ORLYNVAH™ (sulopenem etzadroxil and probenecid) Sample Letter of Appeal

Instructions

[The following is a sample letter of appeal template, which can be used to help support an insurer's coverage of ORLYNVAH. The magenta bracketed text is templated and should be replaced with pertinent information for the individual patient on whose behalf you are submitting the letter and the text made black. Optional black bracketed text has also been included throughout the letter, which may be included, if appropriate.

Before sending, ensure that all brackets have been removed, all text is black, and this instructional section has been deleted. It is also recommended to use your organization's official letterhead for this communication.]

Sample Letter Template

[Date]
ATTENTION: [Medical or Pharmacy Director Name]
[Payer/Health Plan Name]
[Payer/Health Plan Street Address]
[Payer/Health Plan City, State, ZIP Code]

REGARDING: Denied claim for ORLYNVAH™ (sulopenem etzadroxil and probenecid)

PATIENT NAME: [Patient's First and Last Name]
DATE OF BIRTH: [Patient's Date of Birth]
POLICY ID NUMBER: [Patient's Policy ID Number]
POLICY GROUP NUMBER: [Patient's Policy Group Number]
POLICY HOLDER: [Policy Holder's Name]
PROVIDER ID NUMBER: [Provider ID Number]
CASE ID NUMBER: [Case ID Number]
[Optional: Claim Rejection Number]

Dear [Payer/Health Plan Medical or Pharmacy Director Contact Name, or Payer/Health Plan Organization Name],

I am writing to appeal the denied claim for ORLYNVAH™ (sulopenem etzadroxil and probenecid) for my patient, [Patient's First and Last Name]. [Payer/Health Plan] denied

coverage for ORLYNVAH on [date of denial letter] due to [insert reason for denial from denial letter].

ORLYNVAH is medically necessary for this patient because [explanation as to why the drug is medically necessary for the patient].

Attached to this request are clinical notes regarding this patient's condition and the ORLYNVAH prescribing information. I am requesting this denial be reconsidered in light of [Patient's First and Last Name]'s past and current medical circumstances as noted below. The circumstances of [Patient's First and Last Name]'s condition present the need for an expedited approval for ORLYNVAH.

Patient Clinical History and Diagnosis

- [From relevant medical records and clinical notes, indicate 1 or more of the following reasons for medical necessity of ORLYNVAH:]
    - [History of multidrug-resistant infections and/or contraindications]
    - [Worsening symptoms]
    - [Patient allergies, if applicable]
    - [Relevant comorbidities that may preclude usage of other treatment options]
    - [Explanation of why alternate treatments are not suitable or have been ineffective]
    - [Patient's diagnosis and medical history]
    - [Healthcare provider notes]
    - [Current or previous diagnostic procedure(s) and date(s) of service]
    - [Relevant laboratory reports]
    - [Medication records, including reasons for discontinuation, if relevant and available]
    - [Specific symptoms and how they are affecting the patient's life]

Please call my office at [telephone number] if you require additional information. I look forward to receiving your timely response and approval of this authorization.

Sincerely,
[Provider Name]
[NPI]
[Title, Institution]
[Email/Phone Number]

Attachments

- Copy of the health plan's denial letter (Explanation of Benefits)
- Any appeals forms required by the health plan
- ORLYNVAH full Prescribing Information
- [OPTIONAL: supporting clinical evidence]
    - [OPTIONAL: pertinent peer-reviewed journal articles]
- [OPTIONAL: relevant guidelines]

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