

sotatercept-csrk (Winrevair)**Medical Benefit Drug Policy**Place of Service

Infusion Center Administration

Office Administration

Outpatient Facility Administration

Self-Administration (may be covered by your Pharmacy Benefit)

Drug Details**USP Category:** RESPIRATORY TRACT/PULMONARY AGENTS**Mechanism of Action:** Activin signaling inhibitor**HCPCS:**

C9399:Unclassified drugs or biologicals

J3490:Unclassified drugs

J3590:Unclassified biologics

How Supplied:

One 45 mg single dose vial (NDC: 0006-5090-01)

One 60 mg single dose vial (NDC: 0006-5091-01)

Two 45 mg single dose vials (NDC: 0006-5087-01)

Two 60 mg single dose vials (NDC: 0006-5088-01)

Condition(s) listed in policy *(see coverage criteria for details)*

- Pulmonary Arterial Hypertension (PAH)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria**The following condition(s) require Prior Authorization/Preservice.****Pulmonary Arterial Hypertension (PAH)****Meets medical necessity if all the following are met:**

1. WHO group 1 classification
2. Age is consistent with the FDA-approved indication (18 years of age and older)
3. Platelet count is 50,000/mm³ (50 x 10⁹/L) or higher

4. Winrevair will be used as add-on treatment to existing dual or triple regimen [e.g., PDE5-I (sildenafil, tadalafil), ERA (bosentan, ambriesentan, Opsumit), Uptravi, Adempas]

Covered Doses:

Up to 0.7 mg/kg given subcutaneously every 3 weeks

Coverage Period:

Yearly, based on continued response to therapy

ICD-10:

I27.0, I27.20, I27.21

Additional Information

World Health Organization (WHO) pulmonary hypertension groups/Clinical classification of pulmonary hypertension (6th World Symposium on Pulmonary HTN)

1 PAH
1.1 Idiopathic PAH
1.2 Heritable PAH
1.3 Drug- and toxin-induced PAH
1.4 PAH associated with:
1.4.1 Connective tissue disease
1.4.2 HIV infection
1.4.3 Portal hypertension
1.4.4 Congenital heart disease
1.4.5 Schistosomiasis
1.5 PAH long-term responders to calcium channel blockers
1.6 PAH with overt features of venous/capillaries (PVOD/PCH) involvement
1.7 Persistent PH of the newborn syndrome
2 PH due to left heart disease
2.1 PH due to heart failure with preserved LVEF
2.2 PH due to heart failure with reduced LVEF
2.3 Valvular heart disease
2.4 Congenital/acquired cardiovascular conditions leading to post-capillary PH
3 PH due to lung diseases and/or hypoxia
3.1 Obstructive lung disease
3.2 Restrictive lung disease
3.3 Other lung disease with mixed restrictive/obstructive pattern
3.4 Hypoxia without lung disease
3.5 Developmental lung disorders
4 PH due to pulmonary artery obstructions
4.1 Chronic thromboembolic PH

4.2 Other pulmonary artery obstructions

5 PH with unclear and/or multifactorial mechanisms

5.1 Haematological disorders

5.2 Systemic and metabolic disorders

5.3 Others

5.4 Complex congenital heart disease

Simonneau G, Montani D, Celermajer DS, et al. Haemodynamic definitions and updated clinical classification of pulmonary hypertension. European Respiratory Journal 2019; 53: 1801913

References

1. Humbert M, McLaughlin VV, Badesch DB, et al. Sotatercept in Patients with Pulmonary Arterial Hypertension at High Risk for Death. *N Engl J Med*. 2025; 392(20):1987-2000. <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2415160>.
2. Simonneau G, Montani D, Celermajer DS, et al. Haemodynamic definitions and updated clinical classification of pulmonary hypertension. *European Respiratory Journal* 2019; 53: 1801913 [<https://doi.org/10.1183/13993003.01913-2018>].
3. Winrevair (sotatercept) Prescribing Information. Merck Sharp & Dohme LLC., Rahway, NJ: 3/2024.

Review History

Date of Last Annual Review: 2Q2025

Changes from previous policy version:

- Pulmonary arterial hypertension: Removed requirement for functional class status [Rationale: Prescribing information; Phase 3 ZENITH trial demonstrated reduced mortality with sotatercept as add-on therapy in severe in PAH (FC III or IV and high risk of death)]

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*