

# VENTAVIS® (ILOPROST) INHALATION SOLUTION FAX COVER SHEET

TO: Janssen CarePath

FAX NUMBER: 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 JANSSEN CAREPATH AT:  
**866-279-0669**  
FOR MORE INFORMATION, CALL JANSSEN CAREPATH :  
**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

# VENTAVIS® PATIENT ENROLLMENT FORM

# 1

Fax To: 866-279-0669

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

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 have made the determination, based on my independent clinical judgement, that the medication ordered is medically necessary for the patient for the intended use. I am personally supervising the care of this patient. I authorize Janssen Pharmaceuticals US, Inc., its affiliates, agents, and contractors to act on my behalf for the limited purposes of transmitting this prescription to the appropriate pharmacy designated by the patient utilizing their benefit plan. This authorization includes permitting Janssen to communicate to payers on my behalf to confirm this patient's health plan eligibility and benefits.

PHYSICIAN SIGNATURE REQUIRED TO VALIDATE PRESCRIPTIONS. 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

Prescription	<b>VENTAVIS® (Iloprost) Inhalation Solution</b>	
	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.	
	<b>Nursing services requested.</b> 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.	
<b>Patient training:</b>	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.		
<b>Check this box to order a nursing visit to conduct an I-neb Insight download to measure patient compliance and assess patient breathing technique.</b>		
_____ week(s) post therapy initiation.		

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

Specialty Pharmacy	Indicate specialty pharmacy preference:	Benefit verification only. Do not send drug at this time. Request pre-training demonstration visit only at this time.
	If no preference is indicated, this referral will be sent to the appropriate specialty pharmacy based on the patient's existing insurance benefits.	

Physician Information	Name:	DEA #:	NPI #:
	Name of facility:	MD specialty:	Phone #:
	Contact name and phone #:	State license #:	Fax #:
	Address:	City:	State:

Patient Information	Name:		DOB:	
	Address:	City:	State:	ZIP:
	Preferred language, if not English:		Phone #:	Sex: <input type="checkbox"/> Male <input type="checkbox"/> 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 #:

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 Janssen PAH therapies ("my information") with Janssen Pharmaceuticals US, Inc., its affiliates, agents, and contractors. I understand that once my information is shared with Janssen, my information may be protected by certain state privacy laws but not by federal health privacy laws, and may be redisclosed by Janssen. Janssen 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 Janssen as allowed under this Authorization. I authorize my health care organizations to share my information with Janssen, in order for Janssen 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 Janssen 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 Janssen 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 Janssen 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 866-875-0277 and may cancel it by writing a letter saying I cancel my Authorization, and mailing it to Actelion Pharmaceuticals US, Inc., a Janssen Pharmaceutical Company, PO Box 826, South San Francisco, CA 94083. My cancellation will not be effective until after Janssen receives it and my health care organizations are notified of it by Janssen, and it will not apply to prior actions taken by Janssen 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.

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

Patient: \_\_\_\_\_ DOB: \_\_\_\_\_

Physician: \_\_\_\_\_

**Prescriber signature:** \_\_\_\_\_

**Date:** \_\_\_\_\_

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**

- Idiopathic PAH
- Heritable PAH

**ICD-10 I27.21 Secondary PAH associated with:**

- Connective tissue disease
- Drugs/toxins induced
- Congenital heart disease
- HIV

**Other:** \_\_\_\_\_

**MEDICAL RATIONALE FOR OTHER**

---



---



---



---



---



---

Fax To: 866-279-0669

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 distance
- Change in functional class
- Worsening dyspnea on exertion
- Change in patient-reported symptoms (eg, increased fatigue)
- Other: \_\_\_\_\_

**Fax To: 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.<sup>1</sup>

The above named patient was trialed as follows:

**A CCB WAS NOT TRIALED BECAUSE:**

- Patient did not meet ACCP Guidelines<sup>2</sup> for Vasodilator Response (ie, a fall in mPAP  $\geq 10$  mmHg to  $\leq 40$  mmHg, with an unchanged or increased cardiac output)
- Patient is hemodynamically unstable or has history of postural hypotension
- Patient has systemic hypotension (SBP  $\leq 90$  mmHg)
- Patient has depressed cardiac output (cardiac index  $\leq 2.4$  L/min/m<sup>2</sup>)
- 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 November 3, 2022.  
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: _____			
Hi: _____ cm	Wt: _____ kg	BSA: _____		Age: _____			
Physician: _____		Tech: _____		Nursing: _____		Birthdate: _____	
Diagnosis: R/O PPH							
Time Measured	Baseline	Nitro/Glyc	Exercise	End Ex	Dose 1	Dose 2	Baseline
Heart Rate							
Body Temp							
Resp. rate							
FiO2 %							
SaO2 %							
RV							
PA sys/dias							
PA mean							
PA wedge							
AO sys/dias							
AO mean							
CVP							
sd C.O.C.I							
sd SVR/SVRI							
PVR/PVRI/dvms							
TPR							
PVR/wood							
Stroke Vol. ml/b							
Hepatic wedge							
hepatic vein							
PAAw 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:**