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.**

Drug Requested: Winrevair™ (sotatercept)

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 #: _____

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 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

$$\text{Injection Volume (mL)} = \frac{Weight\ (kg)\ x\ (\frac{0.3\ mg}{kg}\ or\ \frac{0.7mg}{kg})}{50mg/mL}$$

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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

- ❑ Member is ≥ 18 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 **ALL** 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 ≥ 20 mmHg at rest
  - ❑ A pulmonary artery wedge pressure (PAWP) measured ≤ 15 mmHg
  - ❑ A pulmonary vascular resistance (PVR) measured ≥ 2 Woods unit]

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- ❑ Member's functional class defined by the World Health Organization classification meets **ONE** 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 **TWO (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 NOT be initiated if the platelet count is < 50,000/mm^3]**
- ❑ 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 **NOT** 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

Reauthorization: 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
  - ❑ Pulmonary vascular resistance on a right heart catheterization
  - ❑ N-terminal pro b-type natriuretic peptide (NT-proBNP) level

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- ❑ Member is **NOT** 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 – Proprium Rx

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.*