

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

amivantamab (Rybrevant)

(Janssen Inc.)

Indication: Non-small cell lung cancer

October 21, 2022

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.



Stakeholder information			
CADTH project number	PC0289-000		
Brand name (generic)	Amivantamab		
Indication(s)	For the treatment of adult patients with locally advanced or m non-small cell lung cancer (NSCLC) with activating epiderma factor receptor (EGFR) Exon 20 insertion mutations whose d progressed on, or after platinum-based chemotherapy.	l-growth	n
Organization	Ontario Health (CCO) Lung Cancer Drug Advisory Committee	е	
Contact information ^a	Name: Dr. Donna Maziak		
Stakeholder agreement w	ith the draft recommendation		
1. Does the stakeholder ag	gree with the committee's recommendation.	Yes No	
data. The response rates, p would be seen with docetax Clinically would prefer to us response rates in this popul There have been multiple re	ve recommendation for other agents that have been approved a progression free survival and overall survival are significantly r cel which is the alternative chemotherapy option in this line of tr e amivantamab more than pembrolizumab or nivolumab that h ation of patients with NSCLC. eal world data suggest a large clinical benefit benefit. CADTH dence as a part of drug submissions but then dismiss the evide tations	nore tha eatmen ave low appears	an ht. /
Expert committee conside	eration of the stakeholder input		
	on demonstrate that the committee has considered the our organization provided to CADTH?	Yes No	\square
Reference is made to the cl that the available data is co	inician and CCO submissions, but does not appear to accept the not of the second term in the second term of the second term is the second term of ter	heir beli	ief
Clarity of the draft recomm	nendation		
	recommendation clearly stated?	Yes No	
similar quality has resulted i	be the uncertainty of clinical benefit from amivantamab. However, in positive funding recommendations for other agents. The alter very modest benefit and significant potential for toxicity and is	rnative	
4. Have the implementatio addressed in the recom	n issues been clearly articulated and adequately mendation?	Yes No	
N/A			
	mbursement conditions clearly stated and the rationale ded in the recommendation?	Yes No	
N/A			

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

Appendix 2. Conflict of Interest Declarations for Clinician 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 <u>Procedures for CADTH Drug Reimbursement Reviews</u> for further details.
- For conflict of interest declarations:
 - Please 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.
 - Please note that declarations are required for each clinician that contributed to the input.
 - If your clinician group provided input at the outset of the review, only conflict of interest declarations that are new or require updating need to be reported in this form. For all others, please list the clinicians who provided input are unchanged
 - Please add more tables as needed (copy and paste).
 - All new and updated declarations must be included in a single document.

1. Did you receive help from outside your clinician group to complete this submission?	
Mar	
Yes	\boxtimes
Ontario Health provided secretariat function to the DAC.	
2. Did you receive help from outside your clinician group to collect or analyze any No	\boxtimes
information used in this submission? Yes	
B. Previously Disclosed Conflict of Interest	
3. Were conflict of interest declarations provided in clinician group input that was No	
submitted at the outset of the CADTH review and have those declarations remained Yes	\boxtimes
unchanged? If no, please complete section C below.	l
If yes, please list the clinicians who contributed input and whose declarations have not changed:	
Dr. Donna Maziak	
 Dr. Peter Ellis 	
• Dr. Peter Ellis	



Stakeholder information	
CADTH project number	PC0289-000
Brand name (generic)	Amivantamab (Rybrevant)
Indication(s)	For the treatment of adult patients with locally advanced or metastatic
	non-small cell lung cancer (NSCLC) with activating epidermal-growth
	factor receptor (EGFR) Exon 20 insertion mutations whose disease has
	progressed on, or after platinum-based chemotherapy.
Organization	Lung Cancer Canada – Clinician Group
Contact information ^a	Name: Shem Singh
Stakeholder agreement wi	ith the draft recommendation

1. Does the stakeholder agree with the committee's recommendation.

Yes □ No ⊠

"The CADTH pCODR Expert Review Committee (pERC) recommends that anivantamab not reimbursed for the treatment of adult patients with locally advanced or metastatic NSCLC with activating EGFR Exon 20 insertion mutations whose disease has progressed on, or after platinum-based chemotherapy."

We completely disagree with this. This is doing a disservice to our patients with advanced NSCLC EGFR mutated Exon 20 insertion progressing on or who have progressed on a platinum doublet.

Cohort D in the CHRYSALIS was a phase I/Ib, multicenter, multinational, open-label, single arm study with 81 patients who had progressed on a platinum doublet. The primary endpoint of overall response rate (ORR) was 43.2% [95% CI, 32.2% to 54.7%]) per blinded independent central review (BICR).

The median progression free survival (PFS) per BICR was 8.31 months. The median overall survival (OS) per investigator assessment was 22.77 months.

These are outstanding results in the second line setting for this group of patients. There is no uncertainty with the clinical evidence.

Patients with NSCLC whose tumors harbour any activating EGFR mutations have efficacious therapeutics like EGFR inhibitors. The patients with EGFR Exon 20 insertion have no targeted therapy approved, as it does not work¹. First, second and third generation EGFR tyrosine kinase inhibitors do not work due to the size of the binding site. Checkpoint inhibitors if tried should only be tried last line due to a response rate of 4 % and mPFS of <2 months². Patients with EXON 20 insertion are treated in the first line setting with platinum doublet and when they progress their only treatment choice outside of a clinical trial is docetaxel. Docetaxel has a response rate of less than 6% and PFS of 3 months and OS of 7 months³. To date, the benefit to docetaxel will be at best comparable in those with actionable mutations, like EGFR (nishiyama et al. Lung Cancer 2015;89(3):301-305), ALK (Novello et al. Ann Oncol 2018 29(1):1409-1416), or without actionable mutations (Garassino et al Lancet Oncol 2013:14(10):981-988). and those with any PDL-1 level (CHECKMATE 017, 051 and KN010), it is our expectation that docetaxel benefit will be comparable

in the EGFR EXON 20 population. If CADTH does not approve amivantinib this is what we are subjecting out patients to.

CADTH agrees that EGFR Exon 20 insertions are rare. They make up approximately 0.4% to 0.6% of overall NSCLC cases in Canada.

CADTH agrees that this patient subset has an unmet need for treatment options.

CADTH agrees that a randomized trial in the second line setting in this group of patients is not feasible.

CADTH is uncertain of the clinical benefit given the single arm trial.

If a randomized trial is not feasible, the results of Cohort D in the CHRYSALIS study have to be recognized and accepted.

Those of us who have treated patients with this antibody in this setting of EGFR EXON 20 insertion know it is efficacious as we see our patient respond. That can only lead to improvement in quality of life and improvement in survival.

1. Yang et al, The Lancet Volume 16, Issue 7, July 2015, Pages 830-838

2. Gainor JF, et al. EGFR mutations and ALK rearrangements are associated with low response rates to PD-1 pathway blockade in non–small cell lung cancer: a retrospective analysis. Clin Cancer Res. 2016;22:4585–4593.

3 Shepherd FA et al, Prospective randomized trial of docetaxel vs best supportive care in patients with non-small-cell lung cancer patients previously treated with platinum-based chemotherapy. J ClinOncol 18:2095-2103, 2000.

2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?

CADTH has not accepted of the clinical data in this rare mutation where the only option after platinum doublet is docetaxel, which is known to have significant toxicity in additional to modest ORR, mPFS and mOS.

There is no uncertainty of the clinical benefit in this group of patients.

We disagree with the clinical experts that "amivantamab would likely offer improved and clinically meaningful benefits compared with currently available therapies". We are certain of this and wonder if the pERC members have data on the comparative benefit with amivantamab and docetaxel in EGFR Exon 20 mutated NSCLC. As acknowledged by pERC members that a randomized phase III study is not feasible in this setting while the current single arm study with central radiological review is not convincing enough, what prospective study should be conducted that will provide convincing data to support reimbursement?

 \boxtimes

Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	\boxtimes
5. Are the reasons for the recommendation clearly stated?	No	
Yes but we disagree with the rationale. This is a rare mutation where a randomized trial can done in the second line setting and yet, they refuse to accept the data on efficacy because single arm trial.		e
4. Have the implementation issues been clearly articulated and adequately	Yes	
addressed in the recommendation?		
N/A		
5. If applicable, are the reimbursement conditions clearly stated and the rationale	Yes	
for the conditions provided in the recommendation?	No	
N/A		

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

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 - Please add more tables as needed (copy and paste).
 - All new and updated declarations must be included in a single document.

A. Assistance with Providing the Feedback		
1. Did you receive help from outside your clinician group to complete this submission?	No	\boxtimes
	Yes	
If yes, please detail the help and who provided it.		
2. Did you receive help from outside your clinician group to collect or analyze any	No	\boxtimes
information used in this submission?	Yes	
If yes, please detail the help and who provided it.		
B. Previously Disclosed Conflict of Interest		
3. Were conflict of interest declarations provided in clinician group input that was	No	
submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	Yes	\boxtimes
If yes, please list the clinicians who contributed input and whose declarations have not changed:		
 Dr. Barbara Melosky (lead) 		
Dr. David Dawe		
Dr. Sunil Yaday		
Dr. Shaqil Kassam		
Dr. Randeep Sangha		
Dr. Rosalyn Juergens		
Dr. Catherine Labbé		
Dr. Kevin Jao		
Dr. Geoffrey Liu		
Dr. Stephanie Snow		
Dr. Ron Burkes		
Dr. Paul Wheatley-Price		

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0289
Name of the drug and	Amivantamab for adult patients with locally advanced or metastatic
Indication(s)	non-small cell lung cancer (NSCLC)
Organization Providing	PAG
Feedback	

1. Recommendation revisions Please indicate if the stakeholder requires the expert review committee to reconsider or clarify its recommendation.				
Request for	Major revisions: A change in recommendation category or patient population is requested			
Reconsideration	Minor revisions: A change in reimbursement conditions is requested			
No Request for	Editorial revisions: Clarifications in recommendation text are requested			
Reconsideration	No requested revisions	х		

2. Change in recommendation category or conditions Complete this section if major or minor revisions are requested None.

3. Clarity of the recommendation

Complete this section if editorial revisions are requested for the following elements

a) Recommendation rationale

None.

b) Reimbursement conditions and related reasons

None.

c) Implementation guidance

None.



Stakeholder information				
CADTH project number	PC0289-000			
Brand name (generic)	Amivantamab (Rybrevant)			
Indication(s)	For the treatment of adult patients with locally advanced or metastatic			
	non-small cell lung cancer (NSCLC) with activating epidermal-growth			
	factor receptor (EGFR) Exon 20 insertion mutations whose disease has			
	progressed on, or after platinum-based chemotherapy.			
Organization	Lung Cancer Canada – Patient Group			
Contact information ^a	Name: Shem Singh			
Stakeholder agreement with the draft recommendation				

1. Does the stakeholder agree with the committee's recommendation.

Yes □ No ⊠

Lung Cancer Canada is extremely disappointed in pERC's decision to not reimburse amivantamab for patients with advanced or metastatic NSCLC with EGFR Exon 20 insertion mutations.

In the rationale for recommendation, pERC states, *"Further, no definitive conclusion could be reached regarding the effects of amivantamab on health-related quality of life (HRQoL) due to the results being based on a small subset of 36 patients."* The rarity of EGFR Exon 20 insertion mutations that yield non small-cell lung cancer (NSCLC) is estimated to be 0.4-0.6% of NSCLC cases in Canada, and less than 4% of all NSCLC cases globally. There are approximately 200-1000 patients diagnosed with this mutation each year based on global estimates, who experience resistance to both first and second generation TKIs, as noted in our initial submission. 2 patients that LCC interviewed that used amivantamab in the 2nd line or beyond, found significant relief with the drug when they had exhausted all previous options that eventually became ineffective. They were both on the drug for over 1 year and still having a good HRQoL, able to maintain their independence throughout treatment, and some even returned to work. LCC understand that the rarity of the disease makes it difficult to find many patients for a robust sample size; however, the results of the CHRYSALIS study have shown that it is effective on this small subset of NSCLC patients and as interviewed, has made a difference in these patients' lives at the end of the day.

There is a high unmet need in this patient subset for treatment options when others have been exhausted. The current standard of care for these EGFR Exon 20 mutation patients in the first line setting remains a systemic treatment of platinum doublet or docetaxel chemotherapy. These treatments come with numerous toxic and harsh side effects and are not specifically targeted to the patient's specific subtype, yielding less than efficacious clinical benefits. Amivantamab has been seen to effectively treat disease with side effects that are manageable. In section 6 of our initial submission, patients mentioned that although the side effect burden was more than what they had experienced with other targeted therapies in the past, they would not consider discontinuing treatment as the hope of survival outweighs the negatives. By denying patients access to this therapy that has shown substantial benefit for this rare subgroup of NSCLC patients, it will cause unnecessary burden and suffering. These patients need access to timely and effective treatments for their cancer and cannot afford to wait. The unmatched potential that access to amivantamab will have

for patient is incredibly positive, and will make a huge difference in the treatment paradigm for this patient population.

Expert committee consideration of the stakeholder input		
2. Does the recommendation demonstrate that the committee has considered the	Yes	
stakeholder input that your organization provided to CADTH?		\boxtimes

The rationale and discussion points in the draft recommendation highlighted only very briefly the importance of patient and caregiver values that LCC highlighted in our initial submission. Additionally, pERC also raised the question of whether amivantamab showed any clinical benefit compared to the other relevant treatments due to the absence of a comparator arm. While LCC cannot comment on the substantiality of the external clinical evidence submitted, between the qualitative experiences that patients interviewed by LCC expressed, patients agreed that they would choose amivantamab over past treatments because previous treatments, including 2 patients who had experience with other EGFR TKIs did not target their specific biomarkers and thus did not yield long term results. When they switched onto amivantamab, they soon saw disease symptoms subside, and they were able to return to a level of functionality and independence similar to before diagnosis. Both of those two patients have been on amivantamab for about 1.5 years at the time of our initial submission, during which both saw their metastases remain either stable or have shrunk significantly. This is further detailed in the Section 6 subheadings, "Amivantamab has given patients treatment options when they've exhausted other options", "Amivantamab is effective at treating patients' disease", and "Patients on amivantamab enjoy a quality of life and level of functionality that is similar to prediagnosis".

Clarity of the draft recommendation				
2 Are the reasons for the recommendation clearly stated?	Yes	\boxtimes		
3. Are the reasons for the recommendation clearly stated?	No			
Yes but we disagree with the rationale. This is a rare mutation impacting a very small number of NSCLC patients, so the limitations that the clinical evidence presents are understandable. The benefits that amivantamab has shown to yield in patients is still important, and should CADTH choose to make a positive recommendation of the reimbursement of this treatment, more robust real world evidence will be generated overtime.				
4. Have the implementation issues been clearly articulated and adequately	Yes			
addressed in the recommendation?				
N/A				
5. If applicable, are the reimbursement conditions clearly stated and the rationale	Yes			
for the conditions provided in the recommendation?				
N/A				

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Appendix 1. Conflict of Interest Declarations for Patient Groups

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A. Patient	Group Information					
Name	Shem Singh					
Position	Executive director, Lung Cancer Canada					
Date	Oct 21,2022					
	I hereby certify that I have the a matter involving this patient gro patient group in a real, potentia	up with a comp	any, organizatio	on, or entity that m		
B. Assista	nce with Providing Feedback					
4 D'I				<i>(</i>) 0	No	\boxtimes
1. Did yo	u receive help from outside you	ir patient grou	p to complete y	our feedback?	Yes	
	u receive help from outside you	r patient grou	p to collect or a	analyze any	No	\boxtimes
inform	u receive help from outside you ation used in your feedback? se detail the help and who provide		p to collect or a	analyze any	No Yes	
inform If yes, pleas C. Previou	ation used in your feedback? se detail the help and who provide sly Disclosed Conflict of Interes	ed it.			Yes	
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inform If yes, pleas C. Previou 1. Were of submin uncha D. New or 3. List an past tw Company	ation used in your feedback? se detail the help and who provide sly Disclosed Conflict of Interest conflict of interest declarations in tted at the outset of the CADTH nged? If no, please complete se Updated Conflict of Interest Dec by companies or organizations to vo years AND who may have dir	ed it. provided in pa review and ha ction D below claration hat have provi ect or indirect	tient group inp ve those declar ided your group interest in the <u>Check Appro</u> \$5,001 to	ut that was rations remained o with financial p drug under revie priate Dollar Rar \$10,001 to	Yes Yes No Yes Yes ayment ew. nge In Exces \$50,000	□ □ ⊠
inform If yes, pleas C. Previou 1. Were of submin uncha D. New or 3. List an	ation used in your feedback? se detail the help and who provide sly Disclosed Conflict of Interest conflict of interest declarations in tted at the outset of the CADTH nged? If no, please complete se Updated Conflict of Interest Dec by companies or organizations t wo years AND who may have dir	ed it. provided in pa review and ha oction D below claration hat have provi ect or indirect \$0 to 5,000	tient group inp ve those declar ided your group interest in the <u>Check Appro</u> \$5,001 to 10,000	ut that was rations remained o with financial p drug under revie priate Dollar Rar \$10,001 to 50,000	Yes Yes No Yes Payment ew. nge In Exces \$50,000	over the



CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

amivantamab (Rybrevant)

(Janssen Inc.)

Indication: Non-small cell lung cancer

February 16, 2023

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Stakeholder information					
CADTH project number	PC0289-000 (Reconsideration)				
Brand name (generic)	Rybrevant (amivantamab)				
Indication(s)	For the treatment of adult patients with locally advanced or metastatic				
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	factor receptor (EGFR) Exon 20 insertion mutations whose di	sease	has		
	progressed on, or after platinum-based chemotherapy.				
Organization	Ontario Health (Cancer Care Ontario) Lung Cancer Drug Advisory				
	Committee				
Contact information ^a	Name: Dr. Donna Maziak				
Stakeholder agreement wi	ith the draft recommendation				
1 Does the stakeholder as	gree with the committee's recommendation.	Yes	\boxtimes		
1. Does the stakeholder ag	nee with the committee's recommendation.	No			
	eholder agrees or disagrees with the draft recommendation. W	henev	er		
possible, please identify the	specific text from the recommendation and rationale.				
Expert committee conside	eration of the stakeholder input				
2. Does the recommendati	on demonstrate that the committee has considered the	Yes	\boxtimes		
	our organization provided to CADTH?	No			
If not, what aspects are miss	sing from the draft recommendation?				
Clarity of the draft recomm	nendation				
0 A		Yes	\boxtimes		
3. Are the reasons for the	recommendation clearly stated?	No			
If not, please provide details	regarding the information that requires clarification.				
4. Have the implementation issues been clearly articulated and adequately			\boxtimes		
addressed in the recommendation?					
If not, please provide details	regarding the information that requires clarification.				
5. If applicable, are the rei	mbursement conditions clearly stated and the rationale	Yes	\boxtimes		
for the conditions provided in the recommendation?					
If not, please provide details	regarding the information that requires clarification.				
1					

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A. Assistance with Providing the Feedback		
1. Did you receive help from outside your clinician group to complete this submission?	No	
	Yes	X
If yes, please detail the help and who provided it.		
OH-CCO provided secretariat function.		
2. Did you receive help from outside your clinician group to collect or analyze any	No	X
information used in this submission?	Yes	
If yes, please detail the help and who provided it.		
B. Previously Disclosed Conflict of Interest		
3. Were conflict of interest declarations provided in clinician group input that was	No	
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C. New or Updated Conflict of Interest Declarations

New or Up	dated Declaration for Clinician 1
Name	Please state full name
Position	Please state currently held position
Date	Please add the date form was completed (DD-MM-YYYY)

	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.						
Conflict of Interest Declaration							
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.							
years AND	who may have direct or indirect	interest in the d	rug under review	1.			
years AND	who may have direct or indirect	interest in the d		/. priate Dollar Ra	nge		
vears AND	who may have direct or indirect	interest in the d \$0 to 5,000		81263	nge In Excess of \$50,000		
- And			Check Appro \$5,001 to	priate Dollar Ra \$10,001 to	In Excess of		
Company	ny name	\$0 to 5,000	Check Appro \$5,001 to 10,000	priate Dollar Ra \$10,001 to 50,000	In Excess of		

New or Updated Declaration for Clinician 2					
Name	Please state full name				
Position	Please state currently held position				
Date	Please add the date form was completed (DD-MM-YYYY)				
	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.				

Conflict of Interest Declaration

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.

	Check Appropriate Dollar Range				
Company	\$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					

New or Updated Declaration for Clinician 3							
Name	Please state full name						
Position	Please state currently held position						
Date	Please add the date form was completed (DD-MM-YYYY)						
I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.							
Conflict of Interest Declaration							
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				

New or Up	New or Updated Declaration for Clinician 4						
Name	Please state full name						
Position	Please state currently held position						
Date	Please add the date form was completed (DD-MM-YYYY)						
	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.						
	mpanies or organizations that have who may have direct or indirect i		rug under review.				
Company		\$0 to 5,000	\$5,001 to 10,000	riate Dollar Rang \$10,001 to 50,000	ln Excess of \$50,000		
Add company name							
Add compa	any name						
	nove rows as required				51-52		

New or Up	New or Updated Declaration for Clinician 5						
Name	Please state full name						
Position	Please state currently held position						
Date	Please add the date form was completed (DD-MM-YYYY)						
	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.						
List any co	f Interest Declaration mpanies or organizations that hav who may have direct or indirect i				r the past two		
			Check Approp	riate Dollar Rang	je		
Company		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000		
Add company name							
Add compa	any name						

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information PC0289 Name of the drug and Indication(s) Amivantamab for non-small cell lung cancer Organization Providing Feedback PAG 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 No Request for Reconsideration Editorial revisions: Clarifications in recommendation text are requested X No Request for Reconsideration Editorial revisions: Clarifications in recommendation text are requested X No request for Reconsideration Editorial revisions: Clarifications in recommendation text are requested X No request for Reconsideration Complete this section if major or minor revisions are requested Imago 3. Clarity of the recommendation complete this section if editorial revisions are requested for the following elements A) Recommendation rationale None None Imago Imago	CADTH project nur						
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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 Image: Clarification is requested No Request for Reconsideration Editorial revisions: Clarifications in recommendation text are requested No Request for Reconsideration Editorial revisions: Clarifications in recommendation text are requested No request for Reconsideration Editorial revisions 2. Change in recommendation category or conditions Complete this section if major or minor revisions are requested None 3. Clarity of the recommendation category or complete this section if editorial revisions are requested for the following elements a) Recommendation rationale	Feedback						
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Complete this section if editorial revisions are requested for the following elements a) Recommendation rationale	None						
Complete this section if editorial revisions are requested for the following elements a) Recommendation rationale							
a) Recommendation rationale							
None							
	Complete this secti	on if edite	orial revisions are requested for the following elements				
b) Reimbursement conditions and related reasons	Complete this secti a) Recommendat	on if edite	orial revisions are requested for the following elements				
Under Table 1, reimbursement condition for discontinuation, PAG is requesting the following revision:	Complete this secti a) Recommendat None	on if edite	orial revisions are requested for the following elements				
The word "and' should be replaced with "or" in the following statement. Amvantamab should be discontinued for patients who do not exhibit a response to treatment as per physician discretion "OR" for whom treatment is intolerable.	Complete this secti a) Recommendat None b) Reimbursemen Under Table 1, rein	on if edito tion ratio nt condit	orial revisions are requested for the following elements onale				

c) Implementation guidance

Under Table 2 Responses to Questions from the drug programs, PAG is requesting the following revisions:

Under generalizability, the following comment should be removed:

pERC discussed and agreed that switching should only be allowed for toxicity reasons if the patient has not progressed on the previous treatment, or if the patient cannot tolerate an adequate dose of a regimen.

Under Funding Algorithms:

If there is no evidence to inform the sequencing of amivantamab or IO therapy, can a statement be added to indicate the lack of evidence and as such, this is to be addressed via an algorithm.



Stakeholder information			
CADTH project number	PC0289		
Brand name (generic)	Amivantamab (Rybrevant)		
Indication(s)	For the treatment of adult patients with locally advanced or n	netastat	ic
	non-small cell lung cancer (NSCLC) with activating epiderma	al growt	h
	factor receptor (EGFR) Exon 20 insertion mutations whose d	lisease	has
	progressed on, or after platinum-based chemotherapy		
Organization	Lung Cancer Canada – Patient Group		
	Lung Cancer Canada – Medical Advisory Committee		
Contact information ^a			
Stakeholder agreement w	ith the draft recommendation		
	1021 XX (55% 41%) D7 (25	Yes	\boxtimes
1. Does the stakeholder ag	gree with the committee's recommendation.	No	
patients with this disease. T clinical trial design and also options for targeted therapy current treatment paradigm	th our views that amivantamab is an extremely valuable treatm The recommended inclusion criteria and exclusion criteria are in in line with clinical practice. Patients in this niche population h reatments as it currently stands. The addition of amivantama is positive step forward in the expansion of treatments availab	n line w ave lim b to the	ited
patients with this disease. T clinical trial design and also options for targeted therapy current treatment paradigm patients.	The recommended inclusion criteria and exclusion criteria are in in line with clinical practice. Patients in this niche population h reatments as it currently stands. The addition of amivantama is positive step forward in the expansion of treatments availab	n line w ave lim b to the	ited
patients with this disease. T clinical trial design and also options for targeted therapy current treatment paradigm patients. Expert committee conside	The recommended inclusion criteria and exclusion criteria are in in line with clinical practice. Patients in this niche population h reatments as it currently stands. The addition of amivantama is positive step forward in the expansion of treatments availab	n line w have lim b to the ble to the	ited ese
patients with this disease. T clinical trial design and also options for targeted therapy current treatment paradigm patients. Expert committee conside 2. Does the recommendat	The recommended inclusion criteria and exclusion criteria are in in line with clinical practice. Patients in this niche population h y treatments as it currently stands. The addition of amivantama is positive step forward in the expansion of treatments available eration of the stakeholder input ion demonstrate that the committee has considered the	n line w lave lim b to the le to the	ited ese
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^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 <u>Procedures for CADTH Drug Reimbursement Reviews</u> for further details.

A. Patient Group Information								
Name	Shem Singh							
Position	Executive Director							
Date	Feb 16, 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. Assistan	ce with Providing Feedback							
	No 🛛							
If yes, please	e detail the help and who provide	d it.						
2. Did you	receive help from outside you	r patient grou	p to collect or a	nalyze any	No 🛛			
informa	tion used in your feedback?				Yes 🛛			
If yes, please detail the help and who provided it.								
C. Previous	ly Disclosed Conflict of Interes	ŧ						
submitt	onflict of interest declarations p ed at the outset of the CADTH ged? If no, please complete se	review and ha	ve those declar		ed No □ Yes ⊠			
D. New or U	pdated Conflict of Interest Dec	laration						
 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. 								
				priate Dollar Ra				
Company		\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000			
Add company	ny name							
Add company	ny name							
Add or remo	ve rows as required							

Appendix 2. Conflict of Interest Declarations for Clinician 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.
- For conflict of interest declarations:
 - Please 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.
 - Please note that declarations are required for each clinician that contributed to the input.
 - If your clinician group provided input at the outset of the review, only conflict of interest declarations
 that are new or require updating need to be reported in this form. For all others, please list the
 clinicians who provided input are unchanged
 - Please add more tables as needed (copy and paste).
 - All new and updated declarations must be included in a single document.

A. Assistance with Providing the Feedback		
2. Did you receive help from outside your clinician group to complete this submission?	No	\boxtimes
	Yes	
If yes, please detail the help and who provided it.		
3. Did you receive help from outside your clinician group to collect or analyze any	No	\boxtimes
information used in this submission?	Yes	
If yes, please detail the help and who provided it.		
B. Previously Disclosed Conflict of Interest		
4. Were conflict of interest declarations provided in clinician group input that was	No	
submitted at the outset of the CADTH review and have those declarations remained	Yes	X
unchanged? If no, please complete section C below.		
If yes, please list the clinicians who contributed input and whose declarations have not changed:		
 Dr. Barbara Melosky (lead) 		
Dr. David Dawe		
Dr. Sunil Yadav		
Dr. Shaqil Kassam		
Dr. Randeep Sangha		
Dr. Rosalyn Juergens		
Dr. Catherine Labbé		
Dr. Kevin Jao		
Dr. Geoffrey Liu		
Dr. Stephanie Snow		
Dr. Ron Burkes		
Dr. Paul Wheatley-Price		

C. New or Updated Conflict of Interest Declarations

New or Up	odated Declaration for Clinician	1					
Name	Please state full name						
Position	Please state currently held position						
Date	Please add the date form was o	completed (DD-	-MM-YYYY)				
	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.						
Conflict o	f Interest Declaration						
	ompanies or organizations that have who may have direct or indirect i				er the past two		
			Check Appro	priate Dollar Ran	ge		
Company		\$0 to 5,000	\$5,001 to	\$10,001 to	In Excess of		
			10,000	50,000	\$50,000		
Add comp	any name				\$50,000		
Add compa Add compa	No. 2						

Name	Please state full name
Position	Please state currently held position
Date	Please add the date form was completed (DD-MM-YYYY)
	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation
Conflict o	Interest Declaration
	mpanies or organizations that have provided your group with financial payment over the past two who may have direct or indirect interest in the drug under review.

	Check Appropriate Dollar Range				
Company	\$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					

New or Updated Declaration for Clinician 3				
Name	Please state full name			
Position	Please state currently held position			
Date	Please add the date form was completed (DD-MM-YYYY)			
	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.			

Conflict of Interest Declaration

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.

	Check Appropriate Dollar Range				
Company	\$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					

New or Up	dated Declaration for Clinician	14					
Name	Please state full name						
Position	Please state currently held position						
Date	Please add the date form was completed (DD-MM-YYYY)						
	I hereby certify that I have the matter involving this clinician or place this clinician or clinician g	clinician group	with a company,	organization, or e	entity that may		
283 7242 3 3	Charles (Barden Care						
Conflict of	f Interest Declaration						
List any co	mpanies or organization who may have direct or indirect				er the past two		
List any co	mpanies or organizations that ha		ug under review		an - maar oonte dhis onderwerkerder		
List any co	mpanies or organizations that ha		ug under review		ge		
List any co years AND Company	mpanies or organizations that ha who may have direct or indirect	interest in the dr	Ug under review Check Approp \$5,001 to	riate Dollar Ran \$10,001 to	ge In Excess of		
List any co years AND	mpanies or organizations that ha who may have direct or indirect any name	\$0 to 5,000	ug under review Check Approp \$5,001 to 10,000	riate Dollar Rang \$10,001 to 50,000	ge In Excess of \$50,000		

New or Up	odated Declaration for Clinician	5					
Name	Please state full name						
Position	Please state currently held position						
Date	Please add the date form was completed (DD-MM-YYYY)						
Conflict of	I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this clinician or clinician group with a company, organization, or entity that may place this clinician or clinician group in a real, potential, or perceived conflict of interest situation.						
	ompanies or organizations that hav who may have direct or indirect i				r the past two		
			Check Approp	riate Dollar Rang	je		
Company		\$0 to 5,000	\$5,001 to	\$10,001 to	In Excess of		
			10,000	50,000	\$50,000		

Add company name		
Add or remove rows as required		