Referral Forms for TYVASO and REMODULIN

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 (eg, left sided atrial or ventricular disease, left sided valvular heart disease, etc) or disorders of the respiratory system (eg, 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 25 mm Hg at rest or greater than 30 mm Hg with exertion; and

3. The patient has significant symptoms from the pulmonary hypertension (ie, 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.

Tyvaso is indicated for the treatment of pulmonary arterial hypertension (WHO Group 1) to improve exercise ability. Remodulin is a prostacyclin vasodilator indicated for the treatment of pulmonary arterial hypertension (PAH; WHO Group 1) to diminish symptoms associated with exercise. In patients with PAH requiring transition from Flolan® (epoprostenol sodium), Remodulin is indicated to diminish the rate of clinical deterioration.

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.

Remodulin and Tyvaso are registered trademarks of United Therapeutics Corporation.

Please see full indication and Important Safety Information for Remodulin and Tyvaso on page 6. Please see accompanying Full Prescribing Informations for Remodulin and Tyvaso and the Tyvaso Inhalation System Instructions for Use manual and Patient Package Insert.

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

AMC8009 CRP1709_A0391
United Therapeutics Corporation PAH Therapy Referral Form

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

**STEP 1 - PATIENT INFORMATION**

**A PATIENT INFORMATION**

Name: First  Middle  Last

Date of Birth  Gender  Last 4 digits of 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

☐ By checking this box I authorize SPS to leave a message with a caregiver/family member.

**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 front and back of the patient’s insurance card(s).

Please Note: United Therapeutics cannot guarantee payment for United Therapeutics products. Patients are directed to discuss treatment options and decisions with their healthcare provider. Please see full indication and Important Safety Information for Remodulin and Tyvaso on page 6. Please see accompanying Full Prescribing Informations for Remodulin and Tyvaso and the Tyvaso Inhalation System Instructions for Use manual and Patient Package Insert.
United Therapeutics Corporation PAH Therapy Referral Form

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

Patient Name: ____________________________
Date of Birth: ____________________________

STEP 2 - PRESCRIBER INFORMATION AND PRESCRIPTION INFORMATION

C PRESCRIBER INFORMATION

Prescriber: First __________________________ Last __________________________
NPI # __________________________ State License # __________________________
Facility Name __________________________ State __________________________
Address __________________________ City __________________________ State __________________________ Zip __________________________
Office Contact Name __________________________
Telephone __________________________ Fax __________________________
E-mail Address __________________________ Preferred Method of Communication __________________________

D PRESCRIPTION INFORMATION

☐ TYVASO® (treprostinil) 1.74mg/2.9ml ampule (0.6mg/ml) Inhalation Solution
Target dose: 9 breaths (54 mcg) 4 times a day — Start with 3 breaths (18 mcg) 4 times a day (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) 4 times a day.
Quantity: ☐ TYVASO Inhalation System Starter Kit (28-day supply) ☐ TYVASO Inhalation System Refill Kit (28-day supply) X _________ refills

☐ REMODULIN® (treprostinil) Injection
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 may 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.

Central venous catheter care: ☐ Dressing change every _________ days ☐ Per IV standard of care
Check one:
☐ 0.9% Sodium Chloride for Injection ☐ Remodulin® Sterile Diluent for Injection ☐ Flolan® Sterile Diluent for Injection ☐ Sterile Water for Injection ☐ Epoprostenol Sterile Diluent for Injection
Pumps: ☐ 2 CADD-MS® 3 Pumps ☐ 2 CADD-Legacy® Pumps
Nursing Orders - RN visit to provide assessment and education on administration, dosing, and titration: Location: ☐ Home ☐ Outpatient clinic ☐ Hospital
The prescriber is to comply with their state specific prescription requirements such as e-prescribing, state specific prescription form, fax language, etc. Non-compliance of state specific requirements could result in outreach to the prescriber.

Nurse Visits
Please select an option:
☐ Specialty Pharmacy home healthcare RN visit(s) to provide education on self-administration of Remodulin and Tyvaso to include dose, titration, and side effect management
☐ Prescriber directed Specialty Pharmacy home healthcare RN visit(s) as detailed below:

 Specify any OTC or Side Effect Management measures to be taken:

E PRESCRIBER SIGNATURE: PRESCRIPTION AND STATEMENT OF MEDICAL NECESSITY

I certify that the pulmonary arterial hypertension therapy ordered above is medically necessary and that I am personally supervising the care of this patient.

PHYSICIAN SIGNATURE REQUIRED TO VALIDATE PRESCRIPTIONS.

Physician’s signature __________________________ Date __________________________
(Physician attests this is his/her legal signature. NO STAMPS.) PRESCRIPTIONS MUST BE FAXED.

Remodulin and Tyvaso are registered trademarks of United Therapeutics Corporation.
All other brands are trademarks or registered trademarks of their respective owners. The makers of these brands are not affiliated with and do not endorse United Therapeutics or its products.

Please Note: United Therapeutics cannot guarantee payment for United Therapeutics products. Patients are directed to discuss treatment options and decisions with their healthcare provider.

Please see full indication and Important Safety Information for Remodulin and Tyvaso on page 6. Please see accompanying Full Prescribing Informations for Remodulin and Tyvaso and the Tyvaso Inhalation System Instructions for Use manual and Patient Package Insert.
United Therapeutics Corporation PAH Therapy Referral Form

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

Patient Name: ____________________________

Date of Birth: ____________________________

**STEP 3 - MEDICAL INFORMATION / PATIENT EVALUATION / SUPPORTING DOCUMENTATION**

**F MEDICAL INFORMATION / PATIENT EVALUATION / SUPPORTING DOCUMENTATION**

- Patient UT PAH Product Therapy Status for the requested drug
  - Naïve/New
  - Restart
  - Transition

- Current Specialty Pharmacy
  - Accredo
  - CVS Caremark

- Patient Status
  - Outpatient
  - Inpatient

- Allergies
  - Yes
  - No

- If yes, other: ____________________________

**WHO Group**

- NYHA Functional Class
  - I
  - II
  - III
  - IV

- Weight ________ kg/lb

- Height ________

- Diabetic
  - Yes
  - No

**Diagnosis - The following ICD-10 codes do not suggest approval, coverage or reimbursement for specific uses or indications**

- ICD-10 117.0 Primary pulmonary hypertension
- ICD-10 117.2 Other chronic pulmonary heart diseases: pulmonary arterial hypertension, secondary
- Other ICD-10

**Current Signed and Dated Documents Required For Treprostinil Therapy Initiation**

- Right Heart Catheterization
- Echocardiogram
- History and Physical Including: Onset of Symptoms, PAH Clinical Signs and Symptoms: Need for Specific Drug Therapy, Course of Illness
- Treatment History (included on this page)
- Transition Statement (if applicable)
- Calcium Channel Blocker Statement (included on this page)

**G TREATMENT HISTORY AND TRANSITION STATEMENT**

- Please Indicate Treatment History

  **Medication**

<table>
<thead>
<tr>
<th>Medication</th>
<th>Current</th>
<th>Discontinued</th>
</tr>
</thead>
<tbody>
<tr>
<td>PDE-5 (specify drugs)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Epoprostenol</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flolan® (epoprostenol sodium) for Injection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Letairis® (ambrisentan) Tablets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remodulin® (treprostinil) Injection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tracleer® (bosentan) Tablets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tyvaso® (treprostinil) Inhalation Solution</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Veile® (epoprostenol) for Injection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ventavis® (iloprost) Inhalation Solution</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adempas® (riociguat) Tablets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Opsumit® (macitentan) Tablets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orenitram® (treprostinil) Extended-Release Tablets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Transition Statement
  - It is necessary for this patient (if applicable) to transition FROM __________ TO __________
  - Please provide justification for this transition.

**H CALCIUM CHANNEL BLOCKER STATEMENT**

- Please indicate below if the Patient named above was trialed on a Calcium Channel Blocker prior to the initiation of therapy and indicate the results.

  **A Calcium Channel Blocker was not trialed because**

  - Patient has depressed cardiac output
  - Patient has systemic hypotension
  - Patient has known hypersensitivity
  - Other: ____________________________

  **OR**

  **The following Calcium Channel Blocker was trialed:**

  With the following response(s):

  - Patient hypersensitive or allergic ________________
  - Adverse event
  - Patient became hemodynamically unstable
  - Other: ____________________________
  - Pulmonary arterial pressure continued to rise
  - Disease continued to progress or patient remained symptomatic ________________
  - Other: ____________________________

**I PRESCRIBER SIGNATURE**

- Prescriber Name: ____________________________
- Prescriber Signature: ____________________________
- Date: ____________________________

Remodulin and Tyvaso are registered trademarks of United Therapeutics Corporation.

All other brands are trademarks or registered trademarks of their respective owners. The makers of these brands are not affiliated with and do not endorse United Therapeutics or its products.

Please note: The responsibility to determine coverage and reimbursement parameters, and appropriate coding for particular patient and/or procedure, is the responsibility of the provider.

The information provided here is not a guarantee of coverage or reimbursement.

Please Note: United Therapeutics cannot guarantee payment for United Therapeutics products. Patients are directed to discuss treatment options and decisions with their healthcare provider.

Please see full indication and Important Safety Information for Remodulin and Tyvaso on page 6.
Please see accompanying Full Prescribing Information for Remodulin and Tyvaso and the Tyvaso Inhalation System Instructions for Use manual and Patient Package Insert.

AMC8009 CRP1709_A0391
**United Therapeutics Corporation PAH Therapy Referral Form**

**STEP 4**

**FAX COVER SHEET**

<table>
<thead>
<tr>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>To:</td>
</tr>
</tbody>
</table>
| ☐ Accredo  
Fax: 1-800-711-3526  
Phone: 1-866-344-4874 |
| From: (Name of agent of prescriber who transmitted the facsimile/Prescription) |
| 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 Note: United Therapeutics cannot guarantee payment for United Therapeutics products. Patients are directed to discuss treatment options and decisions with their healthcare provider. Please see full indication and Important Safety Information for Remodulin and Tyvaso on page 6. Please see accompanying Full Prescribing Informations for Remodulin and Tyvaso and the Tyvaso Inhalation System Instructions for Use manual and Patient Package Insert.
INDICATION FOR TYVASO

Tyvaso is a prostacyclin vasodilator indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I) 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.

INDICATION FOR REMODULIN

Remodulin is a prostacyclin vasodilator indicated for the treatment of pulmonary arterial hypertension (PAH; WHO Group I) 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 TYVASO

Warnings and Precautions

• The efficacy of Tyvaso has not been established in patients with significant underlying lung disease (such as asthma or chronic obstructive pulmonary disease). Patients with acute pulmonary infections should be carefully monitored to detect any worsening of lung disease and loss of drug effect.
• Tyvaso is a pulmonary and systemic vasodilator. In patients with low systemic arterial pressure, Tyvaso may cause symptomatic hypotension.
• Titrate slowly in patients with hepatic or renal insufficiency as exposure to treprostinil may be increased in these patients.
• Tyvaso inhibits platelet aggregation and increases the risk of bleeding, particularly in patients receiving anticoagulants.
• Co-administration of the cytochrome P450 (CYP) 2C8 enzyme inhibitor gemfibrozil may increase exposure to treprostinil. Co-administration of the CYP2C8 enzyme inhibitor rifampin may decrease exposure to treprostinil. Increased exposure is likely to increase adverse events, whereas decreased exposure is likely to reduce clinical effectiveness.

Drug Interactions/Specific Populations

• The concomitant use of Tyvaso with diuretics, antihypertensives, or other vasodilators may increase the risk of symptomatic hypotension.
• Co-administration of the CYP2C8 enzyme inhibitor gemfibrozil increases exposure to oral treprostinil. Co-administration of the CYP2C8 enzyme inducer rifampin decreases exposure to oral treprostinil. It is unclear if the safety and efficacy of treprostinil by the inhalation route are altered by inhibitors or inducers of CYP2C8.
• There are no adequate and well-controlled studies with Tyvaso in pregnant women. It is not known whether treprostinil is excreted in human milk.

Adverse Reactions

• The most common adverse events seen with Tyvaso in ≥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%).

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

IMPORTANT SAFETY INFORMATION FOR REMODULIN

Warnings and Precautions

• Chronic intravenous (IV) 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 (SC) infusion is the preferred mode of administration.
• Avoid abrupt withdrawal or sudden large reductions in dosage of Remodulin, which may result in worsening of PAH symptoms.
• Titrate slowly in patients with hepatic or renal insufficiency because such patients will likely be exposed to greater systemic concentrations relative to patients with normal hepatic or renal function.
• Remodulin dosage adjustment may be necessary if inhibitors or inducers of CYP2C8 are added or withdrawn. Co-administration of Remodulin with a CYP2C8 inhibitor increases exposure to treprostinil, or with an inducer, decreases exposure to treprostinil.

Drug Interactions/Specific Populations

• Remodulin is a potent pulmonary and systemic vasodilator. Concomitant administration of Remodulin with blood pressure lowering agents, such as diuretics, antihypertensive agents, or other vasodilators, may increase the risk of symptomatic hypotension.
• Since Remodulin inhibits platelet aggregation, there may be an increased risk of bleeding, particularly among patients receiving anticoagulants.
• Safety and effectiveness of Remodulin in pediatric patients have not been established. It is unknown if geriatric patients respond differently than younger patients. Caution should be used when selecting a dose for geriatric patients.
• There are no adequate and well-controlled studies with Remodulin in pregnant women. It is not known whether treprostinil is excreted in human milk.

Adverse Reactions

• In clinical studies of SC Remodulin infusion, the most common adverse events reported were infusion site pain and infusion site reaction (redness and swelling). These symptoms were often severe and sometimes required treatment with narcotics or discontinuation of Remodulin. The IV infusion of Remodulin has been associated with a risk of blood stream infections, arm swelling, paresthesias, hematoma, and pain. Other common adverse events (≥3% more than placebo) seen with either SC or IV Remodulin were headache, diarrhea, nausea, jaw pain, vasodilation, and edema.

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