Nucala

CareFirst 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*

Which product is being requested? ❑ Nucala vial ❑ Nucala Prefilled syringe ❑ Nucala auto-injector

What is the ICD-10 code? _____

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

 Nucala 1655-A SGM SOC 5410-A – 09/2024.

CVS Caremark Specialty Pharmacy ● 2211 Sanders Road NBT-6 ● Northbrook, IL 60062
Phone: 1-888-877-0518 ● Fax: 1-855-330-1720 ● www.caremark.com

Site of Service Questions (SOS):

A. Where will this drug be administered?
- ❑ Ambulatory surgical, *skip to Clinical Criteria Questions*
- ❑ Home infusion, *skip to Clinical Criteria Questions*
- ❑ Off-campus Outpatient Hospital, *Continue to B*
- ❑ On-campus Outpatient Hospital, *Continue to B*
- ❑ Physician office, *skip to Clinical Criteria Questions*
- ❑ Pharmacy, *skip to Clinical Criteria Questions*

B. Is the patient less than 14 years of age?
- ❑ Yes, *skip to Clinical Criteria Questions*
- ❑ No, *Continue to C*

C. Is this request to continue previously established treatment with the requested medication? ***Action Required: If No, please attach supporting clinical documentation.***
- ❑ Yes - This is a continuation of an existing treatment., *Continue to D*
- ❑ No - This is a new therapy request (patient has not received requested medication in the last 6 months)*., skip to Clinical Criteria Questions*

D. Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (eg acetaminophen, steroids, diphenhydramine, fluids, other pre-medications or slowing of the infusion rate) 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, *Continue to E*

E. 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, *Continue to F*

F. 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, *skip to Clinical Criteria Questions*
- ❑ No, *Continue to G*

G. Are ***all*** alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) **greater than** 30 miles from the patient's home? ***ACTION REQUIRED: If Yes, please attach supporting documentation.***
- ❑ Yes, *continue to Clinical Criteria Questions*
- ❑ No, *continue to Clinical Criteria Questions*

Criteria Questions:

1. Will the requested drug be used concomitantly with any other biologic or targeted synthetic drug for the same indication?

❒ Yes, *Continue to 2*
❒ No, *Continue to 2*

2. What is the diagnosis?

❒ Severe asthma, *Continue to 3*
❒ Eosinophilic granulomatosis with polyangiitis (EGPA), *Continue to 20*
❒ Hypereosinophilic syndrome (HES), *Continue to 30*
❒ Chronic rhinosinusitis with nasal polyps (CRSwNP), *Continue to 42*
❒ Other, please specify. _____, *No further questions*

3. Is the requested drug being prescribed by or in consultation with an allergist, immunologist, or pulmonologist?

❒ Yes, *Continue to 4*
❒ No, *Continue to 4*

4. Is the patient 6 years of age or older?

❒ Yes, *Continue to 5*
❒ No, *Continue to 5*

5. Is the request for continuation of therapy with the requested drug?

❒ Yes, *Continue to 6*
❒ No, *Continue to 11*

6. Is the patient currently receiving Nucala through samples or a manufacturer's patient assistance program?

❒ Yes, *Continue to 11*
❒ No, *Continue to 7*
❒ Unknown, *Continue to 11*

7. Will the requested drug be used for the treatment of severe asthma?

❒ Yes, *Continue to 8*
❒ No, *Continue to 8*

8. 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 chart notes or medical record documentation supporting improvement in asthma control.

❒ Yes, *Continue to 10*
❒ No, *Continue to 9*

9. 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 chart notes or medical record documentation supporting improvement in asthma control.

❒ Yes, *Continue to 10*
❒ No, *Continue to 10*

10. Will the patient continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Nucala?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

11. Has the patient received in the past year or is currently receiving a biologic drug (e.g., Dupixent, Cinqair) indicated for treatment of asthma (excluding receiving the drug via samples or a manufacturer's patient assistance program)? ***ACTION REQUIRED***: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency and duration.
❒ Yes, *No Further Questions*
❒ No, *Continue to 12*

12. Will the requested drug be used for the treatment of severe asthma?
❒ Yes, *Continue to 13*
❒ No, *Continue to 13*

13. 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 attach chart notes, medical record documentation, or claims history supporting previous corticosteroid use for asthma exacerbations including drug, dose, frequency and duration.
❒ Yes, *Continue to 16*
❒ No, *Continue to 14*

14. Does the patient have uncontrolled asthma as demonstrated by experiencing one or more asthma exacerbation(s) resulting in hospitalization or emergency medical care visit(s) within the past year? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation of previous asthma exacerbation(s) requiring hospitalization or emergency medical visit(s).
❒ Yes, *Continue to 16*
❒ No, *Continue to 15*

15. 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 attach chart notes or medical record documentation of poor symptom control.
❒ Yes, *Continue to 16*
❒ No, *Continue to 16*

16. Prior to requesting Nucala, did the patient have inadequate asthma control despite current treatment with both of the following drugs at optimized doses: A) High-dose inhaled corticosteroid, AND B) Additional controller (i.e., long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)? ***ACTION REQUIRED***: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency and duration.
❒ Yes, *Continue to 17*
❒ No, *Continue to 17*

17. Prior to requesting Nucala, what is the patient's baseline (e.g., before significant oral steroid use) blood eosinophil count in cells per microliter? Indicate baseline blood eosinophil count in cells per microliter. ***ACTION REQUIRED***: Please attach chart notes or medical record documentation with the patient's baseline blood eosinophil count.
❒ Greater than or equal to 150 cells per microliter _____ cells/microliter, ***ACTION REQUIRED****: Submit supporting documentation, Continue to 19*

❒ Less than 150 cells per microliter _____ cells/microliter, ***ACTION REQUIRED****: Submit supporting documentation, Continue to 18*

❒ Unknown, *Continue to 18*

18. Is the patient dependent on systemic corticosteroids? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation showing the patient's dependence on systemic corticosteroids.
❒ Yes, *Continue to 19*
❒ No, *Continue to 19*

19. Will the patient continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Nucala?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

20. Is the patient 18 years of age or older?
❒ Yes, *Continue to 21*
❒ No, *Continue to 21*

21. Is the request for continuation of therapy with the requested drug?
❒ Yes, *Continue to 22*
❒ No, *Continue to 24*

22. Is the patient currently receiving Nucala through samples or a manufacturer's patient assistance program?

❒ Yes, *Continue to 24*

❒ No, *Continue to 23*

❒ Unknown, *Continue to 24*

23. Does the patient have a beneficial response to treatment with Nucala as demonstrated by any of the following: A) A reduction in the frequency of relapses, B) A reduction or discontinuance of the daily oral corticosteroid dose, or C) No active vasculitis. ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation supporting improvement in EGPA control.
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

24. 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%? Indicate blood eosinophil count in cells per microliter or percentage. ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation showing the patient's pretreatment blood eosinophil count or percentage of blood eosinophil level.
❒ Yes - blood eosinophil count greater than 1000 cells per microliter _____cells/microliter, ***ACTION REQUIRED****: Submit supporting documentation, Continue to 25*
❒ Yes - blood eosinophil level greater than 10% _____% ***ACTION REQUIRED****: Submit supporting documentation, Continue to 25*

❒ No*, Continue to 25*

25. Does the patient have at least two of the following disease characteristics of eosinophilic granulomatosis with polyangiitis (EGPA): A) Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation, B) Neuropathy, mono or poly (motor deficit or nerve conduction abnormality), C) Pulmonary infiltrates, non-fixed, D) Sino-nasal abnormality, E) Cardiomyopathy (established by echocardiography or magnetic resonance imaging), F) Glomerulonephritis (hematuria, red cell casts, proteinuria), G) Alveolar hemorrhage (by bronchoalveolar lavage), H) Palpable purpura, and I) Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinase 3)?
❒ Yes, *Continue to 26*
❒ No, *Continue to 26*

26. Has the patient had at least one relapse (i.e., requiring increase in oral corticosteroid dose, initiation/increased dose of immunosuppressive therapy, or hospitalization) within 2 years prior to starting treatment with Nucala?
❒ Yes, *Continue to 28*
❒ No, *Continue to 27*

27. Does the patient have a refractory disease?
❒ Yes, *Continue to 28*
❒ No, *Continue to 28*

28. Is the patient currently receiving treatment with oral corticosteroids? ***ACTION REQUIRED***: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency and duration.
❒ Yes, *No Further Questions*
❒ No, *Continue to 29*

29. Are oral corticosteroids contraindicated or not tolerated? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation of clinical reason to avoid therapy.
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

30. 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, *Continue to 31*
❒ No, *Continue to 31*

31. Does the patient have FIP1L1-PDGFRA kinase-positive hypereosinophilic syndrome (HES)? ***ACTION REQUIRED***: If No, please attach FIP1L1-PDGFRA fusion gene test results.
❒ Yes, *Continue to 32*
❒ No, *Continue to 32*

32. Is the patient 12 years of age or older?
❒ Yes, *Continue to 33*
❒ No, *Continue to 33*

33. Is the request for continuation of therapy with the requested drug?
❒ Yes, *Continue to 34*
❒ No, *Continue to 37*

34. Is the patient currently receiving Nucala through samples or a manufacturer's patient assistance program?

❒ Yes, *Continue to 37*

❒ No, *Continue to 35*

❒ Unknown, *Continue to 37*

35. Has the patient experienced a reduction in hypereosinophilic syndrome (HES) flares since starting treatment with Nucala? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation supporting improvement in HES control.
❒ Yes, *Continue to 36*
❒ No, *Continue to 36*

36. Will the patient receive Nucala as monotherapy (i.e., without any other hypereosinophilic syndrome [HES] medications)?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

37. Has the patient had hypereosinophilic syndrome (HES) for at least 6 months?
❒ Yes, *Continue to 38*
❒ No, *Continue to 38*

38. Does the patient have a history or presence of a blood eosinophil count of at least 1000 cells per microliter? Indicate blood eosinophil count in cells per microliter. ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation showing the patient's pretreatment blood eosinophil count.
_____ cells/microliter
❒ Yes, *Continue to 39*
❒ No, *Continue to 39*

39. Will the patient receive Nucala as monotherapy (i.e., without any other hypereosinophilic syndrome [HES] medications)?
❒ Yes, *Continue to 40*
❒ No, *Continue to 40*

40. Is the patient on a stable dose of hypereosinophilic syndrome (HES) therapy (e.g., oral corticosteroid, immunosuppressive, and/or cytotoxic therapy)?
❒ Yes, *Continue to 41*
❒ No, *Continue to 41*

41. Has the patient experienced at least two hypereosinophilic syndrome (HES) flares within the past 12 months?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

42. Is the requested drug being prescribed by or in consultation with an allergist/immunologist or otolaryngologist?
❒ Yes, *Continue to 43*
❒ No, *Continue to 43*

43. Is the patient an adult (18 years of age or older)?
❒ Yes, *Continue to 44*
❒ No, *Continue to 44*

44. Is the request for continuation of therapy with the requested drug?
❒ Yes, *Continue to 45*
❒ No, *Continue to 49*

45. Is the patient currently receiving Nucala through samples or a manufacturer's patient assistance program?
❒ Yes, *Continue to 49*
❒ No, *Continue to 46*
❒ Unknown, *Continue to 49*

46. Has the patient achieved or maintained a positive clinical response with Nucala therapy as evidenced by improvement in signs and symptoms of chronic rhinosinusitis with nasal polyps (CRSwNP) (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sino-nasal inflammation, hyposmia and/or facial pressure or pain, or reduction in corticosteroid use)? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation supporting positive clinical response.
❒ Yes, *Continue to 47*
❒ No, *Continue to 47*

47. Will the patient continue to use a daily intranasal corticosteroid while being treated with Nucala?
❒ Yes, *No Further Questions*
❒ No, *Continue to 48*

48. Are intranasal corticosteroids contraindicated or not tolerated?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

49. Has the patient received in the past year or is currently receiving a biologic drug (e.g., Dupixent, Xolair) indicated for treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) (excluding receiving the drug via samples or a manufacturer's patient assistance program)? ***ACTION REQUIRED***: If Yes, please attach chart notes, medical record documentation, or claims history of previous medications tried including drug, dose, frequency and duration.
❒ Yes, *No Further Questions*
❒ No, *Continue to 50*

50. Does the patient have bilateral nasal polyposis and chronic symptoms of sinusitis?
❒ Yes, *Continue to 51*
❒ No, *Continue to 51*

51. Has the patient had intranasal corticosteroid treatment for at least 2 months? ***ACTION REQUIRED***: If Yes, please attach chart notes, medical record documentation, or claims history of previous medications tried including drug, dose, frequency and duration.
❒ Yes, *Continue to 53*
❒ No, *Continue to 52*

52. Are intranasal corticosteroids contraindicated or not tolerated? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation of clinical reason to avoid therapy.
❒ Yes, *Continue to 53*
❒ No, *Continue to 53*

53. Has the patient had prior sino-nasal surgery?
❒ Yes, *Continue to 56*
❒ No, *Continue to 54*

54. Has the patient had an inadequate response with systemic corticosteroids within the last two years? ***ACTION REQUIRED***: If Yes, please attach chart notes, medical record documentation, or claims history of previous medications tried including drug, dose, frequency and duration.
❒ Yes, *Continue to 56*
❒ No, *Continue to 55*

55. Are systemic corticosteroids contraindicated or not tolerated? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation of clinical reason to avoid therapy.
❒ Yes, *Continue to 56*
❒ No, *Continue to 56*

56. Has the patient had a bilateral nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation showing nasal endoscopy, rhinoscopy, or CT details (e.g., polyps location, size).
❒ Yes, *Continue to 59*
❒ No, *Continue to 57*

57. Does the patient have a Meltzer Clinical Score of 2 or higher in both nostrils? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation of Meltzer Clinical score.
❒ Yes, *Continue to 59*
❒ No, *Continue to 58*

58. Does the patient have 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 attach chart notes or medical record documentation of endoscopic nasal polyps score.
❒ Yes, *Continue to 59*
❒ No, *Continue to 59*

59. Does the patient have symptoms of nasal blockage, congestion, or obstruction?
❒ Yes, *Continue to 60*
❒ No, *Continue to 60*

60. Does the patient have rhinorrhea (anterior/posterior), reduction or loss of smell, or facial pain or pressure?
❒ Yes, *Continue to 61*
❒ No, *Continue to 61*

61. Will the patient continue to use a daily intranasal corticosteroid while being treated with Nucala?
❒ Yes, *No Further Questions*
❒ No, *Continue to 62*

62. Are intranasal corticosteroids contraindicated or not tolerated?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

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