CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

Maribavir (Livtencity)
Takeda Canada Inc

Indication: Treatment of adults with post-transplant cytomegalovirus (CMV) infection/disease who are refractory (with or without genotypic resistance) to one or more prior antiviral therapies.

October 21, 2022

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	
Brand name (generic)	Maribavir
Indication(s)	Treatment of adults with post-transplant cytomegalovirus (CMV) infection/disease who are refractory (with or without genotypic resistance) to one or more prior antiviral therapies.
Organization	Leukemia Lymphoma Society of Canada.
Contact information[a]	Name: Christina Sit; [redacted]

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

Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale.

While we agree with the draft recommendation, we have the following comments:

1) Issues / acknowledgement of access and impact on patient equity may be further emphasized in the final recommendation.
   a) The patient input indicted the "negative impacts of staying in the hospital… finances". Recognizing these issues are exacerbated with social determinants of health, we encourage CADTH to acknowledge in the final recommendation that coverage of oral treatments may allow patients to be treated close to home and contribute to health equity.
   b) Table 1, point 4 indicates that "Maribavir should be prescribed by clinicians with experience and expertise in transplant medicine, transplant infectious disease, or infectious diseases. In Table 2, row 4 (Considerations for prescribing of therapy), it was acknowledged as a response to questions from drug programs that "patients who live in remote areas and have difficulties assessing specialized care may be followed remotely by relevant clinician specialists or sub-specialists." We recommend adding this to Table 1: Reimbursement Conditions as it will facilitate access and reduce travel.
2) Pediatric use: Table 2, row 7 is titled generalizability. We understand CADTH's consideration that that pediatric use is outside of the scope of CADTH review due to the Health Canada approved indication. This is an example of the current gaps in our system. Even when conditions affect pediatrics, trials are not designed for this population. Pediatric biology is not the same as adult biology and as such they are not little adults. We encourage manufacturers to consider this in future trial designs so that the unmet needs of this population are also met.
3) In general, we are encouraged by this funding recommendation. It identifies a 4.5% price reduction required to meet the cost effectiveness threshold. In consideration of the unmet need this treatment will serve, we urge both the manufacturer and payers to negotiate expeditiously and in good faith so that this treatment can be listed and covered.

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

If not, what aspects are missing from the draft recommendation?

Clarity of the draft recommendation		
2. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐
If not, please provide details regarding the information that requires clarification.		
3. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☐
	No	☒
If not, please provide details regarding the information that requires clarification. We ask CADTH to consider health and social equity as part of implementation deliberations.		
4. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☒
	No	☐
If not, please provide details regarding the information that requires clarification.		

[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	*Christina Sit*
Position	*Manager, Community Strategic Partnerships*
Date	*October 20, 2022*
☒	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	☐
If yes, please detail the help and who provided it.		
2. Did you receive help from outside your patient group to collect or analyze any information used in your feedback?	No	☒
	Yes	☐
If yes, please detail the help and who provided it.		

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

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0720
Name of the drug and Indication(s)	Maribavir (Livtencity) for adults with post-transplant cytomegalovirus (CMV) infection/disease who are refractory (with or without genotypic resistance) to one or more prior antiviral therapies.
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	☐
	No requested revisions	X

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.

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Report Length: 2 Pages

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.