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 1 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 one of the specialty pharmacies listed on page 4 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 your selected specialty pharmacy.

SELECTED 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.

Please see complete Important Safety Information on page 5 and accompanying full Prescribing Information, also available at TrepInjection.com.

Sincerely,

The Treprostinil Injection Team

Treprostinil™ INJECTION

Premix for Treprostinil Injection Program Enrollment Form

Please complete, sign, and fax patient and provider information and prescription, using the enclosed fax cover sheet, to one of the specialty pharmacies listed on page 4.

PATIENT INFORMATION

First name | Middle name | Last name

Date of birth | Gender | Last 4 digits of SSN

Home address

City | State | Zip

Shipping address (if not home address)

City | State | Zip

Phone | Cell | Work phone

Email | Best time to call

Caregiver/Family member | Phone | Email

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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Treprostinil™ INJECTION

Premix for Treprostinil Injection Program Enrollment Form

Please complete, sign, and fax patient and provider information and prescription, using the enclosed fax cover sheet, to one of the specialty pharmacies listed on page 4.

PRESCRIBER INFORMATION

First name _____ Last name _____ NPI # _____

State license # _____ Institution/Office name _____

TIN # _____ Preferred method of communication ◯ Phone ◯ Email ◯ Fax

Address _____

City _____ State _____ Zip _____

Contact name _____ Phone _____ Fax _____ Email _____

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

◯ Sandoz® Sterile Diluent for Treprostinil Injection (default diluent if no selection is made)
◯ Epoprostenol Sterile Diluent for Injection

Infusion route and pumps

◯ Intravenous continuous infusion with 2 CADD-Legacy® pumps

Dosing instructions

- Dispense 1 week of Treprostinil Injection premixed cassettes containing prescribed concentration (compounded by specialty pharmacy), ancillary supplies, and medical equipment necessary to administer medication. Cassette to be changed every 48 hours or as directed.
- Dispense 1 week of Treprostinil Injection for emergency supply, and quantity sufficient of prescribed diluent, syringes, needles, and any other necessary supplies to mix and administer for emergency supply.
- Dispense teaching kits (diluent, syringes, needles, and any other necessary supplies to mix and assess patient's mixing skills). Quantity: up to 4 kits per quarter and refill x1 year.
- Dispense 1 month of drug, needles, syringes, ancillary supplies, and medical equipment necessary to administer medication.

Current dosage _____ ng/kg/min Concentration _____ mg/mL Pump rate _____ mL/24hrs
Patient dosing weight _____ kg Refills: 1 year or _____ refills

Diagnosis

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

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

Other ICD-10
_____
_____
_____

ICD-10 codes do not suggest approval, coverage, or reimbursement.

Allergies

◯ No known drug allergies (NKDA)
◯ Yes (specify) _____

NURSING ORDERS

Nurse visits

Specialty pharmacy home healthcare nurse visit(s) to provide assessment and education on self-administration of Treprostinil Injection to include dose, titration, and the transition to and use of premixed cassettes (using teaching kits) every ◯ 3 months ◯ 6 months

Site care

◯ Dressing change every _____ days ◯ Per standard of care

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 _____ Date _____

Dispense as Written **Substitution Allowed**

PRESCRIBER SIGNATURE REQUIRED TO VALIDATE PRESCRIPTIONS.

Prescriber attests that 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 is not a guarantee of coverage or reimbursement. The prescriber is to comply with his/her state specific prescription requirements such as e-prescribing, state specific prescription form, fax language, etc. Noncompliance with state specific requirements could result in outreach to the prescriber.

Treprostinil™ INJECTION

Premix for Treprostinil Injection Program Enrollment Form

FAX COVER SHEET

Please select a specialty pharmacy and fax this sheet and the completed enrollment form to your selected specialty pharmacy.

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 _____

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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.
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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.

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