

AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-305-671-0200.** No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Pulmonary Arterial Hypertension (PAH) (Pharmacy)

Drug Requested: (select drug below)

Phosphodiesterase Type-5 Inhibitors	
<input type="checkbox"/> sildenafil 20 mg tablet (generic Revatio®)	<input type="checkbox"/> sildenafil oral suspension (generic Revatio®)
<input type="checkbox"/> tadalafil 20 mg tablet (generic Adcirca® or Alyq®)	<input type="checkbox"/> Tadliq® (tadalafil) oral suspension

Endothelin Receptor Antagonists			
<input type="checkbox"/> ambrisentan (generic Letairis®)	<input type="checkbox"/> bosentan (generic Tracleer®)	<input type="checkbox"/> Opsumit® (macitentan)	<input type="checkbox"/> Tracleer® (bosentan) dispersible tablet

Soluble Guanylate Cyclase Stimulator (sGC)
<input type="checkbox"/> Adempas® (riociguat)

Prostacyclin Pathway Agents – Analogues and Receptor Agonist	
<input type="checkbox"/> Orenitram® (treprostinil)	<input type="checkbox"/> Tyvaso® (treprostinil) nebulizer solution
<input type="checkbox"/> Tyvaso DPI™ (treprostinil)	<input type="checkbox"/> Uptravi® (selexipag)
<input type="checkbox"/> Ventavis® (iloprost)	

Endothelin Receptor Antagonists + Phosphodiesterase Type-5 Inhibitors
<input type="checkbox"/> Opsynvi® (macitentan/tadalafil)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

NPI #: _____

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PA Pulmonary Arterial Hypertension Drugs (Pharmacy) (AvMed)
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DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy:** _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

Recommended Dosage and/or Quantity Limits (Maximum Daily Dosage):

<u>Drug Name</u>	<u>Drug strength/formulation</u>	<u>Quantity (units)</u>	<u>Day Supply</u>	<u>Units/Day</u>
Sildenafil	20 mg tablet	90	30	3
	10 mg/mL oral suspension	180 mL	30	6
Tadalafil	20 mg tablet	60	30	2
Tadliq	20 mg/5 mL oral suspension	300 mL	30	10
Ambrisentan	5 mg & 10 mg tablet	30	30	1
Bosentan	62.5 & 125 mg tablet	60	30	2
Tracleer	32 mg dispersible tablet for oral suspension	120	30	4
Opsumit	10 mg tablet	30	30	1
	Month 1 Titration Pack	1	N/A	N/A
	Month 2 Titration Pack	1	N/A	N/A
	Month 3 Titration Pack	1	N/A	N/A
Adempas	All strengths (0.5, 1, 1.5, 2, & 2.5 mg tablets)	90	30	3
Uptravi	All strengths (200, 400, 600, 800, 1000, 1200, 1400, & 1600 mcg tablets)	60	30	2
	Titration Pack	1	N/A	N/A
Orenitram	All strengths (0.125 mg, 0.25 mg, 1 mg, 2.5 mg, 5 mg tablets)	90	30	3
Tyvaso	1.74 mg/2.9 mL ampule	28	28	1
Tyvaso DPI	16 mcg, 32 mcg, 48 mcg, 64 mcg & 32-48 mcg maintenance kits	1	28	4
	16-32 mcg titration kit 16-32-48 mcg titration kit	1	N/A	N/A
Ventavis	10 mcg/mL & 20 mcg/mL ampule	270, 1 mL ampules	30	9
Opsynvi	10-20 mg & 10-40 mg tablets	30	30	1

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

SECTION A: Diagnosis Criteria (required for all selected products)

- Member must meet **ONE** of the following medication-age requirements:
 - Member is at least 18 years old
 - For bosentan (generic Tracleer[®], addressed below) requests: Member is at least 3 years old
 - For sildenafil (generic Revatio), addressed below) requests: Member is at least 1 year old
- For female patients of reproductive potential**, pregnancy has been excluded before initiation of treatment; acceptable methods of contraception will be used during treatment and for 1 month after discontinuing treatment, and pregnancy status will be monitored monthly
- Provider is a clinician with expertise in treating patients with pulmonary arterial hypertension
- Member has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 [**OR** WHO Group 4, for Adempas[®] (riociguat), addressed below]
- Diagnosis of PAH has been confirmed by an expert center meeting **ALL** the following criteria:
 - Hemodynamic definitions obtained from a right heart catheterization
 - Medical chart notes and results from the right heart catheterization, laboratory documentation, imaging results, pulmonary function tests, arterial blood gases, are required to be submitted with this request
 - A mean arterial pressure (mPAP) measured ≥ 20 mmHg at rest confirmed by a right heart catheterization
 - A pulmonary artery wedge pressure (PAWP) measured ≤ 15 mmHg
 - A pulmonary vascular resistance (PVR) measured ≥ 2 Woods units

SECTION B: Risk Status Stratification – complete one of the following below

- FOR INITIATING PAH THERAPY [APPROVAL LENGTH 6 MONTHS]**
 - A PAH risk assessment has been completed, and the member's risk status can be considered **ONE** of the following at the time of diagnosis:
 - Low-risk
 - Intermediate-risk
 - High-risk [IV PAH therapy will require prior authorization]
 - Combination therapy is limited to a two drug regimen from two different therapeutic classes listed below in Section C

OR

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❑ FOR CONTINUING PAH THERAPY [APPROVAL LENGTH 12 MONTHS]

- ❑ List the Current Treatment Regimen and Duration:

Drug & Date: _____

Drug & Date: _____

Drug & Date: _____

- ❑ Member must meet **ONE** of the following:
- ❑ Member's condition is stable (i.e. not experiencing clinical worsening), or has maintained a low-risk clinical status on current therapy, and regimen detailed above will continue
 - ❑ Follow-up to the treatment regimen detailed above resulted in an increase to intermediate or high-risk status and requires escalation in therapy regimen (i.e., combination/addition of agents)

NOTE: IV PAH therapy will require prior authorization

- ❑ Combination therapy will be selected from different therapeutic classes listed below in Section C

SECTION C – Drug Agents

❑ sildenafil 20 mg (generic Revatio®) tablets or oral suspension

- ❑ Member's symptomology is determined to be NYHA Functional Class II or III
- ❑ Sildenafil will **NOT** be used concurrently with Adempas® (riociguat) (**verified by chart notes and/or pharmacy paid claims**)
- ❑ Member is **NOT** receiving organic nitrates (e.g., isosorbide mononitrate, isosorbide dinitrate) either regularly or intermittently due to potentiation of the hypotensive effects (**verified by chart notes and/or pharmacy paid claims**)
- ❑ **If requesting oral suspension:** Member's >18 years of age **MUST** have a clinical/medical preclusion to taking oral tablets (medical documentation must be attached to this request for failure)

❑ tadalafil 20 mg (generic Adcirca® or Alyq®) tablets or Tadliq® (tadalafil) oral suspension

- ❑ Member's symptomology is determined to be NYHA Functional Class II or III
- ❑ Tadalafil will **NOT** be used concurrently with Adempas® (riociguat) (**verified by chart notes and/or pharmacy paid claims**)
- ❑ Member is **NOT** receiving organic nitrates (e.g., isosorbide mononitrate, isosorbide dinitrate) either regularly or intermittently due to potentiation of the hypotensive effects (**verified by chart notes and/or pharmacy paid claims**)
- ❑ **If requesting Tadliq® oral suspension:** Member's >18 years of age **MUST** have a clinical/medical preclusion to taking oral tablets (**medical documentation must be attached to this request for failure**)

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Adempas[®] (riociguat)

For all Diagnoses:

- Adempas will **NOT** be taken in combination with a phosphodiesterase type 5 (PDE-5) inhibitor (**verified by chart notes and/or pharmacy paid claims**)
- All provider and patient-specific requirements of REMS have been satisfied

For WHO Group 4 Only:

- A diagnosis of Chronic Thromboembolic Pulmonary Hypertension (CTEPH) categorized as persistent/recurrent, is confirmed
- Member previously failed surgical treatment (such as a pulmonary endarterectomy) or the member has inoperable CTEPH (**verified by chart notes**)
- Documentation of ventilation-perfusion scan or pulmonary angiography confirming the diagnosis of CTEPH is attached with this request

ambrisentan (generic Letairis[®])

NOTE: diagnosis of idiopathic pulmonary fibrosis, including category WHO Group 3 is a contraindication and excluded from therapy with ambrisentan

- Member's symptomology is determined to be NYHA Functional Class II or III
- All provider and patient-specific requirements of REMS have been satisfied

bosentan (generic Tracleer[®])

- For adults:** Member's symptomology is determined to be NYHA Functional Class II, III, or IV
- For pediatric members ≥ 3 years old:** pulmonary arterial hypertension with idiopathic or congenital etiologies
- For Tracleer[®] Dispersible Tablet, the member is ≥ 3 years of age and ≤ 11 years of age, with a body weight ≥ 4 kg and < 40 kg
- A baseline liver function test has been obtained and provided prior to initiation of therapy, and will be monitored
- All provider and patient-specific requirements of REMS have been satisfied

Opsumit[®] (macitentan)

- Member's symptomology is determined to be NYHA Functional Class II or III
- Provider has submitted medical chart notes and history detailing a failure in therapy with ambrisentan or bosentan (**medical/clinical documentation to include detailed record of decreases in 6MWD, clinical worsening, decreased exercise ability**)

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- ❑ A baseline hemoglobin level has been obtained and provided prior to initiation of therapy, and will be monitored monthly
- ❑ A baseline liver function test has been obtained and provided prior to initiation of therapy, and will be monitored monthly
- ❑ All provider and patient-specific requirements of REMS have been satisfied

❑ **Uptravi[®]** (selexipag)

- ❑ Member's symptomology is determined to be NYHA Functional Class II or III
- ❑ Uptravi[®] is being selected as add-on treatment as a result of the member experiencing clinical worsening and increase in risk status on current therapy
- ❑ Uptravi[®] will be used in combination with an endothelin receptor antagonist and/or a PDE-5 inhibitor (**verified by chart notes and/or pharmacy paid claims**)
- ❑ Uptravi[®] will **NOT** be taken in combination with a prostanoid/prostacyclin analogue (**verified by chart notes and/or pharmacy paid claims**)

❑ **Orenitram[®]** (treprostiril)

- ❑ Member's symptomology is determined to be NYHA Functional Class II or III
- ❑ A baseline liver function test has been obtained and provided prior to initiation of therapy, and will be monitored
- ❑ Orenitram[®] is being selected as add-on treatment as a result of the member experiencing clinical worsening and increase in risk status on current therapy
- ❑ **If currently on an IV Prostacyclin Analogue**, therapy will be transitioned to orenitram and IV PCA will tapered

❑ **Tyvaso[®]** (treprostiril), **Tyvaso DPI[™]** (treprostiril) or **Ventavis[®]** (iloprost)

- ❑ Tyvaso[®], Tyvaso DPI[™] or Ventavis[®] will **NOT** be used for monotherapy or for therapy of treatment-naïve PAH patients
- ❑ Tyvaso[®], Tyvaso DPI[™] or Ventavis[®] is being selected as add-on treatment as a result of the member experiencing clinical worsening and increase in risk status on current therapy
- ❑ For Tyvaso[®] or Tyvaso DPI[™] requests: Member's symptomology is determined to be NYHA Functional Class III
- ❑ For Ventavis[®] requests: Member's symptomology is determined to be NYHA Functional Class III or IV

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Opsynvi[®] (macitentan/tadalafil)

- Member's symptomology is determined to be NYHA Functional Class II or III
- Opsynvi will **NOT** be used concurrently with Adempas[®] (riociguat)
- Member must meet **ONE** of the following:
 - Provider has submitted medical chart notes and history detailing a failure in therapy with ambrisentan or bosentan (**medical/clinical documentation to include detailed record of decreases in 6MWD, clinical worsening, decreased exercise ability**)
 - Member is established on dual therapy with single ingredient Opsumit[®] (macitentan) **AND** tadalafil (generic Adcirca[®]/Alyq[®])
- Member is **NOT** receiving organic nitrates (e.g., isosorbide mononitrate, isosorbide dinitrate) either regularly or intermittently due to potentiation of the hypotensive effects
- A baseline hemoglobin level has been obtained and provided prior to initiation of therapy, and will be monitored monthly
- A baseline liver function test has been obtained and provided prior to initiation of therapy, and will be monitored monthly
- All provider and patient-specific requirements of REMS have been satisfied

Medication being provided by Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan.

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.