Canada's Drug Agency
L'Agence des médicaments du Canada

CDA-AMC REIMBURSEMENT REVIEW

# Stakeholder Feedback on Draft Recommendation

**nivolumab**

(non-sponsored)

**Indication:** With doxorubicin, vinblastine and dacarbazine (AVD) in previously untreated stage III or IV Hodgkin Lymphoma.

**Jan 17, 2025**

CADTH

# CADTH Reimbursement Review
# Feedback on Draft Recommendation

| Stakeholder information | |
|---|---|
| CADTH project number | PX0376-000 |
| Brand name (generic) | Nivolumab (Opdivo) |
| Indication(s) | Nivolumab with doxorubicin, vinblastine and dacarbazine (AVD) in previously untreated stage III or IV Hodgkin Lymphoma. |
| Organization | Lymphoma Canada |
| Contact information[a] | Name: Gurjot Basra gurjot@lymphoma.ca |

| 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.

Lymphoma Canada agrees with the committee's recommendation that Nivolumab in combination with doxorubicin, vinblastine and dacarbazine (AVD) be reimbursed for the first-line treatment of stage III and stage IV classic Hodgkin lymphoma in patients 12 years of age and older.

Currently, there is an unmet need in terms of treatment options for patients with advanced classical Hodgkin lymphoma (cHL). Nivolumab + AVD provides a viable option for patients while aligning with patient preferences in terms of longer progression free survival with fewer associated side effects.

| 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.

Yes the reasons for the recommendation are clearly stated.

| | | |
|---|---|---|
| **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.

In regards to condition 7, we believe that the feasibility of adoption should not be tied strictly to budgetary constraints but should heavily consider clinical benefit to patients.

[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** | *Gurjot Basra* |
| **Position** | *Manager of Patient Programs, Research, and Advocacy* |
| **Date** | *June 19, 2025* |
| ☒ | 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** |
| | ☐ | ☐ | ☐ | ☐ |
| | ☐ | ☐ | ☐ | ☐ |
| | ☐ | ☐ | ☐ | ☐ |

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# Feedback on Draft Recommendation

| Interested party information | |
|---|---|
| Project number | PX0376-000 |
| Brand name (generic) | Opdivo (nivolumab) |
| Indication(s) | With doxorubicin, vinblastine and dacarbazine (AVD) in previously untreated stage III or IV Hodgkin Lymphoma. |
| Organization | The Leukemia & Lymphoma Society of Canada (LLSC) |
| Contact information[a] | Name: Colleen McMillan – colleen.mcmillan@lls.org |

| Interested party agreement with the draft recommendation | | |
|---|---|---|
| **1. Does the interested party agree with the committee's recommendation.** | Yes | ☒ |
| | No | ☐ |
| We believe this recommendation reflects the value of nivolumab as an important treatment option for patients with classical Hodgkin lymphoma who have limited therapeutic alternatives. We agree that there is significant unmet clinical need arising from cHL and that this treatment addresses unmet need. The recommendation aligns with patient priorities for access to effective and tolerable treatments. | | |
| **Expert committee consideration of the input** | | |
| **2. Does the recommendation demonstrate that the committee has considered the input that your organization provided?** | Yes | ☐ |
| | No | ☒ |
| Our organization did not submit initial input for this review. However, we support the input provided by Lymphoma Canada on behalf of those affected by Hodgkin Lymphoma. We are pleased to see that patient perspectives appear to have been considered in shaping this 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] CDA-AMC 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 CDA-AMC 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.
- CDA-AMC may contact your group with further questions, as needed.
- Please see the *Procedures for Drug Reimbursement Reviews* for further details.

| **A. Patient Group Information** | |
|---|---|
| **Name** | *Colleen McMillan* |
| **Position** | *Advocacy Lead* |
| **Date** | *18-06-2025* |
| ☒ | 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 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** |
| *Bristol Myers Squibb* | ☐ | ☐ | ☐ | ☒ |
| *Add company name* | ☐ | ☐ | ☐ | ☐ |
| *Add or remove rows as required* | ☐ | ☐ | ☐ | ☐ |

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# Feedback on Draft Recommendation

| Interested party information | |
|---|---|
| Project number | PX0376 |
| Brand name (generic) | (nivolumab) |
| Indication(s) | Hodgkin Lymphoma |
| Organization | Ontario Health (Cancer Care Ontario) – Hematology Cancer Drug Advisory Committee (DAC) |
| Contact information[a] | Name: Dr. Tom Kouroukis |

| Interested party agreement with the draft recommendation | | |
|---|---|---|
| **1. Does the interested party agree with the committee's recommendation.** | Yes | ☒ |
| | No | ☐ |
| Patients should be eligible for treatment with nivolumab and pembrolizumab following disease recurrence after treatment with nivolumab + AVD if there was a previous response to treatment. Retreatment should be available after 3 months.<br><br>Dosing should align with the trial dose of 240 mg for adult patients.<br><br>Patients with stage IIb and IIb bulky should be eligible for nivolumab-AVD as they are treated similar to Hodgkin Lymphoma Stage III and IV. | | |
| **Expert committee consideration of the input** | | |
| **2. Does the recommendation demonstrate that the committee has considered the input that your organization provided?** | 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] CDA-AMC 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 CDA-AMC 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.
- CDA-AMC may contact your group with further questions, as needed.
- Please see the *Procedures for 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 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 CDA-AMC 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.
- CDA-AMC may contact your group with further questions, as needed.
- Please see the *Procedures for 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 | ☒ |
| Ontario Health (Cancer Care Ontario) provided secretariat support in completing this submission | | |
| **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 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:<br>• Clinician 1<br>• Clinician 2<br>• *Add additional (as required)* | | |

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

| New or Updated Declaration for Clinician 1 | |
|---|---|
| **Name** | *Dr. Tom Kouroukis* |
| **Position** | *Lead, Ontario Health (Cancer Care Ontario) – Hematology Cancer Drug Advisory Committee* |
| **Date** | *05-06-2025* |
| ☒ | **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** | *Dr. Jordan Herst* |
| **Position** | *Member, Ontario Health (Cancer Care Ontario) – Hematology Cancer Drug Advisory Committee* |
| **Date** | *09-06-2025* |
| ☒ | **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* | ☐ | ☐ | ☐ | ☐ |

# CDA-AMC Reimbursement Review

# Feedback on Draft Recommendation

| Stakeholder information | |
|---|---|
| CDA-AMC project number | PX0376 |
| Name of the drug and Indication(s) | Nivolumab in combination with doxorubicin, vinblastine and dacarbazine (AVD) for the first-line treatment of stage III and stage IV classic Hodgkin lymphoma in patients 12 years of age and older |
| Organization Providing Feedback | OWG |

| 1. Recommendation revisions<br>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 | X |
| **No Request for Reconsideration** | **Editorial revisions:** Clarifications in recommendation **text** are requested | ☐ |
| | **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.

**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 Considerations for prescribing of therapy, OWG suggested removing the sentence: "However, the trial design in the evidence reviewed used for adults: 240 mg, and for patients

less than 18 years: 3 mg/kg up to 240 mg." They wish to include a link to CADTH's Dosing and Timing of Immuno-oncology Drugs report to support weight-based dosing of nivolumab.

OWG commented that the FMEC's comments on the use of N-AVD in patients with Stage IIb and Stage IIb bulky will lead to implementation challenges. They wish for new wording in order to expand the use of N-AVD and suggested addressing this issue via a panel algorithm if this is possible.

# Outstanding Implementation Issues

In the event of a positive draft recommendation, drug programs can request further implementation support from CDA-AMC 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 CDA-AMC (oncology only)** |
| 1. OWG has requested a rapid algorithm in Hodgkin Lymphoma. PH0079 project has already been initiated.<br>2. |
| **2. Please specify other implementation questions or issues that should be addressed by CDA-AMC** |
| 1.<br>2. |
| **Support strategy** |
| **3. Do you have any preferences or suggestions on how CDA-AMC should address these issues?** |
| May include implementation advice panel, evidence review, provisional algorithm (oncology), etc. |

Bristol Myers Squibb™

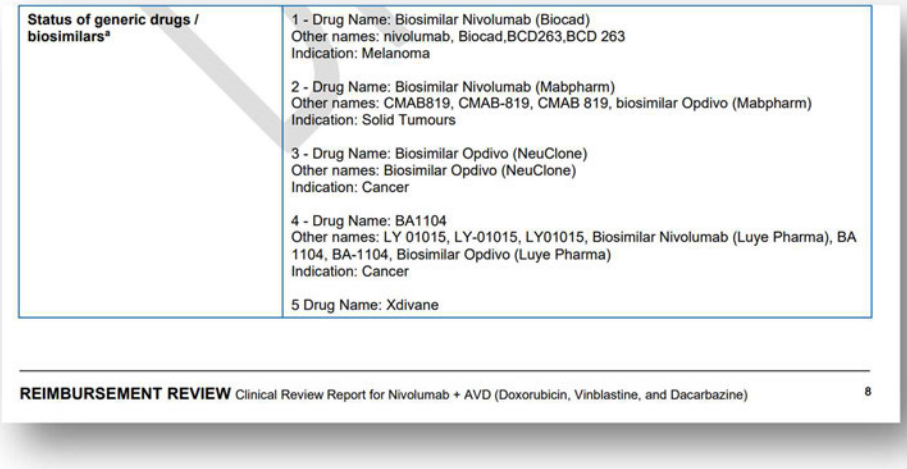
Montreal, June 18 2025

Mr Peter Dyrda
Director Pharmaceutical Reviews
Canada's Drug Agency-L'Agence des médicaments du Canada (CDA-AMC)

Mr Dyrda,

The following letter is in response to the draft report published by the Canadian Drug Agency (CDA) for the non-sponsored review of nivolumab in combination with doxorubicin, vinblastine and dacarbazine (AVD) for the first-line treatment of stage III and stage IV classic Hodgkin lymphoma in patients 12 years of age and older for the first-line treatment of Hodgkin lymphoma. Bristol Myers Squibb (BMS) commends the thoroughness and objective intent behind the assessment and recognizes the importance of providing transparent and comprehensive reviews. However, we have identified certain elements within the draft report that warrant reconsideration to ensure accuracy and relevance.

The current draft reimbursement recommendation (available at: : Enzalutamide) includes information on biosimilars, which are neither Health Canada approved nor confirmed for commercialization in Canada. BMS acknowledges the desire to provide context related to the later stage of the drug's life cycle, but feel this information diverges from the primary focus of a clinical and pharmacoeconomic assessment. Such details may not align with the central purpose of the evaluation and could potentially mislead stakeholders. Table 1 on page 8 of the "Draft Clinical and Pharmacoeconomic Combined Report" (available at: PX0376-Nivolumab_DRAFT_Combined.pdf) lists biosimilars that are not currently targeting the Canadian market (screenshot below).



| | |
|---|---|
| **Status of generic drugs / biosimilars[a]** | 1 - Drug Name: Biosimilar Nivolumab (Biocad)<br>Other names: nivolumab, Biocad,BCD263,BCD 263<br>Indication: Melanoma<br><br>2 - Drug Name: Biosimilar Nivolumab (Mabpharm)<br>Other names: CMAB819, CMAB-819, CMAB 819, biosimilar Opdivo (Mabpharm)<br>Indication: Solid Tumours<br><br>3 - Drug Name: Biosimilar Opdivo (NeuClone)<br>Other names: Biosimilar Opdivo (NeuClone)<br>Indication: Cancer<br><br>4 - Drug Name: BA1104<br>Other names: LY 01015, LY-01015, LY01015, Biosimilar Nivolumab (Luye Pharma), BA 1104, BA-1104, Biosimilar Opdivo (Luye Pharma)<br>Indication: Cancer<br><br>5 Drug Name: Xdivane |

| Item | Description |
|---|---|
| | Other names: Biosimilar Nivolumab (Xbrane/STADA),Biosimilar Opdivo (Xbrane/STADA),nivolumab, Xbrane Biopharma,opdivo, Xbrane Biopharma<br>Indication: Melanoma |
| **Information on the CDA-AMC review** | |
| **Requestor** | Provincial Advisory Group |
| **Indication under consideration for reimbursement** | Nivolumab in combination with AVD for the first-line treatment of stage III and stage IV cHL 12 years and older |

cHL = classic Hodgkin lymphoma; DNA = deoxyribonucleic acid; PD-1: Programmed death receptor 1; RNA = ribonucleic acid.

[a] All of these biosimilars have not yet been reviewed or approved by Health Canada.

Additionally, the assertion on page 24, stating "There are several biosimilar products under review at Health Canada (Table 1)," (screenshot below) could be misleading as well given that there are currently no biosimilars of nivolumab listed on the Health Canada website "Drug and Health Product Submissions Under Review" as of April 30, 2025. In any case, products under review by Health Canada may not achieve approval or commercial intent in Canada.

- As of March 2025, nivolumab is only available as a brand name product in Canada. There are several biosimilar products under review at Health Canada (Table 1).

To avoid potential confusion, BMS recommends removing the list of biosimilars as well as the statement that there are biosimilars under review at Health Canada, from the final report. Additionally, the link currently labeled "Enzalutamide" should be renamed "Nivolumab" for accuracy. These revisions will enhance the report's clarity, precision, and utility for all stakeholders.

Your attention to these matters is greatly appreciated.

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[redacted]

[redacted]
Director Market Access Strategy
Bristol Myers Squibb Canada