least 3 months of ORAL corticosteroids with or without an immunosuppressant (e.g., cyclophosphamide, azathioprine, methotrexate)] OR has a contraindication or intolerance to oral corticosteroids and immunosuppressants
AND
3. Documentation of baseline disease severity to assess efficacy (asthma symptoms or asthma exacerbations, severity, or frequency of EGPA- related symptoms, frequencyand/or severity of relapses, maintenance doses of systemic corticosteroids and/or immunosuppressant, blood eosinophil count or inflammatory markers, Birmingham Vasculitis Activity Score (BVAS) score
AND
4. Prescriber attests that requested therapy is NOT prescribed for, or intended for, combination therapy or concurrent therapy with other monoclonal antibodies [i.e., Xolair(omalizumab) OR other IL-5 inhibitors [Cinqair (reslizumab), Nucala (mepolizumab)]

C. CHRONIC RHINOSINUSITIS WITH NASAL POLYPS:
1. Documentation of diagnosis of chronic rhinosinusitis with nasal polyposis
AND
2. Prescriber attests that member has a history of sino-nasal surgery or is not eligible for surgery
AND
3. Documentation that the member has experienced an inadequate response (after 3 consistent months of use) or intolerance to ONE of the following medications unless contraindicated: preferred formularyintranasal steroids OR preferred formulary oral corticosteroids
AND
4. Member is concurrently receiving treatment with one of the following agents (a, b, c, OR d): (a)Intranasal steroids, (b) Oral corticosteroids, (c) Nasal saline irrigations or (d) Antibiotics
AND
5. Prescriber attests that Nucala (mepolizumab) will not be used as monotherapy

D. HYPEREOSINIPHILIC SYNDROME (HES):
1. Documentation of diagnosis of hypereosinophilic syndrome for $\geq$ 6 months
AND
2. Documentation of BOTH of the following: (a) there is no identifiable non-hematologic secondary cause of the patient's HES (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non- hematologic malignancy); AND (b) HES is not FIP1L1-PDGRαkinase-positive

AND

3. Documentation of baseline (pre-mepolizumab treatment) blood eosinophil level ≥ 1000cells/μL within the past 4 weeks
   AND
4. Documentation member is currently receiving a stable dose of background HES therapy (e.g., oral corticosteroid, immunosuppressor, or cytotoxic therapy)
   AND
5. Prescriber attests that Nucala (mepolizumab) is NOT being prescribed as concurrent therapy with other monoclonal antibodies used to treat asthma [i.e., Xolair (omalizumab) OR other IL-5 inhibitors [benralizumab (Fasenra), Cinqair (reslizumab) OR IL-4 agonist Dupixent (dupilumab)]

CONTINUATION OF THERAPY:

A. SEVERE ASTHMA WITH EOSINOPHILIC PHENOTYPE:
   1. Adherence to therapy at least 85% of the time as verified by Prescriber and member's medication fill history (review Rx history for compliance) AND
   2. Nucala (mepolizumab) therapy has resulted in clinical improvement as documented by ONE (1) or more of the following from baseline:
      a) Improvement in lung function (increase in percent predictedFEV1 or PEF) from pre-treatment baseline
      b) Decreased utilization of rescue medications, decreased frequencyof exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids)
      c) Decreased frequency of unscheduled clinic, urgent care, or emergency department visits
      d) Reduction in reported symptoms: chest tightness, coughing, shortness of breath, nocturnal wakening wheezing, sustainedimprovement in Asthma Control Test (ACT) scores
      e) Reduction use of ICS, leukotriene, or beta agonist therapy

      AND
   3. Consultation notes must be submitted for initial request and for continuation of treatment requests at least ONCE annually. The prescribing physician should periodically re- assess the need for continuation of therapy based on the member's disease severity andlevel of asthma control. Continuation of therapy requires submission of relevant medical records or chart notes documenting continued efficacy
      AND
   4. Member has not experienced ANY of the following: Intolerable adverse effects or absence of unacceptable toxicity from the drug [e.g., symptoms of anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema), malignancy, symptoms similar to serum sickness (fever, arthralgia, and rash); parasitic (helminth) infection, eosinophilic conditions (e.g., vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy, especially upon reduction of oral corticosteroids]; Poor response to treatment as evidenced by physical findings and/or clinical symptoms
      AND
   5. Member is currently treated and is compliant with standard therapy (e.g., inhaled corticosteroids, long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LRTA), long-acting muscarinic antagonist (LAMA), theophylline) within the past 90 days,OR Has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL standard therapies
      AND
   6. Prescriber attests that requested therapy is NOT prescribed for, or intended for, combination therapyor concurrent therapy with other monoclonal antibodies [i.e., Xolair (omalizumab) OR other IL-5 inhibitors [Cinqair (reslizumab), Nucala (mepolizumab)]

B. EOSINOPHILIA GRANULOMATOSIS WITH POLYANGITIS (EGPA):
1. Adherence to therapy at least 85% of the time as verified by Prescriber and member's medication fill history (review Rx history for compliance)
AND
2. Nucala (mepolizumab) therapy has resulted in clinical improvement of signs and symptoms compared to baseline as evidenced by ONE (1) or more of the following from baseline: Improvement in asthma symptoms or asthma exacerbations, Improvement in duration of remission or decrease in the rate of relapses, Decrease in severity or frequency of EGPA-related symptoms, Decrease in the frequency and/or severity of relapses, Reduction or discontinuation of maintenance doses of systemic corticosteroids and/or immunosuppressant, Decreased blood eosinophil count or inflammatory markers, Improvement in Birmingham Vasculitis Activity Score (BVAS) score compared to baselineor Member is in remission as defined by BVAS score = 0 and a prednisone/prednisolone daily dose of ≤ 7.5 mg
AND
3. Member has not experienced ANY of the following: Intolerable adverse effects or absenceof unacceptable toxicity from the drug [e.g. symptoms of anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema), malignancy, symptoms similar to serum sickness (fever, arthralgia, and rash); parasitic (helminth) infection, eosinophilic conditions (e.g. vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy, especially upon reduction of oral corticosteroids]; Poor response to treatment as evidenced by physical findings and/or clinical symptoms
AND
4. Prescriber attests that requested therapy is NOT prescribed for, or intended for, combination therapyor concurrent therapy with other monoclonal antibodies [i.e., Xolair (omalizumab) OR other IL-5 inhibitors [Cinqair (reslizumab), Nucala (mepolizumab)]

C. CHRONIC RHINOSINUSITIS WITH NASAL POLYPS:
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of aninfection, causing temporary discontinuation (documentation required)
AND
2. Documentation of no intolerable adverse effects or drug toxicity
AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms
AND
4. Prescriber attests that requested therapy is NOT prescribed for, or intended for, combination therapyor concurrent therapy with other monoclonal antibodies [i.e., Xolair (omalizumab) OR other IL-5 inhibitors [Cinqair (reslizumab), Nucala (mepolizumab)]

D. HYPEREOSINIPHILIC SYNDROME (HES):
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of aninfection, causing temporary discontinuation (documentation required)
AND
2. Documentation of no intolerable adverse effects or drug toxicity
AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms (i.e., Reduction in frequency of HES flares, Maintenance, or reduction in background HES therapy requirements)
AND
4. Prescriber attests that requested therapy is NOT prescribed for, or intended for, combination

therapyor concurrent therapy with other monoclonal antibodies [i.e., Xolair (omalizumab) OR other IL-5 inhibitors [Cinqair (reslizumab), Nucala (mepolizumab)]

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of treatment: up to 12 months at a time

PRESCRIBER REQUIREMENTS:
Prescribed by, or in consultation with, a board-certified asthma specialist (allergist, immunologist, pulmonologist, or cardiologist) or physician experienced in the management of asthma.[If prescribed in consultation, consultation notes must be submitted within initial request and reauthorization requests]

AGE RESTRICTIONS:
Severe Asthma, add on maintenance in patients with eosinophilic phenotype: 6 years of age and older Eosinophilic Granulomatosis with Polyangiitis: 18 years of age and older Hypereosinophilic syndrome: 12 years of age and older
Chronic rhinosinusitis with nasal polyps: 18 years of age and older

QUANTITY:
Severe asthma (eosinophilic phenotype) for add-on maintenance treatment of patients:
Children 6 years to 11 years: 40 mg once every 4 weeks.
Children and adults (12 years and older): 100 mg once every 4 weeks
Eosinophilic granulomatosis with polyangiitis: 300 mg (as 3 separate 100-mg injections) once every 4 weeks
Hypereosinophilic syndrome: 300 mg (as 3separate 100-mg injections) once every 4 weeks
Chronic rhinosinusitis with nasal polyps: 100 mg once every 4 weeks.

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable products administered in a place of service that is a non- hospital facility-based location as per the Molina Health Care Site of Care program.

Note: Site of Care Utilization Management Policy applies for Nucala (mepolizumab). For information on site of care, see
Specialty Medication Administration Site of Care Coverage Criteria (molinamarketplace.com)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
Interleukin-5 Antagonists (IgG1 kappa)

FDA-APPROVED USES:
NUCALA is indicated for:

- Add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma and with an eosinophilic phenotype.
- Add-on maintenance treatment of adult patients 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP).
- The treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
- 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

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Nucala, an interleukin (IL)-5 antagonist immunoglobulin G (IgG)1κ monoclonal antibody, is indicated for add-on maintenance treatment of patients with severe asthma aged ≥ 12 years who have an eosinophilic phenotype.1 Nucala is also indicated for treatment of Eosinophilic Granulomatosis with Polyangiitis (EGPA).Limitations of Use: Nucala is not indicated for the treatment of other eosinophilic conditions or for the relief of acute bronchospasm/status asthmaticus. Nucala is a human IL-5 antagonist; IL-5 is the main cytokine involved in the growth, differentiation, recruitment, activation, and survival of eosinophils. The most important factor in the pathogenesis of asthma is inflammation, which involves multiple mediators and cell types, including eosinophils. By inhibiting the signaling of IL-5, Nucala decreases the production and survival of eosinophils. However, the exact mechanism of action of Nucala in asthma has not been established. Nucala is not indicated for intravenous (IV) use; it should be administered as a 100 mg subcutaneous (SC) injection once every 4 weeks by a healthcare professional

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Nucala (mepolizumab) that are not an FDA-approved indication or not included in this policy are considered experimental/investigational or not a covered benefit of this policy. This subject to change based on research and medical literature, or at the discretion of Molina Healthcare. Exclusions:
1) Concurrent Respiratory Disease: Presence of a clinically important lung condition other than asthma; 2) Concurrent use with Xolair (omalizumab) NOTE: If currently treated with Xolair (omalizumab), then Xolair (omalizumab) must be discontinued when starting Nucala; 3) Concurrent use with any other IL-5 inhibitor [Cinqair (reslizumab), Fasenra]; 4) Known or suspected infection; Helminth infections NOTE: Members with pre-existing helminth infections should undergo treatment of the infection prior to initiation of reslizumab therapy. It is unknown if reslizumab will influence a patient's response against parasitic infections (patients with known parasitic infections were excluded from the clinical trials), AND 5) Non- FDA approved indications [includes: urticaria and other eosinophilic conditions; severe allergic asthma without documentation of severe eosinophilia]; Aspirin- exacerbated respiratory disease (AERD); Hypereosinophilic syndromes (other than indicated), including: Angio lymphoid hyperplasia, Atopic dermatitis, Eosinophilic esophagitis, Nasal polyposis, Acute bronchospasm and/or status asthmaticus

OTHER SPECIAL CONSIDERATIONS:

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION

J2182	Injection, mepolizumab, 1 mg

AVAILABLE DOSAGE FORMS:
Nucala SOLR 100MG
Nucala SOAJ 100MG/ML (auto-injector)
Nucala SOSY 100MG/ML (pre-filled syringe)

REFERENCES

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