

ALASKA MEDICAID
Prior Authorization Criteria

**Winrevair™
(sotatercept-csrk)**

FDA INDICATIONS AND USAGE¹

Winrevair™ is an activin signaling inhibitor indicated for the treatment of adults with pulmonary arterial hypertension (PAH, WHO Group 1) to increase exercise capacity, improve WHO functional class (FC) and reduce the risk of clinical worsening events.

APPROVAL CRITERIA^{1,2,3,4}

1. Patient meets FDA labeling age **AND**;
2. Prescribed by or in consultation with a cardiologist or pulmonologist **AND**;
3. Patient has the diagnosis of WHO Group 1 PAH, confirmed by right heart catheterization **AND**;
4. Patient is classified as WHO Functional Class II, III ,or IV **AND**;
5. Patient is currently receiving PAH therapies from at least two of the following categories, each for a minimum of 60 days.
 - a. phosphodiesterase type 5 (PDE5) inhibitor
 - b. prostacyclin agent
 - c. endothelin receptor antagonist (ERA)
 - d. guanylate cyclase stimulator (sGCs) **AND**;
6. Prescriber attests patient is not and will not become pregnant during treatment.

DENIAL CRITERIA¹

1. Failure to meet approval criteria.

CAUTIONS¹

- Serious bleeding events have been reported and may be more likely when sotatercept is used concomitantly with some other agents, including prostacyclins and antithrombotics.
- Erythrocytosis, sometimes severe, has been observed.
- Severe thrombocytopenia has been reported.
- Male and female fertility may be impaired

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to one year

QUANTITY LIMIT

- 0.7mg/kg injected subcutaneously once every three weeks

REFERENCES / FOOTNOTES:

Winrevair™ Criteria
Version: 1
Original: 10/15/2024
Accepted: 11/15/2024
Effective: 01/01/2025

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1. Winrevair (sotatercept-csrk) [prescribing information]. Rahway, NJ: Merck & Co. Inc.; March 2024
2. Hooper M, Badesch D, Ghofrani H. et al.; Phase 3 Trial of Sotatercept for Treatment of Pulmonary Arterial Hypertension N Engl J Med 2023;388:1478-1490 DOI: 10.1056/NEJMoa2213558.
3. Humbert M, McLaughlin V, Gibbs J. et al.; Sotatercept for the Treatment of Pulmonary Arterial Hypertension N Engl J Med 2021;384:1204-1215 DOI: 10.1056/NEJMoa2024277
4. Institute for Clinical and Economic Review: Final Evidence Report – Sotatercept for Pulmonary Arterial Hypertension. January 8, 2024. Available at: https://icer.org/wp-content/uploads/2023/05/PAH_Final-Evidence-Report_For-Publication_01082024.pdf