

# Tips for Drafting an Appeal 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.

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 TYVASO DPI® (treprostinil)

Attn:

**RE: Appeal for Denial of TYVASO DPI® (treprostinil) Inhalation Powder and Dosage for treating  
[PAH/PH-ILD]**

**Dear**

I am writing to request a review of a denied authorization of coverage for TYVASO DPI® (treprostinil) Inhalation Powder on behalf of my patient, . Your company has denied this authorization for the following reason(s):

TYVASO DPI is a dry powder formulation of treprostinil administered through a small, portable, dry powder inhaler. TYVASO DPI is approved 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 the ability to exercise. I believe that TYVASO DPI is appropriate for my patient based on their relevant clinical history (provided below). I am requesting that your company reconsider your denial of TYVASO DPI coverage for,

**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 treating , 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 for 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:**

## 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](http://www.TYVASOHCP.com) or call United Therapeutics Cares™ at 1-844-UNITHER (1-844-864-8437).**

TYVISIhcpMAY2022

**Reference:** 1. TYVASO DPI [package insert]. Research Triangle Park, NC: United Therapeutics Corporation; 2022. 2. Spikes LA, Bajwa AA, Burger CD, et al. BREEZE: Open-label clinical Study to Evaluate the Safety and Tolerability of Treprostinil Inhalation Powder as Tyvaso DPI™ in Patients With Pulmonary Arterial Hypertension. *Pulm Circ*. 23 March 2022. <https://doi.org/10.1002/pul2.12063>. 3. Channick RN, Voswinckel R, Rubin LJ. Inhaled treprostinil: a therapeutic review. *Drug Des Devel Ther*. 2012;6:19-28.

United Therapeutics Cares is a trademark of United Therapeutics Corporation. TYVASO DPI is a registered trademark of United Therapeutics Corporation.

©2024 United Therapeutics Corporation. All rights reserved US/PTR/0056

**United  
Therapeutics  
Cares™**