



**AETNA BETTER HEALTH®**  
Coverage Policy/Guideline

Name:	Winrevair	Page:	1 of 4
Effective Date:	1/1/2026	Last Review Date:	9/2025
Applies to:	<input type="checkbox"/> Illinois <input type="checkbox"/> New Jersey <input checked="" type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Florida <input checked="" type="checkbox"/> Maryland <input type="checkbox"/> Virginia	<input checked="" type="checkbox"/> Florida Kids <input type="checkbox"/> Michigan <input checked="" type="checkbox"/> Kentucky PRMD

**Intent:**

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Winrevair under the patient’s prescription drug benefit.

**Description:**

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<sup>1</sup>

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.

**Applicable Drug List:**

Winrevair

**Policy/Guideline:**

**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.

**Prescriber Specialties**

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

**Coverage Criteria**

Pulmonary Arterial Hypertension (PAH)<sup>1-7</sup>

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).



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- PAH was confirmed by right heart catheterization with all of the following pretreatment (before any PAH therapy) results:
  - Mean pulmonary arterial pressure (mPAP) > 20 mmHg
  - Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg
  - Pulmonary vascular resistance (PVR) > 2 Wood units
- 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)<sup>6</sup>

Note: Patients with heritable PAH or PAH associated with drugs and toxins might be long-term responders to calcium channel blockers.

#### Group 1: Pulmonary Arterial Hypertension (PAH)

- Idiopathic
  - Long-term responders to calcium channel blockers
- Heritable
- Associated with drugs and toxins
- Associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis



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- PAH with features of venous/capillary (pulmonary veno-occlusive disease [PVOD]/pulmonary capillary hemangiomatosis [PCH]) involvement
- Persistent PH of the newborn

#### Group 2: PH associated with Left Heart Disease

- Heart failure:
  - With preserved ejection fraction
  - With reduced or mildly reduced ejection fraction
  - Cardiomyopathies with specific etiologies (i.e., hypertrophic, amyloid, Fabry disease, and Chagas disease)
- Valvular heart disease:
  - Aortic valve disease
  - Mitral valve disease
  - Mixed valvular disease
- Congenital/acquired cardiovascular conditions leading to post-capillary PH

#### Group 3: PH associated with Lung Diseases and/or Hypoxia

- Chronic obstructive pulmonary disease (COPD) and/or emphysema
- Interstitial lung disease
- Combined pulmonary fibrosis and emphysema
- Other parenchymal lung diseases (i.e., parenchymal lung diseases not included in Group 5)
- Nonparenchymal restrictive diseases:
  - Hypoventilation syndromes
  - Pneumonectomy
- Hypoxia without lung disease (e.g., high altitude)
- Developmental lung diseases

#### Group 4: PH associated with Pulmonary Artery Obstructions

- Chronic thromboembolic PH
- Other pulmonary artery obstructions:
  - Sarcomas (high- or intermediate-grade or angiosarcoma)
  - Other malignant tumors (e.g., renal carcinoma, uterine carcinoma, germ-cell tumors of the testis)
  - Non-malignant tumors (e.g., uterine leiomyoma)
  - Arteritis without connective tissue disease
  - Congenital pulmonary artery stenoses



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- Hydatidosis

#### Group 5: PH with Unclear and/or Multifactorial Mechanisms

- Hematological disorders, including inherited and acquired chronic hemolytic anemia and chronic myeloproliferative disorders
- Systemic disorders: Sarcoidosis, pulmonary Langerhans cell histiocytosis, and neurofibromatosis type 1
- Metabolic disorders, including glycogen storage diseases and Gaucher disease
- Chronic renal failure with or without hemodialysis
- Pulmonary tumor thrombotic microangiopathy
- Fibrosing mediastinitis
- Complex congenital heart disease

#### Approval Duration and Quantity Restrictions:

**Approval:** 12 months

**Quantity limit:** 1 kit (two vials) every 21 days

#### References:

1. Winrevair [package insert]. Rahway, NJ: Merck Sharp & Dohme LLC; March 2024.
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3. Hoepfer 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. 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
5. 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.
6. Kovacs G, Bartolome S, Denton CP, et al. Definition, classification and diagnosis of pulmonary hypertension. *Eur Respir J.* 2024;64(4):2401324. doi: 10.1183/13993003.01324-2024
7. Chin KM, Gaine SP, Gerges C, et al. Treatment algorithm for pulmonary arterial hypertension. *Eur Respir J.* 2024;64(4):2401325. doi: 10.1183/13993003.01325-2024