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.)

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.
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**

<table>
<thead>
<tr>
<th>A</th>
<th>PATIENT INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: First</td>
<td>Middle</td>
</tr>
<tr>
<td>Date of Birth</td>
<td>Gender</td>
</tr>
<tr>
<td>Home Address</td>
<td></td>
</tr>
<tr>
<td>City</td>
<td>State</td>
</tr>
<tr>
<td>Shipping Address</td>
<td>(if not home address)</td>
</tr>
<tr>
<td>City</td>
<td>State</td>
</tr>
<tr>
<td>Telephone</td>
<td>Alternate Telephone</td>
</tr>
<tr>
<td>E-mail Address</td>
<td>Cell Phone</td>
</tr>
<tr>
<td>Caregiver/Family Member</td>
<td>Telephone</td>
</tr>
</tbody>
</table>

**B | INSURANCE INFORMATION**

<table>
<thead>
<tr>
<th>Pharmacy Benefits Manager:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subscriber ID #</td>
</tr>
<tr>
<td>Primary Medical Insurance:</td>
</tr>
<tr>
<td>Subscriber ID #</td>
</tr>
<tr>
<td>Secondary Medical Insurance:</td>
</tr>
<tr>
<td>Subscriber ID #</td>
</tr>
</tbody>
</table>

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 ____________________ TIN # ____________________
Address ____________________ ____________________ ____________________
City ____________________ State ____________________ Zip ____________________
Office Contact Name ____________________
Telephone ____________________ Fax ____________________
E-mail Address ____________________ Preferred Method of Communication ____________________

D PRESCRIPTION INFORMATION

☐ TYVASO® (treprostinil) 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) × _______ 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 × _______ 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.
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 ☐ Remodulin® Sterile Diluent for Injection ☐ Flolan® Sterile Diluent for Injection ☐ Sterile Water for Injection ☐ Epoprostenol Sterile Diluent for Injection

Pumps: ☐ 2 CADD-M5® 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.

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 ____________________
Dispense as Written ____________________ Substitution Allowed ____________________ 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.
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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
- Naive/New
- Restart
- Transition

Current Specialty Pharmacy
- Accredro
- CVS Caremark

Patient Status
- Outpatient
- Inpatient

Allergies
- Yes
- No

If yes: _______________________

WHO Group
- I
- II
- III
- IV

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: 127.0 Primary pulmonary hypertension
ICD-10: 127.2 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: 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)

Please complete, sign, and fax steps 1-3, along with requested clinical documentation, to your preferred specialty pharmacy using the enclosed fax cover sheet.

G TREATMENT HISTORY AND TRANSITION STATEMENT

Please indicate treatment history

Medication | Current | Discontinued
--- | --- | ---
PDE-5 (specify drugs) | | |
Epoprostenol | | |
Flolan® (epoprostenol sodium for injection) | | |
Letaris® (ambriatant) Tablets | | |
Remodulin® (treprostinil) Injection | | |
Tracleer® (bosentan) Tablets | | |
Tyvaso® (treprostinil) Inhalation Solution | | |
Veletri® (epoprostenol) for Injection | | |
Ventavis® (fliport) Inhalation Solution | | |
Adempas® (nociguan) Tablets | | |
Opsunt® (macitentan) Tablets | | |
Orenitram® (treprostinil) Extended-Release Tablets | | |
Other | | |

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 hemodynamically unstable or has a history of postural hypotension
- Patient did not meet ACCP Guidelines for Vasodilator Response
- Patient has known hypersensitivity
- Patient has documented bradycardia or second- or third-degree heart block

Other: _______________________

OR

The following Calcium Channel Blocker was trialed: _______________________

With the following response(s):

- Patient hypersensitive or allergic
- Adverse event
- Patient became hemodynamically unstable
- 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.

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.
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United Therapeutics Corporation PAH Therapy Referral Form

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

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 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

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 because 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 inducer rifampin may decrease exposure to treprostinil. Increased exposure is likely to increase adverse effects, 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).

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

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 CYP2CB are added or withdrawn. Co-administration of Remodulin with a CYP2CB 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, vasodilatation, and edema.

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