CADTH

CADTH REIMBURSEMENT REVIEW

Stakeholder Feedback on Draft Recommendation

NIVOLUMAB (Opdivo)

(Bristol-Myers Squibb Canada)

Indication: Gastric, gastroesophageal junction or esophageal adenocarcinoma.

February 17, 2022

CADTH Reimbursement Review

Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0259
Name of the drug and Indication(s)	Nivolumab for gastroesophageal junction or esophageal adenocarcinoma
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
None.
b) Reimbursement conditions and related reasons
In the Cost and Cost-Effectiveness summary table, in the “Treatment Cost” row, PAG is requesting the removal of the word cycle.
c) Implementation guidance
In Table 2 Implementation Guidance, under condition 4, PAG is seeking clarity whether treatment with nivolumab can be resumed at time of progression (i.e., if patients stopped treatment while on nivolumab and did not experience progression, can they resume).

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CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0259-000
Brand name (generic)	Opdivo (nivolumab)
Indication(s)	In combination with fluoropyrimidine- and platinum-containing chemotherapy, for the treatment of adult patients with advanced or metastatic gastric, gastroesophageal junction or esophageal adenocarcinoma.
Organization	Ontario Health (CCO) Gastrointestinal Cancer Drug Advisory Committee
Contact information[a]	Name: [redacted] Title: [redacted] Email: [redacted]

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

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	☐
The DAC highlights a consideration for a recommendation on nivolumab with alternate chemotherapy combinations (such as nivolumab+FOLFIRI) in patients who were treated and progressed on or shortly after oxaliplatin-based treatment (e.g., patients who received curative-intent adjuvant FLOT). This would be a small subset of patients. While the benefit of this combination is uncertain as it is not the regimen used in CheckMate 649, clinicians may not want to retreat these patients with an oxaliplatin-based treatment and use an alternate chemotherapy backbone (e.g., FOLFIRI) instead. [In reference to Prescribing 6]		
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	☒
OH-CCO provided secretariat support to the DAC in completing this input.		
2. Did you receive help from outside your clincian 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. Erin Kennedy • Dr. Christine Brezden-Masley • Dr. Tim Asmis • Dr. Jim Biagi		

CADTH

CADTH Reimbursement Review
Feedback on Draft Recommendation

Stakeholder information	
CADTH project number	PC0259
Brand name (generic)	OPDIVO (nivolumab)
Indication(s)	OPDIVO in combination with fluoropyrimidine- and platinum-containing chemotherapy, for the treatment of adult patients with advanced or metastatic gastric, gastroesophageal junction or esophageal adenocarcinoma.
Organization	Bristol-Myers Squibb Canada
Contact information[a]	Name: [redacted]

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

Bristol-Myers Squibb Canada (BMS) agrees with the pERC draft recommendation for nivolumab in combination with fluoropyrimidine- and platinum-containing chemotherapy, for the treatment of adult patients with advanced or metastatic gastric, gastroesophageal junction or esophageal adenocarcinoma. The pERC acknowledged the statistically significant and clinically meaningful improvement in overall survival (OS) in all randomized patients regardless of PD-L1 CPS. pERC also acknowledged that nivolumab was associated with a manageable toxicity profile. BMS is committed to working with the provinces to facilitate access to Canadian patients with gastric, gastroesophageal junction or esophageal adenocarcinoma.

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.