Nucala

Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-855-330-1720**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-888-877-0518.** For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

Patient's Name: _____ **Date**: _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

Referring Provider Info: ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Rendering Provider Info: ❑ **Same as Referring Provider** ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Required Demographic Information:

Patient Weight: _____*kg*

*Patient Height:*_____*cm*

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

Site of Service Questions (SOS):

A. Indicate the site of service requested:
- ❑ On Campus Outpatient Hospital
- ❑ Off Campus Outpatient Hospital
- ❑ Home infusion, *skip to Criteria Questions*
- ❑ Physician office, *skip to Criteria Questions*
- ❑ Ambulatory surgical, *skip to Criteria Questions*
- ❑ Pharmacy, *skip to Criteria Questions*

B. Is this request to continue previously established treatment with the requested medication?
- ❑ Yes – This is a continuation of an existing treatment
- ❑ No – This is a new therapy request (patient has not received requested medication in the last 6 months). *Skip to Clinical Criteria Questions*

C. Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (eg acetaminophen, steroids, diphenhydramine, fluids, or other pre-medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion? ***ACTION REQUIRED: If Yes, please attach supporting clinical documentation.***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

D. Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may limit the member's ability to tolerate a large volume or load or predispose the member to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment?
ACTION REQUIRED: If Yes, please attach supporting clinical documentation.
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

E. Does the patient have significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver?
ACTION REQUIRED: If Yes, please attach supporting clinical documentation. ❑ Yes ❑ No

Criteria Questions:

1. What is the diagnosis?
   - ❑ Asthma
   - ❑ Eosinophilic granulomatosis with polyangiitis (EGPA)
   - ❑ Hypereosinophilic syndrome (HES)
   - ❑ Other _____
2. What is the ICD-10 code? _____

Complete the following section based on the patient's diagnosis, if applicable.

Section A: Asthma

3. Will the patient receive Nucala as monotherapy (i.e., without any other asthma medications such as inhaled corticosteroids)? ❑ Yes ❑ No
4. Will the patient receive Nucala concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Xolair)? ❑ Yes ❑ No
5. Is the request for continuation of therapy with Nucala? ❑ Yes ❑ No *If No, skip to #8*
6. Is the patient currently receiving Nucala through samples or a manufacturer's patient assistance program?
   ❑ Yes ❑ No ❑ Unknown *If Yes or Unknown, skip to #9*
7. Has asthma control improved on Nucala treatment as demonstrated by at least one of the following?
   ❑ Yes ❑ No *No further questions*
   a) A reduction in the frequency and/or severity of symptoms and exacerbations
   b) A reduction in the daily maintenance oral corticosteroid dose
8. Does the patient have inadequate asthma control (e.g., hospitalization or emergency medical care visit within the past year) despite current treatment with both of the following medications at optimized doses?
   ❑ Yes ❑ No If Yes, s*kip to #10*
   a) Inhaled corticosteroid
   b) Additional controller (long acting beta$_2$-agonist, leukotriene modifier, or sustained-release theophylline)

9. Prior to receiving Nucala, did the patient have inadequate asthma control (e.g., hospitalization or emergency medical care visit within the past year) despite current treatment with both of the following medications at optimized doses? ❑ Yes ❑ No
   a) Inhaled corticosteroid
   b) Additional controller (long acting $beta_2$-agonist, leukotriene modifier, or sustained-release theophylline)

10. What is the patient's baseline (e.g., before significant oral steroid use) blood eosinophil count in cells per microliter? ***ACTION REQUIRED: Please attach supporting chart note(s) or medical record with the patient's baseline blood eosinophil count.*** _____ cells per microliter ❑ Unknown

11. Is the patient dependent on systemic corticosteroids? ❑ Yes ❑ No

Section B: Eosinophilic Granulomatosis with Polyangiitis

12. Is the request for continuation of therapy with Nucala? ❑ Yes ❑ No *If No, skip to #15*

13. Is the patient currently receiving Nucala through samples or a manufacturer's patient assistance program? ❑ Yes ❑ No ❑ Unknown *If Yes or Unknown, skip to #15*

14. Does the patient have beneficial response to treatment with Nucala as demonstrated by ANY of the following? ***Indicate below and no further questions.***
   ❑ A reduction in the frequency of relapses
   ❑ A reduction in the daily oral corticosteroid dose
   ❑ No active vasculitis
   ❑ None of the above

15. Does the patient have a history or the presence of a blood eosinophil count greater than 1000 cells per microliter or blood eosinophil level greater than 10%? ***ACTION REQUIRED: Please attach supporting chart note(s) or medical record.***
   ❑ Yes - blood eosinophil count greater than 1000 cells per microliter
   ❑ Yes - blood eosinophil level greater than 10%
   ❑ No

16. Does the patient have at least two of the following disease characteristics of eosinophilic granulomatosis with polyangiitis (EGPA)? ***Indicate ALL that apply or mark " None of the above."***
   ❑ Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
   ❑ Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)
   ❑ Pulmonary infiltrates, non-fixed; sino-nasal abnormality
   ❑ Cardiomyopathy (established by echocardiography or magnetic resonance imaging)
   ❑ Glomerulonephritis (hematuria, red cell casts, proteinuria)
   ❑ Alveolar hemorrhage (by bronchoalveolar lavage)
   ❑ Palpable purpura
   ❑ Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinease 3)
   ❑ None of the above

17. Has the patient had at least one relapse (requiring increase in oral corticosteroids dose, initiation/increased dose of immunosuppressive therapy or hospitalization) within 2 years prior to starting treatment with Nucala? *If Yes, no further questions* ❑ Yes ❑ No

18. Does the patient have a refractory disease? ❑ Yes ❑ No

Section C: Hypereosinophilic syndrome

19. Is the request for continuation of therapy with Nucala? *If No, skip to #23* ❑ Yes ❑ No

20. Is the patient currently receiving Nucala through samples or a manufacturer's patient assistance program? ❑ Yes ❑ No ❑ Unknown *If Yes or Unknown, skip to #23*

21. Has the patient experienced a reduction in hypereosinophilic syndrome (HES) flares since starting treatment with Nucala? ❑ Yes ❑ No

22. Will the patient receive Nucala as monotherapy (i.e., without any other hypereosinophilic syndrome [HES] medications)? *No further questions* ❑ Yes ❑ No

23. Does the patient have hypereosinophilic syndrome (HES) secondary to a non-hematologic cause (e.g., drug hypersensitivity, parasitic helminth infection, [human immunodeficiency virus] HIV infection, non-hematologic malignancy)? ❑ Yes ❑ No

24. Does the patient have FIP1L1-PDGFRA kinase-positive hypereosinophilic syndrome (HES)? ***ACTION REQUIRED*: *Please attach FIP1L1-PDGFRA fusion gene test results.*** ❑ Yes ❑ No

25. Has the patient had hypereosinophilic syndrome (HES) for at least 6 months? ❑ Yes ❑ No

26. Does the patient have a history or presence of a blood eosinophil count of at least 1000 cells per microliter? ***ACTION REQUIRED: Please attach supporting chart note(s) or medical record?*** ❑ Yes ❑ No

27. Will the patient receive Nucala as monotherapy (i.e., without any other hypereosinophilic syndrome [HES] medications)? ❑ Yes ❑ No

28. Is the patient on a stable dose of hypereosinophilic syndrome (HES) therapy (e.g., oral corticosteroid, immunosuppressive, and/or cytotoxic therapy)? ❑ Yes ❑ No

29. Has the patient experienced at least two hypereosinophilic syndrome (HES) flares within the past 12 months? ❑ Yes ❑ No

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X_____
Prescriber or Authorized Signature **Date (mm/dd/yy)**

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720