**Kaiser Permanente Health Plan of Mid-Atlantic States, Inc.**
**Nucala (mepolizumab) Prior Authorization (PA)**
**Pharmacy Benefits Prior Authorization Help Desk**
**Length of Authorizations: Initial- 6 months; Continuation- 12 months**

**Instructions:**

This form is used by Kaiser Permanente and/or participating providers for coverage of **Nucala (mepolizumab) .** Please complete and fax this form back to Kaiser Permanente within 24 hours [fax: 1-866-331-2104]. If you have any questions or concerns, please call 1-866-331-2103. **Requests will not be considered unless all sections are complete.**

**KP-MAS Formulary can be found at:** Pharmacy | Community Provider Portal | Kaiser Permanente

## 1 – Patient Information

Patient Name: _____ Kaiser Medical ID#: _____ Date of Birth: _____

## 2 – Prescriber Information

Prescriber Name: _____ Specialty: _____ NPI: _____

Prescriber Address: _____

Prescriber Phone #: _____Prescriber Fax #: _____

## 3 – Pharmacy Information

Pharmacy Name: _____ Pharmacy NPI: _____

Pharmacy Phone #_____ Pharmacy Fax #: _____

## 4 – Drug Therapy Requested

Drug 1: Name/Strength/Formulation: _____
Sig: _____

Drug 2: Name/Strength/Formulation: _____
Sig: _____

Note: The Virginia Department of Medical Assistance Services considers the use of concomitant therapy with Cinqair®, Dupixent®, Fasenra®, Nucala®, Tezspire™ and Xolair® to be experimental and investigational. Safety and efficacy of these combinations have NOT been established and will NOT be approved

## 5– Diagnosis/Clinical Criteria

1. Is this request for initial or continuing therapy?

□ Initial therapy □ Continuing therapy, state start date: _____

2. Indicate the patient's diagnosis for the requested medication: _____

**Clinical Criteria for *severe asthma:**

1. Member is ≥ 6 years of age
   □ No □ Yes
2. Does the member have a diagnosis of *severe asthma? **AND**

   □ No □ Yes
3. Does the member have asthma with an eosinophilic phenotype defined as blood eosinophils ≥150 cells/µL? **AND**

   □ No □ Yes
4. Will coadministration with another monoclonal antibody be avoided (e.g., omalizumab, reslizumab, benralizumab, dupilumab, tezepelumab-ekko)? **AND**

   □ No □ Yes
5. Will this be used for add-on maintenance treatment in members regularly receiving **both** (unless otherwise contraindicated) of the following:
   - Medium- to high-dose inhaled corticosteroids; **AND**
   - An additional controller medication (e.g., long-acting beta agonist, leukotriene modifiers)?

   □ No □ Yes
6. Has the member had two or more exacerbations in the previous year requiring oral or injectable corticosteroid treatment (in addition to the regular maintenance therapy defined above) or one exacerbation resulting in a hospitalization? AND

   □ No □ Yes
7. Does the member have at least one of the following for assessment of clinical status:
   - Use of systemic corticosteroids
   - Use of inhaled corticosteroids
   - Number of hospitalizations (e.g., ER visits, or unscheduled visits to healthcare providers due to condition)
   - Forced expiratory volume in 1 second ($FEV_1$)?

   □ No □ Yes
8. Has the member tried and failed an adequate trial of the 2 different preferred products (Fasenra® and Xolair®)?

   □ No □ Yes

***Components of severity for classifying asthma as severe may include any of the following (not all-inclusive).**

- Asthma remains uncontrolled despite optimized treatment with high-dose ICS-LABA
- Asthma requires high-dose ICS-LABA to prevent it from being uncontrolled
- Symptoms throughout the day
- Nighttime awakenings, often 7 times/week
- SABA use for symptom control occurs several times per day
- Extremely limited normal activities
- Lung function (percent predicted FEV1) < 60%

- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intensely relative to moderate asthma

**Clinical Criteria for EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS** (EGPA):**

1. Is the member 18 years of age or older? **AND**

   □ No □ Yes

2. Does the member have a confirmed diagnosis of EGPA (aka Churg-Strauss Syndrome)? **AND**

   □ No □ Yes

3. Does the member have blood eosinophils ≥ 1000 cells/µL or ≥ 10% eosinophils on white blood cell differential count? **AND**

   □ No □ Yes

4. Has the member been on stable doses of concomitant oral corticosteroid therapy for at least 4 weeks (i.e., prednisone or prednisolone at a dose of 7.5 mg/day)? **AND**

   □ No □ Yes

5. Has the physician assessed baseline disease severity utilizing an objective measure/tool (e.g., Birmingham Vasculitis Activity Score [BVAS], history of asthma symptoms and/or exacerbations, duration of remission, rate of relapses)?

   □ No □ Yes

6. Has the member tried and failed an adequate trial or has contraindication to the preferred product Fasenra®?

   □ No □ Yes

7. Will coadministration with another monoclonal antibody be avoided (e.g., omalizumab, reslizumab, benralizumab, dupilumab, tezepelumab-ekko)

   □ No □ Yes

****Eosinophilic Granulomatosis Polyangiitis (EGPA) is defined as all of the following:**

- History or presence of asthma
- Blood eosinophil level > 10% or an absolute count > 1000 cells/mm3
- Two or more of the following criteria:
  - Histopathologic evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil rich granulomatous inflammation
  - Neuropathy
  - Pulmonary infiltrates
  - Sinonasal abnormalities
  - Cardiomyopathy
  - Glomerulonephritis
  - Alveolar hemorrhage
  - Palpable purpura
  - Antineutrophil Cytoplasmic Antibody (ANCA) positivity

**Clinical Criteria for HYPEREOSINOPHILIC SYNDROME (HES):**

1. Is the member 12 years of age or older? **AND**

   □ No □ Yes

2. Has the member been diagnosed with HES (without an identifiable non-hematologic secondary cause (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy) or FIP1L1-PDGFRα kinase-positive HES) for at least 6 months prior to starting treatment? **AND**

   □ No □ Yes

3. Has the member had a history of 2 or more HES flares within the previous 12 months (e.g., documented HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy)? **AND**

   □ No □ Yes

4. Will this be used in combination with stable doses of at least one other HES therapy, (e.g., oral corticosteroids, immunosuppressive agents, cytotoxic therapy) unless the member cannot tolerate other therapy?

   □ No □ Yes

5. Will coadministration with another monoclonal antibody be avoided (e.g., omalizumab, reslizumab, benralizumab, dupilumab, tezepelumab-ekko)

   □ No □ Yes

**Clinical Criteria for CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRSwNP):**

1. Is the member 18 years of age or older? **AND**

   □ No □ Yes

2. Does the member have bilateral symptomatic sino-nasal polyposis with symptoms lasting at least 8 weeks? **AND**

   □ No □ Yes

3. Has the member failed at least 8 weeks of intranasal corticosteroid therapy? **AND**

   □ No □ Yes

4. Will therapy be used in combination with intranasal corticosteroids unless unable to tolerate or is contraindicated? **AND**

   □ No □ Yes

5. Has the member tried and failed an adequate trial of the preferred product Xolair®?

   □ No □ Yes

6. Will coadministration with another monoclonal antibody be avoided (e.g., omalizumab, reslizumab, benralizumab, dupilumab, tezepelumab-ekko)

   □ No □ Yes

**For continuation of therapy for all indications, please respond to the <u>additional questions</u> below:**

1. Has the member been assessed for toxicity? **AND**

   □ No □ Yes

**For Severe Asthma renewal**

2. Does the member have improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
    - Use of systemic corticosteroids
    - Hospitalizations
    - ER visits
    - Unscheduled visits to healthcare provider
    - Improvement from baseline in forced expiratory volume in 1 second ($FEV_1$)?

    □ No □ Yes

**For EGPA renewal**

2. Does the member have disease response as indicated by improvement in signs and symptoms compared to baseline as evidenced in one or more of the following:
    - Member is in remission [defined as a Birmingham Vasculitis Activity Score (BVAS) score=0 and a prednisone/prednisolone daily dose of ≤ 7.5 mg]
    - Decrease in maintenance dose of systemic corticosteroids
    - Improvement in BVAS score compared to baseline
    - Improvement in asthma symptoms or asthma exacerbations
    - Improvement in duration of remission or decrease in the rate of relapses?

    □ No □ Yes

**For HES renewal**

2. Does the member have a disease response as indicated by a decrease in HES flares from baseline?

    (Note: An HES flare is defined as worsening of clinical signs and symptoms of HES or increasing eosinophils (on at least 2 occasions), resulting in the need to increase oral corticosteroids or increase/add cytotoxic or immunosuppressive HES therapy.)

    □ No □ Yes

**For CRSwNP renewal**

2. Does the member have disease response as indicated by improvement in signs and symptoms compared to baseline in one or more of the following: nasal/obstruction symptoms, improvement of sinus opacifications as assessed by CT-scans and/or an improvement on a disease activity scoring tool [e.g., nasal polyposis score (NPS), nasal congestion (NC) symptom severity score, sinonasal outcome test-22 (SNOT-22), etc.]? **OR**

    □ No □ Yes
3. Did the member have improvement in at least one of the following response criteria:
    - Reduction in nasal polyp size
    - Reduction in need for systemic corticosteroids
    - Improvement in quality of life
    - Improvement in sense of smell
    - Reduction of impact of comorbidities?

    □ No □ Yes

## 7 – Prescriber Sign-Off

**Additional Information –**

1. **Please submit chart notes/medical records for the patient that are applicable to this request.**
2. **If member has not tried preferred agent(s) please provide rationale/explanation and any additional supporting information that should be taken into consideration for the requested medication:**

_____

_____

_____

**I certify that the information provided is accurate. Supporting documentation is available for State audits.**

| **Prescriber Signature:** | **Date:** |
|---|---|
| | |