

Tips for Drafting a Statement of Medical Necessity Letter

These tips are being provided as an educational resource to support healthcare professionals and the patients they serve. This is not intended to be a step-by-step guide or instructions. It is the healthcare professional's 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 DPI® (treprostinil)

Attn:

RE: LMN for TYVASO DPI® (treprostinil) Inhalation Powder

Dear _____,

I am writing to document the medical necessity and to obtain authorization for TYVASO DPI® (treprostinil) Inhalation Powder on behalf of my patient, _____. TYVASO DPI is a dry powder formulation of treprostinil administered through a small, portable, dry powder inhaler. TYVASO DPI is a prostacyclin mimetic indicated for the treatment of pulmonary arterial hypertension (PAH; WHO Group 1) and pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability.

In a 3-week, open-label, single-sequence, safety and tolerability study (BREEZE) conducted in 51 patients on stable doses of TYVASO who switched to a corresponding dose of TYVASO DPI, the most commonly reported adverse events seen with TYVASO DPI in ≥4% of PAH patients during the 3-week treatment phase included cough (35.3%), headache (15.7%), dyspnea (7.8%), and nausea (5.9%).

Brief summary of Patient's Medical History:

_____ is a _____ patient, _____, who has been diagnosed with _____ as of _____. _____ has been in my care since _____.

Rationale for Treatment

Considering the patient's medical history, current medical condition, and the approval of TYVASO DPI for _____, I believe treatment with TYVASO DPI 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 DPI. Please call my office at _____ if you require any additional information or documentation. I look forward to your timely response.

Sincerely,

Enclosures:

Download and include the full prescribing information.

INDICATION

TYVASO (treprostinil) Inhalation Solution and TYVASO DPI (treprostinil) Inhalation Powder are prostacyclin mimetics indicated for the treatment of:

- Pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability. Studies with TYVASO establishing effectiveness predominately included patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with connective tissue diseases (33%). The effects diminish over the minimum recommended dosing interval of 4 hours; treatment timing can be adjusted for planned activities. While there are long-term data on use of treprostinil by other routes of administration, nearly all clinical experience with inhaled treprostinil has been on a background of an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor. The controlled clinical experience with TYVASO was limited to 12 weeks in duration.
- Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. The study with TYVASO 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%).

TYVASO® (treprostinil) Inhalation Solution

TYVASO DPI® (treprostinil) Inhalation Powder

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- TYVASO and TYVASO DPI are pulmonary and systemic vasodilators. In patients with low systemic arterial pressure, either product may produce symptomatic hypotension.
- Both products inhibit platelet aggregation and increase the risk of bleeding.
- Co-administration of a cytochrome P450 (CYP) 2C8 enzyme inhibitor (e.g., gemfibrozil) may increase exposure (both C_{max} 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.
- Like other inhaled prostaglandins, TYVASO and TYVASO DPI may cause acute bronchospasm. Patients with asthma or chronic obstructive pulmonary disease (COPD), or other bronchial hyperreactivity, are at increased risk for bronchospasm. Ensure that such patients are treated optimally for reactive airway disease prior to and during treatment with TYVASO and TYVASO DPI.

DRUG INTERACTIONS/SPECIFIC POPULATIONS

- The concomitant use of either product 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 C_{max} 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 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 Arterial Hypertension (WHO Group 1) In a 12-week, placebo-controlled study (TRIUMPH I) of 235 patients with PAH (WHO Group 1 and nearly all NYHA Functional Class III), the most common adverse reactions seen with TYVASO in $\geq 4\%$ of PAH patients and more than 3% greater than placebo 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 $\geq 4\%$ of patients were dizziness and diarrhea. In a 3-week, open-label, single-sequence, safety and tolerability study (BREEZE) conducted in 51 patients on stable doses of TYVASO who switched to a corresponding dose of TYVASO DPI, the most commonly reported adverse events seen with TYVASO DPI in $\geq 4\%$ of PAH patients during the 3-week treatment phase included cough (35.3%), headache (15.7%), dyspnea (7.8%), and nausea (5.9%).
- 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 reactions with TYVASO were similar to the experience in studies of PAH.

Please see accompanying Full Prescribing Information for TYVASO or TYVASO DPI, Instructions for Use manuals for TD-100 and TD-300 TYVASO® Inhalation System and TYVASO DPI® Inhalation Powder, and additional information at www.TYVASOHCP.com or call United Therapeutics Cares™ at 1-844-UNITHER (1-844-864-8437).

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Reference: 1. TYVASO DPI [package insert]. Research Triangle Park, NC: United Therapeutics Corporation; 2022. 2. Spikes LA, Shapiro SM, Restrepo R, et al. BREEZE: open-label, clinical study to evaluate the safety and tolerability of a treprostinil dry powder inhaler in subjects with pulmonary arterial hypertension currently using TYVASO. Poster presented at: ERS International Congress; September 5-8, 2021; Virtual. Poster 28458. 3. Channick RN, Voswinckel R, Rubin LJ. Inhaled treprostinil: a therapeutic review. Drug Des Devel Ther. 2012;6:19-28.

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