

# Winrevair (Sotatercept)

## EXCEPTION DRUG STATUS (EDS) REQUEST FORM

Fax: (204) 942-2030 or 1-877-208-3588

Prescriber Name:		Fax Number:	
Prescriber Address:		Phone Number:	
		Prescriber License Number (NOT Billing Number):	
Patient First Name:	PHIN:	MHSC:	
Patient Last Name:	Patient's Date of Birth:		
Initial Request		Renewal Request	
Strength, Dosage Form and Regimen:		Expected Duration of Therapy:	

Exception Drug Status (EDS) approval is only granted upon demonstration that the patient meets the coverage criteria of the EDS listing. Please provide the following details about how this patient meets the specific criteria for coverage. Manitoba Health may request additional documentation to support this EDS request.

For INITIAL Requests:				
Diagnosis/Indication:	Pulmonary Arterial Hypertension (PAH)			
	Other: _____			
Please select YES or NO to the following:				
Patient is 18 years of age or older.			YES	NO
Patient has confirmed World Health Organization (WHO) Group 1 PAH based on guidelines-approved diagnostic procedure including right heart catheterization.			YES	NO
Patient is Functional Class (FC) II or III.			YES	NO
Will Sotatercept be used in combination with standard PAH therapy?			YES	NO
Is the patient <b>currently</b> being treated with <b>a combination of at least 2 other PAH-specific agents</b> (i.e., ERA, PDE5i, prostacyclin analog/agonist), administered <b>at optimal doses</b> according to clinical guidelines, <b>for at least 3 months</b> :			YES	NO
Treatment History (provide information for PAH-specific agents):				
Name of Drug	Dosing Regimen	Start Date	End Date (if applicable)	Outcome of Treatment
				Ineffective Intolerance (specify): Contraindication (specify): Other (specify):
				Ineffective Intolerance (specify): Contraindication (specify) Other (specify):
				Ineffective Intolerance (specify): Contraindication (specify): Other (specify):

				Ineffective Intolerance (specify): Contraindication (specify): Other (specify):	
Is the patient at low risk?				YES	NO
<p><b>Please provide baseline assessments (i.e., prior to initiating treatment with Sotatercept). This will also be used to inform coverage renewal decisions.</b></p> <p><i>(For example: COMPERA 2.0 risk score, Simplified French Score, functional capacity (FC), 6-minute walk distance (6MWD), N-terminal pro-B-type natriuretic peptide (NT-proBNP), BNP, etc.)</i></p>					
Is Sotatercept being prescribed by a clinician with expertise in managing PAH?				YES	NO
<b>Additional Relevant Clinical Information:</b>					

<b>For ALL RENEWAL Requests:</b>					
Has the patient's risk status stabilized or improved since initiating treatment with Sotatercept?				YES	NO
<p><b>Please provide proof of beneficial clinical effect (i.e., post-treatment outcomes for assessments conducted at baseline).</b></p> <p><i>(For example: current COMPERA 2.0 risk score, Simplified French Score, functional capacity (FC), 6-minute walk distance (6MWD), N-terminal pro-B-type natriuretic peptide (NT-proBNP), BNP, etc.)</i></p>					
Has the patient undergone lung and/or heart transplantation?				YES	NO
<b>Additional Relevant Clinical Information:</b>					

<b>Prescriber Signature and Date:</b>	
<input type="checkbox"/> I have discussed with the patient that the purpose of releasing their information to Manitoba Health, Seniors and Long-Term Care is to obtain Exception Drug Status for prescription coverage.	
Date:	Prescriber Signature: