

## QUANTITY LIMIT OVERRIDE REQUEST

Dear Clinician,

Enclosed is a sample Quantity Limit Override Request to serve as a template if your patient's health plan has quantity limitations for the higher doses of YUTREPIA<sup>™</sup> (treprostinil) inhalation powder (224 capsules for 79.5 mcg dose and 224 capsules for 106 mcg dose).

This template is a sample of what can be submitted as a comprehensive and impactful letter so your patient can receive the prescribed quantity of YUTREPIA to achieve the maximum benefit.

Complete the requested information on the template and either insert your business logo in the fields provided or print the letter directly onto your official letterhead.

This template is provided as an example and is intended to be tailored to each prescriber and patient. This letter is not a guarantee of insurance approval. It is the sole responsibility of the health care provider to include the proper information and ensure the accuracy of all statement used in seeing coverage and reimbursement for an individual patient.

Sincerely,

Your Liquidia Team

**Date:**

**To:**

**From:**

**Phone:**

**Fax:**

**Patient:**

**DOB:**

**Therapy:** YUTREPIA™ (treprostinil) inhalation powder

**Strength:**  26.5 mcg  53 mcg  79.5 mcg  106 mcg

**QTY Limits Request:** Up to 8 capsules per day (224 capsules per 28-day supply)

Dear

I am writing on behalf of my patient, named above, and am requesting a quantity limit override for up to 8 capsules per day (224 capsules per 28-day supply) of YUTREPIA, allowing for the use of two identical capsules of the same NDC strength per session when clinically indicated. This dosing approach is consistent with the FDA-approved Prescribing Information, pivotal clinical study design, and standard titration practice for YUTREPIA.

#### **INDICATION**

YUTREPIA is a prostacyclin mimetic indicated for the treatment of:

- Pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability. Studies 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%).
- 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%).

On the following page, I provide detailed information in support of my request for your consideration. Given the nature of this request, I kindly ask for a timely review and authorization.

If I can provide any additional information, please contact my office at the number below.

Sincerely,

Phone:

Fax:

## Manufacturer-Recommended Dosing

YUTREPIA™ is a titrated prostacyclin therapy 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), as described in the Prescribing Information (Sections 1.1–1.2).

Dose (mcg)	Capsules Needed
26.5	 1 Yellow (26.5 mcg)
53	 1 Green (53 mcg)
79.5	 1 Blue (79.5 mcg)
106	 1 Purple (106 mcg)
132.5	  1 Green (53 mcg) + 1 Blue (79.5 mcg)
159	  2 Blue (79.5 mcg)
185.5	  1 Blue (79.5 mcg) + 1 Purple (106 mcg)
212	  2 Purple (106 mcg)

## Clinical Consequences of Limiting the Prescribed FDA-Approved Dose

Restricting the prescribed quantity may result in:

- **Subtherapeutic treprostinil exposure.**
- **Risk of clinical worsening**, including reduced exercise capacity, decline in functional class, increased symptoms, or hospitalization.
- **Increased administrative burden** through unnecessary appeals or patient assistance program referrals.

The requested quantity of **224 capsules per 28 days** ensures the patient receives the clinically appropriate, studied, and titrated maintenance dose consistent with the YUTREPIA Prescribing Information.

YUTREPIA is administered 3 to 5 times daily, with dose increases of 26.5 mcg per week as tolerated, to achieve the individualized maintenance dose (Section 2.1). Patients requiring higher doses (e.g., 159 mcg or 212 mcg per session) may need to use two identical capsules of the same NDC strength per treatment session (e.g., 2×79.5 mcg or 2×106 mcg).

## Clinical Rationale

Restricting YUTREPIA to quantities below the prescribed titrated dose may result in subtherapeutic drug exposure, risking clinical worsening, decreased exercise capacity, functional decline, and hospitalization (Section 14.2, INCREASE study – YUTREPIA PI).

Real-world evidence reinforces this risk. In a retrospective analysis of approximately 5,000 patients treated with inhaled treprostinil, **Shapiro et al. (2021, *Pulmonary Circulation*)** reported that patients receiving doses >9 breaths per session (equivalent to maintenance doses above ~79.5 mcg×4 daily sessions) had **significantly higher one-, two-, and three-year survival rates (P<0.0001)** and longer treatment persistence than those maintained at ≤9 breaths. The authors concluded that higher titrated doses were associated with **improved long-term outcomes and treatment durability**.

Accordingly, approval for up to 8 capsules per day (224 per 28 days) is requested to maintain continuity of care and ensure clinically appropriate dosing consistent with the YUTREPIA Prescribing Information and pivotal clinical studies. Limiting the patient to a quantity less than prescribed places them at potential risk for worsening condition, decreased functional class, increased symptoms, hospitalization, and reduced quality of life.

## Request

Please approve a quantity limit override for up to **8 capsules per day (224 capsules per 28-day supply)** of YUTREPIA, allowing use of **two identical capsules of the same NDC strength per session** when clinically indicated. This dosing approach is consistent with the **FDA-approved Prescribing Information, pivotal clinical study design, and standard titration practice** for YUTREPIA.