MOLINA HEALTHCARE
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: _____

(Form continued on next page.)

Created: 06012024 | Effective: 07012024 VA-ALL-PF-16712-24

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

(Form continued on next page.)

Member's Last Name:

Member's First Name:

For EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS§ (EGPA) initial approval, complete the following questions to receive a 6-month approval: (for NUCALA)

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

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

(Form continued on next page.)

Member's Last Name: | | | | | | | | | | | | |

Member's First Name: | | | | | | | | | | | | |

For HYPEREOSINOPHILIC SYNDROME (HES) initial approval, complete the following questions to receive a 6-month approval: (for NUCALA)

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

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

(Form continued on next page.)

Member's Last Name:

Member's First Name:

For CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRSwNP) initial approval, complete the following questions to receive a 6-month approval: (for NUCALA)

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

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

(Form continued on next page.)

Member's Last Name:

Member's First Name:

*** 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 Molina Healthcare.

The completed form may be: **FAXED** to **(844) 278-5731**, or you may call **(800) 424-4518** (TTY: 711).