CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

odevixibat (Bylvay)

(Medison Pharma Canada Inc.)

Indication: The treatment of pruritus in patients aged 6 months or older with progressive familial intrahepatic cholestasis (PFIC).

January 10, 2024

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0788
Name of the drug and Indication(s)	Odevixibat (Bylvay) for the treatment of pruritus in patients aged 6 months or older with progressive familial intrahepatic cholestasis (PFIC).
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.
Two points requiring clarification:

1. Should standard of care be included as an initiation criterion for this drug? (Reimbursement condition 1.2 notes patients should be receiving standard of care; however, this seems to be at odds with Table 2, where it's noted that "The clinical panel indicated that it should not be required to try other therapies prior to starting odevixibat… CDEC agreed with the clinical panel." 2. If so, can a list of medications that are SOC be defined in the table (prefer recommendation column but would suffice in implementation guidance).

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.