



Prior Authorization Approval Criteria

Tyvaso (treprostinil)

Generic name:	treprostinil inhalation
Brand name:	Tyvaso
Medication class:	peripheral vasodilator
FDA-approved uses:	Pulmonary hypertension WHO Group I to increase walk distance.
Available dosage forms:	Inhalation solution 1.74 mg treprostinil per ampule.
Usual dose:	3 Breaths of Tyvaso (18mcg of treprostinil) per treatment session dosed in 4 separate, equally spaced treatment sessions per day, during walking hours. The treatment should be approximately 4 hours apart. Dosage should be increased by an additional 3 breaths at 1-2 week intervals, until the target and maximum dose of 9 breaths (54mcg of treprostinil) is reached per treatment session.
Approximate monthly cost: (based on AWP 2010)	about \$14,000/month
Duration of therapy:	indefinite
Criteria for use <i>(bullet points below are all inclusive unless otherwise noted):</i>	<ul style="list-style-type: none">• The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.• Must have tried and failed at least one oral agent such as Tracleer (bosentan), Letairis (ambrisentan), Adcirca (tadalafil) or Revatio (sildenafil).• Must have baseline 6 minute walking distance.
Criteria for continuation of therapy:	<ul style="list-style-type: none">• By 12 weeks the patient must show an increase in exercise ability, demonstrated by a 20 meter improvement in 6 minute walking distance.
Contraindication:	<ul style="list-style-type: none">• None listed at this time.
Not approved if:	<ul style="list-style-type: none">• Patient does not meet the above stated criteria.
Special considerations:	<ul style="list-style-type: none">• Part B for Medicare patients.• Commercial members- this is a pharmacy benefit but must be obtained from CVS Caremark Specialty Pharmacy Services Network. 1-800-237-2767.• Must only be used with the Tyvaso inhalation system.• The effects diminish over the minimum recommended dosing interval of 4 hours; treatment timing can be adjusted for planned activities.

- One ampule of Tyvaso should be used each day in the Tyvaso inhalation system. After Tyvaso ampule is opened and transferred to the medicine cup, the solution should remain in the device for no more than 24 hours. Remaining solution should be discarded at the end of the day.
- Tyvaso has not been studied in patients with significant underlying lung disease such as asthma or chronic obstructive pulmonary disease and should be used with caution in those with acute pulmonary infections.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 03/10/10