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®)	❑ **Opsumit®** (macitentan)	❑ **Tracleer®** (bosentan) **dispersible tablet**

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)	

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 #: _____

(Continued on next page)

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):

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
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

(Continued on next page)

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

(Continued on next page)

- ❑ **FOR CONTINUING PAH THERAPY [APPROVAL LENGTH 12 MONHTS]**
  - ❑ 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)**

(Continued on next page)

❑ **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)**

(Continued on next page)

- ❑ 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

❑ **Tyvaso®** (treprostinil), **Tyvaso DPI™** (treprostinil) **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

(Continued on next page)

- ❑ **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**
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**