Referral Forms for TYVASO® and REMODULIN®

Tyvaso® (treprostinil) Inhalation Solution, Remodulin® (treprostinil) Injection

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.

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.

United Therapeutics CORPORATION

United Therapeutics Remodulin® (treprostinil) or Tyvaso® (treprostinil) 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	Cell Phone	Work Phone
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 front and back of the patient's insurance card(s).

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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) 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 will be used if no box is checked):

☐ Remodulin® Sterile Diluent for Injection ☐ Flolan® Sterile Diluent for Injection ☐ Epoprostenol Sterile Diluent for Injection ☐ 0.9% Sodium Chloride for Injection ☐ Sterile Water 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

CHECK HERE

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

OR

☐ **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 superv ising the care of this patient.

SIGN HERE

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.) PRESCRIPTIONS MUST BE FAXED.

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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 _____

WHO Group

NYHA Functional Class
☐ I ☐ II ☐ III ☐ IV

Weight _____ kg/lb Height _____ Diabetic ☐ Yes ☐ No

Diagnosis - The following ICD-9/ICD-10 codes do not suggest approval, coverage or reimbursement for specific uses or indications

ICD-10 I27.0 Primary pulmonary hypertension
☐ Idiopathic PAH ☐ Heritable PAH

ICD-10 I27.2 Other chronic pulmonary heart diseases: pulmonary arterial hypertension, secondary
☐ Connective tissue disease ☐ Congenital Heart Disease ☐ Portal Hypertension
☐ Drugs/Toxins induced ☐ HIV ☐ Other _____

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	Current	Discontinued
PDE-5i (specify drugs) _____		
Epoprostenol		
Flolan® (epoprostenol sodium) for Injection		
Letairis® (ambrisentan) Tablets		
Remodulin® (treprostinil) Injection		
Tracleer® (bosentan) Tablets		
Tyvaso® (treprostinil) Inhalation Solution		
Veletri® (epoprostenol) for Injection		
Ventavis® (iloprost) Inhalation Solution		
Adempas® (riociguat) Tablets		
Opsumit® (macitentan) Tablets		
Orenitram® (treprostinil) Extended-Release Tablets		
Uptravi® (selexipag) Tablets		
Other		

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
☐ Patient is hemodynamically unstable or has a history of postural hypotension
☐ Patient did not meet ACCP Guidelines for Vasodilator Response
☐ 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: _____

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.

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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: (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: