New Hampshire Medicaid Fee-for-Service Program
Winrevair™ (sotatercept-csrk) Criteria

Approval Date: June 5, 2025

Medications

Brand Name	Generic Name	Indication
Winrevair™	sotatercept-csrk	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

Criteria for Approval

1. Patient is ≥ 18 years of age; **AND**
2. Patient has a diagnosis of pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group 1; **AND**
3. Patient's diagnosis has been confirmed by right heart catheterization (medical records required); **AND**
4. Patient's mean pulmonary arterial pressure is > 20 mmHg; **AND**
5. Patient has a pulmonary capillary wedge pressure ≤ 15 mmHg; **AND**
6. Patient has a pulmonary vascular resistance ≥ 3 Wood units; **AND**
7. Patient's WHO functional class is II or greater; **AND**
8. Patient has been stable on background PAH therapy for ≥ 90 days and will continue background PAH therapy during treatment with sotatercept-csrk (Please note: Background therapy refers to combination therapy consisting of drugs from ≥ 2 of the following drug classes: endothelin receptor antagonists [ERA], phosphodiesterase type-5 [PDE5] inhibitor [PDE5i], soluble guanylate cyclase stimulator, and/or prostacyclin analogue or receptor agonist); **AND**
9. Females of reproductive potential have a negative pregnancy test prior to starting therapy; **AND**
10. Females of reproductive potential will use an effective method of contraception during treatment and for ≥ 4 months after the final dose; **AND**
11. Prescriber attestation hemoglobin (Hgb) and platelets will be monitored as appropriate; **AND**
12. Patient does NOT have a baseline platelet count < 50 x 10^9/L; **AND**
13. The prescriber is a cardiologist or pulmonologist or one has been consulted.

Length of Authorization: 12 months of 1 kit per 21 days

Criteria for Renewal

1. Patient must continue to meet the above criteria; **AND**
2. Patient must have disease improvement and/or stabilization OR improvement in the slope of decline (e.g., 6-minute walk distance); **AND**
3. Patient has NOT experienced any treatment-restricting adverse effects (e.g., erythrocytosis, severe thrombocytopenia, serious bleeding).

Criteria for Denial

Criteria for approval are not met.

Revision History

Reviewed by	Reason for Review	Date Approved
DUR Board	New	04/08/2025
Commissioner Designee	Approval	06/05/2025