

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

PEGVALIASE (Palyngiq)

Indication: For the treatment of patients with phenylketonuria (PKU) aged 16 years and older who have inadequate blood phenylalanine control (blood phenylalanine levels greater than 600 $\mu\text{mol/L}$) on existing management.

June 30, 2022

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CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information		
CADTH project number	SR0712	
Name of the drug and Indication(s)	Palyzinq (pegvaliase) for the treatment of patients with phenylketonuria (PKU) aged 16 years and older who have inadequate blood phenylalanine control (blood phenylalanine levels greater than 600 µmol/L) on existing management	
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	<input type="checkbox"/>
	Minor revisions: A change in reimbursement conditions is requested	<input type="checkbox"/>
No Request for Reconsideration	Editorial revisions: Clarifications in recommendation text are requested	X
	No requested revisions	<input type="checkbox"/>
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		
Should the initiation criteria include an appropriate Phe level for consideration of funding? (ie: minimum of 2 Phe levels greater than 600 within 1 month/6 months). Clarification as to whether 3.1 and 3.2 of renewal criteria reflects annual renewal or just 16-weeks.		

c) Implementation guidance
Guidance on prescribing in combination with Kuvan.

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. Could the renewal criteria be further differentiated by after 16 weeks; then annually thereafter? 2.
Support strategy
3. Do you have any preferences or suggestions on how CADTH should address these issues?
Is there potential for a comment on funding in combination with Kuvan?