CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

remdesivir (Veklury)

(Gilead Sciences Canada, Inc)

Indication: Non-hospitalized patients ≥12 years of age (weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

August 1, 2024

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0834-000
Brand name (generic)	Veklury® (remdesivir)
Indication(s)	COVID-19 in non-hospitalized patients
Organization	Gastrointestinal Society
Contact information[a]	Jaymee Maaghop

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	☒
	No	☐

We support the draft recommendation's condition that reimbursement criteria for remdesivir (Veklury®) should align with nirmatrelvir-ritonavir, providing patients with both treatment options when contracting a COVID-19 infection. We also understand and appreciate that in a separate draft recommendation of Veklury® for hospitalized patients, the committee has recommended its reimbursement for children.

We value the committee's recognition that some individuals are unable to receive nirmatrelvir-ritonavir due to contraindications, especially among those who are immunocompromised and are following tailored treatment and care plans for their health condition. However, we know that there are other factors that should be considered, such as those proposed by the Association of Medical Microbiology and Infectious Disease Canada (AMMI) on page 6 (i.e., mild disease, risk, severity, symptom trajectory and duration, local therapy available, and potential drug interactions).

COVID-19 continues to affect (with most as reinfections) individuals across Canada to this day. Thank you for recommending public coverage of remdesivir, giving patients who are immunocompromised an effective treatment option against COVID-19!

Expert committee consideration of the stakeholder input		
2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?	Yes	☒
	No	☐

The draft recommendation recognized the significant impact of COVID-19 on patients with gastrointestinal conditions. However, it overlooks a critical issue, which is that public health agencies within the provinces and territories do not recommend most of the available treatments for COVID-19. Additionally, nirmatrelvir-ritonavir, despite its availability, has its own barriers to access. Without this recommendation supporting remdesivir, immunocompromised patients would have been left with virtually no viable treatment options.

Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐

4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☒
	No	☐

We appreciate the acknowledgement on the differing eligibility requirements among public drug programs, such as BC and ON. We support ON's approach for remdesivir as BC's narrower criteria may overlook patients in need. ON's guidelines allow physicians and patients to consider more

factors (listed on page 8) in their decision-making process, supporting access and coverage of this treatment.		
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☒
	No	☐

[a] CADTH may contact this person if comments require clarification.

Appendix 1. Conflict of Interest Declarations for Patient Groups

- To maintain the objectivity and credibility of the CADTH drug review programs, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest.
- This conflict of interest declaration is required for participation. Declarations made do not negate or preclude the use of the feedback from patient groups and clinician groups.
- CADTH may contact your group with further questions, as needed.
- Please see the *Procedures for CADTH Drug Reimbursement Reviews* for further details.

A. Patient Group Information	
Name	*Jaymee Maaghop*
Position	*Health Policy & Outreach Manager*
Date	*01-08-2024*
☒	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

B. Assistance with Providing Feedback		
1. Did you receive help from outside your patient group to complete your feedback?	No	☒
	Yes	☐
2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?	No	☒
	Yes	☐

C. Previously Disclosed Conflict of Interest		
1. Were conflict of interest declarations provided in patient group input that was submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section D below.	No	☐
	Yes	☒

D. New or Updated Conflict of Interest Declaration

3. List any companies or organizations that have provided your group with financial payment over the past two years AND who may have direct or indirect interest in the drug under review.

Company	**Check Appropriate Dollar Range**			
	$0 to 5,000	**$5,001 to 10,000**	**$10,001 to 50,000**	**In Excess of $50,000**
Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0834
Name of the drug and Indication(s)	Remdesivir (Veklury) for the treatment of coronavirus disease 2019 (COVID-19) in nonhospitalized adults and pediatric patients (weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, and who are at high-risk for progression to severe COVID-19, including hospitalization and death.
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.
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. Review bullets in discussion points for repetition (see bullet 6).

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.