ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Urgent**[1] ☐ **Non-Urgent**

Requested Drug Name: Tyvaso® (treprostinil inhaled)

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit: ☐ New Request ☐ Reauthorization

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Tyvaso® (treprostinil inhaled)

Diagnosis (documentation supportive of diagnosis is required)

☐ Pulmonary Arterial Hypertension (PAH)
☐ WHO Group I
☐ NYHA Functional Class III symptoms
☐ Other (please state): _____

Physician Specialty

☐ Pulmonology
☐ Cardiology
☐ Other (please state): _____

☐ For use in clinical trial? (If yes, provide trial name and registration number):			
Drug Name (Brand Name and Scientific Name)/Strength:			
Dose:	Route:	Frequency:	
Quantity:	Number of Refills:		
Product will be delivered to: ☐ Patient's Home ☐Physician Office		Other:	
Prescriber or Authorized Signature:		Date:	
Dispensing Pharmacy Name and Phone Number:			
☐ **Approved** ☐ **Denied**			
If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:			

1. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Tyvaso (treprostinil) inhalation solution

CLASSIFICATION

- Antihypertensive, Vasodilator
- Prostaglandin

DESCRIPTION

- Tyvaso is indicated for the treatment of pulmonary arterial hypertension (WHO Group 1) to improve exercise ability. Efficacy was established in studies that included predominately patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with connective tissue diseases (33%).
- Treprostinil significantly improved six-minute walking distance (6MWD) compared with placebo in patients with pulmonary arterial hypertension (PAH) receiving concurrent bosentan or sildenafil therapy in the multicenter, randomized, double-blind, placebo-controlled, 12-week TReprostinil Sodium Inhalation Used in the Management of Pulmonary Arterial Hypertension (TRIUMPH) study (n=235). Patients included in this study had PAH (idiopathic, familial, or related to collagen vascular disease, HIV, or anorexigen use), NYHA functional class III (n=230) or class IV (n=5), a baseline 6MWD of 200 to 450 m, and were on concurrent sildenafil (any dose) or bosentan 125 mg daily treatment for at least 3 months prior to start of the study.
- Monitoring parameters include: Improvement in signs and symptoms of pulmonary arterial hypertension (dyspnea or fatigue, chest pain, or near syncope), exercise capacity, WHO functional classification, and a decrease in the rate of clinical worsening are indicative of efficacy.
- Due to the complicated nature and severity of PAH as a disease state as well as the high cost of the agents used for PAH, patients should be managed by a pulmonary specialist
- Tyvaso is a prostacyclin vasodilator. Major pharmacological actions of are direct vasodilation of pulmonary and systemic arterial vascular beds and inhibition of platelet aggregation.
- One ampule of Tyvaso contains sufficient volume of medication for all 4 treatment sessions in a single day and should be used in the Tyvaso Inhalation System.

FORMULARY COVERAGE

Prior authorization:	Required
Good Health Formulary:	Tier 4
Commercial Formulary:	Tier 4
Medicare Part D coverage:	Tier 5

COVERAGE CRITERIA

Tyvaso (treprostinil) meets the definition of **medical necessity** for all FDA approved indications, including the following:

- Pulmonary arterial hypertension (PAH) (WHO Group I) to improve exercise ability and delay clinical worsening.
    - NYHA Functional Class III symptoms

- Safety and efficacy have not been established in pediatric patients.

Tyvaso (treprostinil) is considered **experimental** for the following:

- Any indication that is not FDA approved or Compendia supported.
- Use in patients with significant underlying lung disease (i.e. asthma or COPD) as safety and efficacy have not been established.

Required Provider Specialty:

- Approval is limited to Pulmonologists and Cardiologists

DOSAGE/ADMINISTRATION:

Adult Dosing (safety and efficacy have not been determined for pediatric patients):

- Initial (oral inhalation) for PAH: 3 breaths (18 mcg) via ORAL INHALATION per treatment session, 4 times daily during waking hours (approximately 4 hours apart); reduce to 1 or 2 breaths if 3 breaths are not tolerated.
- Maintenance (oral inhalation) for PAH: titrate by an additional 3 breaths at approximately 1 to 2 week intervals as tolerated, to a target dose of 9 breaths (54 mcg) per treatment session, 4 times daily; MAX dose of 9 breaths per treatment session, 4 times daily
- Treatment timing can be adjusted for planned activities as effects decrease over the recommended minimum dosing interval of 4 hours.

PRECAUTIONS:

- Refer to prescribing information for all precautions.
- Acute pulmonary infection; may result in worsening of lung disease and loss of drug effect (inhalation).
- Increased risk of bleeding due to inhibition of platelet aggregation by treprostinil, particularly in patients treated with anticoagulants.
- Hepatic and renal insufficiency may result in exposure to greater systemic concentrations; slow titration recommended.
- The risk for symptomatic hypotension is increased in patients with low systemic arterial pressure and/or those receiving concomitant blood pressure lowering agents.
- Safety and efficacy have not been established in patients with significant underlying lung disease (i.e. asthma or chronic obstructive pulmonary disease).
- Dose adjustments may be necessary if CYP2C8 inhibitors or inducers are added or withdrawn.

Billing/Coding information

CPT Coding:

J7686	Treprostinil, inhalation solution, FDA-approved final product, non-compounded, administered through DME, unit dose form, 1.74mg

COST

- AWP (November 2011): Tyvaso inhalation solution 1.74mg/2.9ml ampule (28): $12,141.36
- AWP (May 2013): Tyvaso inhalation solution 1.74mg/2.9ml ampule (28): $15,732.64
- AWP (February 2014): Tyvaso inhalation solution 1.74mg/2.9ml ampule (28): $15,843.52
- AWP (February 2015): Tyvaso inhalation solution 1.74mg/2.9ml ampule (28): $16,612.68

COMMITTEE APPROVAL:

- February 2010

GUIDELINE UPDATE INFORMATION:

February 2010	Prior authorization created
November 2011	Coverage Policy created
May 2014	Coverage Policy updated
May 2015	Coverage Policy reviewed; AWP updated

REFERENCES:

- DRUGDEX®, accessed, 11/23/2011, 5/10/2014, 5/27/2015
- Product Information: Tyvaso® (treprostinil) inhalation solution. United Therapeutics Corp., Research Triangle Park, NC, 2011, 2013.