sotatercept-csrk (Winrevair)

Commercial 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 Health and Safety Code section 1367.21 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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF THIS WINREVAIR IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. Patient is initiating on Winrevair (covered for 6 months) or is being re-initiated on Winrevair after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Winrevair based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Winrevair based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

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 (50×10^9/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