

Complete Patient and Physician information (PLEASE PRINT)

STEP
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI Number:

If Applicable: Pharmacy Name: _____
 Pharmacy Phone: _____

Complete the Clinical Assessment:

STEP
2

Diagnosis	<input type="checkbox"/> Pulmonary Arterial Hypertension, primary or secondary etiology <input type="checkbox"/> WHO Group I <input type="checkbox"/> NYHA Functional Class III symptoms	<input type="checkbox"/> Other (please state): _____ _____ _____
Physician Specialty	<input type="checkbox"/> Pulmonology	<input type="checkbox"/> Other (please state): _____ _____
Supporting Documentation	Diagnosis: ICD-9/10 Code #/ Description / J Code (required):	
	Please attach a copy of the prescription or provide ALL of the information below: Tyvaso [®] (treprostinil) inhaled solution Strength _____ Sig _____ Qty _____ Refills _____	
	<i>*Please attach all relevant medical records and test results*</i> We will not process incomplete forms. If we do not receive the completed form & all relevant medical records & test results within 10 calendar days of this request, it will be denied.	

STEP
3

I certify that the above is correct and accurate to the best of my knowledge and that the form is complete. (please sign and date)

 Prescriber Signature

 Date

STEP
4

**Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk:
 970-248-5034**

Name of Person filling out form: _____

Pharmacy Technician initials _____ Date Initiated _____

Confidentiality Notice:

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options. 01/10/12

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, and 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.

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 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 has not been established in pediatric patients less than 18 years old.

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 Pulmonary specialists.

DOSAGE/ADMINISTRATION:

Adult Dosing (safety and efficacy has not been determined for children):

- 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

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
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HCPCS Coding:

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ICD-9 Diagnoses Codes That Support Medical Necessity:

416.0	Primary pulmonary hypertension
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COST

- AWP (November 2011):
 - Tyvaso inhalation solution 1.74mg/2.9ml ampule (28): \$12,141.36

COMMITTEE APPROVAL:

- February 2010

GUIDELINE UPDATE INFORMATION:

February 2010	Prior authorization created
November 2011	Coverage Policy created

REFERENCES:

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