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.

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, mepolizumab, 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 ≥ 150 cells/µL within 6 weeks of dosing? **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

(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:

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

☐ Yes ☐ No

17. 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:

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

☐ Yes ☐ No

19. 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

20. 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

21. 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:

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

☐ Yes ☐ No

23. 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:

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

☐ Yes ☐ No

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

☐ Yes ☐ No

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

☐ Yes ☐ No

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

☐ Yes ☐ No

28. 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:

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

☐ Yes ☐ No

30. 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:**

31. 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

*** Components of severity for classifying asthma as *severe* may include any of the following (not all-inclusive):**
▪ 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 FEV_1) < 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

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

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