ORLYNVAH™ (sulopenem etzadroxil and probenecid) Sample Letter of Medical Necessity

Instructions

[The following is a sample letter of medical necessity template, which can be used to help support the need for 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 Contact Name]
[Payer/Health Plan Name]
[Payer/Health Plan Street Address]
[Payer/Health Plan City, State, ZIP Code]

REGARDING: Request for expedited medical exception 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 [Provider Name, credentials, specialty, hospital/practice], and I am writing on behalf of my patient, [Patient's First and Last Name], to document the medical necessity of ORLYNVAH™ (sulopenem etzadroxil and probenecid).

In brief, I have determined that [initiating] treatment with ORLYNVAH for [Patient's First and Last Name] is medically appropriate and necessary. Outlined below are [Patient's First and Last Name]'s medical history, prognosis, and the clinical rationale for treatment with ORLYNVAH. The circumstances of [Patient's First and Last Name]'s condition present the need for an expedited approval for ORLYNVAH. I have also attached documents to this letter relevant to my patient's current medical condition and the ORLYNVAH prescribing information. The patient meets the following criteria for treatment: [List specific criteria here].

Patient Clinical History and Diagnosis

- [A summary of the patient's diagnosis, including date of diagnosis and current condition]
- [History of patient relationship, including length of time providing care and referring physician name]
- [From relevant medical records and clinical notes, indicate 1 or more of the following reasons for medical necessity of ORLYNVAH:]
    - [Background information about the patient's history with current condition]
    - [Explanation of previous treatments and why no longer suitable or ineffective, if possible]
    - [Current or previous diagnostic procedures and dates of service]
    - [Specific symptoms and their impact on the patient's life]
    - [History of multidrug resistant infections, contraindications]
    - [Patient allergies, if applicable]
    - [Relevant comorbidities that may preclude usage of other treatment options]

I have prescribed ORLYNVAH for [Patient's First and Last Name] because I have concluded that it is a medically appropriate therapeutic option.

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

- ORLYNVAH full Prescribing Information
- Supporting clinical evidence
- Any medical exception request forms required by the health plan
- [OPTIONAL: relevant guidelines]