MEDICATION POLICY

Generic Name: Mepolizumab

Therapeutic Class or Brand Name: Nucala®

Applicable Drugs (if Therapeutic Class)**:** N/A

Date of Origin: 2/5/16 **Date Last Reviewed/Revised:** 2/22/18

GPI Code: 4460405500

Prior Authorization Criteria (may be considered medically necessary when criteria I through II are met):

I. Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis:

A. Severe eosinophilic asthma AND criteria 1 through 4 are met:

1. Documented blood eosinophilia count of one of the following a or b:
   a. At least 300 cells/mcL in the previous 12 months.
   b. At least 150 cells/mcL in the previous 6 weeks.
2. Documentation that patient has been on a minimum of a three-month trial of a high-dose inhaled corticosteroid used in combination with a long-acting inhaled beta-2 agonist AND both criteria a and b are met:
   a. Documentation that patient is compliant to therapy as evidenced by pharmacy claims review (patient must have 3 fills of each inhaler within the previous 90 days).
   b. Documentation that patient's asthma symptoms are poorly controlled despite therapy.
3. Documentation that environmental factors and comorbid conditions that worsen patient's asthma symptoms are being identified and resolved.
4. Minimum age requirement: 12 years old.

B. Eosinophilic granulomatosis with polyangiitis (EGPA) AND criteria 1 through 5 are met:

1. Documentation that patient has at least 4 of the following criteria a through f:
   a. Asthma.
   b. Eosinophilia greater than l0% on differential white blood cell count.
   c. Mononeuropathy (including multiplex) or polyneuropathy.
   d. Non-fixed pulmonary infiltrates on roentgenography.
   e. Paranasal sinus abnormality.

f. Biopsy containing a blood vessel with extravascular eosinophils.

2. Documentation that patient has life- and/or organ-threatening disease manifestations (i.e. heart, GI, central nervous system, severe peripheral neuropathy, severe ocular disease, alveolar hemorrhage and/or glomerulonephritis).
3. Documentation that patient is stable on corticosteroid therapy or has a contraindication to corticosteroid therapy.
4. Documented trial and failure of, intolerance to, or contraindication to at least one other immunosuppressant (i. e. azathioprine, cyclophosphamide, methotrexate).
5. Minimum age requirement: 18 years old.

II. Prescriber must be an allergist, immunologist, pulmonologist, or rheumatologist.

Exclusion Criteria:

- Concurrent use with other anti-asthma monoclonal antibodies (i.e. Cinqair® (reslizumab), Fasenra™ (benralizumab), Xolair® (omalizumab).
- Treatment of other eosinophilic conditions.
- Treatment of acute bronchospasm or status asthmaticus.

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- Severe eosinophilic asthma: 100 mg every 28 days.
- EGPA: 300 mg every 28 days.

Approval Length:

- **Authorization:** 6 months.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

Appendix:

N/A

MEDICATION POLICY

References:

1. https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Nucala/pdf/NUCALA-PI-PIL.PDF.
2. http://www.nhlbi.nih.gov/files/docs/guidelines/asthgdln.pdf.
3. http://onlinelibrary.wiley.com/doi/10.1002/art.1780330806/pdf.
4. http://www.ejinme.com/article/S0953-6205(15)00144-2/fulltext.
5. Medi-Span.
6. http://blue.regence.com/trgmedpol/drugs/dru428.pdf.
7. https://unityhealth.com/practitioners/medication-prior-authorization?did=1223.
8. https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/nucala.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
2/22/2018	1. **Changed** "I. Documented diagnosis of severe eosinophilic asthma AND a documented blood eosinophilia count of one of the following A or B: A. At least 300 cells/mcL in the previous 12 months; B. At least 150 cells/mcL in the previous 6 weeks; II. Documentation that patient has been on a minimum of a three-month trial of a high-dose inhaled corticosteroid used in combination with a long-acting inhaled beta-2 agonist AND both criteria A and B are met: A. Documentation that patient is compliant to therapy as evidenced by pharmacy claims review (patient must have 3 fills of each inhaler within the previous 90 days); B. Documentation that patient's asthma symptoms are poorly controlled despite therapy; III. Documentation that environmental factors and comorbid conditions that worsen patient's asthma symptoms are being identified and resolved; IV. Minimum age requirement: 12 years old; V. Prescriber must be an allergist, immunologist, or pulmonologist" **to** "I. Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis: A. Severe eosinophilic asthma AND criteria 1 through 4 are met: 1. Documented blood eosinophilia count of one of the following a or b: a. At least 300 cells/mcL in the previous 12 months; b. At least 150 cells/mcL in the previous 6 weeks; 2. Documentation that patient has been on a minimum of a three-month trial of a high-dose inhaled corticosteroid used in combination with a long-acting inhaled beta-2 agonist AND both criteria a and b are met: a. Documentation that patient is compliant to therapy as evidenced by pharmacy claims review (patient must have 3 fills of each inhaler within the previous 90 days); b. Documentation that patient's asthma symptoms are poorly controlled despite therapy; 3. Documentation that environmental factors and comorbid conditions that worsen patient's asthma symptoms are being identified and resolved; 4. Minimum age requirement: 12 years old; B. Eosinophilic granulomatosis with polyangiitis (EGPA) AND criteria 1 through 5 are met: 1. Documentation that patient has at least 4 of the following criteria a through f: a. Asthma; b. Eosinophilia greater than l0% on differential white blood cell count; c. Mononeuropathy (including multiplex) or polyneuropathy; d. Non-fixed pulmonary infiltrates on roentgenography; e. Paranasal sinus abnormality; f. Biopsy containing a blood vessel with extravascular eosinophils; 2. Documentation that patient has life- and/or organ-threatening disease manifestations (i.e. heart, GI, central nervous system, severe peripheral neuropathy, severe ocular disease, alveolar hemorrhage and/or glomerulonephritis); 3. Documentation that patient is stable on corticosteroid therapy or has a contraindication to corticosteroid therapy; 4. Documented trial and failure of, intolerance to, or contraindication to at least one other immunosuppressant (i. e. azathioprine, cyclophosphamide, methotrexate); 5. Minimum age requirement: 18 years old; II. Prescriber must be an allergist, immunologist, pulmonologist, or rheumatologist" **under Prior Authorization Criteria**. 2. **Changed** "Concurrent use with Cinqair® (reslizumab) or Xolair® (omalizumab)" **to** "Concurrent use with other anti-asthma monoclonal antibodies (i.e. Cinqair® (reslizumab), Fasenra™ (benralizumab), Xolair® (omalizumab)" **under Exclusion Criteria**. 3. **Changed** "One 100 mg injection every 28 days" **to** "Severe eosinophilic asthma: 100 mg every 28 days; EGPA: 300 mg every 28 days" **under Quantity/Days Supply Restrictions**. 4. **Added** "http://onlinelibrary.wiley.com/doi/10.1002/art.1780330806/pdf"**,** "http://www.ejinme.com/article/S0953-6205(15)00144-2/fulltext"**, and** "https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/nucala" **under References**.
7/14/2017	1. **Changed** "Concurrent use with Xolair® (omalizumab)" **to** "Concurrent use with Cinqair® (reslizumab) or Xolair® (omalizumab)" **under Exclusion Criteria**.