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Reimbursement Recommendation

Brentuximab Vedotin

Reimbursement request: As part of BrECADD for the treatment of adult patients with newly diagnosed, advanced-stage, classical Hodgkin lymphoma

Requester: Public drug programs

Final recommendation: Reimburse with conditions

Summary

What Is the Reimbursement Recommendation for Brentuximab Vedotin?

The Formulary Management Expert Committee (FMEC) recommends that brentuximab vedotin as part of BrECADD (brentuximab vedotin, etoposide, cyclophosphamide, doxorubicin, dacarbazine, and dexamethasone) be reimbursed for the treatment of adult patients with newly diagnosed, advanced-stage, classical Hodgkin lymphoma (cHL) provided certain conditions are met.

What Are the Conditions for Reimbursement?

Brentuximab vedotin as part of BrECADD may be initiated for the treatment of cHL if all the following conditions are met: adult patient with newly diagnosed cHL, advanced-stage (stage III or IV or stage II with B symptoms and 1 or both risk factors of large mediastinal mass or extranodal involvement), and good performance status. Brentuximab vedotin should be discontinued if there are either of the following: disease progression or unacceptable toxicities. Initiation of brentuximab vedotin as part of BrECADD should be limited to clinicians with expertise in the diagnosis and management of Hodgkin lymphoma (HL). A price reduction may be required.

Why Did CDA-AMC Make This Recommendation?

FMEC reviewed the Canada's Drug Agency (CDA-AMC) report, which included a review of the clinical evidence, specifically the HD21 trial, and a cost comparison of brentuximab vedotin as part of BrECADD versus other treatments used in Canada. In this trial, BrECADD improved progression-free survival compared with eBEACOPP (escalated doses of bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, and prednisone) and the benefit is noted to be clinically meaningful. However, there is no comparative evidence between BrECADD and other treatment options for cHL. FMEC also considered input received from Lymphoma Canada, the Lymphoma Canada Clinician Group, and Ontario Health (Cancer Care Ontario) Hematology Drug Advisory Committee (DAC).

FMEC concluded there was uncertainty in the clinical value demonstrated by brentuximab vedotin as part of BrECADD for cHL. However, there is significant unmet clinical need arising from the condition. The reimbursement conditions were further developed based on distinct social and ethical considerations, economic considerations, and impact on health systems.

Review Background

What Is HL and cHL?

HL is a B-cell lymphoid malignancy that is generally associated with a favourable prognosis (high cure rate and 5-year overall survival rates exceeding 90%). However, there is often an increased risk for both acute and long-term treatment-related toxicities, which have a significant impact on patients' quality of life (QoL) and their ability to work, socialize, maintain mental health, and engage in daily routines. In Canada, the estimated incidence of HL was approximately 3 cases per 100,000 persons in 2024, corresponding to approximately 1,200 new diagnoses and 110 deaths. The most common subtype of HL is cHL. At least 90% of patients with HL have cHL; it accounts for approximately 15% to 25% of all lymphomas, 0.5% of all cancers, and 0.2% of all cancer deaths.

What Are the Current Treatment Options?

Current treatment options for cHL include a combination of nonpharmacological and pharmacological interventions. Nonpharmacological interventions include radiation therapy, PET-guided treatment adaptation, and stem cell transplant (autologous or allogeneic). Standard pharmacological treatments involve chemotherapy regimens such as ABVD (doxorubicin, bleomycin, vinblastine, and dacarbazine), which is often combined with radiation therapy for early-stage disease. For advanced or high-risk cHL, more intensive regimens, such as BEACOPP, or newer combinations, such as brentuximab vedotin–AVD (doxorubicin, vinblastine, dacarbazine) or BrECADD, are used. PD-1 inhibitors, including nivolumab and pembrolizumab, are increasingly incorporated into frontline and salvage therapies.

What Is the Treatment Under Review?

Brentuximab vedotin as part of BrECADD is an antibody-drug conjugate that targets CD30-positive cells. It has the following Health Canada–approved indications: brentuximab vedotin–AVD for previously untreated patients with HL, after autologous stem cell transplant (ASCT) consolidation treatment of patients with HL at increased risk of relapse or progression, and HL after failure of ASCT or after failure of at least 2 multiagent chemotherapy regimens in patients who are not candidates for ASCT. This review on the use of brentuximab vedotin as part of BrECADD for adult patients with newly diagnosed, advanced-stage cHL is outside the Health Canada–approved indications.

Why Did We Conduct This Review?

The participating public drug programs requested a reimbursement review of brentuximab vedotin as part of BrECADD in patients with newly diagnosed advanced-stage cHL. This request was prompted by emerging evidence for a treatment regimen with the potential to fulfill an unmet need in patients with newly diagnosed HL. Specifically, this treatment regimen has the advantage of shorter treatment duration and potentially improved tolerability compared to other treatment options. The data protection for brentuximab expired in 2021, so this drug is eligible for a nonsponsored reimbursement review as per the Procedures for Reimbursement Reviews.

Highlights of Input From Interested Parties

- **Lymphoma Canada**, as a patient group, provided input summarizing patient experiences and perspectives on living with HL, drawing from 2 anonymous online surveys. In the first survey, patients reported that HL had a significant impact on their QoL, including persistent fatigue, anxiety, and stress, along with physical symptoms, such as body aches and pains, indigestion, abdominal pain or bloating, itching, and night sweats. These challenges affected their ability to work, socialize, and maintain mental health and daily routines, often leading to emotional distress, sleeping disorders, and financial strain. Patients emphasized the importance of treatment options that offer longer remission, improved QoL, and fewer side effects. In the second survey, a patient who received BrECADD reported bone pain and infections as the most difficult side effects but rated the overall experience as good and would recommend BrECADD.
- **The Lymphoma Canada Clinician Group** noted that HL is treated using PET-guided approaches. ABVD, eBEACOPP, and newer medications, such as brentuximab vedotin or nivolumab, are current options. Clinicians identified unmet needs in first-line therapy, including improving progression-free survival and reducing treatment-related toxicities. BrECADD is expected to shift the treatment paradigm for newly diagnosed cHL and is suitable for patients aged 60 years and younger with stage II (unfavourable), III, or IV disease, and may be considered for older patients with dose adjustments. Treatment response is assessed via PET scans, and discontinuation is considered in cases of disease progression or treatment-related toxicity.
- **Ontario Health (Cancer Care Ontario) Hematology DAC** as a clinician group emphasized that BrECADD may be preferred over BEACOPP and ABVD for stage IIB bulky, stage III, and stage IV HL due to better tolerability and PET-directed shorter treatment duration. It may also serve as an alternative for patients who have an intolerance to checkpoint inhibitors, such as nivolumab-AVD. Clinicians highlighted the need for more options for patients with stage IIB HL and highlighted the importance of minimizing long-term toxicities. BrECADD is suitable for outpatient administration and may be considered for patients older than 60 years of age if clinically appropriate.

► **Refer to the main report and the supplemental material document for this** review.

Person With Lived Experience

A person with lived experience from British Columbia who was diagnosed with stage IIA cHL in June 2020 at the age of 32 shared her treatment journey with FMEC. The patient described how her life became a series of chemotherapy, ultrasounds, biopsies, CT scans, PET scans, and blood tests. The patient underwent 4 months of ABVD chemotherapy. Due to the risk of lung toxicity with bleomycin, this agent was removed halfway through her treatment. The patient described her experience with fatigue and exhaustion after each chemotherapy cycle, “chemo brain” including forgetfulness and difficulty concentrating, hair loss and skin sensitivity, body discomfort and soreness, mouth sensitivity, increased appetite, febrile neutropenia, and emotional ups and downs. The patient also suffered from ongoing vein access issues. The patient described the long-term effects she experienced after treatment, including mouth sensitivity, foot cramps, persistent fatigue and brain fog, difficulty concentrating, and lingering emotional vulnerability and anxiety. For the patient, the most important treatment outcomes were remission and survival, maintaining QoL, reducing long-term side effects, preserving functionality, and preventing relapse to ensure longevity. The patient also described the unique challenges she faced being a young cancer patient, including having to take medical leave from work and facing the decision to pursue a graduate degree while undergoing treatment. Although her medical costs were covered by the province, financial stress still weighed heavily during treatment due to time away from work, reduced energy, and lifestyle adjustment. For the patient, her cancer journey was more than just a fight against the disease — it was a transformative life experience. The patient was declared cancer-free in December 2020 and “graduated” from BC Cancer in January 2023.

Disclaimer: The perspectives shared by people with lived experience who present to the committee reflect their individual experiences and are not necessarily representative of all people with the same condition or course of treatment. Their insights provide valuable context about what a patient, support person, or caregiver might go through when facing this condition or treatment, helping to inform the committee’s deliberations. These narratives complement other forms of evidence and input and should be considered as part of a broader understanding of the condition and treatment under review. Where gender or gendered pronouns are used in these narratives, they are included with the permission of the individual.

Recommendation

With a vote of 9 to 0, FMEC recommends that brentuximab vedotin as part of BrECADD for the treatment of adult patients with newly diagnosed, advanced-stage cHL be reimbursed if the conditions presented in Table 1 are met.

Table 1: Conditions, Reasons, and Guidance

Reimbursement condition	Reason	Implementation guidance
Initiation		
1. Brentuximab vedotin as part of BrECADD may be initiated for the treatment of	There is evidence from a phase III, multicentre, parallel, open-label, randomized	Patients meeting the eligibility requirements in the HD21 trial

Reimbursement condition	Reason	Implementation guidance
classical Hodgkin lymphoma if all the following conditions are met: 1.1. adult patient with newly diagnosed classical Hodgkin lymphoma 1.2. advanced stages (stage III or IV or stage II with B symptoms and 1 or both risk factors of large mediastinal mass or extranodal involvement) 1.3. good performance status.	controlled trial (HD21 trial) comparing BrECADD with eBEACOPP in adult patients aged 18 to 60 years with histologically confirmed classical Hodgkin lymphoma at advanced stages. In this trial, BrECADD improved progression-free survival compared to eBEACOPP, and the benefit is noted to be clinically meaningful.	had an ECOG performance status of 0 to 2. FMEC noted it may be clinically appropriate to treat patients with a higher performance score, especially if it is related to Hodgkin lymphoma.
Discontinuation and renewal		
2. Brentuximab vedotin should be discontinued upon occurrence of either of the following: 2.1. disease progression 2.2. unacceptable toxicities.	Consistent with clinical practice, patients in the HD21 trial discontinued treatment upon disease progression or unacceptable toxicities.	Treatment with BrECADD should be for a maximum of 6 cycles.
Prescribing		
3. Initiation of brentuximab vedotin as part of BrECADD should be limited to clinicians with expertise in the diagnosis and management of Hodgkin lymphoma.	This will ensure that appropriate treatment is prescribed for patients and adverse events are optimally managed.	—
Pricing		
4. A price reduction may be required.	FMEC concluded that reimbursement of BrECADD will be associated with higher drug acquisition costs than that of comparators based on publicly available list prices. Based on the available evidence, BrECADD may improve clinical outcomes compared with eBEACOPP, with unknown benefit compared with other regimens. The cost-effectiveness of BrECADD against its comparators is unknown. A price reduction may be required.	—

BrECADD = brentuximab vedotin, etoposide, cyclophosphamide, doxorubicin, dacarbazine, and dexamethasone; cHL = classical Hodgkin lymphoma; eBEACOPP = escalated doses of bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, and prednisone; ECOG = Eastern Cooperative Oncology Group.

Summary of Deliberation

FMEC deliberated on all domains of value in the deliberative framework before developing their recommendation: clinical value, unmet clinical need, distinct social and ethical considerations, economic considerations, and impacts on health systems. For further information on the domains of value, please refer to the Expert Committee Deliberation at Canada's Drug Agency document.

FMEC considered the following key discussion points, organized by the 5 domains of value.

Clinical Value

- **FMEC concluded it is uncertain whether brentuximab vedotin as part of BrECADD demonstrates acceptable clinical value versus appropriate comparators in the Canadian setting. There is demonstrated clinical value based on the comparative evidence between BrECADD and eBEACOPP. However, there is a lack of comparative evidence with other appropriate treatment options for HL.**
- Through reflection on the input from patient groups or insights shared by people with lived experience, FMEC members noted the following important patient values or perspectives: In addition to prolonging survival, achieving longer remission, controlling symptoms and improving QoL, patients also value the need to minimize side effects, maintain daily functioning and employment, and reduce caregiver burden. Patients are willing to tolerate mild, short-term side effects in exchange for better outcomes. Patients also value more treatment options and personal choice in therapy decisions.
- **FMEC** members highlighted the following discussion points:
  - **Efficacy versus eBEACOPP and clinical importance of treatment effects:** Based on the HD21 trial, brentuximab vedotin as part of BrECADD improved 4-year progression-free survival compared to eBEACOPP (eBEACOPP: 90.9%; BrECADD: 94.3%; hazard ratio = 0.66; 95% confidence interval [CI], 0.45 to 0.97; P = 0.035). The guest specialists indicated that this benefit is clinically meaningful. Further, 4-year overall survival was similar between BrEACOPP and eBEACOPP groups (eBEACOPP: 98.2%; BrECADD: 98.6%). The HD21 trial did not formally compare health-related quality of life (HRQoL) between the BrECADD and eBEACOPP groups. However, BrECADD reduced treatment-related morbidity, which was negatively associated with HRQoL. These findings suggest that BrECADD may be associated with a better HRQoL.
  - **Appropriate comparators:** FMEC discussed the use of the comparator eBEACOPP in the HD21 trial versus other available treatment options. As per the guest specialists consulted for this review, the use of eBEACOPP is available in many jurisdictions for patients who are at high risk with stage II, stage III, or stage IV cHL. Although the available evidence informs the comparative efficacy between BrECADD and eBEACOPP, it is unclear how BrECADD compares with other available treatment options for this patient population. These treatment options include brentuximab vedotin–AVD, ABVD, and nivolumab-AVD. FMEC noted that it would be valuable to review the comparative evidence among these treatment options, recognizing that such evidence is lacking at this time.
  - **Harms:**
    - **Tolerability:** BrECADD showed significantly lower treatment-related morbidity (BrECADD: 42%; eBEACOPP: 59%; relative risk = 0.72; 95% CI, 0.65 to 0.80; P < 0.0001). For certain serious adverse events, such as febrile neutropenia and infections, there were numerically higher rates reported in the BrECADD group than in the eBEACOPP group. As per the guest specialists, treatment with BrECADD may lead to increased unscheduled visits to hospitals.

- **Gonadal toxicity:** Recovery of gonadal function after 4 years was higher among patients in the BrECADD group (women: 95.3%; men: 85.6%) than in the eBEACOPP group (women: 73.3%, men: 39.7%). Compared to eBEACOPP, BrECADD was associated with significantly higher 5-year incidence of parenthood among men, but not among women.

Unmet Clinical Need

- **FMEC concluded there is a significant unmet clinical need arising from HL despite available treatments.**
- Through reflection on the input from patient groups and insights shared by people with lived experience, FMEC members noted the following important patient values or perspectives: Patients report they value treatments with fewer side effects, improved survival rates, rapid control of symptoms and complete remissions, and improved QoL. Patients also value treatment regimens that support better recovery of gonadal function and improved posttreatment fertility.
- **FMEC** members highlighted the following discussion points:
  - **Severity of the disease:** FMEC discussed that the currently available and funded treatment options are effective and safe for HL. Although HL is associated with significant morbidity, the condition is associated with a high cure rate and 5-year overall survival rates exceeding 90%, but there is still risk of relapse and mortality.
  - **Availability of treatment options:** FMEC discussed whether this treatment regimen — as part of BrECADD — addresses an unmet need, given there are already effective treatments available, such as brentuximab vedotin–AVD and nivolumab-AVD.
  - **Significant unmet clinical need:**
    - Based on input by the guest specialists, the main advantage of BrECADD is the potentially shorter treatment duration. Greater than 60% of patients treated with BrECADD in the trial had only 4 cycles. For the majority of patients, BrECADD is administered as 4 cycles over the course of 3 months, which is advantageous for younger patients who want to complete their treatment quickly with the goal to return to their regular life routines (e.g., work or school with minimal disruption). In comparison, nivolumab-AVD requires treatment with 6 cycles over the course of 6 months.
    - When compared with eBEACOPP, BrECADD had improved 4-year progression-free survival. The guest specialists noted that this survival benefit may translate to a higher cure rate and lower likelihood of ASCT for individuals who have received the BrECADD treatment regimen.
    - Compared with eBEACOPP, BrECADD showed improved tolerability, particularly in terms of hematologic toxicities, such as anemia and thrombocytopenia, and lower transfusion rates. The guest specialist also highlighted the improved tolerability of BrECADD addresses an unmet need for patients with HL.

Distinct Social and Ethical Considerations

- **FMEC concluded it is unclear whether brentuximab vedotin as part of BrECADD would potentially address a significant nonclinical need associated with HL despite available treatments. FMEC did not identify any important measures that should be implemented to ensure the use of brentuximab vedotin addresses relevant social and ethical implications.**
- Through reflection on the input from patient groups and insights shared by people with lived experience, FMEC members noted the following important patient values or perspectives: Some patients have difficulty accessing appropriate care. This may be related to delayed diagnosis, delays in diagnostic testing (e.g., waiting months for a biopsy), and geographic barriers (e.g., living at a far distance from a treatment centre). Input from patient groups reported that some medications for management of side effects were not funded by provincial drug programs so patients needed to pay out-of-pocket. Patients are also impacted; resources such as time and family vehicles are tied up for the support of treatment and not available for other activities such as employment.
- **FMEC** members highlighted the following discussion points:
  - **Significant unmet nonclinical need or health inequity.**
    - As noted in the patient input, treatment with BrECADD must be accessed at urban cancer centres, which causes difficulty for patients who must travel to receive this treatment. In addition, this treatment may increase the risk of febrile neutropenia, which may require additional travel for patients to manage complications arising from febrile neutropenia. However, because BrECADD may be given over a shorter duration compared with other treatments, it may be advantageous for patients who require significant travel for treatment and for those who wish to minimize disruption to their usual activities (e.g., employment and school).

Economic Considerations

- **FMEC concluded there are economic considerations that are important to address when implementing brentuximab vedotin as part of BrECADD.**
- **FMEC** members highlighted the following discussion points:
  - At the publicly available prices, the reimbursement of brentuximab vedotin as part of BrECADD is expected to increase overall drug acquisition costs compared with all relevant comparators.
  - Based on the available evidence, BrECADD may improve clinical outcomes when compared to eBEACOPP; however, its benefit compared with other regimens is unknown.
  - The cost-effectiveness of BrECADD compared with its comparators is unknown.
  - BrECADD is associated with higher drug acquisition costs and likely more clinical benefit compared to one of its comparators, but it has unknown benefit compared to other comparators; therefore, price reductions may be required to ensure cost-effectiveness.

Impacts on Health Systems

- **FMEC is uncertain if there are impacts on health systems that are important to address when implementing brentuximab vedotin as part of BrECADD.**
- **FMEC** members highlighted the following discussion points:
  - **Organizational implications.**
    - FMEC noted that brentuximab vedotin is already available for other indications. As such, there is not any significant impact on the health care system for the implementation of brentuximab vedotin as part of the BrECADD regimen.
    - FMEC also discussed that there may be some minor impact on health systems because there may be potentially more hospital admissions for the management of febrile neutropenia related to treatment with BrECADD.

Sources of Information Used by the Committee

To make its recommendation, the committee considered the following information (links to the full documents for this review can be found on the brentuximab vedotin project webpage

- the CDA-AMC review of the clinical and pharmacoeconomic evidence related to brentuximab vedotin (refer to the Clinical and Pharmacoeconomic Combined Report and Supplemental Material document)
- patients' perspectives gathered by 1 patient group, Lymphoma Canada (refer to the Patient and Clinician Group Input document)
- input from a person with lived experience who delivered a brief presentation and answered questions from the committee (refer to the Person With Lived Experience section in this report)
- input from 2 clinician groups, the Lymphoma Canada Clinician Group and Ontario Health (Cancer Care Ontario) Hematology DAC (refer to the Patient and Clinician Group Input document)
- input from public drug programs that participate in the reimbursement review process (refer to the Responses to Questions From the Drug Programs document)
- input from 2 clinical experts with expertise in the management of HL consulted by CDA-AMC.

Feedback on Draft Recommendation

CDA-AMC received feedback from 2 patient groups (The Leukemia & Lymphoma Society of Canada and Lymphoma Canada), 1 clinician group (the Ontario Health [Cancer Care Ontario] Hematology Cancer DAC), and the public drug programs. All partners agreed with the recommendation. The public drug programs requested a minor editorial change for consistency among the recommendations, and the clinician group made a few suggestions that were already addressed in the recommendation or the Drug Program Input table.

All feedback received in response to the draft recommendation is available on the CDA-AMC project webpage.

FMEC Information

Members of the committee: Dr. Emily Reynen (Chair), Dr. Zaina Albalawi, Dr. Hardit Khuman, Ms. Valerie McDonald, Ms. Marilyn Barrett, Dr. Bill Semchuk, Dr. Jim Silvius, Dr. Marianne Taylor, Dr. Maureen Trudeau, Dr. Dominika Wranik. Two guest specialists from Ontario and Nova Scotia participated in this review.

Meeting date: November 20, 2025

Conflicts of interest: None

Special thanks: CDA-AMC extends special thanks to Jovanna Sauro, who presented directly to FMEC, and to The Leukemia & Lymphoma Society of Canada for representing and supporting the community of individuals living with HL.

Note: CDA-AMC makes every attempt to engage with people with lived experience as closely to the indication and treatments under review as possible. However, at times, CDA-AMC is unable to do so and instead engages with individuals with similar treatment journeys or experience with comparators under review to ensure lived experience perspectives are included and considered in Reimbursement Reviews. CDA-AMC is fortunate to be able to engage with individuals who are willing to share their treatment journey with FMEC.

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