CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

foslevodopa foscarbidopa (Vyalev)

(AbbVie Corporation)

Indication: Parkinson's disease

June 2, 2023

Disclaimer: The views expressed in this submission are those of the submitting organization or individual. As such, they are independent of CADTH and do not necessarily represent or reflect the view of CADTH. No endorsement by CADTH is intended or should be inferred.

By filing with CADTH, the submitting organization or individual agrees to the full disclosure of the information. CADTH does not edit the content of the submissions.

CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no identifying personal information or personal health information is included in the submission. The name of the submitting stakeholder group and all conflicts of interest information from individuals who contributed to the content are included in the posted submission.

CADTH

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0768
Name of the drug and Indication(s)	Foslevodopa/foscarbidopa (Vyalev) for Parkinson's Disease
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.

Version: 1.0
Publication Date: TBC
Report Length: 3 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.

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	SR0768-000
Brand name (generic)	Vyalev
Indication(s)	Parkinson's disease
Organization	Parkinson Canada
Contact information[a]	Name: Lauren Rettinger, Director, Government Relations

Stakeholder agreement with the draft recommendation

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

The overall recommendation is aligned with our original feedback and that of the patient community.

"Patients expressed a need for treatment options that can eliminate motor fluctuations, does not increase dyskinesia over time, treat cognitive issues, reduce pill burden, and reduce sleep interruptions. CDEC concluded that foslevodopa/foscarbidopa met some of the needs identified by patients in terms of reducing motor fluctuations and pill burden. CDEC noted that patient groups indicated a reluctance towards surgical approaches for the treatment of advanced PD, which include deep brain stimulation (DBS) and levodopacarbidopa intestinal gel (LCIG), and some patients were interested in subcutaneous approaches, which is the mode of administration of foslevodopa/foscarbidopa."

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	☐

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

Clarity of the draft recommendation

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

If not, please provide details regarding the information that requires clarification.

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

Recommendation 1.4 states, "the patient does not have severe psychosis or severe dementia." However, this appears to be in opposition to the clinical expertise as it appears under the "Considerations for Initiation for Therapy," where the clinical expert has noted, "patients with cognitive impairment should not be excluded from treatment as cognitive impairment is not a medical contraindication to foslevodopa/foscarbidopa." The rationale for the above recommendation (1.4) is therefore, unclear. We understand, appreciate, and support the need for the patient to demonstrate correct understanding and use of the delivery system and that this capability would be limited for persons with severe dementia; however, recommendation 1.5 already includes the provision that the patient *or* caregiver are able to demonstrate such understanding and correct use. Therefore, we ask that CADTH please clarify the rationale for recommendation 1.4.

Recommendation 3 states, Foslevodopa/foscarbidopa should be prescribed by neurologists who are movement disorder specialists, or with ***expertise*** in managing ***advance PD***." It is noted as part of the clinical expertise, however, that "the clinical expert preferred to leave the prescribing condition broad by allowing prescribing by neurologists who have ***experience*** in the treatment of patients with PD to prescribe foslevodopa/foscabidopa." We agree with the condition to limit prescribing to practitioners who are experienced, qualified, and trained to administer and monitor foslevodopa/foscarbidopa. However, we are concerned that recommending prescribing by only those with "expertise in advanced PD" will result in access barriers for patients, particularly those in rural or remote communities. Therefore, we ask that CADTH please clarify the rationale for recommendation 3.

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☐
	No	☒
Refer to feedback provided in section 4.		

[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	*Lauren Rettinger*
Position	*Director, Government Relations*
Date	*02-06-2023*
☒	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	☐	☐	☐	☐