# Criteria-Based Consultation Prescribing Program
# CRITERIA FOR DRUG COVERAGE
# 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

**Initiation (new start) criteria:** Non-formulary **mepolizumab (Nucala)** will be covered on the prescription drug benefit for **12 months** 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
        - One or more exacerbation(s) in the past 12 months leading to hospitalization
        - 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)

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)
        - 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)

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

**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 **12 months** 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

- 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

**Continued use criteria (12 months after initiation):** Non-formulary **mepolizumab (Nucala)** will continue to be covered on the prescription drug benefit for **12 months** 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

- 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