# SENTARA COMMUNITY PLAN (MEDICAID)

## PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST\*

<u>Directions</u>: <u>The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request</u>. All other information may be filled in by office staff; <u>fax to 1-800-750-9692</u>. No additional phone calls will be necessary if all information <u>(including phone and fax #s)</u> on this form is correct. <u>If the information provided is not complete, correct, or legible, the authorization process can be delayed</u>.

## **Drug Requested: Winrevair<sup>™</sup>** (sotatercept)

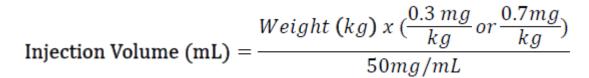
### MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name:			
Member Sentara #:	Date of Birth:		
Prescriber Name:			
Prescriber Signature:			
Office Contact Name:			
Phone Number:	Fax Number:		
NPI #:			
DRUG INFORMATION: Authoriz	zation may be delayed if incomplete.		
Drug Name/Form/Strength:			
Dosing Schedule:			
Diagnosis:	ICD Code, if applicable:		
Weight (if applicable):	Date weight obtained:		

**Recommended Dosing:** SUBQ: Initial: 0.3 mg/kg once every 3 weeks; increase to target dose 0.7 mg/kg once every 3 weeks once Hb and platelet counts are verified to be within an acceptable range

#### **Quantity Limit:**

- 1 kit per 21 days (both strengths)
- Maximum 120 mg every 3 weeks



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Winrevair Kit Type Based on Injection Volume for Dose of 0.3 mg/kg		
Injection Volume (mL)	Kit Type (NDC)	Quantity Limit
0.2 to 0.9	45 mg kit, containing 1 x 45 mg vial (00006-5090-01)	1 kit per 21 days
1 to 1.1	60 mg kit (containing 1 x 60 mg vial) (00006-5091-01)	1 kit per 21 days
Winrevair Kit Type Based on Injection Volume for Dose of 0.7 mg/kg		
Injection Volume (mL)	Kit Type (NDC)	Quantity Limit
0.4 to 0.9	45 mg kit, containing 1 x 45 mg vial (00006-5090-01)	1 kit per 21 days
1 to 1.2	60 mg kit, containing 1 x 60 mg vial (00006-5091-01)	1 kit per 21 days
1.3 to 1.8	90 mg kit, containing 2 x 45 mg vials (00006-5087-01)	1 kit (2 vials) per 21 days
1.9 to 2.4	120 mg kit, containing 2 x 60 mg vials (00006-5088-01)	1 kit (2 vials) per 21 days

**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.

## **Initial Authorization: 6 months**

- $\Box \quad \text{Member is} \ge 18 \text{ years old}$
- □ 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
- Diagnosis of PAH has been confirmed by an expert center meeting <u>ALL</u> the following criteria:
  - Hemodynamic definitions obtained from a right heart catheterization (RHC)
  - 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  $\ge$  20 mmHg at rest
  - □ A pulmonary artery wedge pressure (PAWP) measured  $\leq$  15 mmHg
  - □ A pulmonary vascular resistance (PVR) measured  $\geq$  2 Woods unit]

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- □ Member's functional class defined by the World Health Organization classification meets <u>ONE</u> of the following:
  - Functional Class II: Patients with PH resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity causes undue dyspnea or fatigue, chest pain, or near syncope.
  - □ Functional Class III: Patients with PH resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes undue dyspnea or fatigue, chest pain, or near syncope.
- Member is currently established on therapy for PAH on at least <u>TWO</u> (2) treatments for at least 90 days from the following drug classes: Phosphodiesterase Type-5 Inhibitor, Endothelin Receptor Antagonist, Soluble cGMP Stimulator, or Prostacyclin Receptor Agonist. (NOTE: in the absence of medical and pharmacy claims history to confirm current maintenance treatment, medical history submitted by the provider will be required)
- □ Member's pre-treatment 6-minute Walking Distance (6MWD) has been recorded prior to starting therapy with Winrevair and submitted with this request
- Member's baseline platelet count has been obtained prior to starting therapy and that documentation has been attached to this request [NOTE: the provider attests Winrevair will <u>NOT</u> be initiated if the platelet count is < 50,000/mm<sup>3</sup>]
- Member's baseline hemoglobin level has been obtained prior to starting therapy and that documentation has been attached to this request
- Provider attests to assessing that the patient's current status and history for risk of bleeding (i.e., comorbidities, concomitant treatments) does <u>NOT</u> preclude the member from initiating Winrevair
- □ Females of childbearing potential have a negative pregnancy test prior to start of therapy, and have been counseled to use an effective method of contraception

**<u>Reauthorization</u>: 12 months.** 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.

- Member has been observed to have a positive clinical response since the beginning of therapy evidenced by disease stability, or mild progression, in any of the following (submitted in documentation and charted in clinical notes):
  - □ 6MWD
  - □ WHO Functional Class
  - D Pulmonary vascular resistance on a right heart catheterization
  - □ N-terminal pro b-type natriuretic peptide (NT-proBNP) level

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- □ Member is <u>NOT</u> experiencing unacceptable intolerability or toxicity from therapy (i.e., excessive bleeding, decreased platelet count, increased hemoglobin)
- Platelet count and hemoglobin levels have been monitored since the start of therapy, and follow-up documentation has been submitted confirming levels do not warrant pausing of therapy
- □ Females of childbearing potential have been counseled to use an effective method of contraception

### **Medication being provided by Specialty Pharmacy - PropriumRx**

\*\*Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.\*\* \*<u>Previous therapies will be verified through pharmacy paid claims or submitted chart notes.</u>\*