Sotatercept (WINREVAIR)
Criteria for Use
August 2024

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES. The Product Information should be consulted for detailed prescribing information. See the VA National Formulary Committee Monograph on this drug at the *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive sotatercept.

- ☐ Platelet count less than 50,000/mm^3 ^1
- ☐ Uncontrolled or untreated erythrocytosis^1
- ☐ Uncontrolled systemic hypertension
- ☐ Active serious bleeding
- ☐ Pregnancy
- ☐ Lactating

Inclusion Criteria

All of the following criteria must be met.

- ☐ Care provided by a VA/VA Community Care provider experienced in the management of Pulmonary Arterial Hypertension (PAH)
- ☐ World Health Organization (WHO) Group 1 PAH (idiopathic, heritable, drug-induced, connective tissue disease induced, or after shunt correction)^2
- ☐ Definitive PAH confirmed by right-heart catheterization and hemodynamic diagnosis: mean pulmonary artery pressure greater than 20 mmHg, pulmonary capillary wedge pressure 15 mmHg or less, and pulmonary vascular resistance greater than 5 Wood units
- ☐ WHO functional class II or III ^3
- ☐ On stable doses of background PAH therapy for at least 90 days ^4
- ☐ Risk factors for bleeding have been considered and addressed, including evaluating the continued need for use of drugs that increase bleeding risk (e.g., anticoagulants, NSAIDs, antiplatelets) ^5

Additional Inclusion Criteria (Select if applicable)

- ☐ All patients of reproductive potential (female or male): Counseling provided on potential risk of fertility impairment.
- ☐ Patients who can become pregnant: Pregnancy should be excluded prior to receiving sotatercept. Counseling provided on potential risks vs benefits of treatment and use of effective contraception during therapy and for 4 months after stopping treatment.

Other Justification

- ☐ _____

1. Sotatercept is associated with thrombocytopenia and erythrocytosis. See prescribing information for details on recommended monitoring and dosing adjustments especially during the initial 5 doses.
2. Patients with PAH Group 1 due to portopulmonary disease, schistosomiasis, HIV infection, or veno-occlusive disease were excluded from clinical trials.
3. Until evidence evaluating patients with WHO functional class IV symptoms is available, use of sotatercept may be considered when no further medical treatment options are available.
4. Monotherapy, dual therapy, or triple therapy includes any of the following: endothelin receptor antagonists, phosphodiesterase-5 inhibitors, guanylate cyclase stimulators, prostacyclin analogs or prostacyclin receptor agonists.
5. Sotatercept is associated with serious bleeding. The risk appears to be higher in patients with other risk factors (e.g., additional antithrombotic drugs, prostacyclin therapy, thrombocytopenia, age of 65 or older).

Prepared: August 2024. Contact: Lisa Longo, Pharm.D., BCPS, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services (12PBM)