A patient's health insurance plan/payer may require prior authorization or supporting documentation in order to process and cover a claim for treatment with NUCALA® (mepolizumab). A prior authorization allows the health plan to review the reason for the requested therapy and to determine medical appropriateness. A patient-specific letter of medical necessity will help to explain the physician's rationale and clinical decision-making in choosing NUCALA. Please note that some health plans have specific forms that must be completed in order to request prior authorization or to document medical necessity.

The following is a template letter of appeal for NUCALA that can be customized based on your patient's medical history and demographic information.

SAMPLE LETTER OF MEDICAL NECESSITY

[Date]

[Plan/Payer Name]

[Payer street address]

[Payer city, state ZIP code]

Re: Letter of Medical Necessity [HCPCS Code] [Drug Name, Billing Unit]

Patient: [Patient Full Name]

Group/Policy Number: [Patient group and policy number]

Date(s) of Service: [Date(s)]

Diagnosis: [Code & Description]

Dear [Insert payer contact name and/or department]:

I am writing on behalf of my patient, [Patient Name/Policy Number], to document medical necessity for treatment with NUCALA® (mepolizumab). The patient will be treated with NUCALA for [Diagnosis].

This letter serves to document that [Patient Name] needs NUCALA and that NUCALA is medically necessary for [him/her] as prescribed. On behalf of the patient, I am requesting approval for use and subsequent payment for the treatments.

NUCALA is indicated for the:

• add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma and with an eosinophilic phenotype. NUCALA is not indicated for the relief of acute bronchospasm or status asthmaticus.

• add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.

• treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

• treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥6 months without an identifiable non-hematologic secondary cause

[Patient Name] is a [age]-year-old [Male/Female] diagnosed with [Diagnosis]. [Patient Name] has been in my care since [date]. As a result of [Diagnosis], my patient [enter a brief description of patient history]. Additionally, [Patient Name] has tried [previous therapies] and [outcomes]. The patient is currently on [current therapy] for the treatment of [Severe Asthma/CRSwNP/EGPA/HES/]. The attached medical records document [Patient Name]'s clinical condition and medical necessity for treatments with NUCALA.

Based on the above facts, I am confident that you will agree that NUCALA is indicated and medically necessary for this patient. The plan of treatment is to start the patient on NUCALA [dose]. Administration of NUCALA is planned on [date] and will be continued approximately once every 4 weeks.

Please consider coverage of NUCALA on [Patient Name]'s behalf and approve use and subsequent payment for NUCALA as planned. Please refer to the enclosed Prescribing Information for NUCALA. If you have any further questions regarding this matter, please do not hesitate to call me at [physician telephone number].

Thank you for your prompt attention to this matter.

Sincerely,
[Physician's Name], [Degree Initials] [Physician's Practice Name]

Suggested Enclosures:

- Medical records and clinical notes & labs
- FDA approval letter available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=browseByLetter.page&productLetter=N&ai=0
- Prescribing Information (PI) - please also visit https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Nucala/pdf/NUCALA-PI-PIL-IFU-COMBINED.PDF for full prescription information
- Important Safety Information