

## CADTH REIMBURSEMENT REVIEW

# Stakeholder Feedback on Draft Recommendation

**pembrolizumab (Keytruda)**  
(Merck Canada)

**Indication:** In combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of adult patients with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma.

**September 19, 2024**

**Disclaimer:** The views expressed in this submission are those of the submitting organization or individual. As such, they are independent of CADTH and do not necessarily represent or reflect the view of CADTH. No endorsement by CADTH is intended or should be inferred.

By filing with CADTH, the submitting organization or individual agrees to the full disclosure of the information. CADTH does not edit the content of the submissions.

CADTH does use reasonable care to prevent disclosure of personal information in posted material; however, it is ultimately the submitter's responsibility to ensure no identifying personal information or personal health information is included in the submission. The name of the submitting stakeholder group and all conflicts of interest information from individuals who contributed to the content are included in the posted submission.

# CADTH Reimbursement Review

## Feedback on Draft Recommendation

| Stakeholder information   |  |
|---|--|
| CADTH project number  | PC0356   |
| Brand name (generic)  | Pembrolizumab (Keyruda)  |
| Indication(s)   | in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of adult patients with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma |
| Organization  | OH (CCO) Gastrointestinal Cancer Drug Advisory Committee ("GI DAC")  |
| Contact information <sup>a</sup>  | Name: Dr. Erin Kennedy   |
| Stakeholder agreement with the draft recommendation   |  |
| <b>1. Does the stakeholder agree with the committee's recommendation.</b>   | Yes <input checked="" type="checkbox"/>  |
|   | No <input type="checkbox"/>  |
| Please explain why the stakeholder agrees or disagrees with the draft recommendation. Whenever possible, please identify the specific text from the recommendation and rationale. |  |
| Expert committee consideration of the stakeholder input   |  |
| <b>2. Does the recommendation demonstrate that the committee has considered the stakeholder input that your organization provided to CADTH?</b>                                   | Yes <input checked="" type="checkbox"/>  |
|   | No <input type="checkbox"/>  |
| If not, what aspects are missing from the draft recommendation?   |  |
| Clarity of the draft recommendation   |  |
| <b>3. Are the reasons for the recommendation clearly stated?</b>  | Yes <input checked="" type="checkbox"/>  |
|   | No <input type="checkbox"/>  |
| If not, please provide details regarding the information that requires clarification.   |  |
| <b>4. Have the implementation issues been clearly articulated and adequately addressed in the recommendation?</b>   | Yes <input checked="" type="checkbox"/>  |
|   | No <input type="checkbox"/>  |
| If not, please provide details regarding the information that requires clarification.   |  |
| <b>5. If applicable, are the reimbursement conditions clearly stated and the rationale for the conditions provided in the recommendation?</b>                                     | Yes <input checked="" type="checkbox"/>  |
|   | No <input type="checkbox"/>  |
| If not, please provide details regarding the information that requires clarification.   |  |

<sup>a</sup> 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  |     |                                     |
|--|-----|-------------------------------------|
| 2. Did you receive help from outside your clinician group to complete this submission?   | No  | <input type="checkbox"/>            |
|  | Yes | <input checked="" type="checkbox"/> |
| If yes, please detail the help and who provided it.<br>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  | <input checked="" type="checkbox"/> |
|  | Yes | <input type="checkbox"/>            |
| 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  | <input type="checkbox"/>            |
|  | Yes | <input type="checkbox"/>            |
| If yes, please list the clinicians who contributed input and whose declarations have not changed: <ul style="list-style-type: none"> <li>Dr. Erin Kennedy</li> <li>Dr. Michael Raphael</li> </ul>                        |     |                                     |

### C. New or Updated Conflict of Interest Declarations

| New or Updated Declaration for Clinician 1 |   |
|--|---|
| <b>Name</b>                                | Dr. Suneil Khanna   |
| <b>Position</b>                            | Member, OH (CCO) GI DAC   |
| <b>Date</b>                                | 06-09-2024  |
| <input checked="" type="checkbox"/>        | <b>I hereby certify</b> 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    |
| Merck                          | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Add company name               | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Add or remove rows as required | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

### New or Updated Declaration for Clinician 2

|                                     |   |
|-------------------------------------|---|
| <b>Name</b>                         | Dr. Rachel Goodwin  |
| <b>Position</b>                     | Member, OH (CCO) GI DAC   |
| <b>Date</b>                         | 06-09-2024  |
| <input checked="" type="checkbox"/> | <b>I hereby certify</b> 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    |
| Merck                          | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Add company name               | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Add or remove rows as required | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

### New or Updated Declaration for Clinician 3

|                                     |   |
|-------------------------------------|---|
| <b>Name</b>                         | Dr. Tim Asmis   |
| <b>Position</b>                     | Member, OH (CCO) GI DAC   |
| <b>Date</b>                         | 06-09-2024  |
| <input checked="" type="checkbox"/> | <b>I hereby certify</b> 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    |
| Merck            | <input type="checkbox"/>       | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Add company name | <input type="checkbox"/>       | <input type="checkbox"/>            | <input type="checkbox"/> | <input type="checkbox"/> |

# CADTH Reimbursement Review

## Feedback on Draft Recommendation

| Stakeholder information  |   |
|--|---|
| CADTH project number   | PC0356  |
| Name of the drug and Indication(s)   | <b>Pembrolizumab</b> in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of adult patients with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma |
| Organization Providing Feedback  | PAG   |
| <b>1. Recommendation revisions</b>   |   |
| Please indicate if the stakeholder requires the expert review committee to reconsider or clarify its recommendation.   |   |
| <b>Request for Reconsideration</b>   | <b>Major revisions:</b> A change in recommendation <b>category</b> or patient <b>population</b> is requested <input type="checkbox"/>   |
|  | <b>Minor revisions:</b> A change in reimbursement <b>conditions</b> is requested <input type="checkbox"/>   |
| <b>No Request for Reconsideration</b>  | <b>Editorial revisions:</b> Clarifications in recommendation <b>text</b> are requested <input checked="" type="checkbox"/>  |
|  | <b>No requested revisions</b> <input type="checkbox"/>  |
| <b>2. Change in recommendation category or conditions</b>  |   |
| 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.   |   |
| <b>3. Clarity of the recommendation</b>  |   |
| Complete this section if editorial revisions are requested for the following elements  |   |
| <b>a) Recommendation rationale</b>   |   |
| Please provide details regarding the information that requires clarification.  |   |
| <b>b) Reimbursement conditions and related reasons</b>   |   |
| Please provide details regarding the information that requires clarification.  |   |
| In table 1 under Discontinuation, PAG suggested removing "at a dose of 200mg" and only stating "e.g. 35 cycles administered every 3 weeks" as jurisdictions will implement with weight-based dosing. |   |

### 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.

In table 2, PAG suggested repeating the following statement from the Discussion Points: “pERC further discussed that chemotherapy may be initiated pending results of HER2 testing and pembrolizumab added upon confirmation of HER2-negative status. If HER2 status cannot be determined (e.g., insufficient tissue for testing), patients may be considered for the treatment with pembrolizumab plus chemotherapy.”

In table 2 under Considerations for initiation of therapy (question #4), PAG suggested adding pERC’s position/opinion (i.e., pERC agreed...) on the following statement: “The clinical experts noted that retreatment with pembrolizumab, alone or in combination with chemotherapy, should be based on a joint decision-making process between the oncologist and patient, considering disease burden, residual treatment side effects, and patient symptoms, values and preferences.”

In table 2, under Relevant Comparators, PAG suggested adding: “pERC noted that patients should initiate pembrolizumab therapy with platinum- and fluoropyrimidine-containing chemotherapy before discontinuing the platinum drug or switching to an alternative regimen due to intolerance or unacceptable toxicity of platinum agents” if pERC discussed this issue.

## 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. The algorithm needs to be updated (rapid algorithm).
- 2.

#### 2. Please specify other implementation questions or issues that should be addressed by CADTH

- 1.
- 2.

### Support strategy

#### 3. Do you have any preferences or suggestions on how CADTH should address these issues?

## CADTH Reimbursement Review Feedback on Draft Recommendation

| Stakeholder information  |  |
|--|--|
| CADTH project number   | PC0356   |
| Brand name (generic)   | KEYTRUDA (pembrolizumab)   |
| Indication(s)  | In combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of adult patients with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma |
| Organization   | Merck Canada Inc.  |
| Contact information <sup>a</sup>   | [REDACTED]   |
| Stakeholder agreement with the draft recommendation  |  |
| 1. Does the stakeholder agree with the committee's recommendation.   | Yes <input checked="" type="checkbox"/>  |
|  | No <input type="checkbox"/>  |
| <p>Transcription typo<br/>Pg. 3 Under <u>Recommendation</u><br/>"The pCODR Expert Review Committee (pERC) recommends (...) only if the conditions listed in <b>Error! Reference source not found.</b> are met."<br/>➤ Should read: "only if the conditions listed in <b>Table 1 are met</b>"</p> |  |
| 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 <input checked="" type="checkbox"/>  |
|  | No <input type="checkbox"/>  |
| 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 <input checked="" type="checkbox"/>  |
|  | No <input type="checkbox"/>  |
| 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 <input checked="" type="checkbox"/>  |
|  | No <input type="checkbox"/>  |
| 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 <input checked="" type="checkbox"/>  |
|  | No <input type="checkbox"/>  |
| If not, please provide details regarding the information that requires clarification.  |  |

<sup>a</sup> CADTH may contact this person if comments require clarification.