Mepolizumab (Nucala) for Asthma

**Initiation (new start) criteria:** Non-formulary mepolizumab (Nucala) will be covered on the prescription drug benefit for 6 months when the following criteria are met:

- Prescriber is an Allergist or Pulmonologist; **-AND-**
- Patient is at least 12 years of age; **-AND-**
- Patient has diagnosis of asthma AND an eosinophilic phenotype (Type 2 asthma) defined as: an eosinophil count of at least 150 cells/microliter in the past 6 weeks OR an eosinophil count of at least 300 cells/microliter in the past 52 weeks. **-AND-**
- Patient has uncontrolled asthma defined as any of the following:
  1. Two or more exacerbations in the past 12 months requiring oral corticosteroids
  2. One or more exacerbation(s) leading to hospitalization in the past 12 months;
  3. Asthma Control Test (ACT) is consistently less than 20 over past 12 months;
  4. Dependence on oral corticosteroids for asthma control. **-AND-**
- Patient has uncontrolled asthma despite good adherence (at least 75% over the past 3 months) to a regimen containing: a high dose inhaled corticosteroid (ICS), **AND** at least one additional asthma controller medication, such as a: long-acting beta\(_2\) agonist (LABA); **OR** leukotriene receptor antagonist (LRTI [e.g., montelukast]); **OR** long-acting muscarinic antagonist (e.g., tiotropium); **OR** daily oral corticosteroids. **-AND-**
- Mepolizumab is to be used in combination with a high dose inhaled corticosteroid (ICS) **AND** at least one additional asthma controller medication, such as a: long-acting beta\(_2\) agonist (LABA); **OR** leukotriene receptor antagonist (LRTI [e.g., montelukast]); **OR** long-acting muscarinic antagonist (e.g., tiotropium); **OR** daily oral corticosteroids. **-AND-**
- Mepolizumab is NOT used in combination with any of the following: benralizumab (Fasenra), dupilumab (Dupixent), reslizumab (Cinqair), or omalizumab (Xolair). **-AND-**
- Contraindication, allergy or intolerance, or inadequate response to benralizumab (Fasenra).
Criteria-Based Consultation Prescribing Program
CRITERIA FOR DRUG COVERAGE
mepolizumab (Nucala)

Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously: Non-formulary mepolizumab (Nucala) will be covered on the prescription drug benefit when the following criteria are met:

- Prescriber is an Allergist or Pulmonologist; -AND-
- Patient is at least 12 years of age; -AND-
- Patient is currently using mepolizumab AND it is being used with an at least one additional asthma controller medication, such as an: inhaled corticosteroid (ICS), OR long-acting beta2 agonist (LABA); OR leukotriene receptor antagonist (LRTI [e.g., montelukast]); OR long-acting muscarinic antagonist (e.g., tiotropium); OR daily systemic corticosteroids.

Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary mepolizumab (Nucala) will be covered on the prescription drug benefit for 6 months when the following criteria are met:

- Prescriber is an Allergist or Pulmonologist; -AND-
- Patient is at least 12 years of age; -AND-
- Patient is currently using mepolizumab AND it is being used with an at least one additional asthma controller medication, such as an: inhaled corticosteroid (ICS), OR long-acting beta2 agonist (LABA); OR leukotriene receptor antagonist (LRTI [e.g., montelukast]); OR long-acting muscarinic antagonist (e.g., tiotropium); OR daily systemic corticosteroids -AND-
- Contraindication, allergy or intolerance, or inadequate response to benralizumab (Fasenra).

Continued use criteria (6 months after initiation): Non-formulary mepolizumab (Nucala) will continue to be covered on the prescription drug benefit when the following criteria are met:

- Improvement from baseline documented by any of the following:
  i. Fewer asthma exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids);
  ii. Lowered daily dose of oral corticosteroids;
  iii. An increase of at least 3 points on the asthma control test (ACT);
  iv. Fewer asthma exacerbations, lowered daily dose of oral corticosteroids, or improved quality of life documented by the prescriber.
Criteria-Based Consultation Prescribing Program
CRITERIA FOR DRUG COVERAGE
mepolizumab (Nucala)

Mepolizumab (Nucala) for Eosinophilic Granulomatosis with Polyangiitis (EGPA)

Initiation (new start) criteria: Non-formulary mepolizumab (Nucala) will be covered on the prescription drug benefit for 6 months when the following criteria are met:

- Prescriber is an Allergist, Pulmonologist, or Rheumatologist; -AND-
- Patient is at least 18 years of age; -AND-
- Documented diagnosis of Eosinophilic Granulomatosis with Polyangiitis EGPA by a Rheumatologist, Allergist or Pulmonologist
  -AND-
- Documentation of severe disease (e.g., vasculitis with cerebral, cardiac, renal, or gastrointestinal involvement), OR disease flares with tapering of corticosteroid therapy
  -AND-
- Documented trial and failure of at least 2 oral immunosuppressant medications (e.g., azathioprine, cyclophosphamide, methotrexate); OR contraindication to use of azathioprine, and cyclophosphamide, and methotrexate.

Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously: Non-formulary mepolizumab (Nucala) will be covered on the prescription drug benefit for 6 months when the following criteria are met:

- Prescriber is an Allergist, Pulmonologist, or Rheumatologist; -AND-
- Patient is at least 18 years of age; -AND-
- Documented diagnosis of Eosinophilic Granulomatosis with Polyangiitis EGPA by a Rheumatologist, Allergist or Pulmonologist.
  -AND-
- Documentation of severe disease (e.g., vasculitis with cerebral, cardiac, renal, or gastrointestinal involvement) OR disease flares with tapering of corticosteroid therapy
  -AND-
- Documented trial and failure of at least 2 oral immunosuppressant medications (e.g., azathioprine, cyclophosphamide, methotrexate); OR contraindication to use of azathioprine, and cyclophosphamide, and methotrexate.
Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary mepolizumab (Nucala) will be covered on the prescription drug benefit for 6 months when the following criteria are met:

- Prescriber is an Allergist, Pulmonologist, or Rheumatologist
  -AND-
- Patient is at least 18 years of age
  -AND-
- Documented diagnosis of Eosinophilic Granulomatosis with Polyangitis (EGPA) by a Rheumatologist, Allergist or Pulmonologist.
  -AND-
- Documented trial and failure of at least 2 oral immunosuppressant medications (e.g., azathioprine, cyclophosphamide, methotrexate); OR contraindication to use of azathioprine, and cyclophosphamide, and methotrexate.

Continued use criteria (6 months after initiation): Non-formulary mepolizumab (Nucala) will continue to be covered on the prescription drug benefit when the following criteria are met:

- Improvement from baseline as documented by any of the following:
  i. Improvement in duration of remission or decrease in the rate of relapses (relapse is defined as: active vasculitis, active asthma symptoms, active nasal or sinus disease, increase in use of glucocorticoid therapy, increase in use of immunosuppressive therapy, or hospitalization.)
  ii. Decrease in use of systemic corticosteroids.