VELETRI® (EPOPROSTENOL) FOR INJECTION

Fax cover sheet

To: _____

Fax number: _____

Date/time: _____

From: _____

Fax number: _____

Number of pages (including this one): _____

Comments:

REQUIRED DOCUMENTATION

- ☐ 1) Complete patient enrollment
- ☐ 2) Document PAH diagnosis
- ☐ 3) Determine PAH clinical status
- ☐ 4) Complete CCB trial
- ☐ 5) Provide required documentation: right heart catheterization, echocardiogram results, and history and physical notes

Reminder: Please include photocopy of both sides of patient insurance card.

Fax completed forms to your patient's specialty pharmacy:

Accredo Specialty Pharmacy
Fax: 1-800-711-3526
Phone: 1-866-344-4874

CVS/specialty
Fax: 1-877-943-1000
Phone: 1-877-242-2738

Submission of the VELETRI enrollment form is not a guarantee of patient approval. Additional testing and clinical information may be requested in some cases, including:

- Antinuclear antibody results
- Pulmonary function tests
- V/Q perfusion scan
- Chest CT

VELETRI® (EPOPROSTENOL) FOR INJECTION FORM

1 Complete patient prescription and enrollment form

Fax to your patient's specialty pharmacy:

Accredo Specialty Pharmacy **Fax:** 1-800-711-3526

CVS/specialty **Fax:** 1-877-943-1000

Referral date: _____ ☐ **New patient** ☐ **Current**

Prescription

VELETRI–continuous IV infusion administered via ambulatory pump

Dosing weight: _____ ☐lbs ☐kg Height: _____ ☐in ☐cm

☐NKDA ☐Known drug allergies:_____

Diabetic: ☐Yes ☐No Initial dose: _____ ng per kg per min

Titrate by ____ng per kg per min every _____days until goal of _____ng per kg per min is reached.

Discharge dose: _____ ng per kg per min Concentration: _____ ng/mL

Dispense two (2) ambulatory infusion pumps appropriate for VELETRI if the patient does not currently have appropriate ambulatory infusion pumps.

Refills: 1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐ 8☐ 9☐ 10☐ 11☐

Patients should keep at least a 7-day backup supply of medication and supplies at all times.

Ship-to directions: ☐Physician's office ☐Patient's home ☐Hospital

Address (no PO Box):

City:

State: ZIP:

Ship Attn:

Quantity: Dispense 1 month of drug and supplies, including pump(s)

Choose one: ☐Sterile water for injection ☐Sodium chloride 0.9% injection

I certify that I am prescribing VELETRI for this patient as a medically appropriate treatment.

Prescriber's Signature _____

Prescriber's printed name: _____ **Date:** _____

(Physician attests this is his/her legal signature. **NO STAMPS**)

This prescription is valid only if transmitted by means of a facsimile machine.

Choose one: ☐Urgent: Patient in hospital ☐Emergent: Admission after 48-72 hours ☐Standard: Admission within 4+ days

Start-of-care date (REQUIRED): _____ **Tentative discharge date:** _____

Nursing services requested to be provided by the specialty pharmacy staff (Check all that apply):

☐In-hospital training ☐Postdischarge visit/in-home follow-up ☐Home assessment/training prior to initiation of therapy ☐Dispense teaching kits ☐DECLINE: All referenced nursing

If nursing services will be required for therapy administration, the home health nurse will call for additional orders per state regulations.

Discharge planner/coordinator name _____

Date: _____ Time: _____ Fax #: _____ Office/page phone #: _____

REQUIRED: PLEASE PROVIDE COPIES OF PATIENT'S CURRENT MEDICAL INSURANCE AND PRESCRIPTION CARDS.

Physician Information

All fields must be completed to expedite prescription fulfillment.

Name:		DEA # (optional):	NPI #:
Name of facility:		MD specialty:	UPIN #:
Contact name and phone #:		State license #:	Phone #:
Address: Suite:	City:	State: ZIP:	Fax #:
Referral source: (check one) ☐Prescribing physician ☐Patient self-referral ☐No referring MD		PCP (if applicable/different from prescribing MD): _____ Phone #: _____	

Patient Information

Name:			DOB:
Address:	City:	State:	ZIP:
Preferred language, if not English:		Phone #:	Sex: ☐Male ☐Female
Parent/guardian (if applicable):			Alternate phone #:
May we contact the patient regarding insurance benefits and product delivery? ☐Yes ☐No			

Insurance Information

Primary insurance company:			Phone #:
Policy holder name:			DOB:
Relationship to patient:		ID #:	Group/policy #:
Secondary insurance company:			Phone #:
Policy holder name:			DOB:
Relationship to patient:		ID #:	Group/policy #:
Drug card company:	Phone #:	ID #:	Group/policy #:
	Rx BIN #:	PCN #:	Person code:

2 Document diagnosis

Fax to your patient's specialty pharmacy:

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Fax: 1-800-711-3526

CVS/specialty
Fax: 1-877-943-1000

Patient: _____ DOB: _____

Physician: _____

It is the responsibility of the Prescriber to complete this form with information that most accurately and completely describes the condition of the patient, regardless of the potential impact on insurance coverage or reimbursement. Actelion makes no representation that the diagnosis information printed on this form is accurate or complete or that it will support insurance coverage or reimbursement.

Please select the diagnosis information that most accurately and completely describes the signs, symptoms, and condition of the patient:

DIAGNOSIS—THE FOLLOWING ICD 10 CODES DO NOT SUGGEST APPROVAL, COVERAGE, OR REIMBURSEMENT FOR SPECIFIC USES OR INDICATIONS. (CHECK THE BOX FOR THE APPROPRIATE CODE BELOW.)

- ☐ ICD-10 I27.0 Primary pulmonary hypertension
- ☐ ICD-10 I27.21 Secondary pulmonary arterial hypertension
- ☐ Other: _____

MEDICAL RATIONALE FOR OTHER

Prescriber signature: _____ **Date:** _____

3 Determine clinical status

Fax to your patient's specialty pharmacy:

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CVS/specialty
Fax: 1-877-943-1000

Patient: _____ DOB: _____

Physician: _____

NYHA functional class: (Check only one)

- ☐ Class III
- ☐ Class IV
- ☐ Other: _____

Clinical signs and symptoms: (Check all appropriate)

- ☐ Fatigue
- ☐ Shortness of breath or dyspnea on exertion
- ☐ 6-minute walk distance: _____ meters Date of evaluation: _____
- ☐ Chest pain or pressure (angina)
- ☐ Syncope or near syncope
- ☐ Edema or fluid retention
- ☐ Increasing limitation of physical activity
- ☐ Other: _____

Course of illness: (Check all appropriate)

- ☐ Evidence of worsening heart failure (eg, rales on physical exam, worsening edema, increased NT-proBNP, increased CRP)
- ☐ Worsening pulmonary hemodynamics (eg, mPAP, RAP, PVR, CO)
- ☐ Decreasing 6-minute walk test
- ☐ Change in functional class
- ☐ Worsening dyspnea on exertion
- ☐ Change in patient-reported symptoms (eg, increased fatigue)
- ☐ Other: _____

Prescriber signature: _____ **Date:** _____

4 Complete calcium channel blocker trial

Fax to your patient's specialty pharmacy:

Accredo Specialty Pharmacy
Fax: 1-800-711-3526

CVS/specialty
Fax: 1-877-943-1000

Patient: _____ DOB: _____

Physician: _____

Prior to the initiation of VELETRI® (epoprostenol) for Injection, Medicare policy requires documentation that a calcium channel blocker (CCB) has been tried, failed, or considered and ruled out.

The above named patient was trialed as follows:

☐ **A CCB was not trialed because:**

- ☐ Patient did not meet ACCP Guidelines for Vasodilator Response (ie, a fall in mPAP ≥10 mmHg to ≤40 mmHg, with an unchanged or increased cardiac output)
- ☐ Patient is hemodynamically unstable or has history of postural hypotension
- ☐ Patient has systemic hypotension (SBP ≤90 mmHg)
- ☐ Patient has depressed cardiac output (cardiac index ≤2.4 L/min/m^2)
- ☐ Patient has known hypersensitivity
- ☐ Patient has documented bradycardia or second- or third-degree heart block
- ☐ Patient has signs of right-sided heart failure
- ☐ Other: _____

OR

☐ **The following CCB was trialed:**

CCB: _____

With the following response:

- ☐ Pulmonary arterial pressure continued to rise
- ☐ Disease continued to progress or patient remained symptomatic
- ☐ Patient hypersensitive or allergic
- ☐ Adverse event: _____
- ☐ Patient became hemodynamically unstable
- ☐ Other: _____

Prescriber signature: _____ **Date:** _____

5 Provide required documentation

Fax to your patient's specialty pharmacy:

Accredo Specialty Pharmacy
Fax: 1-800-711-3526

CVS/specialty
Fax: 1-877-943-1000

Patient: _____ DOB: _____

Physician: _____

Please check each box once completed.

☐ **Right heart catheterization** has been performed. Results form is attached.

The right heart catheterization report should include:

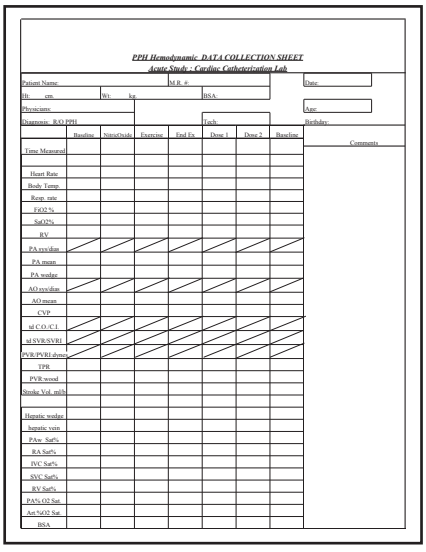
- Mean pulmonary artery pressure (or systolic and diastolic pressure)
- Cardiac output (CO)
- Pulmonary vascular resistance (PVR)
- Pulmonary artery wedge pressure (PAWP)

☐ **Echocardiogram** has been performed to rule out left-sided heart or valvular disease. Results form is attached.

☐ **Current history and physical** notes with need for therapy and PAH symptoms (ie, dyspnea on exertion, and either fatigue, angina, or syncope) documented. Notes are attached.

Prescriber Initials: _____ Date: _____

Sample right heart catheterization results form

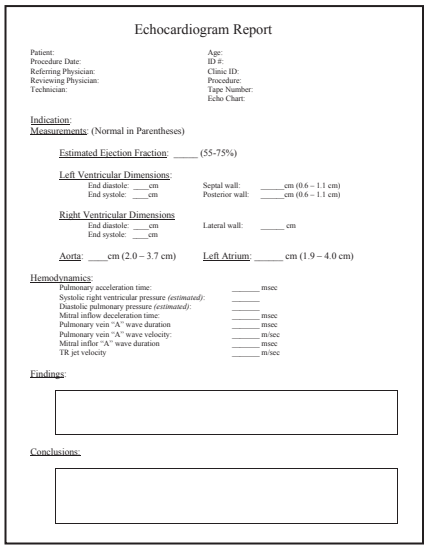


PPH Hemodynamic DATA COLLECTION SHEET
Acute Study - Cardiac Catheterization Lab

Patient Name: M.R. #: Date:
Ht cm Wt: kg BSA:
Physicians: Age:
Diagnosis: IAO/PPH Tech: Birthday:

	Baseline	Nitric/Iloprost	Exercise	End Ex	Dose 1	Dose 2	Baseline	Comments
Time Measured								
Heart Rate								
Body Temp.								
Resp. rate								
FiO2 %								
SaO2%								
RV								
PA sys/dias								
PA mean								
PA wedge								
AO sys/dias								
AO mean								
CVP								
ad C.O./C.I.								
ad SVR/SVRI								
PVR/PVRI dynes								
TPR								
PVR woods								
Stroke Vol. ml/b								
Hepatic wedge								
hepatic vein								
PAw Sat%								
RA Sat%								
IVC Sat%								
SVC Sat%								
RV Sat%								
PA% O2 Sat								
Art.%O2 Sat								
BSA								

Sample echocardiogram results form



Echocardiogram Report

Patient: Age:
Procedure Date: ID #:
Referring Physician: Clinic ID:
Reviewing Physician: Procedure:
Technician: Tape Number:
Echo Chart:

Indication:
Measurements: (Normal in Parentheses)

Estimated Ejection Fraction: _____ (55-75%)

Left Ventricular Dimensions:
End diastole: ____cm
End systole: ____cm
Septal wall: _____cm (0.6 – 1.1 cm)
Posterior wall: _____cm (0.6 – 1.1 cm)

Right Ventricular Dimensions
End diastole: ____cm
End systole: ____cm
Lateral wall: _____ cm

Aorta: ____cm (2.0 – 3.7 cm) Left Atrium: _____ cm (1.9 – 4.0 cm)

Hemodynamics:
Pulmonary acceleration time: _____ msec
Systolic right ventricular pressure *(estimated)*: _____
Diastolic pulmonary pressure *(estimated)*: _____
Mitral inflow deceleration time: _____msec
Pulmonary vein "A" wave duration _____ msec
Pulmonary vein "A" wave velocity: _____ m/sec
Mitral inflor "A" wave duration _____msec
TR jet velocity _____m/sec

Findings:

Conclusions: