Dear Prescriber,

**Thank you for your interest in the Premix for Treprostinil Injection program.**
We are pleased to be able to offer this program to your patients. The program is not meant to completely replace the need to self-mix but is intended to support patients.

**Not all patients are candidates for the premix program.** Please carefully read and evaluate the program requirements and eligibility criteria before you complete the enrollment form.

To be eligible, the patient (or the patient's mixing partner) must:

- ☐ Have self-mixed intravenous prostacyclin for at least 3 months before entering the program
- ☐ Have been on a stable dose for at least 1 month before entering the program and have no immediate plans to titrate
- ☐ Live within a 2-hour drive of an emergency room or pulmonary arterial hypertension (PAH) center
- ☐ Have a working refrigerator to store premixed cassettes
- ☐ Be reliably available for contact: answer phone calls, maintain functioning voicemail, return messages in a timely manner, and provide at least one alternative contact number
- ☐ Understand that weekly shipments require a signature on delivery
- ☐ Be willing to have home nursing visits every 3 to 6 months to assess self-mixing competence

Please note that this is not a comprehensive list of the inclusion and exclusion criteria. Please contact the specialty pharmacy listed on page 6 if you have any questions about the program.

In an emergency, the patient or mixing partner should be prepared to self-mix from a backup supply and should notify his or her dispensing specialty pharmacy immediately.

To enroll your patient in the Premix for Treprostinil Injection program, please complete the enrollment form and fax it to the specialty pharmacy.

Sincerely,
The Treprostinil Injection Team

## 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.

Treprostinil INJECTION™

# Premix Program Enrollment Form



## 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 Phone ☐ Home ☐ Cell ☐ Other

Alternate Phone ☐ Home ☐ Cell ☐ Other

Caregiver Email

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

**SECONDARY** Medical Insurance Carrier

Policyholder Name

Policyholder Name

Policy ID Number | Group No (if applicable)

Policy ID Number | Group No (if applicable)

Medical Insurance Phone | Relationship to Policyholder

Medical Insurance Phone | Relationship to Policyholder

Treprostinil INJECTION™

# Premix Program Enrollment Form



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 | Office Contact 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 | **Date weight taken:** | **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**

SIGN HERE

Prescriber Signature*

**Substitution Permitted / May Substitute / Product Selection Permitted**

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.*

Treprostinil INJECTION™

# Premix Program Enrollment Form



| 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 _____

## 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

## 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 Premix 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 Premix 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)