



Commercial PA Criteria

Effective: June 28, 2024

Prior Authorization: Winrevair (sotaterept-csrk)

Products Affected: Winrevair™ (sotaterept-csrk subcutaneous injection)

Medication Description: Winrevair, an activin signaling inhibitor, is indicated for the treatment of **pulmonary arterial hypertension (PAH)** [World Health Organization {WHO} Group 1] in adults to increase exercise capacity, improve WHO functional class (FC), and reduce the risk of clinical worsening events.

Covered Uses: Pulmonary arterial hypertension (PAH, WHO Group 1)

Exclusion Criteria:

1. None

Required Medical Information:

1. Diagnosis
2. Medical History

Prescriber Restriction: The medication is prescribed by or in consultation with a cardiologist or a pulmonologist.

Age Restriction: Patients is ≥ 18 years of age

Coverage Duration:

Initial: 6 months

Continuation: 1 year

Other Criteria:

Initial Approval Criteria

1. Pulmonary Arterial Hypertension (PAH) [World Health Organization {WHO} Group 1].

Approve for the duration noted if the patient meets ONE of the following;

A. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv **AND** v):

- i. Patients is ≥ 18 years of age; **AND**
- ii. Patient meets the following (a **AND** b):
 - a. The patient has had a right heart catheterization; **AND**
 - b. The results of the right heart catheterization confirmed the diagnosis of WHO Group 1 PAH; **AND**
- iii. Patient is in Functional Class II or III; **AND**
- iv. Patient meets ONE of the following (a **OR** b):

- a. Patient is currently receiving at least two other PAH therapies from the following different pharmacologic categories each for > 60 days: phosphodiesterase type 5 inhibitors (PDE5i),

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endothelin receptor antagonists (ERAs), soluble guanylate cyclase stimulator (sGCs), and prostacyclins; **OR**

- b. Patient is currently receiving at least one other PAH therapy for > 60 days and is intolerant to combination therapy with a phosphodiesterase type 5 inhibitors (PDE5i), endothelin receptor antagonists (ERAs), soluble guanylate cyclase stimulator (sGCs), or prostacyclin; **AND**

Note: Examples of PDE5i include sildenafil and tadalafil. Examples of ERAs include bosentan, ambrisentan, and Opsumit (macitentan tablets). Example of sGCs includes Adempas (riociguat tablets). Examples of prostacyclins include Tyvaso (treprostinil inhalation solution), Tyvaso DPI (treprostinil inhalation solution), Ventavis (iloprost inhalation solution), Orenitram (treprostinil tablets), Uptravi (selexipag tablets), treprostinil injection and epoprostenol injection.

- v. The medication is prescribed by or in consultation with a cardiologist or a pulmonologist.

Renewal Criteria

1. Pulmonary Arterial Hypertension (PAH) [World Health Organization {WHO} Group 1]

Approve for 1 year if the patient meets BOTH of the following (A **AND** B):

- A. Patient meets BOTH of the following (i and ii):

- i. Patient has had a right heart catheterization; **AND**

Note: This refers to prior starting therapy with a medication for WHO Group 1 PAH.

- ii. Results of the right heart catheterization confirmed the diagnosis of WHO Group 1 PAH; **AND**

- B. The medication is prescribed by or in consultation with a cardiologist or a pulmonologist.

References:

- 1. Winrevair[®] subcutaneous injection [prescribing information]. Rahway, NJ: Merck; March 2024.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	06/28/2024

