CareSource Rxinnovations

PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Winrevair (sotatercept-csrk)
BENEFIT TYPE	Medical or Pharmacy
STATUS	Prior Authorization Required

Winrevair, initially approved by the FDA in 2024, is an activin signaling inhibitor indicated for the treatment of adults with pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group 1 to increase exercise capacity, improve WHO functional class (FC) and reduce the risk of clinical worsening events.
PAH is a rare but serious condition characterized by elevated pulmonary arterial resistance. Symptoms develop slowly over time and can include shortness of breath, fatigue, and chest pain. WHO group 1 encompasses a variety of different types of PAH including idiopathic, heritable and drug induced.
The phase 3 STELLAR trial showed that 29% patients treated with Winrevair had an improvement from baseline by at least 1 WHO FC at Week 24 compared to 14% of patients treated with placebo ($p<0.001$). Winrevair also lead to an 84% reduction in the occurrence of death from any cause or PAH clinical worsening events compared to placebo.

Winrevair (sotatercept-csrk) will be considered for coverage when the following criteria are met:

Pulmonary Arterial Hypertension [WHO Group 1]

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a cardiologist or pulmonologist; AND
3. Member must have a diagnosis of WHO Group 1 PAH confirmed by right heart catheterization; AND
4. Member has functional class II or III (see appendix); AND
5. Member must have documentation of **ONE** of the following:
   a) Patient had an acute response to vasodilator testing AND has tried a calcium channel blocker (CCB) for at least 3 months;
   b) Patient did not have a response to vasodilator testing;
   c) Patient cannot undergo vasodilator testing;
   d) Patient cannot take CCB therapy; AND
6. Member has tried and failed **BOTH** of the following oral medications: phosphodiesterase type 5 inhibitor (ie. sildenafil, tadalafil) AND endothelin receptor antagonist (ie. ambrisentan, bosentan, macitentan); OR
7. Member has tried and failed a prostacyclin (ex. treprostinil, selexipag, etc); AND
8. Chart notes document platelet count greater than 50 x 10^9/L; AND
9. Provider attests that member is **NOT** pregnant.
10. **Dosage allowed/Quantity limit:** the recommended starting dose is 0.3 mg/kg by subcutaneous injection. Increase to target dose of 0.7 mg/kg every three weeks. Quantity limit: 1 kit per 21 days.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Member has documentation of improvement in signs and symptoms of disease as evidenced by at least **ONE** of the following:
   a) Stabilization or improvement in WHO functional class (see appendix);
   b) Stabilization or improvement in 6MWD (6-minute walk distance).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Winrevair (sotatercept-csrk) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
04/08/2024	New policy for Winrevair created.

Appendix

World Health Organization Functional Assessment Classification	
Class I	Patients without resulting limitation of physical activity. Ordinary physical activity does not cause undue dyspnea, fatigue, chest pain or near syncope.
Class II	Patients with slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity increases dyspnea, fatigue, chest pain, or near syncope.
Class III	Patients with marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity increases dyspnea, fatigue, chest pain, or near syncope.
Class IV	Patients unable to carry out any physical activity without symptoms. These patients may have signs of right-heart failure. Dyspnea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

References:

1. Winrevair [prescribing information]. Merck Sharp & Dohme LLC; 2024.
2. Maron BA. Revised Definition of Pulmonary Hypertension and Approach to Management: A Clinical Primer. *J Am Heart Assoc.* 2023;12(8):e029024. doi:10.1161/JAHA.122.029024
3. Humbert M, Kovacs G, Hoeper MM, et al. 2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension. *Eur Respir J.* 2023;61(1):2200879. Published 2023 Jan 6. doi:10.1183/13993003.00879-2022
4. Coons, J.C., Pogue, K., Kolodziej, A.R. et al. Pulmonary Arterial Hypertension: a Pharmacotherapeutic Update. *Curr Cardiol Rep*. 2019; 21(141)
5. Klinger JR, Elliott CG, Levine DJ, et al. Therapy for Pulmonary Arterial Hypertension in Adults: Update of the CHEST Guideline and Expert Panel Report [published correction appears in Chest. 2021 Jan;159(1):457]. *Chest*. 2019;155(3):565-586. doi:10.1016/j.chest.2018.11.030
6. Hoeper MM, Badesch DB, Ghofrani HA, et al. Phase 3 Trial of Sotatercept for Treatment of Pulmonary Arterial Hypertension. *N Engl J Med.* 2023;388(16):1478-1490. doi:10.1056/NEJMoa2213558

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Revised date: 04/08/2024