Print Reset

CardinalCare
Virginia's Medicaid Program

COMMONWEALTH OF VIRGINIA DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Service Authorization (SA) Form

NUCALA® Prefilled Autoinjector and Syringe (mepolizumab)

If the following information is not complete, correct, or legible, the SA process can be delayed.

Please use one form per member.

Physician Administered Drug: This form is only to be used for members obtaining the medication from a pharmacy through billing the pharmacy benefit at point-of-sale. Please refer to the Virginia Medicaid Nucala Clinical Criteria for members/providers who will obtain the medication through the medical benefit.

MEMBER INFORMATION

Last Name: _____

First Name: _____

Medicaid ID Number: _____

Date of Birth: _____

Weight in Kilograms: _____

PRESCRIBER INFORMATION

Last Name: _____

First Name: _____

NPI Number: _____

Phone Number: _____

Fax Number: _____

DRUG INFORMATION

Drug Name/Form: _____

Strength: _____

Dosing Frequency: _____

Length of Therapy: _____

Quantity per Day: _____

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 theses combinations have **NOT** been established and will **NOT** be permitted.

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

DIAGNOSIS AND MEDICAL INFORMATION

For severe* asthma initial approval, complete the following questions to receive a 6-month approval:

1. Is the member 6 years of age or older? **AND**
   ☐ Yes ☐ No
2. Does the member have a diagnosis of severe* asthma? **AND**
   ☐ Yes ☐ No
3. Does the member have asthma with an eosinophilic phenotype defined as blood eosinophils ≥ 150 cells/µL? **AND**
   ☐ Yes ☐ No
4. Will coadministration with another monoclonal antibody be avoided (e.g., omalizumab, reslizumab, benralizumab, dupilumab, tezepelumab-ekko)? **AND**
   ☐ Yes ☐ No
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)?

   ☐ Yes ☐ No
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**
   ☐ Yes ☐ No
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, ER visits, or unscheduled visits to healthcare provider due to condition
   - Forced expiratory volume in 1 second (FEV_1)? **AND**

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

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

For severe asthma renewal, complete the following questions to receive a 12-month approval:

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

☐ Yes ☐ No

10. 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)?

☐ Yes ☐ No

For eosinophilic granulomatosis with polyangiitis§ (EGPA) initial approval, complete the following questions to receive a 6-month approval:

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

☐ Yes ☐ No

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

☐ Yes ☐ No

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

☐ Yes ☐ No

14. 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**

☐ Yes ☐ No

15. 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)?

☐ Yes ☐ No

16. Has the member tried and failed an adequate trial of the preferred product Fasenra®?

☐ Yes ☐ No

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

For EGPA renewal, complete the following questions to receive a 12-month approval:

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

☐ Yes ☐ No

18. 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?

☐ Yes ☐ No

For hypereosinophilic syndrome (HES) initial approval, complete the following questions to receive a 6-month approval:

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

☐ Yes ☐ No

20. 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**

☐ Yes ☐ No

21. 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**

☐ Yes ☐ No

22. 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?

☐ Yes ☐ No

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

For HES renewal, complete the following questions to receive a 12-month approval:

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

☐ Yes ☐ No

24. Does the member have 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.

☐ Yes ☐ No

For chronic rhinosinusitis with nasal polyps (CRSwNP) initial approval, complete the following questions to receive a 6-month approval:

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

☐ Yes ☐ No

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

☐ Yes ☐ No

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

☐ Yes ☐ No

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

☐ Yes ☐ No

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

☐ Yes ☐ No

For CRSwNP renewal, complete the following questions to receive a 12-month approval:

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

☐ Yes ☐ No

31. 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**

☐ Yes ☐ No

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

32. 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?

☐ Yes ☐ No

For inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype initial approval, complete the following questions to receive a 6-month approval:

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

☐ Yes ☐ No

34. Does the member have a diagnosis of COPD with moderate to very severe airflow limitation, as defined by FEV_1/FVC ratio < 0.7 and post-bronchodilator FEV_1 of 20% to 80% predicted? **AND**

☐ Yes ☐ No

35. Does the member have a peripheral blood eosinophil count ≥ 150 cells/µL at screening or ≥ 300 cells/µL in the year prior? **AND**

☐ Yes ☐ No

36. Will therapy be used for add-on maintenance treatment in members regularly receiving background triple inhaled therapies (i.e. ICS, long-acting beta agonist, and long-acting muscarinic antagonist) unless otherwise contraindicated? **AND**

☐ Yes ☐ No

37. Has the member had at least 2 moderate (requiring treatment with oral/systemic corticosteroids and/or antibiotics) or 1 severe (requiring inpatient hospitalization) COPD exacerbation in the previous year, despite receiving triple inhaled therapy? **AND**

☐ Yes ☐ No

38. Has the member tried and failed an adequate trial of Dupixent, unless contraindicated?

☐ Yes ☐ No ☐ N/A

a. **If N/A was selected,** does the member have a peripheral blood eosinophil count < 300 cells/µL at screening?

☐ Yes ☐ No

For COPD renewal, complete the following questions to receive a 12-month approval:

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

☐ Yes ☐ No ☐ N/A

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

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

    ☐ Yes ☐ No

*** Components of severity for classifying asthma as *severe* may include any of the following (not all-inclusive):**
▪ Asthma that remains uncontrolled despite optimized treatment with high-dose ICS-LABA ▪ Asthma that 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 intense relative to moderate asthma
§ 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/mm^3 ▪ 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

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

Prescriber Signature (Required) **Date**

By signature, the physician confirms the above information is accurate and verifiable by member records.

Please include ALL requested information; Incomplete forms will delay the SA process.

Submission of documentation does NOT guarantee coverage by the Department of Medical Assistance Services. The completed form may be: **FAXED TO 800-932-6651**, phoned to 800-932-6648, or mailed to:

Prime Therapeutics Management LLC

Attn: GV – 4201

P.O. Box 64811

St. Paul, MN 55164-0811