PriorityHealth

Medicare Part B Prior Authorization/Step Therapy Form

Fax completed form to: 877 974-4411 toll free, or 616 942-8206

This form applies to: ☒ **Medicare Part B**
This request is: ☐ **Urgent** (life threatening) ☐ **Non-Urgent** (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

Nucala vial (mepolizumab)

Member Information

Last Name: _____ First Name: _____
ID #: _____ DOB: _____ Gender: _____
Primary Care Physician: _____

Provider Information

Requesting Provider: _____ Phone: _____ Fax: _____
Address: _____
NPI: _____ Contact Name: _____

Provider Signature: _____ Date: _____

Drug and Billing Information *(Please fill out the following information)*

☐ New request ☐ Continuation request - **Original therapy start date**: _____

Drug Product: ☐ Nucala vial

Patient Dosing Information:

Date of last dose (if applicable): _____ **Total doses/cycles/duration requested:** _____
Date of next dose (if applicable) _____ **Height: _____ Weight: _____ BSA: _____**
Dose: _____ **Dose Frequency**: _____

Place of Administration:

☐ Patient self-administration
☐ Physician's office
☐ Outpatient infusion Facility: _____NPI: _____ Fax:_____
☐ Home infusion Agency: _____NPI: _____ Fax:_____
☐ Other (specify): _____

Billing:

☐ **Physician** to buy and bill
☐ Facility to buy and bill
☐ Specialty Pharmacy: _____NPI: _____ Fax:_____

ICD-10 Diagnosis Code(s): _____ **HCPCS Code:** _____

All fields must be complete and legible for review. Your office will receive a response via fax.

Created 06/2022
No changes made since 06/2022
Last reviewed 06/2022

Precertification Requirements

Step therapy (trial with the below listed drug[s]) is only applicable to members who are enrolled in a Medicare Advantage Prescription Drug (MAPD) plan and will not apply to members who are actively receiving treatment with the non-preferred drug (have a paid drug claim within the past 365 days).

Before this drug is covered, the patient must meet the following:

1. Must be used for a medically accepted indication[1] and follow any applicable NCD, LCD and/or LCA requirements[2]
2. Must not be used in combination with other biologic drugs.
3. For severe eosinophilic asthma, the following criteria must also be met:
   - For initial coverage, an elevated eosinophil level of greater than or equal to 150 cells/μL at therapy start, OR greater than or equal to 300 cells/μL in the previous 12 months.
   - Documented trial and failure with 1 ICS/LABA inhaler drug in combination with 1 other asthma controller medication in the past 6 months. Failure is defined as an intolerance or inability to improve the condition on required therapy for at least 4 weeks.
4. For eosinophilic granulomatosis with polyangiitis (EGWP), the following criteria must also be met:
   - Documented trial and failure (defined as an inability to improve symptoms) with a non-biologic immunomodulator (e.g., azathioprine, cyclophosphamide).
5. For Hypereosinophilic Syndrome (HES), the following criteria must also be met:
   - Patient has had 2 flares of HES in the past year (e.g., symptoms requiring steroid or increase in steroid).
   - Documented trial and failure (defined as an inability to improve symptoms) with a generic steroid-sparing drug (e.g., methotrexate, hydroxyurea).
   - Blood eosinophil count at least 1,000 cells/mcL.
6. For chronic rhinosinusitis with nasal polyps, the following criteria must also be met:
   - For initial approval, documentation of disease persistence despite at least 8 weeks of treatment with intranasal steroids - AND - Must be used in combination with an intranasal steroid.

For continuation, the patient must also meet the following:

1. Must have documentation showing clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use).

[1]See *Medically accepted indication* section below
[2]See *NCD, LCD, and LCA* section below

Additional information

1. When criteria are met, initial approval duration is 1 year, and continuation approval duration is 2 years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.

2. Only Nucala vial is coverable under Medicare Part B. Nucala autoinjector and prefilled syringe are Self-Administered Drugs (SADs) and not eligible for Part B coverage. For prior authorization criteria for Nucala autoinjector and prefilled syringe, please refer to our Medicare Part D criteria on the Priority Health website.

3. Authorization for indications not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, Lexi-Drugs, and Clinical Pharmacology) require supporting evidence for coverage. Please provide published peer-reviewed literature supporting the drug's use for this individual patient case.

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Medically accepted indication[1]

If no NCD, LCD, or LCA criteria[2] are available for the state in which the member is receiving services, Medicare Part B drugs will be reviewed for a medically accepted indication, defined in the Medicare Benefit Policy Manual Chapter 15 § 50:

A medically accepted indication for a drug that is not a part of an anti-cancer regimen is a use that is:

- approved by the Food and Drug Administration. (That is, the Food and Drug Administration has approved the drug for the diagnosis or condition for which it is being prescribed.)
- — or — supported by certain references, taking into consideration the major drug compendia (e.g. American Hospital Formulary Service-Drug Information, Micromedex DrugDex, Lexi-Drugs), authoritative medical literature, and/or accepted standards of medical practice.

National and Local Coverage Determination/Article (NCD, LCD, and LCA) Criteria[2]

Priority Health applies Medicare NCD, LCD, and LCA criteria for Part B drugs. The following apply to Nucala: **N/A**

Precertification Documentation

A. What condition is this drug being requested for?

- ☐ Severe eosinophilic asthma
- ☐ Eosinophilic granulomatosis with polyangiitis (EGWP)
- ☐ Chronic rhinosinusitis with nasal polyps
- ☐ Hypereosinophilic syndrome (HES)
  1. **Has the patient had HES for at least 6 months?**
     - ☐ Yes.
     - ☐ No. **Are you asking for an exception to this requirement?**
       - ☐ Yes. ***Rationale for exception***: _____
       - ☐ No
  2. **Is there an identifiable, nonhematologic secondary cause of HES?**
     - ☐ No.
     - ☐ Yes. **Are you asking for an exception to this requirement?**
       - ☐ Yes. ***Rationale for exception***: _____
       - ☐ No
- ☐ Other: _____
  Rationale for Other use: _____

B. Will Nucala be used in combination with other biologic drugs (e.g., Fasenra, Dupixent)?

- ☐ No.
- ☐ Yes. **Are you requesting an exception to the criteria?**
  - ☐ Yes. ***Rationale for exception***: _____
  - ☐ No

C. For severe eosinophilic asthma:

1. **Does the patient have an elevated eosinophil level greater than or equal to 150 cells/µL at therapy start – OR – greater than or equal to 300 cells/µL in the previous 12 months?**
   - ☐ Yes.
     Eosinophil level: _____**cells/mcL** **Date drawn:** _____
   - ☐ No. **Are you requesting an exception to the criteria?**
     - ☐ Yes. ***Rationale for exception***: _____
     - ☐ No

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2. **Has the patient tried and failed 1 ICS/LABA inhaler drug in combination with 1 other asthma controller medication in the past 6 months?** Failure is defined as an intolerance or inability to improve the condition on required therapy for at least 4 weeks.
   - ☐ Yes.
     - a. **Select or Fill-In all that apply.**
       - ☐ Symbicort
       - ☐ Dulera
       - ☐ Advair Diskus
       - ☐ Breo Ellipta
       - ☐ Trelegy
       - ☐ Spiriva
       - ☐ Incruse Ellipta
       - ☐ Tudorza
       - ☐ Other: _____
     - b. **Describe the failure or intolerance:** _____
   - ☐ No. **Are you requesting an exception to the criteria?**
     - ☐ Yes. ***Rationale for exception***: _____
     - ☐ No

D. For eosinophilic granulomatosis with polyangiitis (EGWP):

1. **Has the patient had documented trial and failure (defined as an inability to improve symptoms) with a non-biologic immunomodulator (e.g., azathioprine, cyclophosphamide)?**
   - ☐ Yes.
     - ☐ azathioprine
     - ☐ cyclosporine
     - ☐ Other: _____\
   - ☐ No. **Are you requesting an exception to the criteria?**
     - ☐ Yes. ***Rationale for exception***: _____
     - ☐ No

E. For Hypereosinophilic Syndrome (HES):

1. **Has the patient had 2 flares of HES in the past year (e.g., symptoms requiring steroid or increase in steroid)?**
   - ☐ Yes.
   - ☐ No. **Are you requesting an exception to the criteria?**
     - ☐ Yes. ***Rationale for exception***: _____
     - ☐ No

2. **Has the patient had a documented trial and failure (defined as an inability to improve symptoms) with a generic steroid-sparing drug (e.g., methotrexate, hydroxyurea)?**
   - ☐ Yes.
     - ☐ methotrexate
     - ☐ hydroxyurea
     - ☐ Other: _____\
   - ☐ No. **Are you requesting an exception to the criteria?**
     - ☐ Yes. ***Rationale for exception***: _____
     - ☐ No

3. **Does the patient have a blood eosinophil count of at least 1,000 cells/mcL?**
   - ☐ Yes.
     Eosinophil level: _____**cells/mcL** **Date drawn:** _____
   - ☐ No. **Are you requesting an exception to the criteria?**
     - ☐ Yes. ***Rationale for exception***: _____
     - ☐ No

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F. For chronic rhinosinusitis with nasal polyps:

1. **Has documentation of disease persistence despite at least 8 weeks of treatment with intranasal steroids been provided?**
   - ☐ Yes.
   - ☐ No. **Are you requesting an exception to the criteria?**
     - ☐ Yes. ***Rationale for exception***: _____
     - ☐ No

2. **Will Nucala be used in combination with an intranasal steroid?**
   - ☐ Yes.
   - ☐ No. **Are you requesting an exception to the criteria?**
     - ☐ Yes. ***Rationale for exception***: _____
     - ☐ No

G. For continuation, has documentation of clinical benefit been provided (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use)?
   - ☐ Yes.
   - ☐ No. **Are you requesting an exception to the criteria?**
     - ☐ Yes. ***Rationale for exception***: _____
     - ☐ No

Priority Health Medicare Exception Request *(exceptions to the above criteria)*

Do you believe one or more of the prior authorization requirements should be waived? ☐ Yes ☐ No
If yes, you must provide a statement explaining the medical reason why the exception should be approved.

Would Nucala likely be the most effective option for this patient?
☐ No
☐ Yes, because: _____

If the patient is currently using Nucala, would changing the patient's current regimen likely result in adverse effects for the patient?
☐ No
☐ Yes, because: _____

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