

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

macitentan and tadalafil (Opsynvi)

(Janssen Inc.)

Indication: Pulmonary arterial hypertension.

December 2, 2021

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CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder inform	nation						
CADTH project number		SR0690					
Name of the drug and Indication(s)		Macitentan and tadalafil (Opsynvi) for the long-term treatment of pulmonary arterial hypertension (PAH, World Health Organization [WHO] Group 1) to reduce morbidity in patients of WHO functional class (FC) II or III whose PAH is idiopathic, heritable or associated with connective tissue disease or congenital heart disease. Opsynvi should be used in patients who are currently treated concomitantly with stable doses of macitentan 10 mg and tadalafil 40 mg (20 mg x 2) as separate tablets.					
Organization Providing Feedback		FWG					
. 50000011		<u> </u>					
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	Editorial revisions: Clarifications in recommendation text are requested X						
Reconsideration	No requested revisions						
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.							



h١	Reimbursement	conditions a	nd rolated	raseane
N)	Reilliburseillent	Conditions at	na relateu	reasons

Please provide details regarding the information that requires clarification.

c) Implementation guidance

Clarify how long a patient needs to be on stable doses of macitentan and tadalafil as separate tablets prior to switching to Opsynvi.

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 Reimbursement Review Feedback on Draft Recommendation

Stakeholder Information						
CADTH project number	SR0690					
Brand name (generic)	OPSYNVI® (macitentan and tadalafil)					
Indication(s)	For the long-term treatment of pulmonary arterial hypertension World Health Organization [WHO] Group 1) to reduce morbiding patients of WHO functional class (FC) II or III whose PAH is in heritable or associated with connective tissue disease or congleart disease. OPSYNVI should be used in patients who are treated concomitantly with stable doses of macitentan 10 mg tadalafil 40 mg (20 mg x 2) as separate tablets.	ity in diopath genital current	nic,			
Organization	Janssen Inc.					
Contact information ^a						
Stakeholder agreement w	ith the draft recommendation					
			\boxtimes			
1. Does the stakeholder agree with the committee's recommendation.						
possible, please identify the Janssen Inc. agrees with th	seholder agrees or disagrees with the draft recommendation. We specific text from the recommendation and rationale. The committee's recommendation to reimburse OPSYNVI® as pernanttee's reimbursement conditions are clear and highlight cost	rits He	alth			
Expert committee conside	eration of the stakeholder input					
2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?						
If not, what aspects are mis	sing from the draft recommendation?					
Clarity of the draft recomm	mendation					
2 Are the reasons for the	recommendation clearly stated?	Yes	\boxtimes			
3. Are the reasons for the	recommendation clearly stated?	No				
If not, please provide details	s regarding the information that requires clarification.					
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?			\boxtimes			
If not, please provide details	s regarding the information that requires clarification.					

5. If applicable, are the reimbursement conditions clearly stated and the rationale		
for the conditions provided in the recommendation?	No	
If not, please provide details regarding the information that requires clarification.		

^a CADTH may contact this person if comments require clarification.