AvMed

MEDICAL 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 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: IV Pulmonary Arterial Hypertension Drugs

Phosphodiesterase Type-5 Inhibitors
❑ **sildenafil IV** (generic Revatio®) **(J3490) (NDC: 55150-0166-13)**

Prostacyclin Pathway Agents – Analogues and Receptor Agonist	
❑ **epoprostenol IV** (generic Flolan®) **(J1325)**	❑ **epoprostenol IV** (generic Veletri®) **(J1325)**
❑ **treprostinil IV** (generic Remodulin®) **(J3285)**	❑ **Uptravi® IV** (selexipag) **(J3490) (NDC: 66215-0718-01)**

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:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

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

Weight: _____ **Date:** _____

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FDA Approved Dosing & Administration:

- epoprostenol - Initiate intravenous infusion through a central venous catheter at 2 ng/kg/min. Change dose in 1-to 2-ng/kg/min increments at intervals of at least 15 minutes based on clinical response. Avoid sudden large dose reductions.
- treprostinil - Initial dose for patients new to prostacyclin infusion therapy: 1.25 ng/kg/min; increase based on clinical response (increments of 1.25 ng/kg/min per week for the first 4 weeks of treatment, later 2.5 ng/kg/min per week). Avoid abrupt cessation.
- sildenafil - 2.5 mg or 10 mg three times a day administered as an intravenous bolus injection
- selexipag - For injection dose is determined by the patient's current dose of UPTRAVI tablets (see below). Administer for injection by intravenous infusion, twice daily

selexipag current oral dose	selexipag corresponding IV dose
200 mcg twice daily	225 mcg twice daily
400 mcg twice daily	450 mcg twice daily
600 mcg twice daily	675 mcg twice daily
800 mcg twice daily	900 mcg twice daily
1000 mcg twice daily	1125 mcg twice daily
1200 mcg twice daily	1350 mcg twice daily
1400 mcg twice daily	1575 mcg twice daily
1600 mcg twice daily	1800 mcg twice daily

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 is 18 years o age or older
  - ❑ Member is at least 17 years of age for Remodulin® (treprostinil) requests

AND

- ❑ The provider is a clinician with expertise in treating patients with pulmonary arterial hypertension

AND

- ❑ The member has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1

AND

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- ❑ The diagnosis of PAH has been confirmed by an expert center meeting **ALL** of 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, etc. 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 ≥ 3 Woods units

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

- ❑ **FOR INITIATING PAH THERAPY [APPROVAL LENGTH 6 MONTHS]**
  - ❑ A risk assessment has been completed for the member's diagnosis of PAH, and determined to be high risk

AND

  - ❑ Combination therapy is not approved unless otherwise specified below in section C **(verified by chart notes and/or pharmacy paid claims)**

OR

- ❑ **FOR CONTINUING PAH THERAPY [APPROVAL LENGTH 12 MONTHS]**
  - ❑ List the Current Treatment Regimen and Duration:

Drug: _____ Dates: _____

Drug: _____ Dates: _____

Drug: _____ Dates: _____

AND

  - ❑ The patient has experienced clinical worsening on previous therapy, and status has increased to intermediate or high risk

AND

  - ❑ Combination therapy is not approved unless otherwise specified below in section C **(verified by chart notes and/or pharmacy paid claims)**

SECTION C: Drug Agents – complete one of the following below

❑ IV/SubQ prostacyclin derivatives

- ❑ **For Remodulin®-** Member's symptomology is determined to be New York Heart Association (NYHA) Functional Class II, III, or IV

OR

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- **For Flolan®, Veletri®:** Member's symptomology is determined to be New York Heart Association (NYHA) Functional Class III or IV

❑ Revatio® (sildenafil)

- Member's symptomology is determined to be New York Heart Association (NYHA) Functional Class II or III

AND

- Provider has submitted medical documentation as to why oral sildenafil cannot be taken

AND

- Provider attests Revatio IV will not be used concurrently with Adempas® (riociguat) **(verified by chart notes and/or pharmacy paid claims)**

AND

- The member is not receiving organic nitrates either regularly or intermittently due to potentiation of the hypotensive effects **(verified by chart notes and/or pharmacy paid claims)**

❑ Uptravi® (selexipag)

- Member's symptomology is determined to be New York Heart Association (NYHA) Functional Class II or III

AND

- Uptravi® is being selected as add-on treatment as a result of the patient experiencing clinical worsening and increase in risk status on current therapy

AND

- Uptravi® will be used in combination with an endothelin receptor antagonist and/or a PDE-5 inhibitor

AND

- Uptravi® will not be taken in combination with a prostanoid/prostacyclin analogue **(verified by chart notes and/or pharmacy paid claims)**

AND

- Provider has submitted medical documentation as to why oral selexipag cannot be taken

AND

- The provider attests that IV Uptravi therapy will only be administered temporarily according to the dosing chart listed above

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Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – BriovaRx**

For urgent reviews: Practitioner should call AvMed's Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

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.

***Approved by Pharmacy and Therapeutics Committee**: 9/16/2021
REVISED/UPDATED/REFORMATTED: ~~11/3/2021;~~ **3/27/2024**