ACTELION Pathways®

VENTAVIS® (ILOPROST) INHALATION SOLUTION FAX COVER SHEET

TO: *Actelion Pathways®*

FAX NUMBER: 1-866-279-0669

FAXED FROM: _____

DATE/TIME: _____

FROM: _____

NUMBER OF PAGES (INCLUDING THIS ONE): _____

COMMENTS: _____

REQUIRED DOCUMENTATION

- ❑ 1) COMPLETE PATIENT ENROLLMENT
- ❑ 2) DOCUMENT DIAGNOSIS
- ❑ 3) DETERMINE 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: **1-866-279-0669**

FOR MORE INFORMATION, CALL *ACTELION PATHWAYS*:

1-866-ACTELION **1-866-228-3546**

The physician is to comply with her/his state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance of state-specific requirements could result in outreach to the prescriber.

Submission of the VENTAVIS 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*

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VENTAVIS PATIENT ENROLLMENT FORM

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Fax To: 1-866-279-0669

PO Box 826, South San Francisco, CA 94083-0826
Phone 1-866-ACTELION (1-866-228-3546) or Fax 1-866-279-0669

Prescription

VENTAVIS® (iloprost) Inhalation Solution
2.5 mcg or 5 mcg (10 mcg/mL) inhalation via I-neb® AAD® System, as tolerated. 6 to 9 times per day during waking hours.

Start with 2.5 mcg × 1. If tolerated, go to 5 mcg (10 mcg/mL) ongoing. If not tolerated, resume 2.5 mcg.

If patient is maintained at 5 mcg (10 mcg/mL) dose and repeatedly experiences extended treatment times, consider transitioning to 5 mcg (20 mcg/mL).

☐ If patient is maintained at VENTAVIS 5 mcg (10 mcg/mL) for 1 month, consider transitioning to VENTAVIS 5 mcg (20 mcg/mL) starting at month 2, unless contacted by physician.

☐ Or please provide dosing instructions: _____

_____

Dispense 1-month supply.

Refills (select 1): ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10 ☐11

Send one (1)* I-neb AAD System if this is an initial order.

**If the patient resides in a remote area that does not allow for timely delivery (delivery within 8 hours), two (2) I-neb AAD Systems will be dispensed.*

Nursing services requested. Skilled nursing visit for patient education related to therapy and disease state, administration of medication as prescribed, and assessment of general status and response to therapy. One to 3 visits to be provided for patient training.

Patient training:

☐ Specialty pharmacy to conduct initial patient training; initial training with I-neb Insight™ breathing monitor required.

☐ PAH treatment center to conduct initial patient training; initial training with I-neb Insight breathing monitor required.

Or please provide patient training instructions: _____

Follow-up nursing visits as ordered by physician to ensure patient is proficient in medication use and I-neb AAD System administration.

☐ **Check this box to order a nursing visit to conduct an I-neb Insight download to measure patient compliance and assess patient breathing technique.**

_____ **week(s) post therapy initiation.**

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

If shipped to physician's office, physician accepts delivery on behalf of patient for administration in office.

Address (no PO Box):	
City:	
State:	ZIP:
Ship Attn:	

I certify that the above therapy ordered is medically necessary and that the information provided is accurate to the best of my knowledge. Further, I hereby authorize Actelion Pathways® ("the Hub") to transmit this prescription to the dispensing pharmacy. PHYSICIAN SIGNATURE (REQUIRED TO VALIDATE PRESCRIPTION). Physician attests this is his/her legal signature (NO STAMPS). PRESCRIPTIONS MUST BE FAXED.

PHYSICIAN SIGNATURE (no stamps) (substitution permitted) **DATE**

PHYSICIAN SIGNATURE (no stamps) (dispense as written) **DATE**

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

Specialty Pharmacy

Indicate specialty pharmacy preference:
If no preference is indicated, this referral will be sent to the appropriate specialty pharmacy based on the patient's existing insurance benefits.

☐ Benefit verification only. Do not send drug at this time.
☐ Request pre-training demonstration visit only at this time.

Physician Information

Name:		DEA #:	NPI #:
Name of facility:		MD specialty:	Tax ID #:
Contact name and phone #:		State license #:	Phone #:
Address:	City:	State: ZIP:	Fax #:

Patient Information

Name:			DOB:
Address:	City:	State:	ZIP:
Preferred language, if not English:		Phone #:	Sex: ☐ Male ☐ Female
Caregiver name:		Relationship:	Alternate phone #:

Insurance Information

Primary insurance company:			Phone #:
Policyholder name:		ID #:	Group/policy #:
Secondary insurance name:			Phone #:
Policyholder name:		ID #:	Group/policy #:
Prescription coverage name:	Phone #:	ID #:	Group/policy #:

By signing below, I authorize my healthcare providers, pharmacies, health plans, or payers ("my health care organizations") to share personal and health information about me related to my Actelion PAH therapies ("my information") with Actelion Pharmaceuticals US, Inc., its affiliates, agents, and contractors (collectively, "Actelion"). I understand that once my information is shared with Actelion, my information may be protected by certain state privacy laws but not by federal health privacy laws, and may be redisclosed by Actelion. Actelion agrees to protect my information and to use and share it only for the reasons listed below. I understand that my pharmacy may receive compensation in connection with sharing my information with Actelion as allowed under this Authorization. I authorize my health care organizations to share my information with Actelion, in order for Actelion to: (1) contact me or my healthcare organizations, or others I have identified, about my disease or treatment; (2) confirm my health plan eligibility and benefits, identify other payers for my therapy, or determine whether I may be eligible for assistance programs; (3) enroll me in Actelion PAH therapies–related programs and provide therapy access support services; (4) perform analyses or improve or develop products, services, programs, or treatment related to my disease; (5) provide me by any means of communication, including by e-mail, mail, or telephone (including voicemail), with information to educate or inform me about Actelion PAH therapies and ways to help me maintain my prescribed treatment; and (6) use and disclose my information for safety reasons or as required by law. I understand that if I do not sign this form, I will still be eligible for health plan benefits and my treatment and payment for my treatment by my healthcare providers and pharmacy will not be affected, but I will not have access to the Actelion services and support described above. This Authorization will expire 10 years from the date signed below unless a shorter period is required by the law of my state of residence. I may discuss the scope of my Authorization at any time by calling 1-866-875-0277 and may cancel it by writing a letter saying I cancel my Authorization, and mailing it to Actelion Pharmaceuticals US, Inc.: PO Box 826, South San Francisco, CA 94083. My cancellation will not be effective until after Actelion receives it and my health care organizations are notified of it by Actelion, and it will not apply to prior actions taken by Actelion and my health care organizations based on this Authorization. I have a right to request and receive a copy of this Authorization in the same ways described above for cancellation.

Patient Name (Print):	**Patient or Parent/Guardian/Representative Signature:**	**Date:**	If this form is signed by someone who is not the patient listed, describe the signer's legal authority to act for the patient:

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DOCUMENT DIAGNOSIS

Fax To: 1-866-279-0669

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Patient: _____ DOB: _____

Physician: _____

Prescriber signature: _____

Date: _____

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-9/ICD-10 CODES DO NOT SUGGEST APPROVAL, COVERAGE, OR REIMBURSEMENT FOR SPECIFIC USES OR INDICATIONS. (CHECK THE BOX FOR THE APPROPRIATE CODE BELOW.)

- ❑ ICD-9 416.0/ICD-10 I27.0 Primary pulmonary hypertension
- ❑ ICD-9 416.8/ICD-10 I27.2 Other chronic pulmonary heart diseases
- ❑ Other: _____

MEDICAL RATIONALE FOR OTHER

_____

_____

_____

_____

_____

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DETERMINE PAH CLINICAL STATUS

Fax To: 1-866-279-0669

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Patient: _____ DOB: _____

Physician: _____

Prescriber signature: _____

Date: _____

NYHA/WHO 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
- ❑ 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: _____

ACTELION Pathways®

COMPLETE CALCIUM CHANNEL BLOCKER TRIAL

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Fax To: 1-866-279-0669

Patient: _____ DOB: _____

Physician: _____

Prescriber signature: _____

Date: _____

Prior to the initiation of VENTAVIS® (iloprost) Inhalation Solution, Medicare policy requires documentation that a calcium channel blocker (CCB) has been tried, failed, or considered and ruled out.[1]

The above named patient was trialed as follows:

A CCB WAS NOT TRIALED BECAUSE:

- ❑ Patient did not meet ACCP Guidelines[2] 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: _____

References: 1. Centers for Medicare and Medicaid Services. Local coverage determination (LCD): nebulizers. http://www.cms.gov/medicare-coverage-database. Accessed September 22, 2015.
2. McLaughlin VV, Archer SL, Badesch DB, et al. ACCF/AHA 2009 expert consensus document on pulmonary hypertension. *J Am Coll Cardiol.* 2009;53:1573-1619.

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 (eg, dyspnea on exertion, fatigue, angina, 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: 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:dynes								
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: