

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.

PATIENT INFORMATION

Patient Name (first, MI, last)			Date of Birth (mm/dd/yyyy)	Gender: _____		
Address			Email	Home Cell Other	Home Cell Other	
City	State	Zip	Phone	Alternate Phone		
SHIPPING ADDRESS (if different from above):			Preferred contact: <input type="radio"/> Phone <input type="radio"/> Email			
Address			Best time to call: <input type="radio"/> Morning <input type="radio"/> Afternoon <input type="radio"/> Night			
City			OK to leave message with Caregiver? <input type="radio"/> Yes <input type="radio"/> No			
State						
Zip						

CAREGIVER

Caregiver Name			Caregiver Phone	Home Cell Other	Home Cell Other	
Caregiver Email			Alternate Phone			
			Preferred contact: <input type="radio"/> Phone <input type="radio"/> Email			
			Best time to call: <input type="radio"/> Morning <input type="radio"/> Afternoon <input type="radio"/> 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	

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: _____ Date weight taken: _____ Initiation dosage: _____
kg lb 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.

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

Prescriber Full Name (print)

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 #
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PATIENT EVALUATION

Patient Status:
 Outpatient
 Inpatient

Treprostinil Injection Status:
 Naive / New
 Restart
 Transition

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

Diabetic?
 Yes
 No

Current Medications (list all):

WHO Group: _____

NYHA Functional Class: I II III IV

Date Taken _____ kg
 _____ lb
 Weight _____ cm
 _____ in
 Height _____

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.

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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

Date

Prescriber Full Name (print) _____

Prescriber Signature _____

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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

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- Do not abruptly lower the dose or withdraw dosing.
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- 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 ($\geq 3\%$ 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](#).

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.

- | | |
|---|---|
| <input type="checkbox"/> Fully completed Treprostinil Premix Enrollment Form, including: <ul style="list-style-type: none">- Patient/Insurance Information- Prescriber/Prescription Information- Medical Information/Patient Evaluation | <input type="checkbox"/> Echocardiogram |
| <input type="checkbox"/> Copy of front and back of Patient's Insurance card(s) | <input type="checkbox"/> 6-minute walk test results |
| <input type="checkbox"/> Right heart catheterization | <input type="checkbox"/> History and physical, including onset of symptoms, PAH clinical signs and symptoms and course of illness |
| | <input type="checkbox"/> Need for specific drug therapy |

Comments:

Number of Pages (including this cover sheet)