UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2024 P 2343-1 |
| Program | Prior Authorization/Medical Necessity |
| Medication | Winrevair™ (sotatercept-csrk) |
| P&T Approval Date | 6/2024 |
| Effective Date | 9/1/2024 |

**1. Background:**

Winrevair (sotatercept-csrk) 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.[1]

**2. Coverage Criteria[a]:**

**A. Initial Authorization**

1. **Winrevair** will be approved based on **all** of the following criteria:

   a. **One** of the following:

      (1) **All** of the following:

         (a) Diagnosis of pulmonary arterial hypertension (PAH)

         **-AND-**

         (b) PAH has been confirmed by right heart catheterization

         **-AND-**

         (c) Prescriber attestation that other types of pulmonary hypertension (PH) are excluded as a diagnosis

         **-AND-**

         (d) Pulmonary arterial hypertension is symptomatic

      **-OR-**

      (2) **Both** of the following:

         (a) Diagnosis of pulmonary arterial hypertension

         **-AND-**

         (b) Patient is currently on Winrevair therapy as documented by claims history or submission of medical records (document date and duration of therapy)

**-AND-**

b. **One** of the following:

(1) **Both** of the following:

(a) Patient has a cardiopulmonary comorbidity (e.g., obesity, hypertension, diabetes mellitus, coronary heart disease)

**-AND-**

(b) Patient is currently taking at least **one** of the following oral therapies:

i. Endothelin receptor antagonist (ERA) [e.g., ambrisentan, bosentan, Opsumit (macitentan)]
ii. Phosphodiesterase-5 inhibitor (PDE5i) (e.g., sildenafil, tadalafil)

**-OR-**

(2) **Both** of the following:

(a) Patient does not have a cardiopulmonary comorbidity (e.g., obesity, hypertension, diabetes mellitus, coronary heart disease)

**-AND-**

(b) Patient is currently taking oral combination therapy with **both** of the following:

i. Endothelin receptor antagonist (ERA) [e.g., ambrisentan, bosentan, Opsumit (macitentan)]
ii. **One** of the following:
- Phosphodiesterase-5 inhibitor (PDE5i) (e.g., sildenafil, tadalafil)
- Soluble guanylate cyclase stimulator (sGC) [e.g., Adempas (riociguat)]

**-AND-**

c. Prescribed by, or in consultation with, a cardiologist, pulmonologist, or rheumatologist

**Authorization will be issued for 12 months.**

**B. Reauthorization**

1. **Winrevair** will be approved based on **both** of the following criteria:

a. Documentation of a positive clinical response to Winrevair therapy [e.g., improvement in symptoms of right heart failure, exercise tolerance, six-minute walk distance (6MWD), resting and ambulatory oximetry]

**-AND-**

b. Prescribed by, or in consultation with, a cardiologist, pulmonologist, or rheumatologist

**Authorization will be issued for 12 months.**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limitations may be in place.

**4. References:**


1. Winrevair [package insert]. Rahway, NJ: Merck & Co., Inc; March 2024.
2. Humbert M, Kovacs G, Hoeper MM, et al. 2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension. Eur Heart J 2022; 43:3618.


| Program | Prior Authorization/Medical Necessity – Winrevair™ (sotatercept-csrk) |
|---|---|
| **Change Control** | |
| 6/2024 | New program. |