Reference number(s)
6455-A

Specialty Guideline Management
Winrevair

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Winrevair	sotatercept-csrk

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Winrevair is indicated for the 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.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review for initial requests: Chart notes, medical record documentation, or claims history supporting current pulmonary arterial hypertension (PAH) therapy.

Reference number(s)
6455-A

Prescriber Specialties

This medication must be prescribed by or in consultation with a pulmonologist or cardiologist.

Coverage Criteria

Pulmonary Arterial Hypertension (PAH)[1-7]

Authorization of 12 months may be granted for treatment of PAH in members 18 years of age and older when All of the following criteria are met:

- Member has PAH defined as Who Group 1 class of pulmonary hypertension (refer to Appendix).
- PAH was confirmed by right heart catheterization with all of the following results:
    - Mean pulmonary arterial pressure (mPAP) > 20 mmHg
    - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
    - Pulmonary vascular resistance (PVR) ≥ 5 Wood units while member is stable on at least two PAH medications
- The requested medication will be used as add-on therapy.
- Member is currently receiving PAH therapy with medications from at least two of the following drug classes:
    - Endothelin receptor antagonist (e.g., Letairis, Opsumit, Tracleer)
    - Phosphodiesterase-5 inhibitor (e.g., Adcirca, Revatio)
    - Soluble guanylate cyclase stimulator (e.g., Adempas)
    - Prostacyclin analog (e.g., Flolan, Orenitram, Remodulin, Tyvaso, Veletri, Ventavis)
    - Prostacyclin receptor agonist (e.g., Uptravi)

Continuation of Therapy

Authorization of 12 months may be granted for members with an indication listed in the coverage criteria section who are currently receiving the requested medication through a paid pharmacy or medical benefit, and who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

Appendix

WHO Classification of Pulmonary Hypertension (PH)[5]

Pulmonary Arterial Hypertension (PAH)

- Idiopathic PAH
- Heritable PAH
- Drug- and toxin-induced PAH
- PAH associated with:
    - Connective tissue disease
    - Human immunodeficiency virus (HIV) infection
    - Portal hypertension
    - Congenital heart disease
    - Schistosomiasis
- PAH long-term responders to calcium channel blockers
- PAH with overt features of venous/capillaries (pulmonary veno-occlusive disease [PVOD]/pulmonary capillary hemangiomatosis [PCH]) involvement
- Persistent PH of the newborn syndrome

PH due to Left Heart Disease

- PH due to heart failure with preserved left ventricular ejection fraction (LVEF)
- PH due to heart failure with reduced LVEF
- Valvular heart disease
- Congenital/acquired cardiovascular conditions leading to post-capillary PH

PH due to Lung Diseases and/or Hypoxia

- Obstructive lung disease
- Restrictive lung disease
- Other lung disease with mixed restrictive/obstructive pattern
- Hypoxia without lung disease
- Developmental lung disorders

PH due to Pulmonary Artery Obstructions

- Chronic thromboembolic PH
- Other pulmonary artery obstructions
    - Sarcoma (high or intermediate grade) or angiosarcoma
    - Other malignant tumors
        - Renal carcinoma
        - Uterine carcinoma
        - Germ cell tumors of the testis
        - Other tumors
    - Non-malignant tumors
        - Uterine leiomyoma
    - Arteritis without connective tissue disease
    - Congenital pulmonary artery stenosis
    - Parasites
        - Hydatidosis

PH with Unclear and/or Multifactorial Mechanisms

- Hematologic disorders: Chronic hemolytic anemia, myeloproliferative disorders
- Systemic and metabolic disorders: Pulmonary Langerhans cell histiocytosis, Gaucher disease, glycogen storage disease, neurofibromatosis, sarcoidosis
- Others: Chronic renal failure with or without hemodialysis, fibrosing mediastinitis
- Complex congenital heart disease

References

1. Winrevair [package insert]. Rahway, NJ: Merck Sharp & Dohme LLC; March 2024.
2. Hoeper MM, Badesch DB, Ghofrani HA, et al. Phase 3 trial of sotatercept for treatment of pulmonary arterial hypertension. N Engl J Med. 2023;388(16):1478-1490. doi: 10.1056/NEJMoa2213558
3. Hoeper MM, Badesch DB, Ghofrani HA, et al. Phase 3 trial of sotatercept for treatment of pulmonary arterial hypertension. Supplementary appendix. N Engl J Med. 2023;Suppl Appendix.
4. Galie N, McLaughlin VV, Rubin LJ, Simonneau G. An overview of the 6th World Symposium on Pulmonary Hypertension. Eur Respir J. 2019;53(1):1802148. doi: 10.1183/13993003.02148-2018
5. Simonneau G, Montani D, Celermajer DS, et al. Haemodynamic definitions and updated clinical classification of pulmonary hypertension. Eur Respir J. 2019;53(1):1801913. doi:10.1183/13993003.01913-2018
6. Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Pulmonary Arterial Hypertension (PAH) Clinical Programs. April 2024.
7. Acceleron Pharma, Inc. A Study of Sotatercept for the Treatment of Pulmonary Arterial Hypertension (MK-7962-003/A011-11)(STELLAR). In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [4/25/2024]. Available from: https://clinicaltrials.gov/study/NCT04576988. NLM Identifier: NCT04576988.