maryland physicians care
Medicaid with a Heart

# PRIOR AUTHORIZATION REQUEST

## NUCALA

**Patient Information:**

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|---|---|
| Name: | |
| Member ID: | |
| Address: | |
| City, State, Zip: | |
| Date of Birth: | |

**Prescriber Information:**

| | |
|---|---|
| Name: | |
| NPI: | |
| Phone Number: | |
| Fax Number | |
| Address: | |
| City, State, Zip: | |

**Requested Medication**

| | |
|---|---|
| Rx Name: | |
| Rx Strength | |
| Rx Quantity: | |
| Rx Frequency: | |
| Rx Route of Administration: | |
| Diagnosis and ICD Code: | |

Your patient's prescription benefit requires that we review certain requests for coverage with the prescriber. You have prescribed a medication for your patient that requires Prior Authorization before benefit coverage or coverage of additional quantities can be provided. Please complete the following questions then fax this form to the toll-free number listed below. Upon receipt of the completed form, prescription benefit coverage will be determined based on the plan's rules.

SECTION A: Please note that supporting clinical documentation is required for **ALL** PA requests. Pharmacy prior authorization reviews can be subject to trial with additional medications that are not listed within the criteria. The policies are subject to change based on COMAR requirements, MDH transmittals and updates to treatment guidelines.

**CRITERIA FOR APPROVAL**

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| 1 | Will Nucala be used in combination with another anti-interleukin (IL) monoclonal antibody (for example, Cinqair, Dupixent, Fasenra, or Xolair)? [If yes, no further questions.] | Yes | No |
| 2 | Is the patient currently receiving the requested medication? [If no, skip to question 8.] | Yes | No |

**If you have any questions, call: 1-888-258-8250**

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| 3 | Has the patient been receiving medication samples for the requested medication?<br>[If yes, skip to question 8.] | Yes | No |
| 4 | Does the patient have a previously approved prior authorization (PA) on file with the current plan?<br>[Note: If the patient does NOT have a previously approved PA on file for the requested medication with the current plan, the renewal request will be considered under initial therapy.]<br>[If no, skip to question 8.] | Yes | No |
| 5 | What is the diagnosis or indication?<br>[] Asthma (If checked, go to 6)<br><br>[] Chronic rhinosinusitis with nasal polyposis (CRSwnP) (If checked, go to 6)<br><br>[] Eosinophilic Granulomatosis with Polyangiitis (EGPA) [formerly known as Churg-Strauss Syndrome] (If checked, go to 6)<br><br>[] Hypereosinophilic syndrome (If checked, go to 6)<br><br>[] Chronic Obstructive Pulmonary Disease (COPD) with an eosinophilic phenotype (If checked, go to 6)<br><br>[] Atopic dermatitis (If checked, no further questions)<br><br>[] Eosinophilic esophagitis, eosinophilic gastroenteritis, or eosinophilic colitis (If checked, no further questions)<br><br>[] Other (If checked, no further questions) | | |
| 6 | Has the patient been on established therapy for at least 3 months?<br>[If no, skip to question 8.] | Yes | No |
| 7 | Has documentation been submitted to confirm that the patient has had a clinically significant response to therapy, as determined by the prescriber? ACTION REQUIRED: Submit supporting documentation.<br>[No further questions.] | Yes | No |
| 8 | What is the diagnosis or indication?<br>[] Asthma (If checked, go to 9)<br><br>[] Chronic rhinosinusitis with nasal polyposis (CRSwnP) (If checked, go to 36)<br><br>[] Eosinophilic Granulomatosis with Polyangiitis (EGPA) [formerly known as Churg-Strauss Syndrome] (If checked, go to 21)<br><br>[] Hypereosinophilic syndrome (If checked, go to 28)<br><br>[] Chronic Obstructive Pulmonary Disease (COPD) with an eosinophilic phenotype (If checked, go to 46) | | |

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[] Atopic dermatitis (If checked, no further questions)

[] Eosinophilic esophagitis, eosinophilic gastroenteritis, or eosinophilic colitis (If checked, no further questions)

[] Other (If checked, no further questions)

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| 9 | Is the patient 6 years of age or older?<br>[If no, no further questions.] | Yes | No |
| 10 | Is the requested medication being prescribed by or in consultation with an allergist, immunologist, or pulmonologist?<br>[If no, no further questions.] | Yes | No |
| 11 | Does the patient have a blood eosinophil level of 150 cells/microliter or greater within the previous 6 weeks or within 6 weeks prior to treatment with any anti-interleukin-5 therapy?<br>[Note: Examples of anti-interleukin-5 therapies include Fasenra, Nucala, and Cinqair.]<br>[If no, no further questions.] | Yes | No |
| 12 | Has the patient received at least 3 consecutive months of combination therapy with BOTH of the following: A) An inhaled corticosteroid AND B) At least one additional asthma controller/maintenance medication?<br>[Note: Examples of additional asthma controller/maintenance medications are inhaled long-acting beta2-agonists, inhaled long-acting muscarinic antagonists, leukotriene receptor antagonists, and theophylline. Use of a combination inhaler containing both an inhaled corticosteroid and a long-acting beta2-agonist would fulfil the requirement.]<br>[If no, no further questions.] | Yes | No |
| 13 | Is the requested medication being used in combination with an inhaled corticosteroid (ICS) OR inhaled corticosteroid- containing combination inhaler?<br>[If no, no further questions.] | Yes | No |
| 14 | Does the patient have asthma that is uncontrolled as defined by two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year?<br>[If yes, skip to question 19.] | Yes | No |
| 15 | Does the patient have asthma that is uncontrolled as defined by one asthma exacerbation requiring hospitalization in the previous year?<br>[If yes, skip to question 19.] | Yes | No |
| 16 | Does the patient have asthma that is uncontrolled as defined by a forced expiratory volume in 1 second (FEV1) less than 80% predicted?<br>[If yes, skip to question 19.] | Yes | No |

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| 17 | Does the patient have an FEV1/forced vital capacity (FVC) less than 0.80?<br>[If yes, skip to question 19.] | Yes | No |
| 18 | Does the patient have asthma that is uncontrolled as defined by asthma that worsens upon tapering of oral corticosteroid therapy?<br>[If no, no further questions.] | Yes | No |
| 19 | Does the dose of the requested medication exceed the FDA approved label dosing for the indication?<br>[If yes, no further questions.] | Yes | No |
| 20 | Will the requested medication be used in combination with other monoclonal antibodies used to treat asthma?<br>[Note: Examples of monoclonal antibody therapies include benralizumab, mepolizumab and dupilumab.]<br>[No further questions.] | Yes | No |
| 21 | Is the patient 18 years of age or older?<br>[If no, no further questions.] | Yes | No |
| 22 | Is the requested medication being prescribed by or in consultation with an allergist, immunologist, pulmonologist or a rheumatologist?<br>[If no, no further questions.] | Yes | No |
| 23 | Has the patient tried a minimum of 4 weeks of therapy with a corticosteroid (for example, prednisone)?<br>[If no, no further questions.] | Yes | No |
| 24 | Does the patient have/or had a blood eosinophil level of 150 cells/microliter or greater within the previous 6 weeks or within 6 weeks prior to treatment with any anti-interleukin (IL)-5 therapy?<br>[Note: Examples of anti-interleukin-5 therapies include Nucala, Cinqair, and Fasenra.]<br>[If no, no further questions.] | Yes | No |
| 25 | Will the requested medication be used in combination with other monoclonal antibodies?<br>[Note: Examples of monoclonal antibody therapies include benralizumab, mepolizumab and dupilumab.]<br>[If yes, no further questions.] | Yes | No |
| 26 | Does the dose of the requested medication exceed the FDA approved label dosing for the indication?<br>[If yes, no further questions.] | Yes | No |
| 27 | Does the patient have active, non-severe disease?<br>[Note: Non-severe disease is defined as vasculitis without life- or organ- | Yes | No |

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| | threatening manifestations and examples of symptoms in patients with non-severe disease include rhinosinusitis, asthma, mild systemic symptoms, uncomplicated cutaneous disease and mild inflammatory arthritis.]<br>[No further questions.] | | |
| 28 | Is the patient 12 years of age or older?<br>[If no, no further questions.] | Yes | No |
| 29 | Has the patient had hypereosinophilic syndrome for at least 6 months?<br>[If no, no further questions.] | Yes | No |
| 30 | Does the patient have FIP1L1-PDGFRalpha-negative disease?<br>[If no, no further questions.] | Yes | No |
| 31 | Does the patient have an identifiable non-hematologic secondary cause of hypereosinophilic syndrome, according to the prescriber?<br>[Note: Examples of secondary causes of hypereosinophilic syndrome include drug hypersensitivity, parasitic helminth infection, human immunodeficiency virus infection, and non-hematologic malignancy.]<br>[If yes, no further questions.] | Yes | No |
| 32 | Prior to initiating therapy with any anti-interleukin-5 therapy, did/does the patient have a blood eosinophil level of at least 1,000 cells per microliter?<br>[Note: Examples of anti-interleukin-5 therapies include Nucala, Cinqair, and Fasenra.]<br>[If no, no further questions.] | Yes | No |
| 33 | Has the patient tried at least ONE other treatment for hypereosinophilic syndrome for a minimum of 4 weeks?<br>[Note: Treatments for hypereosinophilic syndrome include systemic corticosteroids, hydroxyurea, cyclosporine, imatinib, methotrexate, tacrolimus, and azathioprine.]<br>[If no, no further questions.] | Yes | No |
| 34 | Is the requested medication being prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist?<br>[If no, no further questions.] | Yes | No |
| 35 | Does the dose of the requested medication exceed the FDA approved label dosing for the indication?<br>[No further questions.] | Yes | No |
| 36 | Is the patient 18 years of age or older?<br>[If no, no further questions.] | Yes | No |
| 37 | Does the patient have chronic rhinosinusitis with nasal polyposis as evidenced by direct examination, endoscopy, or sinus computed tomography (CT) scan?<br>[If no, no further questions.] | Yes | No |

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| 38 | Has the patient experienced TWO or more of the following symptoms for at least 6 months: nasal congestion, nasal obstruction, nasal discharge, and/or reduction/loss of smell?<br>[If no, no further questions.] | Yes | No |
| 39 | Has the patient received at least 3 months of therapy with an intranasal corticosteroid?<br>[If no, no further questions.] | Yes | No |
| 40 | Will the patient continue to receive therapy with an intranasal corticosteroid while on the requested medication?<br>[If no, no further questions.] | Yes | No |
| 41 | Does the dose of the requested medication exceed the FDA approved label dosing for the indication?<br>[If yes, no further questions.] | Yes | No |
| 42 | Is the requested medication prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist (ear, nose and throat [ENT] physician specialist)?<br>[If no, no further questions.] | Yes | No |
| 43 | Has the patient received at least ONE course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years?<br>[If yes, no further questions.] | Yes | No |
| 44 | Does the patient have a contraindication to systemic corticosteroid therapy?<br>[If yes, no further questions.] | Yes | No |
| 45 | Has the patient had prior surgery for nasal polyps?<br>[No further questions.] | Yes | No |
| 46 | Is the patient 18 years of age or older?<br>[If no, no further questions.] | Yes | No |
| 47 | Does the patient have a diagnosis of COPD with moderate to severe airflow limitation (Post-bronchodilator FEV1/FVC ratio less than 0.7 and post-bronchodilator FEV1 of 20 % to 80 % predicted)?<br>[If no, no further questions.] | Yes | No |
| 48 | Has the patient's COPD remained inadequately controlled despite adherence to optimized inhaled maintenance therapy, including triple therapy with inhaled corticosteroid (ICS), long-acting beta agonists (LABA) and long-acting muscarinic antagonist (LAMA)?<br>[If no, no further questions.] | Yes | No |

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| 49 | Does the patient have a blood eosinophil level of 150 cells/microliter or greater within the previous 6 weeks or within 6 weeks prior to treatment with any anti-interleukin-5 therapy?<br>[Note: Examples of anti-interleukin-5 therapies include Fasenra, Nucala, and Cinqair.]<br>[If no, no further questions.] | Yes | No |
| 50 | Has the patient experienced at least two moderate or one severe COPD exacerbation(s) (requiring systemic corticosteroids, emergency department visit, or hospitalization) in the past 12 months despite optimized inhaled therapy?<br>[If no, no further questions.] | Yes | No |
| 51 | Will the requested medication be used in combination with other monoclonal antibodies used to treat COPD?<br>[Note: Examples of monoclonal antibody therapies include benralizumab, mepolizumab and dupilumab.]<br>[If yes, no further questions.] | Yes | No |
| 52 | Will the requested medication be used in addition to inhaled maintenance therapy used in treatment of COPD?<br>[If no, no further questions.] | Yes | No |
| 53 | Is the requested medication being prescribed by or in consultation with an allergist, immunologist, or pulmonologist?<br>[If no, no further questions.] | Yes | No |
| 54 | Does the dose of the requested medication exceed the FDA approved label dosing for the indication? [Dosing: 100mg every 4 weeks.] | Yes | No |

***Please document the diagnoses, symptoms, and/or any other information important to this review:***

SECTION B: Physician Signature

PHYSICIAN SIGNATURE DATE

**FAX COMPLETED FORM TO: 1-833-896-0656**

**Disclaimer:** An authorization is not a guarantee of payment. Member must be eligible at the time services are rendered. Services must be a covered Health Plan Benefit and medically necessary with prior authorization as per Plan policy and procedures.

**If you have any questions, call: 1-888-258-8250**

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**1-888-258-8250**