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)
   - ❑ Chronic rhinosinusitis with nasal polyps (CRSwNP)
   - ❑ Other _____
2. What is the ICD-10 code? _____

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

Section A: Asthma

3. Is the medication prescribed by or in consultation with an allergist, immunologist, or pulmonologist?
   ❑ Yes ❑ No
4. Is the request for continuation of therapy with Nucala? ❑ Yes ❑ No *If No, skip to #10*
5. Is the patient currently receiving Nucala through samples or a manufacturer's patient assistance program?
   ❑ Yes ❑ No ❑ Unknown *If Yes or Unknown, skip to #10*
6. Has asthma control improved on Nucala treatment as demonstrated by a reduction in the frequency and/or severity of symptoms and exacerbations? ***ACTION REQUIRED: If Yes, please attach supporting chart notes or medical record documentation of improved asthma control. ACTION REQUIRED: Submit supporting documentation***
   ❑ Yes ❑ No ❑ Unknown *If Yes, skip to #8*
7. Has asthma control improved on Nucala treatment as demonstrated by a reduction in the daily maintenance oral corticosteroid dose? ***ACTION REQUIRED: If yes, please attach supporting chart notes or medical record documentation of improved asthma control. ACTION REQUIRED: Submit supporting documentation***
   ❑ Yes ❑ No

8. Will the patient continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Nucala? ❑ Yes ❑ No

9. Will the patient receive Nucala concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Tezspire, Xolair)? ❑ Yes ❑ No *No further questions*

10. Does the patient have uncontrolled asthma as demonstrated by experiencing two or more asthma exacerbations requiring oral or injectable corticosteroid treatment within the past year? ***ACTION REQUIRED: If yes, please submit supporting chart notes, medical records, or claims history of previous corticosteroid use for asthma exacerbations. ACTION REQUIRED: Submit supporting documentation*** ❑ Yes ❑ No *If Yes, skip to #13*

11. Does the patient have uncontrolled asthma as demonstrated by experiencing one or more asthma exacerbation resulting in hospitalization or emergency medical care visit within the past year? ***ACTION REQUIRED: If yes, please submit supporting chart notes, medical records of previous asthma exacerbations requiring hospitalization or emergency medical visit. ACTION REQUIRED: Submit supporting documentation*** ❑ Yes ❑ No *If Yes, skip to #13*

12. Does the patient have uncontrolled asthma as demonstrated by experiencing poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma) within the past year? ***ACTION REQUIRED: If yes, please submit supporting chart notes or medical records. ACTION REQUIRED: Submit supporting documentation*** ❑ Yes ❑ No

13. Prior to receiving Nucala, did the patient have inadequate asthma despite current treatment with both of the following medications at optimized doses: 1) High dose inhaled corticosteroids AND 2) Additional controller (i.e., long acting beta2-agonist, long acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)? ***ACTION REQUIRED: If "Yes", please attach supporting chart notes, medical records, or claims history of previous medications tried including drug, dose, frequency, and duration. ACTION REQUIRED: Submit supporting documentation*** ❑ Yes ❑ No

14. What is the patient's baseline (e.g., before significant oral steroid use) blood eosinophil count in cells per microliter? Indicate blood eosinophilic 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, *If greater than 150 cells per microliter skip to #16* ❑ Unknown

15. Is the patient dependent on systemic corticosteroids? ***ACTION REQUIRED: Please attach supporting chart note(s) or medical record showing patient's dependance on systemic corticosteroids. ACTION REQUIRED: Submit supporting documentation*** ❑ Yes ❑ No

16. Will the patient continue to use maintenance asthma treatments (i.e., inhaled corticosteroids, additional controller) in combination with Nucala? ❑ Yes ❑ No

17. Will the patient receive Nucala concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Tezspire, Xolair)? ❑ Yes ❑ No *No further questions*

<u>Section B: Eosinophilic Granulomatosis with Polyangiitis</u>

18. Is the request for continuation of therapy with Nucala? ❑ Yes ❑ No *If No, skip to #21*

19. Is the patient currently receiving Nucala through samples or a manufacturer's patient assistance program? ❑ Yes ❑ No ❑ Unknown *If Yes or Unknown, skip to #21*

20. Does the patient have beneficial response to treatment with Nucala as demonstrated by ANY of the following? ***ACTION REQUIRED: If Yes, please attach supporting chart notes or medical record documentation of improved EGPA control. ACTION REQUIRED: Submit supporting documentation*** 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

21. 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 with the patient's pretreatment blood eosinophil count. Indicate blood eosinophil count in cells per microliter or percentage.***
    - ❑ Yes - blood eosinophil count greater than 1000 cells per microliter
    - ❑ Yes - blood eosinophil level greater than 10%
    - ❑ No

22. 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

23. 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

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

Section C: Hypereosinophilic syndrome

25. Is the request for continuation of therapy with Nucala? *If No, skip to #29* ❑ Yes ❑ No

26. Is the patient currently receiving Nucala through samples or a manufacturer's patient assistance program? ❑ Yes ❑ No ❑ Unknown *If Yes or Unknown, skip to #29*

27. Has the patient experienced a reduction in hypereosinophilic syndrome (HES) flares since starting treatment with Nucala? ***ACTION REQUIRED: If 'Yes', please attach supporting chart notes or medical record documentation of improved HES control. ACTION REQUIRED: Submit supporting documentation*** ❑ Yes ❑ No

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

29. 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

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

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

32. 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 with the patient's pretreatment blood eosinophil count. Indicate blood eosinophil count in cells per microliter.*** _____ ***ACTION REQUIRED: Submit supporting documentation*** ❑ Yes ❑ No

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

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

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

Section D: Chronic rhinosinusitis with nasal polyps

36. Is the medication prescribed by or in consultation with an allergist/immunologist or otolaryngologist?
❑ Yes ❑ No

37. Will the patient receive Nucala concomitantly with other biologics indicated for chronic rhinosinusitis with nasal polyps (e.g., Dupixent, Xolair)? ❑ Yes ❑ No

38. Is the request for continuation of therapy with Nucala? ❑ Yes ❑ No *If No, skip to #41*

39. Is the patient currently receiving Nucala through samples or a manufacturer's patient assistance program?
❑ Yes ❑ No ❑ Unknown *If Yes or Unknown, skip to #41*

40. Has the patient achieved or maintained a positive clinical response to Nucala therapy as evidenced by improvement in signs and symptoms of chronic rhinosinusitis with nasal polyposis CRSwNP (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sinonasal inflammation, hyposmia and/or facial pressure or pain or reduction in corticosteroid use)? ***ACTION REQUIRED: If Yes, please attach supporting chart notes or medical record documentation of positive clinical response. ACTION REQUIRED: Submit supporting documentation.*** ❑ Yes ❑ No *No further questions.*

41. Does the patient have bilateral nasal polyps and chronic symptoms of sinusitis? ❑ Yes ❑ No

42. Has the patient had intranasal corticosteroid treatment for at least 2 months? ***ACTION REQUIRED: If Yes, please attach supporting chart notes, medical records, or claims history of previous medications tried. ACTION REQUIRED: Submit supporting documentation.*** *If Yes, skip to #44* ❑ Yes ❑ No

43. Are intranasal corticosteroids contraindicated or not tolerated? ***ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation***
❑ Yes ❑ No

44. Has the patient had prior sino-nasal surgery? *If Yes, skip to #47* ❑ Yes ❑ No

45. Has the patient had an inadequate response with systemic corticosteroids within the last two years? ***ACTION REQUIRED: If 'Yes', please attach supporting chart notes, medical records, or claims history of previous medications tried.*** *If Yes, skip to #47* ❑ Yes ❑ No

46. Are systemic corticosteroids contraindicated or not tolerated? ***ACTION REQUIRED: If Yes, please attach documentation of clinical reason to avoid therapy. ACTION REQUIRED: Submit supporting documentation.***
❑ Yes ❑ No

47. Has the patient had a bilateral nasal endoscopy or anterior rhinoscopy showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril? ***ACTION REQUIRED: If Yes, please attach supporting chart note(s) or medical record showing endoscopy, rhinoscopy, or CT details (e.g., polyps location, size). ACTION REQUIRED: Submit supporting documentation*** *If Yes, skip to #50* ❑ Yes ❑ No

48. Has the patient had a Meltzer Clinical Score of 2 or higher in both nostrils? ***ACTION REQUIRED: If 'Yes', please submit chart notes or medical records of Meltzer Clinical score. ACTION REQUIRED: Submit supporting documentation*** *If Yes, skip to #50* ❑ Yes ❑ No

49. Has the patient had a total endoscopic nasal polyps score (NPS) of at least 5 with a minimum score of 2 for each nostril? ***ACTION REQUIRED: If 'Yes', please submit chart notes or medical records of endoscopic nasal polyps score. ACTION REQUIRED: Submit supporting documentation*** ❑ Yes ❑ No

50. Does the patient have nasal blockage? ❑ Yes ❑ No

51. Does the patient have rhinorrhea (anterior/posterior), reduction or loss of smell, or facial pain or pressure?
❑ Yes ❑ No

52. Will the patient continue to use a daily intranasal corticosteroid while being treated with Nucala?
If Yes, no further questions ❑ Yes ❑ No

53. Are intranasal corticosteroids contraindicated or not tolerated? ❑ 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