

PA Criteria	Criteria Details						
<b>Covered Uses (FDA approved indication)</b>	Winrevair subcutaneous powder for solution is an activin signaling inhibitor 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.						
<b>Exclusion Criteria</b>	None.						
<b>Required Medical Information</b>	<p>For initial requests, documentation of the following is required:</p> <ol style="list-style-type: none"> <li>1. Must have a confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1, by right heart catheterization.</li> <li>2. Must have WHO functional class II or III symptoms.</li> </ol> <p>For reauthorization requests: Documentation must be provided demonstrating that the patient has had a beneficial response to Winrevair compared to pretreatment baseline in one or more of the following: improvement in WHO functional class, risk status, or 6MWD.</p>						
<b>Age Restriction</b>	Patient is at least 18 years of age.						
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with a specialist for the condition.						
<b>Coverage Duration</b>	Initial: one year; Reauthorization: two years. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.						
<b>Other Criteria/Information</b>	<p>Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.</p> <table border="1"> <thead> <tr> <th>HCPCS</th> <th>Description</th> <th>Billing Units/How Supplied</th> </tr> </thead> <tbody> <tr> <td>J3590*, C9399*</td> <td>Winrevair (sotatercept-csrk)</td> <td>Additional information required: National Drug Code (NDC), Strength, Dosage administered, Route of administration.  45mg, 60mg SDV</td> </tr> </tbody> </table>	HCPCS	Description	Billing Units/How Supplied	J3590*, C9399*	Winrevair (sotatercept-csrk)	Additional information required: National Drug Code (NDC), Strength, Dosage administered, Route of administration.  45mg, 60mg SDV
HCPCS	Description	Billing Units/How Supplied					
J3590*, C9399*	Winrevair (sotatercept-csrk)	Additional information required: National Drug Code (NDC), Strength, Dosage administered, Route of administration.  45mg, 60mg SDV					

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	3/26/2025	3/26/2025	Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG)	N/A
Approved	N/A	8/21/2025	Pharmacy & Therapeutics (P&T) Committee	8/21/2025