CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

CEMIPLIMAB (LIBTAYO NSCLC)

(Sanofi Genzyme, a division of Sanofi-Aventis Canada Inc.)

Indication: For the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) expressing PD-L1 in ≥ 50% of tumour cells (Tumour Proportion Score [TPS] ≥ 50%), as determined by a validated test, with no EGFR, ALK or ROS1 aberrations, who have locally advanced NSCLC who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC.

May 19, 2022

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0262-000
Brand name (generic)	Libtayo (Cemiplimab)
Indication(s)	First-line treatment of adult patients with non-small cell lung cancer (NSCLC) expressing PD-L1 (Tumour Proportion Score [TPS] ≥ 50%), as determined by a validated test, with no EGFR, ALK, or ROS1 aberrations, who have locally advanced NSCLC who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC
Organization	Ontario Health (Cancer Care Ontario) 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	☐

The main reason for using this instead of currently approved options (which can be given every 6 wks instead of every 3), is if it is cheaper given the millions spent on these drugs per year. (The pCODR recommendation was "Cemiplimab should be negotiated so that it does not exceed the drug program cost of treatment with pembrolizumab." – it would be nice if it read "Cemiplimab should be negotiated so that it is a reduction in drug program cost compared to pembrolizumab." (particularly given the every 3 wks schedule).

A small point for funding is whether funding should be considered for cross-over due to infusion reactions/hypersensitivity. For pembrolizumab, this is rare (~0.2%), but is higher for cemiplimab (~3%). Obviously cross-over due to an iRAE doesn't make much sense, but hypersensitivity should allow cross-over, particularly if cemiplimab is chosen first.

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	☐
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	☐

[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 *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		
1. Did you receive help from outside your clinician group to complete this submission?	No	☐
	Yes	☒
Ontario Health provided secretariat functions to the DAC.		
2. Did you receive help from outside your clinician group to collect or analyze any information used in this submission?	No	☒
	Yes	☐
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		

C. New or Updated Conflict of Interest Declarations

New or Updated Declaration for Clinician 1	
Name	*Dr. Donna Maziak*
Position	*Ontario Health (CCO) Lung Cancer Drug Advisory Committee Lead*
Date	*18-05-2022*
☒	**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.	

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0262-000
Brand name (generic)	Libtayo (Cemiplimab)
Indication(s)	First line treatment of adult patients with non-small cell lung cancer (NSCLC) expressing PD-L1 (Tumour Proportion Score [TPS] ≥50%), as determined by a validated test, with no EGFR, ALK or ROS1 aberrations, who have locally advanced NSCLC who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC.
Organization	Lung Cancer Canada – Clinician Group
Contact information[a]	Name: Dr. Paul Wheatley-Price: [redacted]

Stakeholder agreement with the draft recommendation		
1. Does the stakeholder agree with the committee's recommendation.	Yes	☒
	No	☐
The recommendation is comprehensive, recognizing the efficacy of cemiplimab, it's role as an alternative to pembrolizumab in this population, and the potential advantage for some patients of the flat dosing that may allow treatment closer to home. We agree with the committee extending this indication to patients with ECOG PS2 and never-smokers, and the ability for up to 12 months of re-treatment if patients experience progression following completion of an initial 108 week course of cemiplimab.		

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	☒
At Lung Cancer Canada we submitted both patient input and clinician input, however due to a clerical mistake at CADTH, the clinician input was not provided to the Expert Committee. We have received an apology from CADTH and have been invited to provide feedback on the draft recommendation. In general we agree with the draft recommendation and have only one amendment to suggest. However, we would also appreciate if the Expert Committee would acknowledge the clinician input from LCC and review that submission.		

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	☒
The area that we would recommend clarification is the statement 2.3, that patients should not have uncontrolled CNS metastases. Our opinion is that this statement can be open to interpretation. With		

improved imaging small asymptomatic brain metastases may be identified that are not a contraindication to cemiplimab, but nor do they require urgent radiotherapy intervention. Further, some centres only recommend brain imaging if patients have symptoms. We have good data to support the efficacy of this class of drugs intracranially. We would recommend this is amended to say: “2.3 Uncontrolled AND symptomatic CNS metastases. CNS imaging not mandated.”

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

Appendix 2. Conflict of Interest Declarations for Clinician Groups

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- 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		
1. 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.		
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	☒
If yes, please list the clinicians who contributed input and whose declarations have not changed: • Dr. Paul Wheatley-Price, • Dr. Ron Burkes, • Dr. Geoffrey Liu, • Dr. Shaqil Kassam, • Dr. Silvana Spadafora, • Dr. Quincy Chu, • Dr. Donna Maziak, • Dr. Rosalyn Juergens, • Dr. Randeep Sangha, • Dr. Callista Phillips, • Dr. Stephanie Snow, • Dr. David Dawe, • Dr. Mahmoud Abdelsalam,		

- Dr. Sunil Yadav,
- Dr. Nicole Bouchard,
- Dr. Catherine Labbé,
- Dr. David Stewart,
- Dr. Normand Blais,
- Dr. Kevin Jao,
- Dr. Barb Melosky,
- Dr. Cheryl Ho

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)*

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0262
Name of the drug and Indication(s)	Cemiplimab for 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
None.

3. Clarity of the recommendation Complete this section if editorial revisions are requested for the following elements
a) Recommendation rationale
In the Drug Program Input section, Table 2 Responses to Questions from the Drug Programs, under the heading Considerations for Initiation of Therapy, fifth row, PAG is requesting an editorial revision to state that patients who have progressed within 6 months of their last dose of adjuvant/neo adjuvant chemotherapy be eligible to receive single agent cemiplimab.
b) Reimbursement conditions and related reasons
None.
c) Implementation guidance
None.

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0262-000
Brand name (generic)	Cemiplimab (Libtayo)
Indication(s)	For the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) expressing PD-L1 in ≥ 50% of tumour cells (Tumour Proportion Score [TPS] ≥ 50%), as determined by a validated test, with no EGFR, ALK or ROS1 aberrations, who have locally advanced NSCLC who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC.
Organization	Lung Cancer Canada – Patient Group
Contact information[a]	Name: Shem Singh [redacted]

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

Lung Cancer Canada is pleased that the Expert Review Committee has agreed to reimburse cemiplimab and recognises the need for additional treatment options for patients in this PD-L1 NSCLC setting. Undoubtedly, this positive recommendation will allow for patients to receive equitable access to this treatment closer to home that otherwise may not have had the opportunity to.

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	☐

Overall, LCC believes the recommendation demonstrates thorough consideration of our organization's patient input provided to CADTH and have no amendments to suggest from the patient perspective. In our initial submission, LCC highlighted the importance of an additional treatment option that cemiplimab would bring to patients in Canada. As pembrolizumab is the current comparator, cemiplimab would allow for an alternative treatment option for patients with PD-L1 NSCLC that is equally as efficacious and offer treatments closer to home with the fixed-dosing model cemiplimab provides. Allowing patients living away from city centers or major hospitals to access their treatment at a local community hospital or clinic will mitigate the travel and financial barriers that patients may face, and allow for better quality of life, increased independence, quicker return to life activities, and increased recovery time at home. These are highlighted within discussion point one.

Additionally, drug wastage is also associated with the weight-based dosing model pembrolizumab brings, and LCC is pleased pERC has taken this into consideration within their review as noted in discussion point two. The small patient numbers at local community hospitals with a weight-based dosage model lead to higher potential for drug wastage and complicate administration; however, the fixed-dosing model will mitigate this.

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

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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	*Shem Singh*
Position	*Executive Director*
Date	*May 19, 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.

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	PC0262-000
Brand name (generic)	LIBTAYO™ (cemiplimab for injection)
Indication(s)	First-line treatment of adult patients with non-small cell lung cancer (NSCLC) expressing PD-L1 (Tumour Proportion Score [TPS] ≥ 50%), as determined by a validated test, with no EGFR, ALK, or ROS1 aberrations, who have locally advanced NSCLC who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC
Organization	Sanofi Genzyme, a division of Sanofi-Aventis Canada Inc.
Contact information[a]	Name: [redacted]

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

Sanofi agrees with pERC's recommendation to reimburse cemiplimab for the requested indication. However, Sanofi respectfully disagrees with the CADTH evaluation of the submitted economic model, the exploratory reanalysis of the economic model, and the resulting ICERs and price reduction condition.

Clinical Evidence – Critical appraisal p.11 and Economic Evidence – 1st key limitation p.13
CADTH noted that few inferences can be made from the results of the NMA because of important limitations with the included studies and the methods and assumptions made in the NMA. The key limitation related to the choice of relevant comparators did not include pembrolizumab in combination with chemotherapy, a comparator considered to be relevant in the Canadian treatment landscape for patients with NSCLC expressing PD-L1 50% or greater. Sanofi acknowledges the heterogeneity within the NMA included trials, however, as noted within the submitted NMA report section on page 106, there were considerations to address the heterogeneity between trial designs. The CADTH clinical report for nivolumab in combination with ipilimumab noted similar concerns with trial comparisons. Finally, at the time of the submission, the information available on possible direct comparators to cemiplimab resulted in excluding the combination of pembrolizumab in combination with chemotherapy due to its extremely low utilization in 1L NSCLC patients with PD-L1≥50% according to the ONCO-CAPPS data capture rate, and the opinion of clinical experts consulted who indicated that pembrolizumab in monotherapy would be the main comparator and considered the standard of care in these patients. Therefore, Sanofi believes that the included comparators and the submitted NMA are applicable to the Canadian context.

Economic Evidence – 2nd key limitation on the inappropriate inclusion of chemotherapy as a comparator p.13
CADTH's base case analysis excluded chemotherapy as a comparator. Sanofi agrees that currently, the most relevant comparator is pembrolizumab monotherapy rather than chemotherapy. However, the inclusion of chemotherapy as a comparator should not be considered inappropriate as it was the comparator in EMPOWER Lung-1 trial. The chemotherapy comparator for this study was selected during the period of trial planning under early scientific advice and agreed to with major regulatory agencies. In addition, as mentioned in the clinical review report (p. 54), pembrolizumab was not funded across Canada for this indication at the time of the submission. As such, its exclusion would be

inappropriate. Furthermore, chemotherapy remains a valid first-line treatment option in patients with advanced non-small cell lung carcinoma based on the Cancer Care Ontario treatment guidelines for lung cancer.

Economic evidence – 3rd key limitation on lack of clinical validity in survival outcomes p.13
CADTH indicated that the OS and PFS extrapolation for cemiplimab and pembrolizumab lacked clinical validity. The PFS and OS for pembrolizumab predicted from the sponsor's model were substantially lower than those reported in the KEYNOTE-024 trials. The totality of PFS evidence suggests that cemiplimab and pembrolizumab confer a survival advantage to advanced/metastatic NSCLC patients with high PD-L1 levels relative to chemotherapy. To extrapolate the OS and PFS benefits of cemiplimab and pembrolizumab, time varying HRs for relative treatment effect for cemiplimab and pembrolizumab were modelled using second order fractional polynomial (FP) models. The second order FP models used to model the time varying HRs are extensions of the exponential, Weibull and Gompertz models. The best fitting model for OS and PFS according to BIC and AIC was the second order FP which was applied within the submitted model in accordance to accepted standards of economic evaluation to utilize the model with the best fit. Sanofi reiterates its support for the economic model submitted to CADTH, which is grounded in the clinical evidence, aligns with clinical expert feedback, and results in an ICER of $26,521/QALY compared to chemotherapy with pembrolizumab being extendedly dominated.

Economic Evidence – 4th key limitation on the treatment dosage for pembrolizumab and subsequent treatment regimens p.13
CADTH indicated that the treatment dosage for pembrolizumab and subsequent treatment regimens did not reflect the standard of care in Canada. As per the monograph of Keytruda™, the 200 mg flat dose is the recommended dose for pembrolizumab in previously untreated NSCLC as monotherapy in Canada, as such we did not use weight-based dosing as suggested by CADTH as this is not on-label. We recognize that vial sharing dose occur in practice potentially based on extrapolation from other disease setting. Of note, vial sharing for pembrolizumab is not consistently implemented across jurisdictions. Although this practice was included in CADTH base case, it was inherently assumed that vial sharing would be implemented on 100% of the patients modelled in the analysis despite evidence of 47% of cancer drug administrations incurring wastage. As such, CADTH overestimated the savings from vial sharing for pembrolizumab.

CADTH reanalysis – CADTH exploratory reanalysis using various assumptions p. 13
CADTH performed an exploratory reanalysis using different assumptions leading to inflated ICERs and results suggesting a 61% price reduction to achieve cost-effectiveness. Sanofi stands firmly behind the cemiplimab pharmacoeconomic submission. The CADTH exploratory analysis ICER and price reduction estimates are based on inadequate assumptions that greatly underestimate the benefits and cost-effectiveness of cemiplimab. In addition to the earlier comments, Sanofi believes that the QoL data taken from R2810-ONC-1624 trial are robust and should not be replaced with utilities derived from the Keynote-024 trial. CADTH justified this assumption on the basis of a perceived alignment with clinical expectations. Accounting for all the above, the CADTH exploratory reanalysis and the resulting inflated ICERs and price reduction are not considered to be appropriate. Sanofi reiterates its support for the economic model submitted to CADTH, which is grounded in the clinical evidence, aligns with clinical expert feedback, and results in an ICER of $26,521/QALY compared to chemotherapy with pembrolizumab being extendedly dominated.

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 part: Although the committee may have considered some of the stakeholder input, the recommendation does not align with the pharmacoeconomic evidence provided within the submission. In addition, CADTH used assumptions in their reanalysis that did not consider clinical expert opinions and the critically appraised economic model structure already accepted by CADTH for NSCLC patients. This resulted in inflated ICERs and price reduction estimates for cemiplimab in the treatment of previously untreated NSCLC.		
Clarity of the draft recommendation		
3. Are the reasons for the recommendation clearly stated?	Yes	☒
	No	☐
In part: Sanofi is unclear as to why CADTH opted to use some of the assumptions that did not appropriately account for the clinical evidence submitted. Sanofi believes it made considerable efforts to reflect the opinions of Canadian and international oncology experts in the treatment of advanced NSCLC, the clinical evidence available and submitted to CADTH, in addition to using a model structure and findings accepted by CADTH's Economic Guidance Panel of experts for an oncology drug in a similar context.		
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	☐

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