RareGen

Treprostinil™ INJECTION Referral Form

SANDOZ A Novartis Division

Treprostinil Injection is available only through select specialty pharmacy (SP) providers, listed on page 7.

Please complete each section of the referral form in the 4 steps noted.

1. Complete Sections A and B (Patient Information). Let your patient know that an SP will be calling to process their prescription and that it is important to answer or return any messages.
2. Complete and sign Sections C through G, the Prescription, Statement of Medical Necessity, and Nursing Orders.
3. Complete Sections H through K, signing on Page 6, attesting to the Medical Information, Patient Evaluation, and Supporting Documentation.
4. Use the fax cover sheet (page 7) to fax the referral form and signed supporting documents (including right heart catheterization, echocardiogram results, and history and physical) to your preferred SP.

Information regarding the Centers for Medicare and Medicaid Services (CMS) established and expected coverage criteria for prostacyclin is included for your convenience.

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 25 mm Hg at rest or greater than 30 mm 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.

Medicare coverage criteria provided for informational purposes only. Please check with the payer to verify billing requirements. RareGen and Sandoz do not make any representation or guarantees concerning reimbursement or coverage for any service or item.

Please complete, sign, and fax patient and provider information and prescription, along with requested clinical documentation, to the SP 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

Phone | Alternate phone | Best time to call

Email address | Cell phone | Work phone

Caregiver/Family member | Phone | Alternate phone

B: INSURANCE INFORMATION

Pharmacy Benefits Manager

Subscriber ID # | Group # | Phone

Primary medical insurance | Policyholder/Relationship

Subscriber ID # | Group # | Phone

Secondary medical insurance | Policyholder/Relationship

Subscriber ID # | Group # | Phone

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

Name: First | Last | NPI # | State license #

Institution/Office name | TIN # | Preferred method of communication

Address | City | State | Zip

Contact name | Phone | Fax | Email address

D: PRESCRIPTION INFORMATION

Sandoz® 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)

Diluent (0.9% Sodium Chloride will be used if no box is checked)

- ◯ 0.9% Sodium Chloride for Injection
- ◯ Sandoz® Sterile Diluent for Treprostinil Injection
- ◯ Sterile Water for Injection
- ◯ Epoprostenol Sterile Diluent for Injection

Infusion route and pumps

- ◯ Subcutaneous continuous infusion with 2 CADD-MS® 3 pumps
- ◯ Intravenous continuous infusion with
  - ◯ 2 CADD-MS® 3 pumps
  - ◯ 2 CADD-Legacy® pumps

Dosing and titration instructions

To specify initial dosing and titration instructions, fill in the blanks OR use the space below.

Patient dosing weight: _____ kg Initiation dosage: _____ ng/kg/min

Titrate by _____ ng/kg/min every _____ days until goal of _____ ng/kg/min is achieved.

Indicate any alternative or additional titration instructions here:

Dispense 1 month of drug, needles, syringes, ancillary supplies, and medical equipment necessary to administer medication
x _____ refills.

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.

PRESCRIBER SIGNATURE REQUIRED TO VALIDATE PRESCRIPTIONS.

Dispense as written Substitution permitted

Prescriber signature | Prescriber signature | Date

Prescriber attests that this is his/her legal signature.

NO STAMPS. PRESCRIPTIONS MUST BE FAXED.

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Patient name

Date of birth

F: NURSING ORDERS

Nurse visits

Please select an option:

- ◯ SP home healthcare RN visit(s) to provide assessment and education on self-administration of Treprostinil Injection to include dose, titration, and side effect management.

OR

- ◯ Prescriber-directed SP home healthcare RN visit(s) as detailed below:

Location

- ◯ Home
- ◯ Outpatient clinic
- ◯ Hospital

Specify any over-the-counter or side effect management measures to be taken.

Site care

- ◯ Dressing change every _____ days
- ◯ Per standard of care

The prescriber is to comply with their state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Noncompliance of state-specific requirements could result in outreach to the prescriber.

G: PRESCRIBER SIGNATURE

Prescriber name (please print)

PRESCRIBER SIGNATURE REQUIRED TO VALIDATE PRESCRIPTIONS.

Prescriber signature

Date

Prescriber attests that this is his/her legal signature.

NO STAMPS. PRESCRIPTIONS MUST BE FAXED.

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Patient name | Date of birth

STEP 3: MEDICAL INFORMATION/PATIENT EVALUATION/SUPPORTING DOCUMENTATION

H: MEDICAL INFORMATION/PATIENT EVALUATION/ SUPPORTING DOCUMENTATION

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
- ◯ Other ICD-10:
- ◯ Heritable PAH

ICD-10 I27.2 Other secondary pulmonary hypertension
- ☐ Connective tissue disease
- ☐ Drugs/Toxins induced
- ☐ Congenital heart disease
- ☐ HIV
- ☐ Portal hypertension
- ☐ Other

Patient status
- ◯ Outpatient
- ◯ Inpatient

Patient status for Treprostinil Injection
- ◯ Naive/New
- ◯ Restart
- ◯ Transition

WHO Group
◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5

NYHA Functional Class
◯ I ◯ II ◯ III ◯ IV

Weight _____ kg

Height _____ ◯ cm ◯ in

Diabetic Yes ◯ No ◯

Allergies
- ◯ No Known Drug Allergies (NKDA)
- ◯ Yes (specify)

Current medications (list all)

Current signed and dated documents required for Treprostinil Injection Initiation
- ☐ Right heart catheterization
- ☐ Echocardiogram
- ☐ 6-minute walk test results
- ☐ History and physical, including onset of symptoms, PAH clinical signs and symptoms, need for specific drug therapy, and course of illness
- ☐ Treatment history (included on this page)
- ☐ Transition statement (if applicable)
- ☐ Calcium channel blocker statement (included on page 6)

I: TREATMENT HISTORY AND TRANSITION STATEMENT

Please indicate treatment history

PDE-5i (specify drugs) _____
◯ Current ◯ Discontinued

Adempas® (riociguat) Tablets
◯ Current ◯ Discontinued

Epoprostenol sodium for injection
◯ Current ◯ Discontinued

Flolan® (epoprostenol sodium) for Injection
◯ Current ◯ Discontinued

Letairis® (ambrisentan) Tablets
◯ Current ◯ Discontinued

Remodulin® (treprostinil) Injection
◯ Current ◯ Discontinued

Tracleer® (bosentan) Tablets
◯ Current ◯ Discontinued

Tyvaso® (Treprostinil) Inhalation solution
◯ Current ◯ Discontinued

Opsumit® (macitentan) Tablets
◯ Current ◯ Discontinued

Orenitram® (treprostinil) Extended-Release Tablets
◯ Current ◯ Discontinued

Uptravi® (selexipag) Tablets
◯ Current ◯ Discontinued

Veletri® (epoprostenol) for Injection
◯ Current ◯ Discontinued

Ventavis® (iloprost) Inhalation Solution
◯ Current ◯ Discontinued

Other _____
◯ Current ◯ Discontinued

Please see Important Safety Information on page 8 and accompanying full Prescribing Information, also available at TrepInjection.com.

(continued)

Please complete, sign, and fax patient and provider information and prescription, along with requested clinical documentation, to the SP using the enclosed Fax Cover Sheet.

Patient name

Date of birth

I: TREATMENT HISTORY AND TRANSITION STATEMENT (continued)

Transition statement: It is necessary for this patient (if applicable) to transition FROM _____ TO _____

Please provide justification for this transition.

J: CALCIUM CHANNEL BLOCKER STATEMENT

Please indicate whether the patient named above was trialed on a calcium channel blocker prior to the initiation of therapy and provide the results.

A calcium channel blocker was not trialed because

- ☐ Patient has depressed cardiac input
- ☐ Patient has systematic 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 brachycardia or second- or third-degree heartblock
- ☐ 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 _____

K: PRESCRIBER SIGNATURE

Prescriber name (please print)

Prescriber signature

Date

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 is not a guarantee of coverage or reimbursement.

Please complete, sign, and fax patient and provider information and prescription, along with requested clinical documentation, to the SP using the enclosed Fax Cover Sheet.

INDICATE THE SPECIALTY PHARMACY AND FAX THE COMPLETED REFERRAL FORM AND DOCUMENTATION TO THE SPECIALTY PHARMACY.

STEP 4: FAX COVER SHEET

Date _____ Number of pages _____

To ☐ **Accredo Health Group, Inc.**
Fax 1-800-711-3526
Phone 1-866-344-4874

☐ **CVS Specialty™**
Fax 1-877-943-1000
Phone 1-877-242-2738

From _____

Facility name _____

Phone _____

Fax _____

Comments _____

Referral Form Checklist:

- ☐ Completed Treprostinil Injection Referral Form, including
  - ☐ Step 1: Patient/Insurance Information
  - ☐ Step 2: Prescriber/Prescription Information
  - ☐ Step 3: Medical Information/Patient Evaluation
  - ☐ Step 4: Completed Fax Cover Sheet
- ☐ Signed and dated documents
  - ☐ Right heart catheterization results
  - ☐ Echocardiogram results
  - ☐ 6-minute walk test results
  - ☐ History and physical (including onset of symptoms, PAH clinical signs and symptoms, course of illness)
  - ☐ Need for specific drug therapy

INDICATION

Treprostinil Injection is a prostacyclin vasodilator indicated for

- Treatment of pulmonary arterial hypertension (PAH), World Health Organization (WHO) Group 1, to diminish symptoms associated with exercise. Studies establishing effectiveness included patients with New York Heart Association (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%).
- Patients who require transition from epoprostenol to reduce the rate of clinical deterioration. The risks and benefits of each drug should be carefully considered prior to transition.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

- Chronic intravenous (IV) infusions delivered using an external infusion pump with an indwelling central venous catheter are associated with the risk of bloodstream infections (BSIs) and sepsis, which may be fatal. Therefore, continuous subcutaneous (SC) infusion is the preferred mode of administration.
- Do not abruptly lower the dose or withdraw dosing.
- Treprostinil Injection may cause symptomatic hypotension.
- 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.
- Treprostinil Injection inhibits platelet aggregation and increases the risk of bleeding.

ADVERSE REACTIONS

During clinical trials with SC infusion of treprostinil, infusion site pain and infusion site reaction (eg, erythema, induration, or rash) were the most common adverse events and occurred in majority of those treated with treprostinil. Infusion site reactions were sometimes severe and led to discontinuation of treatment. Rash and hypotension (14% and 4%, respectively) were also commonly reported with SC infusion of treprostinil. Other common adverse events (≥9% of patients in the treprostinil arm) included headache, diarrhea, jaw pain, edema, vasodilatation, and nausea, and these are generally considered to be related to the pharmacologic effects of treprostinil, whether administered subcutaneously or intravenously. The adverse reactions reported with treprostinil IV included bloodstream infections, arm swelling, paresthesias, hematoma, and pain.

DRUG INTERACTIONS

Treprostinil Injection dosage adjustment may be necessary if inhibitors or inducers of CYP2C8 are added or withdrawn.

USE IN SPECIFIC POPULATIONS

- Safety and effectiveness of Treprostinil Injection 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 Treprostinil Injection in pregnant women.
- It is not known whether Treprostinil Injection is excreted in human milk.

Please see accompanying full Prescribing Information, also available at TrepInjection.com.