Treprostinil Injection is available through the Specialty Pharmacy (SP) provider listed on page 7.

Complete all sections on this enrollment form. Let your patient know that the Specialty Pharmacy will be calling to process their prescription and that it is important to answer or return any messages.

Sign the Statement of Medical Necessity on page 3 for the Prescription.

Sign at the bottom of pages 4 and 5.

Fax the enrollment form and signed supporting documents (use Fax Cover Sheet provided on page 7) to the 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 the above conditions are present, the following criteria must be met:

- ☐ The pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition; and
- ☐ The mean pulmonary artery pressure is greater than 25 mm Hg at rest or greater than 30 mm Hg with exertion; and
- ☐ The patient has significant symptoms from the pulmonary hypertension (i.e., severe dyspnea on exertion, and either fatigability, angina, or syncope); and
- ☐ 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. Liquidia and Sandoz do not make any representation or guarantees concerning reimbursement or coverage for any service or item.

PATIENT INFORMATION

Patient Name (first, MI, last)

Date of Birth (mm/dd/yyyy)

Gender: _____

Address

Email

City | State | Zip

Phone ☐ Home ☐ Cell ☐ Other

Alternate Phone ☐ Home ☐ Cell ☐ Other

SHIPPING ADDRESS (if different from above):

Address

City | State | Zip

Preferred contact: ○ Phone ○ Email

Best time to call: ○ Morning ○ Afternoon ○ Night

OK to leave message with Caregiver? ○ Yes ○ No

CAREGIVER

Caregiver Name

Caregiver Email

Caregiver Phone ☐ Home ☐ Cell ☐ Other

Alternate Phone ☐ Home ☐ Cell ☐ Other

Preferred contact: ○ Phone ○ Email

Best time to call: ○ Morning ○ Afternoon ○ Night

INSURANCE INFORMATION

Pharmacy Benefits Manager

Please include copies of the front and back of all patient's medical and prescription insurance cards.

PRIMARY Medical Insurance Carrier

Policyholder Name

Policy ID Number | Group No (if applicable)

Medical Insurance Phone | Relationship to Policyholder

SECONDARY Medical Insurance Carrier

Policyholder Name

Policy ID Number | Group No (if applicable)

Medical Insurance Phone | Relationship to Policyholder

Patient Name (first, MI, last) | Date of Birth

PRESCRIBER INFORMATION

Prescriber Name (first, MI, last) | NPI # | State License # | Tax ID #

Office/Clinic/Institution Name | Office Contact Name

Address | Office Contact Email

City | State | Zip | Phone | Fax

Preferred method of communication: ◯ Phone ◯ Email ◯ Fax

PRESCRIPTION INFORMATION

Sandoz® Treprostinil Injection vial concentration

NDC(s) prescribed:

- ◯ 1 mg/mL (20-mL vial) (00781-3420-80)
- ◯ 2.5 mg/mL (20-mL vial) (00781-3425-80)
- ◯ 5 mg/mL (20-mL vial) (00781-3427-80)
- ◯ 10 mg/mL (20-mL vial) (00781-3430-80)

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 appropriate ambulatory infusion pump.
- ◯ Intravenous continuous infusion with appropriate ambulatory infusion pump.

Dosing and titration instructions

Patient dosing weight: ☐ kg ☐ lb

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. _____ refills

STATEMENT OF MEDICAL NECESSITY

Prescriber Signature is Required to Validate Prescriptions.

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 Full Name (print)

Dispense As Written (DAW) / Brand Medically Necessary / No Substitution / May Not Substitute / Do Not Substitute

Substitution Permitted / May Substitute / Product Selection Permitted

SIGN HERE

Prescriber Signature* | Prescriber Signature* | Date

CA, MA, NC & PR: Interchange is mandated unless Prescriber writes the words "No Substitution": _____

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.

*Prescriber attests that this is his/her legal signature.

No Stamps. Prescriptions Must Be Faxed.

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.

Patient Name (first, MI, last)	Date of Birth	Prescriber Name (first, MI, last)	NPI #

NURSING ORDERS

NURSE VISITS (select **one** option)

- ○ SP home healthcare RN visit(s) to provide assessment and education on self-administration of Treprostinil 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 ○ Virtual

SITE CARE

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

CALCIUM CHANNEL BLOCKER STATEMENT

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: _____

The following calcium channel blocker was trialed:

The patient had 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: _____

PRESCRIBER SIGNATURE

SIGN HERE

Prescriber Full Name (print)	Prescriber Signature	Date

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.

Patient Name (first, MI, last) | Date of Birth | Prescriber Name (first, MI, last) | NPI #

PATIENT EVALUATION

Patient Status:
- ○ Outpatient
- ○ Inpatient

Treprostinil Injection Status:
- ○ Naïve / New
- ○ Restart
- ○ Transition

Date Taken

Weight ☐ kg ☐ lb

Height ☐ cm ☐ in

Allergies:
- ○ No known drug allergies (NKDA)
- ○ Yes (specify):_____

Diabetic?
- ○ Yes
- ○ No

WHO Group: _____

NYHA Functional Class: ○ I ○ II ○ III ○ IV

Current Medications (list all):

MEDICAL INFORMATION

REQUIRED: Please select one of the following ICD-10 codes, or Other ICD-10 code, as applicable. The following ICD-10 codes do not suggest approval, coverage, or reimbursement for specific uses or indications.

DIAGNOSIS

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

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

○ **Other ICD-10:** Code | Description

TREATMENT HISTORY

Please indicate treatment history

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

TRANSITION STATEMENT (if applicable)

It is necessary for this patient to transition

from:

to:

Please provide justification for this transition.

PRESCRIBER SIGNATURE

SIGN HERE

Prescriber Full Name (print) | Prescriber Signature | Date

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.

INDICATION

Treprostinil injection is a prostacyclin mimetic 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 insufficiency because such patients will likely be exposed to greater systemic concentrations relative to patients with normal hepatic 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 (e.g., 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 (≥3% more than placebo) 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, paresthesia, 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 for additional safety information, also available by *clicking here*.

Treprostinil INJECTION™

FAX

Using this cover sheet, fax all pages of the enrollment form, along with the requested clinical documentation, to the Specialty Pharmacy below.

Date

TO

Accredo Health Group, Inc.

FAX 1-800-711-3526

Phone: 1-866-344-4874

FROM

(Name of agent of prescriber transmitting this fax/prescription)

Phone

Facility Name

Fax

RE

Patient Name

Date of Birth

DOCUMENTATION CHECKLIST

Indicate all current, signed and dated documents enclosed with this fax.

- ○ Fully completed Treprostinil Enrollment Form, including:
  - – Patient/Insurance Information
  - – Prescriber/Prescription Information
  - – Medical Information/Patient Evaluation
- ○ Copy of front and back of Patient's Insurance card(s)
- ○ Right heart catheterization
- ○ Echocardiogram
- ○ 6-minute walk test results
- ○ History and physical, including onset of symptoms, PAH clinical signs and symptoms and course of illness
- ○ Need for specific drug therapy

Comments:

Number of Pages (including this cover sheet)

SANDOZ

Liquidia™