

HOW TO GET STARTED

Tyvaso and Remodulin are available only through select Specialty Pharmacy Services (SPS) providers. Follow these 5 simple steps to complete each section of the following **referral form**.

- 1** Fill out the Patient Information (**A and B**). Let your patient know that an SPS provider will be calling and it is important to answer or return the call.
- 2** Complete and sign the Prescriber Information, Prescription, and Statement of Medical Necessity (**C through E**).
- 3** Complete and sign the Medical Information, Patient Evaluation, and Supporting Documentation (**F through I**).
- 4** Attach the clinical documents outlined on the **fax cover sheet**, including right heart catheterization test results, history and physical, and echocardiogram results.
- 5** Use the **fax cover sheet** included in this PDF to fax the referral form and signed supporting documents to your preferred SPS provider. (Insurance plans vary and may impact the approval process.)

Information regarding the CMS established and expected coverage criteria for treprostinil is included for your review.

MEDICARE COVERAGE CRITERIA FOR PROSTACYCLIN

The current Local Coverage Determination for Prostacyclin is as follows:

The pulmonary hypertension is not secondary to pulmonary venous hypertension (e.g. left sided atrial or ventricular disease, left sided valvular heart disease, etc.) or disorders of the respiratory system (e.g. chronic obstructive pulmonary disease, interstitial lung disease, obstructive sleep apnea or other sleep disordered breathing, alveolar hypoventilation disorders, etc.); and

The patient has idiopathic/heritable pulmonary hypertension or pulmonary hypertension which is associated with one of the following conditions: connective tissue disease, thromboembolic disease of the pulmonary arteries, human immunodeficiency virus (HIV) infection, cirrhosis, diet drugs, congenital left to right shunts, etc. If these conditions are present, the following criteria must be met:

1. The pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition; and
2. The mean pulmonary artery pressure is greater than 25mm Hg at rest or greater than 30mm Hg with exertion; and
3. The patient has significant symptoms from the pulmonary hypertension (i.e. severe dyspnea on exertion, and either fatigability, angina, or syncope); and
4. Treatment with oral calcium channel blocking agents has been tried and failed, or has been considered and ruled out.

*Remodulin is indicated for PAH (WHO Group 1) to diminish symptoms associated with exercise and to diminish the rate of clinical deterioration in patients transitioning from Flolan® (epoprostenol sodium).**

Tyvaso is indicated for the treatment of pulmonary arterial hypertension (WHO Group 1) to improve exercise ability.

Medicare coverage criteria provided for informational purposes only. Please check with the payer to verify billing requirements. United Therapeutics does not make any representation or guarantees concerning reimbursement or coverage for any service or item.

*The brand listed is a trademark of its respective owner and is not a trademark of United Therapeutics Corporation. The maker of this brand is not affiliated with and does not endorse United Therapeutics Corporation or its products.

Please see full Indications for Tyvaso and Remodulin on page 6.

For more information and additional resources, visit tyvaso.com and remodulin.com.

United Therapeutics Corporation PAH Therapy Referral Form

2

Please complete, sign, and fax Steps 1-3, along with requested clinical documentation, to your preferred Specialty Pharmacy using the following Fax Cover Sheet.

For Patient: _____

DOB: _____

STEP 1 - PATIENT INFORMATION

A PATIENT INFORMATION

Name: First	Middle	Last
Date of Birth	Gender	SSN
Home Address		
City	State	Zip
Shipping Address (if not home address)		
City	State	Zip
Telephone	Alternate Telephone	Best Time to Call
E-mail Address		
Caregiver/Family Member	Telephone	Alternate Telephone

B INSURANCE INFORMATION

Pharmacy Benefits Manager:		
Subscriber ID #	Group #	Telephone #
Primary Medical Insurance:		Policy Holder/Relationship
Subscriber ID #	Group #	Telephone #
Secondary Medical Insurance:		Policy Holder/Relationship
Subscriber ID #	Group #	Telephone #

Please include copies of the patient's current insurance card(s).

Please see full Indications and Important Safety Information for Tyvaso and Remodulin on page 6. Please click links for Full Prescribing Information for [Remodulin](#) and [Tyvaso](#) and the [Tyvaso Inhalation System Instructions for Use manual](#).



United Therapeutics Corporation PAH Therapy Referral Form

3

Please complete, sign, and fax Steps 1-3, along with requested clinical documentation, to your preferred Specialty Pharmacy using the following Fax Cover Sheet.

For Patient: _____

DOB: _____

STEP 2 - PRESCRIBER INFORMATION AND PRESCRIPTION INFORMATION

C PRESCRIBER INFORMATION

Prescriber: First	Last	
NPI #	License #	DEA #
Facility Name	Group NPI # (if applicable)	TIN #
Address		
City	State	Zip
Office Contact Name		
Telephone	Fax	
E-mail Address	Preferred Method of Communication	

D PRESCRIPTION INFORMATION

☐ **TYVASO® (treprostinil) Inhalation Solution** ☐ Dispense as written
Target dose: 9 breaths (54 mcg) QID—Start with 3 breaths (18 mcg) QID (if 3 breaths are not tolerated, use 1 to 2 breaths).
Increase by additional 3 breaths at 1- to 2-week intervals, if tolerated, until the target dose of 9 breaths (54 mcg) QID.

Quantity: ☐ TYVASO Inhalation System Starter Kit (28-day supply) ☐ TYVASO Inhalation System Refill Kit (28-day supply) X _____ refills

☐ **REMODULIN® (treprostinil) Injection** ☐ Dispense as written
Vial concentration: ☐ 1 mg/mL (20-mL vial) ☐ 2.5 mg/mL (20-mL vial) ☐ 5 mg/mL (20-mL vial) ☐ 10 mg/mL (20-mL vial)
Quantity: Dispense 1 month of drug and supplies X _____ refills **Patient dosing weight:** _____ kg/lb

Infusion Type

Prescribing practitioner to specify infusion type by checking the box below:

☐ Subcutaneous continuous infusion ☐ Intravenous continuous infusion

Dosing and Titration Instructions

For Remodulin dosing and titration information, please see the Dosage and Administration section of the Prescribing Information.

To specify initial dosing and titration instructions, fill in the blanks OR use the lines below.

Initiation dosage: _____ ng/kg/min Titrate by _____ ng/kg/min every _____ days until goal of _____ ng/kg/min is achieved

Prescribing practitioner to specify any alternative or additional dosing and titration instructions here (above fields may be left blank if preferred): _____

Specialty Pharmacy to contact prescribing practitioner for adjustments to the written orders specified above.

Specify any palliative measures to be taken: _____

Central venous catheter care: ☐ Dressing change every _____ days ☐ Per IV standard of care

Check one (0.9% sodium chloride will be used if no box is checked): ☐ 0.9% sodium chloride for injection ☐ Flolan® sterile diluent for injection* ☐ Sterile water for injection

Pumps: ☐ 2 CADD-MS™ 3 Pumps ☐ 2 CADD-Legacy® Pumps ☐ 2 Crono Five Pumps

Therapy education orders (nurse training): **Location:** ☐ Hospital ☐ Outpatient clinic ☐ Home

If you are an NY state prescriber, please use original Prescription Form. All other states, if not faxed and applicable, must be on a state-specific form.

E PRESCRIBER SIGNATURE: PRESCRIPTION AND STATEMENT OF MEDICAL NECESSITY

I certify that the pulmonary arterial hypertension therapy ordered above is medically necessary, that it is safe and appropriate to administer in the home setting, and that I am personally supervising the care of this patient. **PHYSICIAN SIGNATURE REQUIRED TO VALIDATE PRESCRIPTIONS.**

Physician's signature _____ Date _____
Dispense as Written Substitution allowed

(Physician attests this is his/her legal signature. NO STAMPS.) By signing, I certify that the above therapy is medically necessary.

*The brand listed is a trademark of its respective owner and is not a trademark of United Therapeutics Corporation. The maker of this brand is not affiliated with and does not endorse United Therapeutics Corporation or its products.

Please see full Indications and Important Safety Information for Tyvaso and Remodulin on page 6. Please click links for Full Prescribing Information for [Remodulin](#) and [Tyvaso](#) and the [Tyvaso Inhalation System Instructions for Use manual](#).



United Therapeutics Corporation PAH Therapy Referral Form

5

FAX THE COMPLETED REFERRAL FORM AND DOCUMENTATION TO THE SPECIALTY PHARMACY OF YOUR CHOICE BELOW.

STEP 4

FAX COVER SHEET

Date:

To: (check one)

☐ **Accredo**

Fax: 1-800-711-3526
Phone: 1-866-344-4874

☐ **CVS Caremark**

Fax: 1-877-943-1000
Phone: 1-877-242-2738

From:

Facility Name:

Fax:

Included in this fax:

☐ **Completed UT PAH Therapy Referral Form including**

Step 1 - Patient Information

Step 2 - Prescriber/Prescription Information

Step 3 - Medical Information/Patient Evaluation

☐ **Included signed and dated documents**

☐ Right Heart Catheterization Results

☐ History and physical (including Onset of Symptoms, PAH Clinical Signs, and Symptoms Course of Illness)

☐ Need for Specific Drug Therapy and 6-minute walk test results

☐ Echocardiogram Results

Number of Pages:

Comments:

Please see full Indications and Important Safety Information for Tyvaso and Remodulin on page 6. Please click links for Full Prescribing Information for [Remodulin](#) and [Tyvaso](#) and the [Tyvaso Inhalation System Instructions for Use manual](#).

TYVASO
(treprostinil) INHALATION
SOLUTION

REMODULIN
(treprostinil) Injection

INDICATION FOR TYVASO

Tyvaso is a prostacyclin vasodilator indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability. Studies establishing effectiveness 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%).

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 controlled clinical experience with inhaled treprostinil has been on a background of bosentan (an endothelin receptor antagonist) or sildenafil (a phosphodiesterase type 5 inhibitor). The controlled clinical experience was limited to 12 weeks in duration.

IMPORTANT SAFETY INFORMATION FOR TYVASO

- Tyvaso is intended for oral inhalation only. Tyvaso is approved for use only with the Tyvaso Inhalation System
- The safety and efficacy of Tyvaso have not been established in patients with significant underlying lung disease (such as asthma or chronic obstructive pulmonary disease) and in patients under 18 years of age. Patients with acute pulmonary infections should be carefully monitored to detect any worsening of lung disease and loss of drug effect
- Tyvaso may increase the risk of bleeding, particularly in patients receiving anticoagulants
- In patients with low systemic arterial pressure, Tyvaso may cause symptomatic hypotension. The concomitant use of Tyvaso with diuretics, antihypertensives, or other vasodilators may increase the risk of symptomatic hypotension
- Hepatic or renal insufficiency may increase exposure to Tyvaso and decrease tolerability. Tyvaso dosage adjustments may be necessary if inhibitors of CYP2C8 such as gemfibrozil or inducers such as rifampin are added or withdrawn
- The most common adverse events seen with Tyvaso in $\geq 4\%$ of PAH patients and more than 3% greater than placebo in the placebo-controlled clinical study 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%)
- Tyvaso should be used in pregnancy only if clearly needed. Caution should be exercised when Tyvaso is administered to nursing women

For additional information about Tyvaso, visit tyvaso.com or call 1-877-864-8437.

INDICATION FOR REMODULIN

Remodulin is a prostacyclin vasodilator indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to diminish symptoms associated with exercise. Studies establishing effectiveness included patients with NYHA Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (58%), PAH associated with congenital systemic-to-pulmonary shunts

(23%), or PAH associated with connective tissue diseases (19%). It may be administered as a continuous subcutaneous infusion or continuous intravenous infusion; however, because of the risks associated with chronic indwelling central venous catheters, including serious blood stream infections, continuous intravenous infusion should be reserved for patients who are intolerant of the subcutaneous route, or in whom these risks are considered warranted.

In patients with PAH requiring transition from Flolan® (epoprostenol sodium), Remodulin is indicated to diminish the rate of clinical deterioration. The risks and benefits of each drug should be carefully considered prior to transition.

IMPORTANT SAFETY INFORMATION FOR REMODULIN

- Chronic intravenous infusions of Remodulin are delivered using an indwelling central venous catheter. This route is associated with the risk of blood stream infections (BSI) and sepsis, which may be fatal. Therefore, continuous subcutaneous infusion is the preferred mode of administration
- Remodulin should be used only by clinicians experienced in the diagnosis and treatment of PAH
- Remodulin is a potent pulmonary and systemic vasodilator. It lowers blood pressure, which may be further lowered by other drugs that also reduce blood pressure
- Remodulin inhibits platelet aggregation and therefore, may increase the risk of bleeding, particularly in patients on anticoagulants
- Remodulin dosage adjustment may be necessary if inhibitors or inducers of CYP2C8 are added or withdrawn
- Initiation of Remodulin must be performed in a setting with adequate personnel and equipment for physiological monitoring and emergency care
- Therapy with Remodulin may be used for prolonged periods, and the patient's ability to administer Remodulin and care for an infusion system should be carefully considered
- Remodulin dosage should be increased for lack of improvement in, or worsening of, symptoms and it should be decreased for excessive pharmacologic effects or for unacceptable infusion site symptoms
- Abrupt withdrawal or sudden large reductions in dosage of Remodulin may result in worsening of PAH symptoms and should be avoided
- Caution should be used in patients with hepatic or renal insufficiency
- The most common side effects of Remodulin included those related to the method of infusion. For subcutaneous infusion, infusion site pain and infusion site reaction (redness and swelling) occurred in the majority of patients. These symptoms were often severe and could lead to treatment with narcotics or discontinuation of Remodulin. For intravenous infusion, line infections, sepsis, arm swelling, tingling sensations, bruising, and pain were most common. General side effects (>5% more than placebo) were diarrhea, jaw pain, vasodilatation, and edema

For additional information about Remodulin, visit Remodulin.com or call 1-877-UNITHER (1-877-864-8437).

Please see accompanying Full Prescribing Information for Remodulin and Tyvaso and the Tyvaso Inhalation System Instructions for Use manual.

