CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

tepotinib (Tepmetko)

(EMD Serono Canada, a division of EMD Inc.)

Indication: For the treatment of adult patients with locally advanced unresectable metastatic non-small cell lung cancer (NSCLC) harbouring mesenchymal-epithelial transition (MET) tyrosine kinase receptor exon 14 skipping alterations.

March 17, 2022

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0255-00
Brand name (generic)	Tepotinib (Tepmetko)
Indication(s)	For the treatment of adult patients with locally advanced unresectable metastatic non-small cell lung cancer (NSCLC) harbouring mesenchymal-epithelial transition (MET) tyrosine kinase receptor exon 14 skipping alterations.
Organization	Ontario Health Lung Cancer Drug Advisory Committee (Lung DAC)
Contact information[a]	Name: Stephanie Susman [redacted]

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

No the Lung DAC does not agree with the committee's recommendation. The DAC believes that the recommendation fails to take into account what we have learned from other molecularly driven NSCLC (ie, high response rates and longer PFS) and the advantages of an oral therapy being a superior treatment in other molecularly driven NSCLC (such as EGFR and ALK).

The broad consensus internationally, is that molecularly driven treatment options should be used in preference to upfront chemotherapy or chemoimmunotherapy.

Joint guidelines from ASCO and OH-CCO recommend both tepotinib or capmatinib as the initial therapy for patients with tumors harboring exon14 met skipping mutations. Therefore the CADTH recommendation is out of step with current Canadian (Ontario) guidelines.

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	☐

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

pERC's conclusion – cannot compare tepotinib to currently used therapies such as immunotherapy/chemotherapy due to lack of comparative data etc. is true, but should acknowledge that tepotinib is almost certainly superior to best supportive care alone for patients who have exhausted those therapies, so consideration of funding in those patients could be considered.

	Yes	☐

4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	No	☒
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☒
	No	☐

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.
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  - 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		
1. Did you receive help from outside your clinician group to complete this submission?	No	☐
	Yes	☒
Yes, Ontario Health provides the Lung DAC secretariat assistance.		
2. Did you receive help from outside your clincian group to collect or analyze any information used in this submission?	No	☒
	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 submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	No	☐
	Yes	☒
If yes, please list the clinicians who contributed input and whose declarations have not changed: • Dr. Peter Ellis • Dr. Andrew Robinson		

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0255-000
Brand name (generic)	Tepmetko (Tepotinib)
Indication(s)	For the treatment of adult patients with locally advanced unresectable metastatic non-small cell lung cancer (NSCLC) harbouring mesenchymal-epithelial transition (MET) tyrosine kinase receptor exon 14 skipping alterations.
Organization	Lung Cancer Canada – Clinician 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	☒

The entirety of the recommendation hinges on the lack of randomized data. We have recently seen positive recommendations in other driver mutant lung cancers (ROS1 - crizotinib) and (BRAF - dabrafenib / trametinib) with similar single arm data despite lack of randomized data.

Discussion Points:
"pERC recognized the need for an effective targeted treatment option for patients with NSCLC harbouring METex14 skipping alterations. However, pERC concluded that the available evidence did not demonstrate that tepotinib meets these needs." The clinical data presented on tepotinib has a very similar objective response rate and PFS (44.6%, 8.5 months) in comparison to what has been seen in previous phase 3 trials of chemotherapy and immunotherapy (47.6%, 8.8 months) and is superior to what would be expected from standard of care chemotherapy (18.9%, 4.9 months) as was found in Keynote 189. The response rate and PFS of tepotinib is also incredibly consistent with other single arm trials of MET inhibitors (capmatinib, crizotinib) in a similar NSCLC patient population, which is typical of what has been seen with targeted therapies in other driver mutant lung cancers. We acknowledge that this is not a direct comparison, but a direct comparison is not forthcoming.

"There was no evidence on the relative safety of tepotinib compared to standard of care therapies, pERC concluded that it remains unknown whether tepotinib addresses this patient need." We do have evidence of the safety of this agent – but again as a direct comparison is not forthcoming with any agent, we can look at measures such as treatment discontinuation which speaks to significant toxicity. A relative comparison was provided in our initial clinician input.

"pERC noted the uncertainty regarding the HRQoL data from the VISION trial due to decreased sample sizes at later treatment cycles, open-label administration of tepotinib, and absence of a comparator arm. While we appreciate there is uncertainty in any data that comes from a non-randomized trial, we want to recognize the fact that QoL data was collected in this study, which is not the norm in other single arm trials. We feel it is important to acknowledge that QoL data and provide merit for the effort. If collection of QoL data in single arm trials detracts from positive recommendations, then future trials and sponsors may eliminate this data from being collected.

pERC notes that with the frequency of MET skipping mutations – those randomized trials could be completed. Please see our commentary in #3 about this statement. Approvals in other jurisdictions

across the world make conducting randomized trials challenging. Even having Health Canada approvals in our own country make it such that we create a two-tier system; patients that can afford to pay out-of-pocket or have private insurance can access these drugs, however those on the fully public system cannot, which creates lack of equity.

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	☒

"The clinician groups generally agreed with the input provided by the clinical experts consulted by CADTH." The pERC recommendation notes general agreement between the clinician stakeholders and the clinical experts of pERC, yet we came to very different conclusions on whether tepotinib should be recommended for funding. In our clinician stakeholder report, we discussed toxicity comparisons that were listed as lacking. We also did not see reference to the Canadian MET consensus publication nor the Canadian published data on MET frequency and efficacy. While our group is unaware of what the pharmaceutical company included in its real-world comparative data, we did include these references in our letter.

Clarity of the draft recommendation

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

"pERC recognized the need for an effective targeted treatment option for patients with NSCLC harbouring METex14 skipping alterations. However, pERC concluded that the available evidence did not demonstrate that tepotinib meets these needs." As no randomized trials are planned in this patient population by any manufacturer, pERC does not specify what, if any, alternative options would exist to provide adequate information to address pERCs concerns and provide access to MET skipping targeted therapy for Canadian patients. Guidance on how large a population globally is required to conduct a randomized trial would be helpful. pERC notes that this population is less than the number of ALK translocated NSCLC patients but considers it similar, so therefore this population should be subjected to randomization. What pERC does not take into consideration is that many other jurisdictions (US, EU) have approved and funded MET inhibitors ,which would make randomization difficult at best and likely unethical in those parts of the world severely limiting the available patient population for randomization. Many of the other parts of the world lag behind in comprehensive molecular testing, which makes identifying patients for participation in these trials extremely challenging. Novel means for garnering evidence beyond randomized controlled trials needs to be discussed or Canadian patients will continue to lag behind in getting access to the agents targeted at niche patient populations.

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

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☐
	No	☐

Not applicable

[a] CADTH may contact this person if comments require clarification.

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A. Assistance with Providing the Feedback		
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	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 information used in this submission?	No	☒
	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 submitted at the outset of the CADTH review and have those declarations remained unchanged? If no, please complete section C below.	No	☐
	Yes	☐
• *Dr. Rosalyn Juergens* • *Dr. David Dawe* • *Dr. Paul Wheatley-Price* • *Dr. Jeffery Rothenstein* • *Dr. Ron Burkes* • *Dr. Geoffrey Liu* • *Dr. Donna Maziak* *All clinicians listed provided input on the feedback and declarations have not changed for anyone.*		

C. New or Updated Conflict of Interest Declarations

New or Updated 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.

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 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.

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 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 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.

Conflict of Interest Declaration

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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 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.

Conflict of Interest Declaration

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Add company name	☐	☐	☐	☐
Add company name	☐	☐	☐	☐
Add or remove rows as required	☐	☐	☐	☐

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PAG
Name of the drug and Indication(s)	Tepotinib for locally advanced NSCLC
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	☐
	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
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.

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0255-000
Brand name (generic)	Tepmetko (Tepotinib)
Indication(s)	For the treatment of adult patients with locally advanced unresectable metastatic non-small cell lung cancer (NSCLC) harbouring mesenchymal-epithelial transition (MET) tyrosine kinase receptor exon 14 skipping alterations.
Organization	Lung Cancer Canada – Patient Group
Contact information[a]	Name: Winky Yau

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

LCC is very disappointed with CADTH's negative recommendation on the public reimbursement of tepotinib. As outlined in our initial submission, MET exon-14 skipping mutations drive roughly 3% of non-small cell lung cancers (NSCLC). LCC recognizes this is a very rare mutation in lung cancer; however, there are currently no targeted treatments available for this specific subset of patients, rather only standard systemic treatments such as chemotherapy, radiation, and immunotherapy, all of which come with toxic and harsh side effects. These treatments are also not specifically targeted to the patient's specific lung cancer subtype, but tepotinib as an oral targeted therapy does. It come with much less severe and toxic side effects, has been seen to be effective at treating one's disease, and improved patients' quality of life. It has been seen to help manage and minimize disease symptoms, and works to shrink tumours, including brain metastases. Tepotinib is currently one of the very few drugs that have shown efficacy for this patient group. By denying patients access to this therapy for which they have shown substantial benefit, it will cause unnecessary burden and suffering. It is not fair or ethical to patients who have a rare mutation as MET to deny them a drug that offers such benefits and should be made available to those who have failed other standard treatment options. These patients need access to timely and effective treatments for their cancer and cannot afford to wait. The unmatched potential that access to tepotinib will have for patients is incredibly positive, and will make a huge difference in the treatment paradigm for this patient population.

There is a large unmet need in this population, and unlike what pERC highlighted in the first discussion point within the recommendation regarding uncertainty of oral targeted therapies in improving health-related QoL, the patients that LCC interviewed in our initial submission had real-world experiences and drastic improvements in their disease with tepotinib in comparison to other treatments in the past. It significantly improved their quality of life, and for most, their disease symptoms previously impeded their ability to live a worthwhile and fulfilling lifestyle. Some patients were even bedridden and in palliative care with other treatment options not working, and tepotinib was a last resort. The impact of their disease was a significant burden on their ability to live a fulfilling life, but with tepotinib, it gave them an additional treatment option that ultimately made a significant difference and lifted an incredibly heavy burden off their health and allowed them to live a quality of life that was worthwhile and fulfilling. This is further highlighted throughout section 6 of LCC's initial patient submission. With a positive recommendation of tepotinib, the therapy can get into the hands of more Canadian lung cancer patients, and in turn, will generate more data with real-world evidence overtime.

There are currently no other treatments available for these patients with MET exon -14 skipping mutations – tepotinib is the very first targeted therapy approved for this population. Other standard IV treatments are systemic and carry a high level of burden for not only the patient, but also the caregivers, particularly with the harsh side effects that impede one's quality of life, independence, and functionality. Oral therapies, such as tepotinib, are much less invasive and offer much greater benefit to patients with less significant impacts on their livelihoods compared to IV treatments like chemotherapy and immunotherapy, or systemic treatments like radiation. The travel requirement for IV and systemic treatments at hospital centers is very burdening, time consuming, and tough for not only patients, but also caregivers as it leads to time off work, long travel times, and treatment in unfamiliar environments, especially for those living in small rural communities who prefer to stay close to home. These patient and caregiver values are critical to consider as it showcases the real-life impacts of how these treatments can change patients' lives. Patients deserve treatments that work and can allow them to return to a lifestyle comparable to what they had before diagnosis, and for the patients LCC had interviewed, this holds true for most if not all. Prior to tepotinib, patients carried a very high symptom burden due to the harsh effects of previous systemic treatments and disease progression, but once they started on tepotinib, the therapy relieved their symptoms relatively quickly, patients were able to regain their independence and perform activities of daily living, some even recovered well enough to potentially return to work. Tepotinib has allowed these patients to the stability to dream bigger than their diagnosis, return to "normal" life, enjoy the extra time they have, and make long term plans for the future.

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	☒

The rationale in the draft recommendation highlighted only very briefly the importance of patient and caregiver values that LCC highlighted for the majority of our initial submission. Additionally, CADTH also raised the question of whether tepotinib showed any clinical benefit compared to the current standard of care due to the single arm, phase II design of the clinical trial. In the first discussion point within the recommendation, pERC made a comment on the uncertainty regarding how oral dosage routes would translate into patient benefits, particularly on health-related quality of life. Oral targeted therapies carry a wide variety of benefits for not only patients, but also for caregivers. It changes the lifestyle that patients have while on treatment, as the oral dosage route allows patients the ease of taking treatment at home or on-the-go, simply taking a few pills per day and then are able to carry on with their activities. As discussed above, systemic IV treatments currently administered for MET patients like immunotherapy and chemotherapy require much more planning, travel time to/from a hospital, and time during treatment infusions. It carries high side effect burdens and doesn't offer the health-related quality-of-life that tepotinib does, thus, patients are more reliant on caregivers for functionality and daily activities, like cooking, cleaning, bathing, and even in financial aspects. These have been well-documented by LCC in past submissions, so there is no reason why LCC's initial submission does not provide evidence that oral therapy significantly improves health-related quality of life. This is further detailed in the Section 6 subheadings, "*Tepotinib helped patients get back to many of the activities they could do before diagnosis, including returning to work*" and "*Tepotinib has allowed patients to regain their independence and relieve the burden on caregivers".*

Patients with such a rare mutation as MET exon-14 deserve timely, effective, and specific targeted treatments for their cancer, just as much as those with more common biomarker types do. Although only 3-4% of lung cancer tumours carry this mutation, CADTH also previously recommended reimbursement of targeted therapies for other similarly rare subtypes, including ROS1, BRAF, and NTRK mutations. It is unfair for Canadian lung cancer patients to be denied access to a treatment

that has shown to work in patients. Other markets that tepotinib is approved in include USA, Japan, and the European Union; thus, there is international data to rely on for how well tepotinib has been working for patients in other markets, yet Canadians will continue to suffer the burden of this disease. There is a large unmet need for these patients and LCC hopes CADTH is able to take this into consideration.

Clarity of the draft recommendation

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

In line 6 of the rationale for recommendation, pERC notes, "As a result, the effect of tepotinib on HRQoL remains unknown". This is untrue, and as highlighted in paragraph 1 of the previous question, tepotinib had a significant positive impact on health-related QoL which was further outlined throughout Section 6 of LCC's initial submission, subsections 5 ("*Tepotinib helped patients get back to many of the activities they could do before diagnosis, including returning to work"*) and 6 *('Tepotinib has allowed patients to regain their independence and relieve the burden on caregivers").*

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

Not Applicable

5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☐
	No	☐

Not Applicable

[a] CADTH may contact this person if comments require clarification.

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A. Patient Group Information	
Name	*Shem Singh*
Position	*Executive Director, Lung Cancer Canada*
Date	*Thursday, March 17, 2022*
☒	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.

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	$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	☐	☐	☐	☐

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	
Brand name (generic)	Tepmetko (Tepotinib)
Indication(s)	Locally advanced or metastatic non-small cell lung cancer
Organization	Lung Health Foundation
Contact information[a]	Name: Peter Glazier

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

Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale.

We do not agree with the draft recommendation to not reimburse tepotinib as this is not aligned with NSCLC patient needs. As stated in our preliminary submission, patients with a METex14 mutation have a very limited amount of treatment options and improved access to treatments is desperately needed. There are currently no funded targeted therapies for patients with METex14 despite the fact that medical guidelines state that patients with driver mutations should be offered targeted treatment options. The current situations gives way to inequities among NSCLC patients given that other mutations have targeted treatment options available and funded.

Further, patients' value having oral cancer drug treatment options given the convenience of administering the medication at home as well as the decreased burden on the caregiver as they don't need to accompany the patient to their appointments.

We urge you to reconsider this recommendation.

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?

While our submission is referenced, the recommendation is not aligned with our feedback.

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	☐

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

	Yes	☐

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. N/A		

[a] CADTH may contact this person if comments require clarification.

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A. Patient Group Information	
Name	*Jessica Sopher*
Position	*National Manager, Policy & Government Relations*
Date	*(15-03-2022)*
☒	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.		

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	Yes	☒

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	$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	☐	☐	☐	☐