CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

CEMIPLIMAB (Libtayo)

(**Sanofi-Aventis Canada Inc.**)

Indication: Cemiplimab in combination with platinum-based chemotherapy for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) whose tumors have no epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK) or c-ROS oncogene 1 (ROS1) aberrations and is locally advanced where patients are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC.

April 18, 2024

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0331-000
Brand name (generic)	Cemiplimab (Libtayo)
Indication(s)	Libtayo (cemiplimab for injection): in combination with platinum-based chemotherapy for the first-line treatment of adult patients with NSCLC whose tumours have no EGFR, ALK or ROS1 aberrations and is:- locally advanced where patients are not candidates for surgical resection or definitive chemoradiation, or - metastatic NSCLC.
Organization	1. Lung Cancer Canada – Patient Group 2. Lung Cancer Canada's Medical Advisory Committee – Clinician Group
Contact information[a]	Name: Shem Singh, Executive Director [redacted]

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

This feedback on the draft recommendation for cemiplimab is on behalf of both Lung Cancer Canada's Medical Advisory Committee (Clinician Group) and Patient Group.

Lung Cancer Canada's Medical Advisory Committee and Patient Group thanks pERC for the positive recommendation to reimburse cemiplimab (Libtayo) in combination with platinum-based chemotherapy for the treatment of NSCLC patients who do not have targetable EGFR, ALK, or ROS1 mutations, and/or metastatic NSCLC patients. The approval of cemiplimab brings a very welcome addition to the treatment paradigm for these patients alongside the current available standard of care in the immunotherapy setting: pembrolizumab, or nivolumab + ipilimumab with platinum-based chemotherapy. As seen with our initial Clinician Input, clinicians agree that cemiplimab is equally as efficacious as the current standard of care.

However, the addition of cemiplimab as a treatment option will allow patients to be treated closer to home as it is a fixed dose regimen. This is a critical advantage that cemiplimab brings, as the current standard for available immunotherapy treatments is a weight-based dosing regimen. Though this allows for the fine-tuning of dosages that cater specifically to each individual patient, it also comes with drawbacks that tie in with accessibility of treatment for patients, particularly for those that live in rural or small communities, far from urban centers with larger hospitals. Having the fixed-dose regimen will allow patients to be treated closer to home at smaller, local community hospitals, alleviating certain financial, emotional, and mental tolls that travel can bring for patients and caregivers. Having cemiplimab as an alternative option is important for those who, for any reason, may be unable to access pembrolizumab or nivolumab, while also bringing numerous additional benefits from a stakeholder perspective, such as cost-effectiveness, better patient compliance, and easier access to care.

Overall, Lung Cancer Canada find this draft recommendation as very positive and excellent news, and hopes that CADTH is able to bring this to a positive final 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	☐
In the draft recommendation provided by CADTH, the *Sources of Information Used by the Committee* lists that only 2 physicians were involved in Lung Cancer Canada's Medical Advisory Committee Clinician Input. This is incorrect, as there were actually 12 physicians signed onto the initial Input submitted by LCC. We understand this may have been a simple typo error; however, we request that CADTH amend this in the final recommendation to accurately represent the support that LCC's Medical Advisory Committee provided in the initial submission. We believe that LCC's Patient Group Input was accurately represented and thoroughly considered by CADTH in 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	☐
If not, please provide details 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?	Yes	☒
	No	☐
If not, please provide details regarding the information that requires clarification.		

[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	*Shem Singh*
Position	*Executive Director*
Date	*April 17, 2024*
☒	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	☐	☐	☐	☐

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	☒
	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 information used in this submission?	No	☒
	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 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. Paul Wheatley-Price (lead), Dr. Kevin Jao, Dr. Michela Febbraro, Dr. Geoffrey Liu, Dr. Ron Burkes, Dr. Shaqil Kassam, Dr. Biniam Kidane, Dr. Barbara Melosky, Dr. Jeffrey Rothenstein, Dr. Rosalyn Juergens, Dr. Quincy Chu, Dr. Sunil Yadav, Dr. Mahmoud Abdelsalam		

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

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 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

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	☐	☐	☐	☐

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0331-000
Brand name (generic)	Libtayo (cemiplimab)
Indication(s)	In combination with platinum-based chemotherapy for the first-line treatment of adult patients with NSCLC whose tumours have no EGFR, ALK or ROS1 aberrations and is:- locally advanced where patients are not candidates for surgical resection or definitive chemoradiation, or - metastatic NSCLC
Organization	(Ontario Health) Lung Cancer Drug Advisory Committee
Contact information[a]	Name: Dr. Donna Maziak

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. The recommendation is consistent with the EMPOWER-3 trial data and other funded therapies.		

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. Recommendation 7 is unclear. It states that cemiplimab should only be reimbursed in combination with platinum based chemotherapy and states there are no data to support the efficacy and safety of cemiplimab as monotherapy. This is not an accurate statement. Cemiplimab monotherapy is recommended (but not funded) in this population of patients with tumors having high PD-L1 expression (TPS > 50%).		
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.		
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☐
	No	☒
If not, please provide details regarding the information that requires clarification.		

Recommendation 7 is unclear. It states that cemiplimab should only be reimbursed in combination with platinum based chemotherapy and states there are no data to support the efficacy and safety of cemiplimab as monotherapy. This is not an accurate statement. Cemiplimab monotherapy is recommended (but not funded) in this population of patients with tumors having high PD-L1 expression (TPS > 50%).

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

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- 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	*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 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	☐	☐	☐	☐

Appendix 2. Conflict of Interest Declarations for Clinician Groups

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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		
2. Did you receive help from outside your clinician group to complete this submission?	No	☐
	Yes	☒
If yes, please detail the help and who provided it. OH(CCO) provided a secretariat function to the group.		
3. 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		
4. 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. Donna Maziak • Dr. Peter Ellis		

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	☐	☐	☐	☐

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0331
Name of the drug and Indication(s)	Cemiplimab in combination with platinum-based chemotherapy for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) whose tumors have no epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK) or c-ROS oncogene 1 (ROS1) aberrations and is locally advanced where patients are not candidates for surgical resection or definitive chemoradiation, or metastatic 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	X
	No requested revisions	☐

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.

- Under Table 1 (Prescribing - 7), PAG suggested changing “administered” to “started” in the sentence: “Cemiplimab + PBC should only be reimbursed when **administered** in combination.”

- Under Table 1 (Prescribing – 7 Implementation guidance), the sentence reads: "Cemiplimab can continue as monotherapy after 4 cycles of PBC." PAG requested clarification if 4 cycles is a requirement and asked whether cemiplimab maintenance can start after 1 cycle of chemotherapy if the patient cannot tolerate the chemotherapy.
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. - Under Table 2 (Considerations for initiation of therapy), PAG requested clarification regarding which drug(s) to use for retreatment: cemiplimab and chemotherapy followed by maintenance, or cemiplimab with or without chemotherapy in the sentence: "pERC noted that patients who completed 2 years of cemiplimab treatment and progressed after the end of treatment should be eligible for retreatment for up to 17 cycles (1 year)."

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. An update to the algorithm is needed (rapid algorithm) 2.
2. Please specify other implementation questions or issues that should be addressed by CADTH
1. 2.
3. Please specify questions or issues that should be addressed by CAPCA. (oncology only)
1. 2.
Support strategy
4. 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	PC0331
Brand name (generic)	LIBTAYO® (cemiplimab for injection)
Indication(s)	Libtayo (cemiplimab for injection) is indicated in combination with platinum-based chemotherapy for the first-line treatment of adult patients with NSCLC whose tumors have no EGFR, ALK or ROS1 aberrations and is: -locally advanced where patients are not candidates for surgical resection or definitive chemoradiation, or -metastatic NSCLC.
Organization	sanofi-aventis Canada Inc.
Contact information[a]	[redacted]

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

Sanofi agrees with the pERC's recommendation to reimburse cemiplimab in combination with platinum-based chemotherapy (cemiplimab + PBC) for the requested indications. Notably cemiplimab + PBC is the only regimen recommended in locally advanced NSCLC where patients are not candidates for surgical resection or definitive chemoradiation. Sanofi also agrees with the pERC's assessment that cemiplimab + PBC aligns with patients' needs as it delays disease progression, prolongs survival, delays the deterioration of quality of life, and offers an important additional treatment option for patients, including those living in rural and remote regions. However, Sanofi respectfully disagrees with CADTH's evaluation of the submitted economic model, the exploratory reanalysis of the economic model, and the resulting ICERs and price reduction condition.

Economic Evidence – Key Limitation, pg 16 and CADTH reanalysis, pg 17
CADTH asserted that pembrolizumab monotherapy is a relevant treatment option for a subset of the indicated population (i.e., those expressing PD-L1 in ≥ 50% of tumour cells) and performed a reanalysis to adjust market shares of cemiplimab and pembrolizumab monotherapy up from 0%.
Canadian clinical experts consulted indicated that pembrolizumab (PEM) monotherapy is the standard of care and the preferred treatment option for patients whose tumours express PD-L1 in ≥ 50% of tumour cells. This was confirmed by recent 2023 Canadian chart audit data of newly treated NSCLC patients without driver mutations which showed that the vast majority of patients with high PD-L1 expression (≥50%) are treated with PEM monotherapy. This is also reflected in the CADTH provisional funding algorithm. Further, patients who are selected for PEM monotherapy are not candidates for IO + PBC therapy and, by extension, would not be candidates for cemiplimab + PBC. Therefore, PEM monotherapy is not an appropriate comparator for cemiplimab + PBC.
This is supported by CADTH's reanalysis of the BIA where market shares for immunotherapy monotherapies were adjusted downward, but cemiplimab + PBC was not assumed to capture market share from those monotherapies.

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	☐
The reasons for the recommendation are clearly stated.		
4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?	Yes	☒
	No	☐
In part. Sanofi respectfully requests that Table 1. Reimbursement Conditions and Reasons, Reimbursement Condition #5 on Page 4 be updated to accurately reflect the implementation advice provided by pERC on Page 9, "pERC noted that patients who completed 2 years of cemiplimab treatment and progressed after the end of treatment should be eligible for retreatment for up to 17 cycles (1 year)." This was suggested by pERC in order to align retreatment eligibility of cemiplimab + PBC with other reimbursed combinations of immunotherapy and chemotherapy combinations.		
5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?	Yes	☒
	No	☐
In part. The reasons for the recommendation are clearly stated. However, with respect to Table 1: Reimbursement Conditions and Reasons, Reimbursement Condition #8 on Page 5, Sanofi would like to offer context regarding the assumption of 100% weight-based dosing of comparators as it influences the cost comparison of cemiplimab to other immunotherapies currently reimbursed for the indicated population. Not every jurisdiction reimburses only weight-based dosing of immunotherapies for this population, but all jurisdictions do reimburse up to the maximum fixed dose (200 mg for pembrolizumab and 360 mg for nivolumab). As well, weight-based dosing is typically delivered in large academic treatment centres where vial sharing is easily accomplished. However, vial sharing may not be feasible in smaller outpatient centres so fixed dosing may be preferred by some centres to alleviate wastage. Recent 2023 Canadian chart audit data of newly treated NSCLC patients without driver mutations have shown that of those patients receiving PEM +/- PBC treatment, much less than 100% receive weight-based dosing. Also, Sanofi respectfully requests that Table 1: Reimbursement Conditions and Reasons, Reimbursement Condition #1 on Page 4 be revised to clarify that the recommendation applies to adult patients with either squamous or non-squamous NSCLC. The EMPOWER-Lung 3 trial enrolled patients irrespective of their histology, whereas patients with squamous NSCLC were typically excluded from previous trials. Further, in EMPOWER-Lung 3, patient randomization was stratified by baseline histology (squamous or non-squamous) so pre-specified subgroup analyses by histology are very robust and demonstrate consistent OS and PFS benefits with cemiplimab + PBC compared to PBC alone regardless of squamous or non-squamous NSCLC. This is an important feature of cemiplimab.		

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