Canada's Drug Agency
L'Agence des médicaments du Canada

CDA-AMC REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

sotatercept (Winrevair)

(Merck Canada Inc.)

Indication: In combination with standard pulmonary arterial hypertension (PAH) therapy, for the treatment of adults with World Health Organization [WHO] Group 1 PAH and Functional Class (FC) II or III.

October 4, 2024

PULMONARY HYPERTENSION
ASSOCIATION OF CANADA

L'ASSOCIATION D'HYPERTENSION
PULMONAIRE DU CANADA

October 4, 2024

CDA-AMC - Via online form

To: Canadian Drug Expert Committee (CDEC)

Re: Draft CADTH Reimbursement Recommendations -- Sotatercept (Winrevair)

Dear CDEC Members,

I write on behalf of the Pulmonary Hypertension Association (PHA) of Canada to comment on the above-noted draft recommendations for sotatercept, to be used in combination with standard pulmonary arterial hypertension (PAH) therapy, for the treatment of adults with WHO Group 1 PAH and Functional Class II or III. Overall, we are pleased to see a positive recommendation that aligns with current clinical guidelines and best practices for managing and treating PAH. The draft recommendation acknowledges the "significant clinical benefits" provided by sotatercept (for eligible patients) and the opportunity for sotatercept to address the unmet needs of patients and clinicians.

PHA Canada supports the initiation conditions identified, particularly that sotatercept must be used in patients who are not at low risk. The condition that patients be on optimal background therapy for at least three months is appropriate and aligns with recent recommendations from the World PH Symposium. For those patients who do not achieve low-risk status within three months of initiating PAH therapy, sotatercept should be considered. We would suggest that the recommendation go further in recognizing the individual variation between patients and make explicit the use of sotatercept in addition to monotherapy due to patient tolerability, as noted by the CDEC in the discussion points. Finally, the renewal, discontinuation, and prescribing conditions also align with clinical guidelines and patient expectations of reasonable care and treatment.

Regarding pricing, we are unsurprised by the condition for a substantial price reduction, given that PAH is a very rare condition. Expecting a novel agent for a rare disease to achieve an ICER of $50,000 per QALY gained seems unrealistic and speaks to the irrelevance of the threshold in a rare disease context. What does seem relevant to patients is the more than four additional life years gained when half of patients don't make it five years past diagnosis. Moreover, although the CDEC requires that the economic feasibility of sotatercept be addressed, there is no effort to account for the societal benefits provided by sotatercept as patients and caregivers spend less time in the hospital and more time on productive work.

In summary, we are pleased that the CDEC has provided a positive recommendation with clear, inclusive initiation criteria that align with clinical recommendations and best practices. In order to ensure equity for patients with contraindications/intolerability, consideration should also be given to patients on monotherapy on a case-by-case basis.

Sincerely,

Jamie Myrah
Executive Director

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0828
Name of the drug and Indication(s)	Sotatercept (Winrevair) In combination with standard pulmonary arterial hypertension (PAH) therapy, for the treatment of adults with World Health Organization [WHO] Group 1 PAH and Functional Class (FC) II or III
Organization Providing Feedback	FWG

1. Recommendation revisions Please indicate if the stakeholder requires the expert review committee to reconsider or clarify its recommendation.		
Request for Reconsideration	**Major revisions:** A change in recommendation **category** or patient **population** is requested	☐
	Minor revisions: A change in reimbursement **conditions** is requested	☐
No Request for Reconsideration	**Editorial revisions:** Clarifications in recommendation **text** are requested	X
	No requested revisions	☐

2. Change in recommendation category or conditions Complete this section if major or minor revisions are requested
Please identify the specific text from the recommendation and provide a rationale for requesting a change in recommendation.

3. Clarity of the recommendation Complete this section if editorial revisions are requested for the following elements
a) Recommendation rationale
Please provide details regarding the information that requires clarification.
b) Reimbursement conditions and related reasons
Please provide details regarding the information that requires clarification. Please provide clarity and rationale for the intended population included in the initiation condition (1) for right heart catheterization and whether this is required to confirm diagnosis. Additional clarity for initiation condition (2) for patients receiving monotherapy and the respective implementation advice, as well as appropriate therapies that would be expected to be used prior to sotatercept. Confirmation of discontinuation condition (6) as the condition states lung

transplantation specifically, whereas the reason mentions patients who previously had solid organ transplantation were excluded from the STELLAR trial. Further clarity on background therapies for first discussion point in relation to the clinical trial.
c) Implementation guidance
Please provide high-level details regarding the information that requires clarification. You can provide specific comments in the draft recommendation found in the next section. Additional implementation questions can be raised here.

Outstanding Implementation Issues

In the event of a positive draft recommendation, drug programs can request further implementation support from CADTH on topics that cannot be addressed in the reimbursement review (e.g., concerning other drugs, without sufficient evidence to support a recommendation, etc.). Note that outstanding implementation questions can also be posed to the expert committee in Feedback section 4c.

Algorithm and implementation questions
1. Please specify sequencing questions or issues that should be addressed by CADTH (oncology only)
1. 2.
2. Please specify other implementation questions or issues that should be addressed by CADTH
1. 2.
Support strategy
3. Do you have any preferences or suggestions on how CADTH should address these issues?
May include implementation advice panel, evidence review, provisional algorithm (oncology), etc.