

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Mepolizumab (Nucala)

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
- Patient is at least 12 years of age
- Patient has diagnosis of asthma **AND** an eosinophilic phenotype defined as:
an eosinophil count of at least 150 cells/microliter ($0.15 \times 10^9/L$) in the past 6 weeks
OR an eosinophil count of at least 300 cells/microliter ($0.3 \times 10^9/L$) in the past 52 weeks.
- Patient has uncontrolled asthma defined as any of the following:
 - i. Two or more exacerbations in the past 12 months requiring oral corticosteroids
 - ii. One or more exacerbation(s) leading to hospitalization in the past 12 months;
 - iii. Asthma Control Test (ACT) is consistently less than 20 over past 12 months;
 - iv. Dependence on oral corticosteroids for asthma control.
- 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 beta₂ agonist (LABA); **OR** leukotriene receptor antagonist (LRTI [e.g., montelukast]); **OR** long-acting muscarinic antagonist (e.g., tiotropium); **OR** daily oral corticosteroids.
- 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 beta₂ agonist (LABA); **OR** leukotriene receptor antagonist (LRTI [e.g., montelukast]); **OR** long-acting muscarinic antagonist (e.g., tiotropium); **OR** daily oral corticosteroids.
- Mepolizumab is NOT used in combination with any of the following: benralizumab (Fasenra), dupilumab (Dupixent), reslizumab (Cinqair), or omalizumab (Xolair).
- Contraindication, allergy or intolerance, or inadequate response to benralizumab (Fasenra).

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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
- Patient is at least 12 years of age
- 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
- Patient is at least 12 years of age
- 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
- Contraindication, allergy or intolerance, or inadequate response to benralizumab.

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:

- Prescriber is an Allergist or Pulmonologist
- 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.

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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
- Patient is at least 18 years of age
- Documented diagnosis of Eosinophilic Granulomatosis with Polyangiitis EGPA by a Rheumatologist, Allergist or Pulmonologist
- Documentation of severe disease (e.g., vasculitis with cerebral, cardiac, renal, or gastrointestinal involvement), **OR** disease flares with tapering of corticosteroid therapy
- Patient has been receiving a stable dose of oral corticosteroid therapy (e.g., prednisone, prednisolone) for at least 4 weeks.
- Documented trial and failure of, contraindication to, or clinical inappropriateness of treatment with at least one oral immunosuppressant medication (e.g., azathioprine, cyclophosphamide, methotrexate, mycophenolate mofetil).

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
- Patient is at least 18 years of age
- Documented diagnosis of Eosinophilic Granulomatosis with Polyangiitis EGPA by a Rheumatologist, Allergist or Pulmonologist.
- Documentation of severe disease (e.g., vasculitis with cerebral, cardiac, renal, or gastrointestinal involvement) **OR** disease flares with tapering of corticosteroid therapy
- Patient has been receiving a stable dose of oral corticosteroid therapy (e.g., prednisone, prednisolone) for at least 4 weeks.

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
- Patient is at least 18 years of age

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CRITERIA FOR DRUG COVERAGE

Mepolizumab (Nucala)

- Documented diagnosis of Eosinophilic Granulomatosis with Polyangiitis (EGPA) by a Rheumatologist, Allergist or Pulmonologist.
- Patient has been receiving a stable dose of oral corticosteroid therapy (e.g., prednisone, prednisolone) for at least 4 weeks.
- Patient reported trial and failure of, contraindication to, or clinical inappropriateness of treatment with at least one oral immunosuppressant medication (e.g., azathioprine, cyclophosphamide, methotrexate, mycophenolate mofetil).

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:

- Prescriber is an Allergist, Pulmonologist, or Rheumatologist
- 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.

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CRITERIA FOR DRUG COVERAGE

Mepolizumab (Nucala)

Mepolizumab (Nucala) for Hypereosinophilic Syndrome (HES)

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:

- Patient is at least 12 years of age
- Prescriber is an Allergist, Pulmonologist, or Hematologist / Oncologist
- Patient has been diagnosed with HES for at least 6 months prior to starting treatment
- Patient is negative for FIP1-like-1-platelet-derived growth factor receptor alpha (FIP1L1-PDGFR α) fusion tyrosine kinase gene
- Patient does not have non-hematologic secondary HES (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy)
- Patient has a history of HES flares (worsening of HES-related clinical symptoms or blood eosinophil counts requiring an escalation in therapy) while on stable therapy (e.g., oral corticosteroids, immunosuppressives, or cytotoxic therapy) in the previous 12 months
- Patient has blood eosinophils of 1,000 cells/mcL ($1 \times 10^9/L$) or greater within the last 12 months

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:

- Patient is at least 12 years of age
- Prescriber is an Allergist, Pulmonologist, or Hematologist / Oncologist
- Patient has been diagnosed with HES for at least 6 months prior to starting treatment
- Patient is negative for FIP1-like-1-platelet-derived growth factor receptor alpha (FIP1L1-PDGFR α) fusion tyrosine kinase gene
- Patient does not have non-hematologic secondary HES (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy)
- Patient has a history of HES flares (worsening of HES-related clinical symptoms or blood eosinophil counts requiring an escalation in therapy) while on stable therapy (e.g., oral corticosteroids, immunosuppressives, or cytotoxic therapy) in the previous 12 months
- Patient has blood eosinophils of 1,000 cells/mcL ($1 \times 10^9/L$) or greater within the last 12 months

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CRITERIA FOR DRUG COVERAGE

Mepolizumab (Nucala)

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:

- Patient is at least 12 years of age
- Patient has been diagnosed with HES
- Patient is receiving concomitant HES therapy (e.g., oral corticosteroids, immunosuppressives, or cytotoxic therapy)

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:

- Prescriber is an Allergist, Pulmonologist, or Hematologist / Oncologist
- Disease response as indicated by a decrease in HES flares (worsening of HES-related clinical symptoms or blood eosinophil counts requiring an escalation in therapy) from baseline or a decrease in HES therapy without HES flares.