TIPS FOR DRAFTING AN APPEAL LETTER

This resource is provided as educational support to assist healthcare professionals and the patients they serve. Healthcare professionals may choose to use these tips to assist in their access to the United Therapeutics treatment prescribed. This is not a guide or instructions. United Therapeutics does not guarantee coverage or reimbursement for the United Therapeutics treatment prescribed. The healthcare professional has the responsibility to ensure correct prior authorization policies are followed. Providers must ensure they accurately complete and submit necessary information to insurance companies.

If a patient's health insurance plan denies your request for coverage or your prior authorization (PA) request for a medication, you may submit an appeal. Including an Appeal Letter, explaining your rationale and clinical decision making behind the choice of a specific therapy may help with this process.

Understand why your choice of therapy was denied. Review the patient's explanation of benefits (EOB) and denial letter thoroughly prior to drafting an appeal.

Ensure you have submitted all required information. Simple errors on insurance forms, including incorrect codes and failure to obtain or submit the necessary documentation, may lead to denials. If there was a documentation error, correct the form or contact the insurance plan.

Identify and meet specific insurer deadlines. Some plans have very short turnaround times, for example, 48 hours from the denial date.

Consider including the following information in the Appeal Letter (See example on next page):

1. Patient Information:
   - Full name
   - Date of birth
   - Insurance ID number
   - Insurance Case ID number or Denial number
2. Physician Information:
   - Full name
   - National Provider Identification (NPI) number
   - Specialty
3. An introduction explaining the purpose of the Appeal Letter, or the reason for appeal.
4. A summary of the patient's diagnosis and the indication for the United Therapeutics therapy being prescribed. The summary should include diagnosis codes (ICD-10), prior treatments with their duration and response to treatment, and the severity of the patient's condition.
5. A clinical rationale for the prescribed treatment. The clinical rationale should include the FDA approved indication and any supporting clinical trial data.
6. If the plan is indicating a preferred formulary treatment, please provide an explanation of why it may not be applicable to your patient.
7. Additional Documents, including but not limited to:
   - Full Prescribing Information
   - Diagnostic test results, such as 6-minute walk test
   - Letter of Medical Necessity
   - Clinical notes and medical records

Be sure to maintain accurate records. Make a copy of anything you send. Record the time, date, and name of any representatives at the insurance company.

SAMPLE APPEAL LETTER FOR ORENITRAM

[Date]

Attn: [Contact/Medical Director First & Last Name]

[Insurance Company]

[Address]

[City, State, ZIP code]

[Patient First & Last Name] [Date of Birth]

[Patient ID Number] [Claim/Case Number]

RE: Appeal for Denial of Orenitram and Dosage for treating PAH: [Dose & Frequency]

Dear [Contact/Medical Director First & Last Name]

I am writing to request a review of a denied authorization of coverage for Orenitram (treprostinil) on behalf of my patient, [Patient First & Last Name] . Your company has denied this authorization for the following reason(s):

FILLABLE

[Fill in reason(s) from Explanation of Benefits (EOB)]

Orenitram is indicated for the treatment of pulmonary arterial hypertension (PAH; WHO Group 1) to delay disease progression and to improve exercise ability. I believe that Orenitram is appropriate for my patient based on their relevant clinical history (provided below). I am requesting that your company reconsider your denial of Orenitram coverage for, [Patient First & Last Name] .

Brief summary of Patient's Medical History:

[Patient First & Last Name] is a [female/male] patient, [age] , who has been diagnosed with PAH as of [MM/DD/YYYY] . [He/She] has been in my care since [MM/DD/YYYY] .

FILLABLE

{Include medical history, including but not limited to: [Patient's diagnosis, date of diagnosis and any applicable diagnosis codes], [Laboratory results and date], [Brief description of patient's current medical condition], [Patient's previous and current treatments/therapies], [Patient's response to those treatments/therapies], [If the patient has discontinued, include information on lack of response or tolerability]}

Rationale for Treatment

Considering the patient's medical history, current medical condition, and the approval of Orenitram for treating PAH, I believe treatment with Orenitram at this time is warranted, appropriate, and medically necessary for this patient.

Thank you for your prompt attention to this matter and for your consideration and anticipated approval for Orenitram. Please call my office at (XXX) XXX-XXXX if you require any additional information or documentation. I look forward to your timely response.

Sincerely,

[Prescriber First & Last Name]

FILLABLE

Enclosures:

[List enclosures, such as Prescribing Information, Important Safety Information, clinical evidence, or lab reports.]

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- Avoid use of Orenitram in patients with severe hepatic impairment (Child Pugh Class C) due to increases in systemic exposure.

WARNINGS AND PRECAUTIONS

- Abrupt discontinuation or sudden large reductions in dosage of Orenitram may result in worsening of PAH symptoms.
- The Orenitram tablet shell does not dissolve. In patients with diverticulosis, Orenitram tablets can lodge in a diverticulum.

ADVERSE REACTIONS

- In the 12-week, placebo-controlled, monotherapy study, and an event-driven, placebo-controlled, combination therapy study, adverse reactions that occurred at rates at least 5% higher on Orenitram than on placebo included headache, diarrhea, nausea, vomiting, flushing, pain in jaw, pain in extremity, hypokalemia, abdominal discomfort, and upper abdominal pain.

DRUG INTERACTIONS

- Co-administration of Orenitram and the CYP2C8 enzyme inhibitor gemfibrozil increases exposure to treprostinil; therefore, Orenitram dosage reduction may be necessary in these patients.

SPECIFIC POPULATIONS

- Animal reproductive studies with Orenitram have shown an adverse effect on the fetus. There are no adequate and well-controlled studies with Orenitram in pregnant women.
- It is not known whether treprostinil is excreted in human milk or if it affects the breastfed infant or milk production.
- Safety and effectiveness of Orenitram in pediatric patients have not been established.
- Use of Orenitram in patients aged 65 years and over demonstrated slightly higher absolute and relative adverse event rates compared to younger patients. Caution should be used when selecting a dose for geriatric patients.
- There is a marked increase in the systemic exposure to treprostinil in hepatically impaired patients.

INDICATION

Orenitram is a prostacyclin mimetic indicated for treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to delay disease progression and to improve exercise capacity. The studies that established effectiveness included predominately patients with WHO functional class II-III symptoms and etiologies of idiopathic or heritable PAH (66%) or PAH associated with connective tissue disease (26%).

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Please see Full Prescribing Information and Patient Information at www.orenitram.com or call 1-877-UNITHER (1-877-864-8437).

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