*Veletri is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity. Studies establishing effectiveness included predominantly patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases.

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Veletri patient enrollment forms

Patient name:

FirstName Last1478851499401

Instructions

1. Review Veletri indication and important safety information on page 2
2. Complete patient enrollment
3. Document PAH* diagnosis
4. Determine PAH* clinical status
5. Complete CCB trial
6. Provide required documentation: right heart catheterization, echocardiogram results, and history and physical notes
7. Fax completed forms to **1-800-711-3526**

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

Please see accompanying full prescribing information for Veletri.

VELETRI®
epoprostenol for Injection

This resource was created and funded by Actelion Pharmaceuticals US, Inc.

Veletri is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity. Studies establishing effectiveness included predominantly patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases.

Important Safety Information: Veletri is contraindicated in patients with congestive heart failure due to severe left ventricular systolic dysfunction, in patients who develop pulmonary edema during dose initiation, and in patients who have known hypersensitivity to the drug or to structurally related compounds.

Veletri should be used only by clinicians experienced in the diagnosis and treatment of pulmonary hypertension after establishing the diagnosis of idiopathic or heritable PAH or PAH/CTD.

Reconstitute Veletri only as directed using Sterile Water for Injection, USP, or Sodium Chloride 0.9% Injection, USP. Do not mix Veletri with any other parenteral medications or solutions prior to or during administration. Do not abruptly lower the dose or withdraw dosing. All dosing initiation and changes should be closely monitored.

The most common and dose-limiting adverse events during dose initiation and escalation were nausea, vomiting, headache, hypotension, flushing, chest pain, anxiety, dizziness, bradycardia, dyspnea, abdominal pain, musculoskeletal pain, and tachycardia. The most common adverse events during chronic administration were headache, jaw pain, flushing, diarrhea, nausea and vomiting, flu-like symptoms, and anxiety/nervousness. Potential adverse events from postmarketing evaluations include anemia, hypersplenism, pancytopenia, splenomegaly, and hyperthyroidism.

Additional reductions in blood pressure may occur when Veletri is administered with diuretics, antihypertensive agents, or other vasodilators. There is the potential for Veletri to increase the risk of bleeding when administered with antiplatelet agents or anticoagulants. Patients on digoxin who receive Veletri may show elevations of digoxin concentration, which may be clinically significant in patients prone to digoxin toxicity.

Please see accompanying full prescribing information for Veletri.

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Fax cover sheet

To: Accredo PAH* Team

Fax number: 1-800-711-3526

Date/time: 2016-11-30 14:02:02 UTC

From: _____

Fax number: 1-800-711-3526

Number of pages (including this one): _____

Comments:

Checklist

- ☐ 1) Review Veletri indication and important safety information on page 2
- ☐ 2) Complete patient enrollment
- ☑ 3) Document PAH* diagnosis
- ☑ 4) Determine PAH* clinical status
- ☐ 5) Complete CCB trial
- ☐ 6) 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:
1-800-711-3526

For more information, call Accredo PAH* Team: **1-866-FIGHT-PH**
1-866-344-4874

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:

- ANA results
- PFTs
- V/Q perfusion scan
- Chest CT

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Please see accompanying full prescribing information for Veletri.

1 Complete patient prescription and enrollment form

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Fax to: 1-800-711-3526

Referral date: _____ ○ **New patient** ◉ **Current**

Prescription

Veletri (continuous IV infusion administered via ambulatory pump)

Dosing weight: 57 ○ lbs ◉ kg Height: 22 ◉ in ○ cm

☐ NKDA Known drug allergies: Iodine

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 office ◉ Patient's home ○ Hospital

Address (no PO Box): address1478851504693

City: city1478851504901

State: MA Zip: 14788

Ship Attn: FirstName Last1478851499401

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. By signing, I certify that the therapy is medically necessary and that I authorize the designated specialty pharmacy to be my designated agent to **(1)** provide any information on this form to the insurer of the named patient and **(2)** to forward the prescription by fax or other mode of delivery to the designated specialty pharmacy. This Appointment and Authorization shall be in force until cancelled in writing by the prescribing physician.

Prescriber's printed name: Lindsay Goldman **Date:** 11/30/2016

Prescriber signature:

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

Dispense as written **Substitution allowed**

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 Accredo staff (Check all that apply):

☐ In-hospital training (Accredo) ☐ 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: Lindsay Goldman	DEA # (optional): LM1234560	NPI #: 6895439888
Name of facility: ZappRx Practice	MD specialty: PAH	UPIN #:
Contact name and phone #: 617-555-5555	State license #: 666-7654-999	Phone #: 617-555-5555

Address: 192 South St Suite:	City: Boston	State: MA	Zip: 02111	Fax #:

Referral source: (Check one) ○ Prescribing physician ○ Patient self-referral ◉ No referring MD PCP (if applicable/different from prescribing MD) _____ Phone_____

Patient Information

Name: FirstName Last1478851499401	SSN:		DOB: 2001-03-03
Address: address1478851504693	City: city1478851504901	State: MA	Zip: 14788
Preferred language, if not English: English	Phone #: 478-851-5058		Sex: ◉ Male ○ Female
Parent/guardian (if applicable):	Employer: Policy Holder Employer Name		Alternate phone #:

May we contact the patient regarding insurance benefits and product delivery? ○ Yes ◉ No

Insurance Information

Primary insurance company: Blue Cross Blue Shield				Phone #: 111-111-1111
Policy holder name: FirstName Last1478851499401			SSN:	DOB: 2001-03-03
Relationship to patient: SELF	Insured employer: Policy Holder Employer Name		ID #: 21931	Group/policy #: FLBCS
Secondary insurance company:				Phone #:
Policy holder name:			SSN:	DOB:
Relationship to patient:	Insured employer:		ID #:	Group/policy #:
Drug card company: Pharmacy Benefits	Phone #:		ID #:	Group/policy #:
	Rx BIN #: 3858.0		PCN #:	Person code:

Please see page 2 for indication and accompanying full prescribing information for Veletri.

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2 Document diagnosis

Fax to: 1-800-711-3526

Patient: FirstName Last1478851499401 DOB: 2001-03-03

Physician: Lindsay Goldman

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:

WHO GROUP 1 PAH* DIAGNOSES

- ☐ ICD-9: 416.0 Primary Pulmonary Arterial Hypertension (Idiopathic PAH*)
- ☐ ICD-9: 416.0 Familial Pulmonary Arterial Hypertension (FPAH)
- ☐ ICD-9: 416.8 Secondary Pulmonary Hypertension (Associated PAH*)

  Please specify one:
  - ○ Connective Tissue Disease (eg, CREST, MCTD, Scleroderma, Lupus)
  - ○ Other: _____

OTHER

ICD-9: 572.3 Description: 572.3 Portal Hypertension

MEDICAL RATIONALE FOR OTHER

Prescriber signature: _____ **Date:** 11/30/2016

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Please see accompanying full prescribing information for Veletri.

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3 Determine clinical status

Fax to: 1-800-711-3526

Patient: FirstName Last1478851499401 DOB: 2001-03-03

Physician: Lindsay Goldman

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: _____ meters Date of evaluation: _____
- ☐ Chest pain or pressure (angina)
- ☐ Syncope or near syncope
- ☐ 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: 11/30/2016

Please see accompanying full prescribing information for Veletri.

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4 Complete calcium channel blocker trial

Fax to: 1-800-711-3526

Patient: FirstName Last1478851499401 DOB: 2001-03-03

Physician: Lindsay Goldman

Prior to the initiation of Veletri, Medicare policy requires documentation that a calcium channel blocker (CCB) has been tried, failed, or considered and ruled out. Because many PAH* patients may become disabled and Medicare eligible, the following documentation is generally required prior to initiation of treatment with Veletri.

The above named patient was trialed as follows:

A CCB was not trialed because:

- ☐ Patient did not meet ACCP Guidelines[1] for Vasodilator Response (ie, a fall in mPAP ≥10 mm Hg to ≤40 mm Hg, with an unchanged or increased cardiac output)
- ☐ Patient is hemodynamically unstable or has history of postural hypotension
- ☐ Patient has systemic hypotension (SBP ≤90 mm Hg)
- ☐ 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
- ☐ 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:** 11/30/2016

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Please see accompanying full prescribing information for Veletri.

Reference: 1. Badesch DB, Abman SH, Simonneau G, Rubin LJ, McLaughlin VV. Medical therapy for pulmonary arterial hypertension: updated ACCP evidence-based clinical practice guidelines. *Chest.* 2007;131;1917-1928.

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5 Provide required documentation

Patient: FirstName Last1478851499401 DOB: 2001-03-03

Physician: Lindsay Goldman

Please check each box once completed.

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

The right heart catheterization report should include:

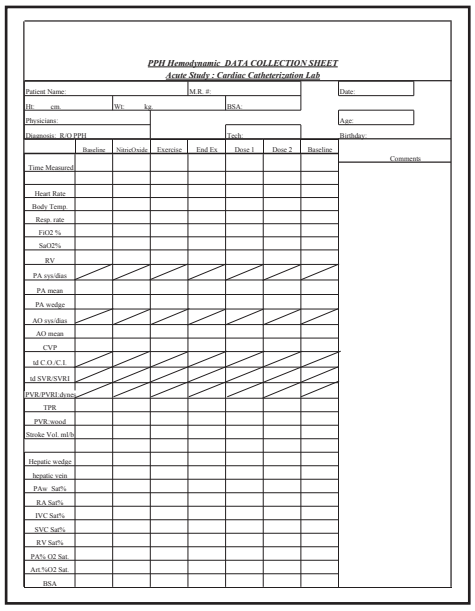
- Mean pulmonary artery pressure (or systolic and diastolic pressure)
- Cardiac output (CO)
- Pulmonary vascular resistance (PVR)
- Pulmonary capillary wedge pressure (or LVEDP)

☐ **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: LG Date: 11/30/2016

Sample right heart catheterization results form

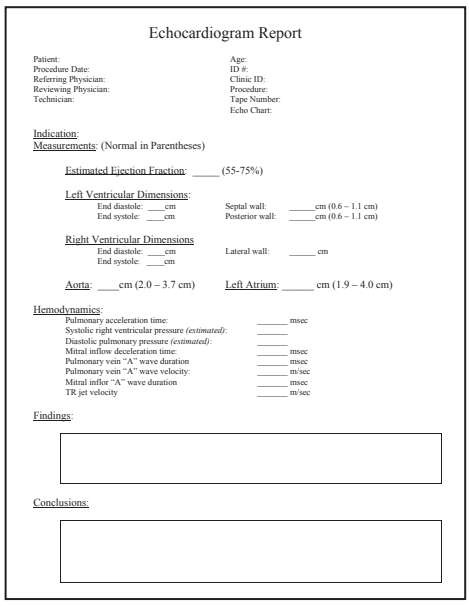


PPH Hemodynamic DATA COLLECTION SHEET
Acute Study : Cardiac Catheterization Lab

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

	Baseline	NitricOxide	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								
td C.O./C.I.								
td SVR/SVRI								
PVR/PVRI dyne/s								
TPR								
PVR.wood								
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 Septal wall: _____cm (0.6 – 1.1 cm)
End systole: ____cm Posterior wall: _____cm (0.6 – 1.1 cm)

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

*Veletri is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity. Studies establishing effectiveness included predominantly patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases.

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