Orenitram® (treprostinil) Extended-Release Tablets Referral Form

orenitram® treprostinil EXTENDED-RELEASE TABLETS

HOW TO GET STARTED

Follow these 3 steps to complete the Referral Form.

1. Obtain all the necessary documentation from your patient to fill out the Patient Information (**A and B**), and have your patient sign (**C**).

- Let your patient know that an Access Solutions and Support Team (ASSIST) representative will be calling to verify insurance coverage or to obtain additional information. It is very important he or she answers or returns the call in a timely manner, or the approval process could be delayed
- Obtain a copy of the patient's insurance cards (front and back) to submit with the Referral Form

2. Complete and sign the following forms:

- Prescriber Information (**D**)
- Medical Information/Patient Evaluation/Supporting Documentation (**E**)
- Prescription Information (**F**)
- Prescriber Signature (**G**)

3. Use the Fax Cover Sheet included in this PDF to fax the completed Referral Form and any relevant clinical documents to ASSIST. Include any comments in the section provided on the Cover Sheet.

SUPPORT FOR YOU AND YOUR PATIENTS

United Therapeutics Support

assist Access Solutions and Support Team

ASSIST is a centralized referral service that helps simplify the referral process by providing support until your patients receive their first shipment of medication.

ASSIST will

- Review Referral Forms and work with your patients to help determine the best coverage for their medication
- Reach out to your patients directly and screen for financial program eligibility*
- Refer to the Specialty Pharmacy Service best suited to provide medication to each patient based on insurance coverage
- Facilitate processing of patients' referrals and keep you informed of the progress

If you or your patients have any questions about completing the Referral Forms, financial assistance options, or program eligibility, please contact ASSIST at 1-877-864-8437.

*Patients must meet certain eligibility criteria to qualify for financial assistance.

Specialty Pharmacy Services (SPS)

SPS providers are available to answer questions from your patients or your practice regarding treatment with Orenitram. SPS nurses provide in-home medication education for patients new to therapy, as well as ongoing support throughout their treatment.

SPS providers will also work with your patient's insurance company and your office to obtain any necessary Prior Authorization. Once the insurance company approves, the SPS will be contacting your patient to review his or her financial responsibility and apply any financial assistance programs offered by United Therapeutics for which the patient qualified.

Think of SPS as a resource to help your patients get the information and support they need to understand the treatment process and manage their condition.

Orenitram is a prostacyclin vasodilator indicated for treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity.

Orenitram® (treprostinil) Extended-Release Tablets Referral Form

Please complete, sign, and fax Steps 1 and 2 to ASSIST using the accompanying Fax Cover Sheet.

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STEP 1 - PATIENT INFORMATION AND AUTHORIZATION

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

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).

C PATIENT AUTHORIZATION FOR THE USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

I authorize the use and/or disclosure of my private health information, described below, which may include "Protected Health Information" or "PHI" as defined by the Health Insurance Portability and Accountability Act of 1996 (as amended, "HIPAA"). In general terms, I understand that Protected Health Information is health information that identifies me or that could reasonably be used to identify me. I understand that this authorization is voluntary.

I authorize my health care providers, including my pharmacies and health plan(s), to disclose information about me as described below to the United Therapeutics Corporation/Lung Biotechnology Inc. Access Solutions and Support Team (ASSIST), its authorized Program Administrator, and its Financial Assistance Partners (collectively, "United Therapeutics") for the purposes stated below.

This information may include

- Information about my health benefits, health insurance coverage or other third-party payers
- Relevant information about my medical condition and history
- Financial information about me
- Contact information, such as my physical and e-mail address and telephone number
- Information about my circumstances, such as my marital, veteran, employment, disability and citizenship status
- Identifying information, such as my name, birth date and social security number

This information may be disclosed to United Therapeutics in order for it to (1) contact me to discuss its various available services; (2) determine my initial and continuing eligibility for the assistance program(s); (3) administer the assistance program(s); (4) identify sources of payment for the provision of medications to me; (5) help me find education and therapy support services; (6) review the success of the services and look at whether patients are happy with them; (7) comply with law; and (8) conduct limited commercial and sales activities.

I understand that once my health care providers, including my pharmacies and health plan(s), share information about me to United Therapeutics, the information is no longer protected by federal health privacy laws and may be given out (re-disclosed) to others by United Therapeutics if permitted by laws that apply to United Therapeutics. I know that I may refuse to sign this authorization, and that this refusal will not affect my treatment, payment for treatment, enrollment in a health plan or eligibility for benefits. However, if I do not sign it, I may not be eligible to receive the education and therapy patient support services provided by United Therapeutics.

This authorization will expire ten (10) years after the date it is signed unless a shorter period is mandated by State Law or I revoke or cancel (i.e., take back) my authorization before then. I understand that I may cancel this authorization at any time by fax at 1-800-380-5294 or by writing to United Therapeutics Corporation/Lung Biotechnology Inc., ASSIST, 1130 S. Harbor City Blvd., Suite 103, Melbourne, Florida 32901 but that the cancellation will not apply to information that my health care providers, including my pharmacies and health plan(s), have already given out based on this authorization and before they learn about my cancellation. I understand I am entitled to receive a copy of this authorization once signed.

I understand that certain of my health care providers, such as my pharmacy, may receive compensation in connection with their disclosure of my information to United Therapeutics for the purposes I allow through this authorization.

I have read this authorization and/or had its contents read to me. I have had an opportunity to ask questions about the uses and disclosures of PHI described above, and all of my questions have been answered to my satisfaction.

Patient Name (Print) _____ **Patient Signature** _____ **Date**_____

If the patient cannot sign, Patient's Representative must sign here. Patient Representative Signature _____ Date_____

Describe relationship to patient and authority to sign this form for patient:_____

Please Note: United Therapeutics cannot guarantee payment for United Therapeutics products and directs patients to discuss treatment options with their healthcare provider.

Please see the complete Important Safety Information on page 6 and click links for the Full Prescribing Information and Patient Information for Orenitram. US/ORE/MAY16/199

United Therapeutics CORPORATION

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Please complete, sign, and fax Steps 1 and 2 to ASSIST using the accompanying Fax Cover Sheet.

orenitram® treprostinil EXTENDED-RELEASE TABLETS

PATIENT NAME: _____ **DATE OF BIRTH:** _____

STEP 2 - PRESCRIBER, MEDICAL AND PRESCRIPTION INFORMATION

D PRESCRIBER INFORMATION

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

E MEDICAL INFORMATION / PATIENT EVALUATION / SUPPORTING DOCUMENTATION

Patient UT PAH Product Therapy Status for the requested drug
☐ Naive/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-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
_____

F PRESCRIPTION INFORMATION (the prescription is only valid if received by fax)

Orenitram® (treprostinil) Extended-Release Tablets

STRENGTHS:
☐ 0.125 mg (NDC 66302-300-01) ☐ 0.25 mg (NDC 66302-302-01) ☐ 1 mg (NDC 66302-310-01) ☐ 2.5 mg (NDC 66302-325-01)

DOSAGE:
☐ **BID** _____mg Titrate by _____mg every _____days until goal of _____mg BID is achieved

or

☐ **TID** _____mg Titrate by _____mg every _____days until goal of _____mg TID is achieved

PRESCRIBER TO SPECIFY ANY ALTERNATIVE OR ADDITIONAL DOSING AND TITRATION INSTRUCTIONS HERE (above fields may be left blank if preferred).

_____

_____

DIRECTIONS: Take tablets by mouth with food

DISPENSE: Quantity sufficient for up to maximum allowable dose for One (1) month's supply Refills_____12 Months OR Refills_____ Time

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

Specialty Pharmacy to contact Prescriber for adjustments to written orders specified above.

NURSE VISITS: RN visit(s) to provide education on self-administration of Orenitram to include dose, titration, and side effect management strategies as per prescriber order.

Location: ☐ Home ☐ Hospital ☐ Outpatient clinic

The prescriber is to comply with his/her state specific prescription requirements such as e-prescribing, state specific prescription form, fax language, etc. Non-compliance with state specific requirements could result in outreach to the prescriber.

G PRESCRIBER SIGNATURE: PRESCRIPTION AND STATEMENT OF MEDICAL NECESSITY

I certify that the medication ordered above is medically necessary and that I am personally supervising the care of this patient. I authorize United Therapeutics ASSIST to act on my behalf for the limited purposes of transmitting this prescription to the appropriate pharmacy designated by the Patient utilizing their benefit plan. PHYSICIAN SIGNATURE REQUIRED TO VALIDATE PRESCRIPTIONS.

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

(Physician attests this is his/her legal signature. NO STAMPS.) **PRESCRIPTIONS MUST BE FAXED.**

Please note: The responsibility to determine coverage and reimbursement parameters, and appropriate coding for a particular patient and/or procedure, is the responsibility of the provider. The information provided here, or through ASSIST, is not a guarantee of coverage or reimbursement.

Please see the complete Important Safety Information on page 6 and click links for the Full Prescribing Information and Patient Information for Orenitram.

US/ORE/MAY16/199

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PATIENT NAME: _____ **DATE OF BIRTH:** _____

OPTIONAL: SIDE EFFECT MANAGEMENT STRATEGIES

By providing your side effect management strategies below, SPS will be able to follow up with the patient regarding your directions for managing side effects. If dose increments are not tolerated, consider titrating slower. Be sure to include directions to SPS for dosing in section F of this form.

NOTE THAT ANY INFORMATION PROVIDED BELOW IS NOT A PRESCRIPTION. RATHER, IF ADDITIONAL PRESCRIPTIONS ARE INTENDED, THEY SHOULD BE PROVIDED TO THE PATIENT SEPARATELY.

Headache

☐ Acetaminophen ☐ Gabapentin **(separate Rx required)** ☐ NSAIDs **(separate Rx may be required)** ☐ Opioids **(separate Rx required)** ☐ Tramadol **(separate Rx required)**

☐ Other _____

Diarrhea

☐ Add fiber to diet ☐ Loperamide ☐ Diphenoxylate/Atropine **(separate Rx required)** ☐ Dicyclomine **(separate Rx required)**

☐ Other _____

Nausea

☐ Metoclopramide **(separate Rx required)** ☐ Ondansetron **(separate Rx required)** ☐ PPIs **(separate Rx may be required)** ☐ Prochlorperazine **(separate Rx required)**

☐ Promethazine **(separate Rx required)**

☐ Other _____

ADDITIONAL INSTRUCTIONS

Provide any additional instructions for SPS on preferred communication or managing other side effects (eg, flushing, pain in jaw, pain in extremity, hypokalemia, abdominal discomfort).

_____

_____

_____

_____

_____

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FAX COVER SHEET

Date:

To: assist Access Solutions and Support Team

Fax Number 1-800-380-5294
Phone Number 1-877-864-8437

From:

Facility Name:

Fax:

Included in this fax:

Completed UT PAH Therapy Referral Form including

- ☐ Step 1 - Patient Information and Authorization
- ☐ Step 2 - Prescriber, Medical, and Prescription Information
- ☐ Copy of Insurance Card(s)
- ☐ OPTIONAL: Side Effect Management Strategies

Number of Pages:

Comments:

Prescriber's Preferred Specialty Pharmacy - To be used if patient's payer does not mandate a particular Specialty Pharmacy be used:

☐ Accredo ☐ CVS Caremark

ORENITRAM® (treprostinil) Extended-Release Tablets

INDICATION

Orenitram is a prostacyclin vasodilator indicated for treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity.

The study that established effectiveness included predominately patients with WHO functional class II-III symptoms and etiologies of idiopathic or heritable PAH (75%) or PAH associated with connective tissue disease (19%). When used as the sole vasodilator, the effect of Orenitram on exercise is about 10% of the deficit, and the effect, if any, on a background of another vasodilator is probably less than this.

IMPORTANT SAFETY INFORMATION FOR ORENITRAM

CONTRAINDICATIONS

- Orenitram is contraindicated in patients with severe hepatic impairment (Child Pugh Class C)

WARNINGS AND PRECAUTIONS

- Abrupt discontinuation or sudden large reductions in dosage of Orenitram may result in worsening of PAH symptoms
- Orenitram inhibits platelet aggregation and increases the risk of bleeding
- The Orenitram tablet shell does not dissolve. In patients with diverticulosis, Orenitram tablets can lodge in a diverticulum

DRUG INTERACTIONS / SPECIFIC POPULATIONS

- Concomitant administration of Orenitram with diuretics, antihypertensive agents, or other vasodilators increases the risk of symptomatic hypotension
- Orenitram inhibits platelet aggregation; there is an increased risk of bleeding, particularly among patients receiving anticoagulants
- Co-administration of Orenitram and the CYP2C8 enzyme inhibitor gemfibrozil increases exposure to treprostinil; therefore, Orenitram dosage reduction may be necessary in these patients
- Pregnancy Category C. Animal reproductive studies with Orenitram have shown an adverse effect on the fetus. There are no adequate and well-controlled studies in humans
- It is not known whether treprostinil is excreted in human milk or absorbed systemically after ingestion. Because many drugs are excreted in human milk, choose Orenitram or breastfeeding
- Safety and effectiveness in patients under 18 years of age have not been established
- There is a marked increase in the systemic exposure to treprostinil in hepatically impaired patients

ADVERSE REACTIONS

- In the 12-week placebo-controlled monotherapy study, adverse reactions that occurred at rates at least 5% higher on Orenitram than on placebo included headache, diarrhea, nausea, flushing, pain in jaw, pain in extremity, hypokalemia, and abdominal discomfort

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Please see the Full Prescribing Information and Patient Information for Orenitram.

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