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 (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.

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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

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: FirstName Last1478851499401

DOB: 2001-03-03

STEP 1 - PATIENT INFORMATION

A PATIENT INFORMATION

Name: First	Middle	Last
FirstName		Last1478851499401
Date of Birth	**Gender**	**SSN**
2001-03-03	M	
Home Address		
address1478851504693		
City	**State**	**Zip**
city1478851504901	MA	14788
Shipping Address	**(if not home address)**	
City	**State**	**Zip**
Telephone	**Alternate Telephone**	**Best Time to Call**
478-851-5058		Any time (9am - 9pm)
E-mail Address		
FirstNameLast1478851499401@zapprx.com		
Caregiver/Family Member	**Telephone**	**Alternate Telephone**
contactName1478851506024	478-851-5063	

B INSURANCE INFORMATION

Pharmacy Benefits Manager:		
Pharmacy Benefits		
Subscriber ID #	**Group #**	**Telephone #**
Primary Medical Insurance:		**Policy Holder/Relationship**
Blue Cross Blue Shield		FirstName Last1478851499401, SELF
Subscriber ID #	**Group #**	**Telephone #**
21931	FLBCS	111-111-1111
Secondary Medical Insurance:		**Policy Holder/Relationship**
Subscriber ID #	**Group #**	**Telephone #**

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

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STEP 2 - PRESCRIBER INFORMATION AND PRESCRIPTION INFORMATION

C PRESCRIBER INFORMATION

Prescriber: First Lindsay	Last Goldman	
NPI # 6895439888	License # 666-7654-999	DEA # LM1234560
Facility Name ZappRx Practice	Group NPI # (if applicable)	TIN #
Address 192 South St		
City Boston	State MA	Zip 02111
Office Contact Name		
Telephone 617-555-5555		Fax
E-mail Address office@zapprx.com	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 11 refills **Patient dosing weight:** 57 KG 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 ng/kg/min Titrate by ___ ng/kg/min ng/kg/min every ___ days days until goal of ___ ng/kg/min 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 12/07/2016

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.

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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.

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DOB: 2001-03-03

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

Patient Status
☐ Outpatient ☐ Inpatient

Allergies
☒ Yes ☐ No If yes Iodine

WHO Group

NYHA Functional Class
☐ I ☐ II ☐ III ☐ IV

Weight 57 KG kg/lb Height 22 IN Diabetic ☐ Yes ☐ No

Diagnosis

ICD 416.0 Primary pulmonary hypertension
☐ Idiopathic PAH ☐ Heritable PAH

ICD 416.8 Other chronic pulmonary heart diseases: pulmonary arterial hypertension, secondary
☐ Connective tissue disease ☐ Congenital Heart Disease ☒ Portal Hypertension
☐ Drugs/Toxins induced ☐ HIV ☐ Other _____

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-5 (specify drug) _____		
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		
Other		

Transition Statement

It is necessary for this patient (if applicable) to transition FROM _____ TO Remodulin SC.

Please provide justification for this transition.

What is this patient's current Specialty Pharmacy?
Accredo

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: Lindsay Goldman Prescriber Signature: Date: 12/07/2016

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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: 2016-12-07

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:
ZappRx Practice

Fax:
1-800-711-3526

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:

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 ≥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.

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