# SENTARA HEALTH PLANS

## 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 1-800-750-9692**. 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** | |
| ❑ **sildenafil 20 mg tablet** (generic Revatio®) | ❑ **sildenafil oral suspension** (generic Revatio®) |
| ❑ **tadalafil 20 mg tablet** (generic Adcirca® or Alyq®) | ❑ **Tadliq®** (tadalafil) **oral suspension** |
| **Endothelin Receptor Antagonists** | |
| ❑ **ambrisentan** (generic Letairis®) | ❑ **bosentan** (generic Tracleer®) **tablet** |
| ❑ **bosentan** (generic Tracleer®) **dispersible tablet** | ❑ **macitentan** (Opsumit®) |
| **Soluble Guanylate Cyclase Stimulator (sGC)** | |
| ❑ **Adempas®** (riociguat) | |
| **Prostacyclin Pathway Agents – Analogues and Receptor Agonist** | |
| ❑ **Orenitram®** (treprostinil) | ❑ **Tyvaso®** (treprostinil) **nebulizer solution** |
| ❑ **Tyvaso DPI™** (treprostinil) | ❑ **Uptravi®** (selexipag) |
| ❑ **Ventavis®** (iloprost) | ❑ **Yutrepia™** (treprostinil) **inhalation powder** |
| **Endothelin Receptor Antagonists + Phosphodiesterase Type-5 Inhibitors** | |
| ❑ **Opsynvi®** (macitentan/tadalafil) | |

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

**Member Name:** _____

**Member Sentara #:** _____ **Date of Birth:** _____

**Prescriber Name:** _____

**Prescriber Signature:** _____ **Date:** _____

**Office Contact Name:** _____

**Phone Number:** _____ **Fax Number:** _____

**NPI #:** _____

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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:** _____

**Requested Medication is ONE of the following:**

- ❑ New Start
- ❑ Continuation of therapy – provide therapy start date: _____

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

| Drug Name | Drug strength/formulation | Quantity (units) | Day Supply | Units/Day |
|---|---|---|---|---|
| **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 |
| **Bosentan** | 32 mg dispersible tablet for oral suspension | 120 | 30 | 4 |
| **Macitentan** | 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 (100, 150, 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 |

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| Drug Name | Drug strength/formulation | Quantity (units) | Day Supply | Units/Day |
|---|---|---|---|---|
| **Tyvaso DPI** | 16, 32, 48, 64 & 80 mcg cartridges, 32-48, 32-64, 48-64 & 48-80 mcg maintenance kits | 1 | 28 | 4 |
| | 16-32 mcg titration kit &16-32-48 mcg titration kit | 1 | N/A | N/A |
| **Yutrepia** | 26.5 mcg, 53 mcg, 79.5 mcg & 106 mcg inhalation capsules | 112 | 28 | 4 |
| **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 |

**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 Uptravi® (selexipag), addressed below) requests: Member is at least 2 years 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

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## SECTION B: Risk Status Stratification – complete <u>one</u> 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 **<u>ONE</u>** 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**

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

    Drug & Date: _____

    Drug & Date: _____

    Drug & Date: _____
  - ❑ Member must meet **<u>ONE</u>** 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 **<u>NOT</u>** be used concurrently with Adempas® (riociguat) **(verified by chart notes and/or pharmacy paid claims)**
- ❑ Member is **<u>NOT</u>** 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)**
- ❑ **<u>If requesting oral suspension</u>**: 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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❑ **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)**

❑ **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 generic bosentan (Tracleer®) dispersible tablet requests:** Member is ≥ 3 years of age and ≤ 11 years of age, with a body weight ≥ 4 kg and < 40 kg

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- ❑ 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

❑ **macitentan** (Opsumit®)

- ❑ 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)**
- ❑ 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®** (treprostinil)

- ❑ 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

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❑ **Tyvaso®** (treprostinil), **Tyvaso DPI™** (treprostinil), **Ventavis®** (iloprost), **Yutrepia™** (treprostinil)

- ❑ Tyvaso®, Tyvaso DPI™, Ventavis® or Yutrepia™ will **NOT** be used for monotherapy or for therapy of treatment- naïve PAH patients
- ❑ Tyvaso®, Tyvaso DPI™, Ventavis® or Yutrepia™ is being selected as add-on treatment as a result of the member experiencing clinical worsening and increase in risk status on current therapy
- ❑ Tyvaso®, Tyvaso DPI™, Ventavis® or Yutrepia™ 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

❑ **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.****



***Approved by Pharmacy and Therapeutics Committee**: ~~1/21/2010; 7/21/2022; 11/18/2022; 7/25/2024; 7/24/2025;~~ **7/23/2026**
**UPDATEDREVISED/REFORMATTED:** ~~7/31/2017; 1/28/2019; 9/6/2019; 4/1/2021; 6/14/2021; 11/3/2021; 11/22/2021; 8/22/2022; 11/30/2022; 4/7/2023; 11/20/2023; 8/21/2024; 8/18/2025; 10/23/2025; 8/10/2026;~~ **10/16/2026**