

<b>Clinical Policy Title:</b>	sotatercept-csrk
<b>Policy Number:</b>	RxA.820
<b>Drug(s) Applied:</b>	Winrevair
<b>Original Policy Date:</b>	12/16/2024
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Pulmonary arterial hypertension (PAH) (must meet all):

1. Diagnosis of pulmonary arterial hypertension (WHO Group 1);
2. Member has tried at least one drug from each of the following classes and continues to experience symptoms in WHO functional class group II or III (a, b, c, and d):
  - a. Prostacyclin analogue: Orenitram, Tyvaso, Tyvaso DPI, Uptravi;
  - b. Endothelin receptor antagonist (ERA): ambrisentan, bosentan, Letairis, Opsumit, Tracleer;
  - c. Phosphodiesterase type 5 (PDE-5) inhibitor: sildenafil, tadalafil;
  - d. Soluble guanylate cyclase (sGC) stimulator: Adempas;
3. Member will continue current therapies for PAH with the addition of the requested medication.

#### Approval Duration

**All Lines of Business (except Medicare):** 6 months

### II. Continued Therapy Approval

#### A. Pulmonary arterial hypertension (PAH) (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance, or member has met initial criteria.

#### Approval Duration

**All Lines of Business (except Medicare):** 12 months

## References

1. Winrevair. Package Insert. Merck Sharp & Dohme LLC; 2024. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=21693ee2-cd23-4137-ac67-066bb3a4a9b7&type=display>. Accessed December 16, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	12/16/2024	12/05/2024
Policy reviewed.	12/11/2025	12/11/2025

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.