

Nucala® (mepolizumab) Prior Authorization Form

Member Name: _____ **Date of Birth:** _____ **Member ID#:** _____

Drug Information

Physician billing (HCPCS code: _____) **Pharmacy billing* (NDC: _____)**

*If Nucala® vial for injection is being used & billed by a pharmacy, the medication should be shipped to the health care facility where it will be administered.

Dose: _____ **Regimen:** _____ **Fill Date:** _____

Billing Provider Information

Provider NPI: _____ **Provider Name:** _____

Provider Phone: _____ **Provider Fax:** _____

If Nucala® vial for injection will be used, please provide the name of outpatient health care facility where Nucala® will be delivered to and administered at: _____

Prescriber Information

Prescriber NPI: _____ **Prescriber Name:** _____

Prescriber Phone: _____ **Prescriber Fax:** _____ **Specialty:** _____

Clinical Information

For Initial Authorization (Initial approval will be for the duration of 6 months):

1. **For Nucala® in a health care facility:**
 - A. Will the injection be administered in a health care setting by a health care professional prepared to manage anaphylaxis? Yes ___ No ___
2. **For Nucala® prefilled autoinjector or prefilled syringe for self-administration:**
 - A. Has the member or caregiver been trained by a health care professional on subcutaneous administration, monitoring for any allergic reactions, and storage of Nucala®? Yes ___ No ___
3. Was Nucala® prescribed by a specialist or has the member been evaluated by a specialist within the last 12 months (or an advanced care practitioner with a supervising physician who is a specialist)? Yes ___ No ___
If yes, please include name of specialist: _____ Specialty: _____
4. **Please indicate diagnosis and information:**
 - Eosinophilic Granulomatosis with Polyangiitis (EGPA)**
 - A. Please check all that apply:
 - Member has a past history of at least 1 confirmed EGPA relapse [requiring increase in oral corticosteroid (OCS) dose, initiation/increased dose of immunosuppressive therapy, or hospitalization] within the past 12 months.
 - Member has refractory disease within the last 6 months following induction of standard treatment regimen administered compliantly for at least 3 months.
 - B. Is diagnosis granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA)? Yes ___ No ___
 - C. Has member failed to achieve remission despite glucocorticoid therapy (oral prednisone equivalent equal to or greater than 7.5mg/day) for a minimum of 4 weeks duration? Yes ___ No ___

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<p><u>PLEASE PROVIDE THE INFORMATION REQUESTED AND RETURN TO:</u></p> <p>University of Oklahoma College of Pharmacy Pharmacy Management Consultants Product Based Prior Authorization Unit</p> <p>Fax: 1-800-224-4014 Phone: 1-800-522-0114 Option 4</p>	<p><u>CONFIDENTIALITY NOTICE</u></p> <p><i>This document, including any attachments, contains information which is confidential or privileged. If you are not the intended recipient, be aware that any disclosure, copying, distribution, or use of the contents of this information is prohibited. If you have received this document in error, please notify the sender immediately by telephone to arrange for the return of the transmitted documents or to verify their destruction.</i></p>
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Clinical Information

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3. Please indicate diagnosis and information, continued:

Eosinophilic Phenotype Asthma

- A. Will this medication be used as add-on maintenance treatment for severe eosinophilic phenotype asthma? Yes ___ No ___
i. If yes, please indicate member's daily medications and dose prescribed for treatment of this diagnosis:
Drug/Dose: _____ Drug/Dose: _____
B. Baseline blood eosinophil count: _____ Date Determined: _____
C. Does member require daily systemic corticosteroids despite compliant use of a medium-to-high-dose inhaled corticosteroid (ICS) plus at least 1 additional controller medication? Yes ___ No ___
i. If no, please list number and dates of exacerbations requiring systemic corticosteroids within last 12 months: Number: _____ Dates of exacerbations: _____
D. Please check all that apply:
Member has failed a medium-to-high-dose ICS used compliantly within the last 3-6 consecutive months.
Drug/Dose: _____
Member has failed at least 1 other asthma controller medication used in addition to the medium-to-high-dose ICS compliantly for at least the past 3 months.
Drug/Dose: _____

Hypereosinophilic Syndrome (HES)

- A. Has member been diagnosed with HES for ≥6 months without an identifiable non-hematologic secondary cause? Yes ___ No ___
B. Does member have a history of at least 2 confirmed HES flares [requiring increase in oral corticosteroid (OCS) dose, initiation/ increased dose of cytotoxic or immunosuppressive therapy, or hospitalization] within the past 12 months? Yes ___ No ___ Flare dates: _____
C. Please provide member's baseline blood eosinophil count: _____ Date taken: _____
D. Is HES FIP1L1-PDGFRα kinase-positive? Yes ___ No ___
E. Has member failed to achieve remission despite corticosteroid therapy (oral prednisone equivalent ≥10mg/day) for a minimum of 4 weeks duration? Yes ___ No ___
i. If no, is member is unable to tolerate corticosteroid therapy due to significant side effects from glucocorticoid therapy? Yes ___ No ___

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Table with 2 columns: PLEASE PROVIDE THE INFORMATION REQUESTED AND RETURN TO: (University of Oklahoma College of Pharmacy, Pharmacy Management Consultants, Product Based Prior Authorization Unit, Fax: 1-800-224-4014, Phone: 1-800-522-0114 Option 4) and CONFIDENTIALITY NOTICE (This document, including any attachments, contains information which is confidential or privileged. If you are not the intended recipient, be aware that any disclosure, copying, distribution, or use of the contents of this information is prohibited. If you have received this document in error, please notify the sender immediately by telephone to arrange for the return of the transmitted documents or to verify their destruction.)

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Clinical Information

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3. Please indicate diagnosis and information, continued:

Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)

- A. Will Nucala[®] be used as add-on maintenance treatment for inadequately controlled CRSwNP?
Yes ___ No ___
- B. Does the member have a trial with intranasal corticosteroid that resulted in failure (or have a contraindication or documented intolerance)? Yes ___ No ___
 - i. If yes, please provide the medication used and dates of use: _____
- C. Has the member required prior sino-nasal surgery? Yes ___ No ___
- D. Has the member been treated with systemic corticosteroids for CRSwNP in the past 2 years (or have a contraindication or documented intolerance)? Yes ___ No ___
- E. Does the member have symptoms of chronic rhinosinusitis (e.g., facial pain/pressure, reduction or loss of smell, nasal blockade/obstruction/congestion, nasal discharge) for 12 weeks or longer despite attempts at medical management? Yes ___ No ___
- F. Does the member have evidence of nasal polyposis by direct examination, sinus CT scan, or endoscopy?
Yes ___ No ___
- G. Will the member continue to receive intranasal corticosteroid therapy? Yes ___ No ___
 - i. If yes, does the member have a contraindication to intranasal corticosteroid therapy?
Yes ___ No ___
 - a. If yes, please provide the member's contraindication: _____
- H. Will Nucala[®] be used concurrently with other biologic medications? Yes ___ No ___
 - i. If yes, please provide patient-specific information to support the concurrent use of Nucala[®] with other biologic medications: _____

Chronic Obstructive Pulmonary Disease (COPD)

- A. Will Nucala[®] be used as add-on maintenance treatment for inadequately controlled COPD?
Yes ___ No ___
- B. Is member symptomatic [i.e., modified Medical Research Council (mMRC) dyspnea scale grade ≥ 2 , COPD Assessment Test (CAT) ≥ 10]? Yes ___ No ___
- C. Member's blood eosinophil count (recent level or historical level prior to treatment): _____
- D. Has member experienced ≥ 2 moderate exacerbations (e.g., required treatment with systemic corticosteroids and/or antibiotics) or ≥ 1 severe exacerbation (e.g., required hospitalization or 24-hour observation in emergency department) in the last 12 months? Yes ___ No ___
- E. Is member inadequately controlled on triple therapy combination (LABA/LAMA/ICS) used compliantly within the last 3-6 consecutive months, unless contraindicated? Yes ___ No ___

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For Continued Authorization:

1. Is the member compliant with therapy? Yes ___ No ___
2. Is the member responding well to therapy? Yes ___ No ___
3. If member's diagnosis includes **EGPA**, please check all that apply:
 - Member has a Birmingham Vasculitis Activity Score (BVAS) of zero
 - Member has few EGPA relapses from baseline
 - Member has had a decrease in daily OCS dose regimen from baseline
 - If none of the above, please provide additional information on member's response to therapy:
4. If member's diagnosis includes **HES**, please provide the following:
 - A. Is the member responding to Nucala[®] therapy? Yes ___ No ___
 - i. If yes, has member had fewer HES flares from baseline? Yes ___ No ___
 - a. Please provide number of HES flares: Baseline: _____ Current: _____
 - ii. If yes, has member had a decrease in daily OCS dosing from baseline? Yes ___ No ___
 - a. Please provide daily OCS dosing: Baseline: _____ Current: _____

Compliance with all of the prior authorization criteria is a condition for payment for this drug by SoonerCare. All information must be provided and SoonerCare may verify through further requested documentation. The member's drug history will be reviewed prior to approval.

Additional Information: _____

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Prescriber Signature: _____ **Date:** _____
 (By signature, the physician confirms the criteria information above is accurate and verifiable in patient records.)

Pharmacist Signature: _____ **Date:** _____
 Please do not send in chart notes. Specific information will be requested if necessary. Failure to complete all pages will result in processing delays.

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