TIPS FOR DRAFTING A STATEMENT OF MEDICAL NECESSITY 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.

It may be helpful to include a Statement of Medical Necessity (SMN) letter, explaining your rationale and clinical decision making behind the choice of a specific therapy, when submitting a prior authorization to a patient's health insurance.

Understand the Insurer's Prior Authorization Process. Review the patient's plan benefits thoroughly prior to drafting a Statement of Medical Necessity letter.

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 SMN 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 SMN Letter, or the reason for the medical necessity of the prescribed medication.

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 STATEMENT OF MEDICAL NECESSITY FOR TYVASO PH-ILD

[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: LMN for Tyvaso

Dear [Contact/Medical Director First & Last Name]

I am writing to document the medical necessity and to obtain authorization for Tyvaso (treprostinil) on behalf of my patient, [Patient First & Last Name] . Tyvaso is the only US Food and Drug Administration (FDA) approved medication for the treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD). I believe that Tyvaso is appropriate for my patient based on their relevant clinical history (provided below).

Tyvaso is an inhaled prostacyclin mimetic approved to treat pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. The efficacy and safety profile of Tyvaso was based on results of INCREASE®, a randomized, double-blind, placebo-controlled, 16-week study that evaluated Tyvaso in 326 adult patients suffering from World Health Organization (WHO) Group 3 PH-ILD.

Brief summary of Patient's Medical History:

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

{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 Tyvaso for PH-ILD, I believe treatment with Tyvaso at this time is warranted, appropriate, and medically necessary for this patient.

Thank you for your prompt attention to this matter and your consideration and anticipated approval for Tyvaso. 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]

Enclosures:

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

Download and include the full Prescribing Information.

TYVASO® (treprostinil) Inhalation Solution

INDICATION

TYVASO (treprostinil) is a prostacyclin mimetic indicated for the treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. The study establishing effectiveness predominately included patients with etiologies of idiopathic interstitial pneumonia (IIP) (45%) inclusive of idiopathic pulmonary fibrosis (IPF), combined pulmonary fibrosis and emphysema (CPFE) (25%), and WHO Group 3 connective tissue disease (22%).

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- TYVASO is a pulmonary and systemic vasodilator. In patients with low systemic arterial pressure, TYVASO may produce symptomatic hypotension.
- TYVASO inhibits platelet aggregation and increases the risk of bleeding.
- Co-administration of a cytochrome P450 (CYP) 2C8 enzyme inhibitor (e.g., gemfibrozil) may increase exposure (both Cmax and AUC) to treprostinil. Co-administration of a CYP2C8 enzyme inducer (e.g., rifampin) may decrease exposure to treprostinil. Increased exposure is likely to increase adverse events associated with treprostinil administration, whereas decreased exposure is likely to reduce clinical effectiveness.

DRUG INTERACTIONS/SPECIFIC POPULATIONS

- The concomitant use of TYVASO with diuretics, antihypertensives, or other vasodilators may increase the risk of symptomatic hypotension.
- Human pharmacokinetic studies with an oral formulation of treprostinil (treprostinil diolamine) indicated that co-administration of the cytochrome P450 (CYP) 2C8 enzyme inhibitor, gemfibrozil, increases exposure (both Cmax and AUC) to treprostinil. Co-administration of the CYP2C8 enzyme inducer, rifampin, decreases exposure to treprostinil. It is unclear if the safety and efficacy of treprostinil by the inhalation route are altered by inhibitors or inducers of CYP2C8.
- Limited case reports of treprostinil use in pregnant women are insufficient to inform a drug-associated risk of adverse developmental outcomes. However, pulmonary arterial hypertension is associated with an increased risk of maternal and fetal mortality. There are no data on the presence of treprostinil in human milk, the effects on the breastfed infant, or the effects on milk production.
- Safety and effectiveness in pediatric patients have not been established.
- Across clinical studies used to establish the effectiveness of TYVASO in patients with pulmonary arterial hypertension (PAH) and PH-ILD, 268 (47.8%) patients aged 65 years and over were enrolled. The treatment effects and safety profile observed in geriatric patients were similar to younger patients. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of hepatic, renal, or cardiac dysfunction, and of concomitant diseases or other drug therapy.

ADVERSE REACTIONS

Pulmonary Hypertension Associated with ILD (WHO Group 3)

In a 16-week, placebo-controlled study (INCREASE) of 326 patients with PH-ILD (WHO Group 3), adverse events were similar to the experience in studies of PAH. The most common adverse reactions seen with TYVASO in ≥4% of PAH patients and more than 3% greater than placebo in the placebo-controlled study (TRIUMPH I) were cough (54% vs 29%), headache (41% vs 23%), throat irritation/pharyngolaryngeal pain (25% vs 14%), nausea (19% vs 11%), flushing (15% vs <1%), and syncope (6% vs <1%). In addition, adverse reactions occurring in ≥4% of patients were dizziness and diarrhea.

Please see Full Prescribing Information, the TD-100 and TD-300 TYVASO® Inhalation System Instructions for Use manuals, and other additional information at www.tyvaso.com or call 1-877-UNITHER (1-877-864-8437).

TYVISIhcpAPR2021(PH-ILD)

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