#### Mepolizumab (Nucala)

#### Notes:

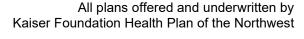
- Quantity Limits: No
- \* Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

<u>Initiation (new start) criteria</u>: Non-formulary **mepolizumab (Nucala)** will be covered on the prescription drug benefit for <u>12 months</u> when the following criteria are met:

- 1. Prescriber is allergist or pulmonologist and patient has moderate-to-severe persistent asthma
  - Patient is at least 6 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 x109/L) in the past 6 weeks OR an eosinophil count of at least at least 300 cells/microliter (0.3 x109/L) in the past 52 weeks
  - Patient has uncontrolled asthma defined as any of the following:
    - Two or more exacerbations in the past 12 months requiring systemic corticosteroids
    - o One or more exacerbation(s) in the past 12 months leading to hospitalization
    - o Asthma Control Test (ACT) is consistently less than 20 over past 12 months
    - Dependence on systemic corticosteroids for asthma control
  - Patient is concurrently treated with a high-dose, or maximally tolerated inhaled corticosteroid AND at least one other asthma controller medication, including: a long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, a leukotriene receptor antagonist, theophylline, or oral corticosteroid
  - Mepolizumab is to be used in combination with a high dose inhaled corticosteroid (ICS) AND at least one additional asthma controller medication, including: a long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, a leukotriene receptor antagonist, theophylline, or oral corticosteroid
  - Mepolizumab is NOT used in combination with any of the following: benralizumab (Fasenra), dupilumab (Dupixent), reslizumab (Cinqair), tezepelumab-ekko (Tezspire), or omalizumab (Xolair)
  - Contraindication, allergy or intolerance, or inadequate response to benralizumab (Fasenra)

kp.org

Revised: 06/08/23 Effective: 08/03/23



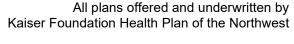


#### Mepolizumab (Nucala)

- 2. Prescriber is an allergist or otolaryngologist and patient has chronic rhinosinusitis with nasal polyps
  - Patient is at least 18 years of age
  - Patient has diagnosis of bilateral sino-nasal polyposis; with polyps filling the middle meatuses
  - Patient has persistent rhinosinusitis (swelling of the sinuses and nasal cavity) symptoms with nasal blockage that includes at least two of the following symptoms for at least 12 weeks:
    - Rhinorrhea (runny nose)
    - o Facial pain, pressure, or fullness
    - Nasal blockage, obstruction, or congestion
    - Partial or complete loss of smell
  - Patient has had a previous full endoscopic sinus surgery
  - Patient remains symptomatic despite at least a 12-week trial of a nasal corticosteroid [e.g., fluticasone (Flonase), mometasone (Nasonex), budesonide (Rhinocort)], or patient has a history of contraindication or intolerance to nasal corticosteroids
  - Patient will continue to receive therapy with a nasal corticosteroid concomitantly with mepolizumab (Nucala); unless contraindication or intolerance to nasal corticosteroids
  - Patient is not planned to concurrently receive treatment with dupilumab (Dupixent), benralizumab (Fasenra), or omalizumab (Xolair)
- 3. Prescriber is allergist, pulmonologist or rheumatologist and patient has eosinophilic granulomatosis with polyangiitis (EGPA)
  - Patient is at least 18 years of age
  - Patient has active, non-severe EGPA defined as:
    - Vasculitis without life- or organ-threatening manifestations. Examples of symptoms in non-severe disease include: rhinosinusitis, asthma, mild systemic symptoms, uncomplicated cutaneous disease, mild inflammatory arthritis.
  - Patient is concurrently treated with oral corticosteroid therapy (e.g. prednisone, prednisolone)

kp.org

Revised: 06/08/23 Effective: 08/03/23





#### Mepolizumab (Nucala)

- 4. Prescriber is allergist, pulmonologist, or hematologist/oncologist and patient has hypereosinophilic syndrome (HES)
  - Patient is at least 12 years of age
  - 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-PDGFRα) 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 worsening of HES-related symptoms or blood eosinophil counts requiring an escalation in therapy (e.g., oral corticosteroids, immunosuppressives, or cytotoxic therapy) in the previous 12 months
  - Patient has blood eosinophils of 1,000 cells/mcL (1 x109/L) or greater within the last 12 months

<u>Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously</u>: Non-formulary mepolizumab (Nucala) will be covered on the prescription drug benefit for <u>12 months</u> when the following criteria are met:

- 1. Prescriber is allergist or pulmonologist and patient has moderate-to-severe persistent asthma
  - Patient is at least 6 years of age
  - Patient is currently using mepolizumab AND at least one additional asthma controller medication, including: a long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, a leukotriene receptor antagonist, theophylline, or oral corticosteroid
  - Contraindication, allergy or intolerance, or inadequate response to benralizumab (Fasenra)
- 2. Prescriber is an allergist or otolaryngologist and patient has chronic rhinosinusitis with nasal polyps
  - Patient is at least 18 years of age
  - Patient has diagnosis of bilateral sino-nasal polyposis
  - Patient has had a previous full endoscopic sinus surgery
  - Patient is using a nasal corticosteroid [e.g., fluticasone, mometasone, budesonide], unless contraindication or intolerance to nasal corticosteroids

kp.org

Revised: 06/08/23 Effective: 08/03/23 All plans offered and underwritten by Kaiser Foundation Health Plan of the Northwest



#### Mepolizumab (Nucala)

- Patient is not concurrently receiving treatment with dupilumab (Dupixent), benralizumab (Fasenra), or omalizumab (Xolair)
- 3. Prescriber is allergist, pulmonologist or rheumatologist and patient has eosinophilic granulomatosis with polyangiitis (EGPA)
  - · Patient is at least 18 years of age
  - Patient has active, nonsevere EGPA
    - Documentation of nonsevere disease (e.g. vasculitis with rhinosinusitis, asthma, mild systemic symptoms, uncomplicated cutaneous disease, mild inflammatory arthritis)
    - Patient is concurrently treated with oral corticosteroid therapy (e.g. prednisone, prednisolone)
- 4. Prescriber is allergist, pulmonologist, or hematologist/oncologist and patient has hypereosinophilic syndrome (HES)
  - 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

<u>Continued use criteria (12 months after initiation)</u>: Non-formulary mepolizumab (Nucala) will continue to be covered on the prescription drug benefit for <u>12 months</u> when the following criteria are met:

- 1. Prescriber is allergist or pulmonologist and patient has moderate-to-severe persistent asthma
  - Improvement from baseline documented by any of the following:
    - Fewer asthma exacerbations (defined as worsening of asthma that requires increase in ICS dose or treatment with systemic corticosteroids)
    - Lowered daily dose of oral corticosteroids
    - An increase of at least 3 points on the asthma control test (ACT)
    - Fewer asthma exacerbations, lowered daily dose of oral corticosteroids, or improved quality of life documented by the prescriber
- 2. Prescriber is an allergist or otolaryngologist and patient has chronic rhinosinusitis with nasal polyps

kp.org

Revised: 06/08/23 Effective: 08/03/23 All plans offered and underwritten by Kaiser Foundation Health Plan of the Northwest

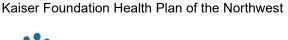


### Mepolizumab (Nucala)

- The patient has a documented clinical benefit (e.g., improvement in nasal congestion, improvement in sense of smell, reduction in size of polyps)
- Patient is currently using mepolizumab with a nasal corticosteroid; unless history of contraindication or intolerance to nasal corticosteroids
- 3. Prescriber is allergist, pulmonologist or rheumatologist and patient has eosinophilic granulomatosis with polyangiitis (EGPA)
  - Improvement from baseline as documented by any of the following:
    - 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.)
    - Decrease in use of systemic corticosteroids
- 4. Prescriber is allergist, pulmonologist, or hematologist/oncologist and patient has hypereosinophilic syndrome (HES)
  - 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

kp.org

Revised: 06/08/23 Effective: 08/03/23





All plans offered and underwritten by