Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Brentuximab Vedotin - In Combination with Chemotherapy for Previously Untreated Stage IV Hodgkin Lymphoma

(This form should be completed before the first dose is dispensed.)

1. Patient Profile

* Surname: .....
* Given Name: .....
* OHIN: ..... * Chart Number: .....
* Postal Code: .....
* Height (cm): ..... * Weight (kg): .....
* BSA (m^2): ..... * Gender: ○ Male ○ Female ○ Other
* Date of Birth: ....
  Day Month Year
* Site:
* Attending Physician (MRP- Most Responsible Physician): .....

Requested Prior Approval ☐ Yes * Patient on Clinical Trial ○ Yes ○ No

Other (specify): .....

Specify Arm:
○ Standard of care arm ○ Experimental arm
○ Blinded / Unknown

Prior Approval Request

* Select the appropriate prior approval scenario:

- ○ 1-Unknown primary (submit pathology report and clinic note)
- ○ 2-Clinical document review (identify the patient history that needs to be reviewed against eligibility criteria in Additional Comments below)
- ○ 3-Regimen modification - schedule (complete questions a and b)
- ○ 4-Regimen modification - drug substitutions (complete questions a and c)
- ○ 5-Withholding a drug in combination therapy from start of treatment (complete questions d, e and f)
- ○ 6-Maintenance therapy delay (submit clinic note)
- ○ 7-Prior systemic therapy clinical trials (complete question g)
- ○ 8-Modification due to supply interruption/drug shortage
- ○ Other (specify)

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All relevant supporting documentation must be submitted at the time of prior approval. Documentation may include a pathology report, clinic note, and/or CT scans.

a. Co-morbidities / toxicity / justification:

.....

b. Intended regimen schedule: .....

c. Intended regimen: .....

d. Drug(s) to be held: .....

e. Rationale for holding drug(s): .....

f. Intention to introduce drug at a later date? ☐ Yes

g. Prior clinical trial identifier (e.g., NCT ID, trial name) and treatment description (e.g., arm, drug/regimen): .....

h. Anticipated date of first treatment: ....
Day Month Year

i. Additional comments:

2. Eligibility Criteria

The patient must meet the following criteria:

Brentuximab vedotin is used for the treatment of previously untreated patients with Stage IV Hodgkin lymphoma (HL) in combination with doxorubicin, vinblastine and dacarbazine (AVD). ☐ Yes

3. Baseline Information

a. ECOG Performance Status at the time of enrolment ○ 0 ○ 1 ○ 2

b. Is the patient transitioning from a private pay/compassionate program? ○ Yes ○ No

c. If yes, how many cycles did the patient have prior to the transition?
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9
○ 10 ○ 11

4. Funded Dose

Brentuximab vedotin 1.2 mg/kg intravenously (IV) once on day 1 and 15 of each 28 day-cycle with AVD.

Treatment should be continued up to a maximum of six cycles, until disease progression or unacceptable toxicity, whichever comes first.

[ST-QBP regimen code: AVD+BREN]

5. Notes

1. As per the manufacturer's product monograph, the dose for patients weighing greater than 100 kg should be calculated based on a weight of 100 kg (i.e., a maximum single dose of 120 mg).
2. Brentuximab vedotin must be used with AVD chemotherapy to be eligible for funding.
3. Patients with nodular lymphocyte-predominant Hodgkin lymphoma, or cerebral or meningeal disease (including signs and symptoms of progressive multifocal leukoencephalopathy) are not eligible for funding under this policy.
4. There is currently insufficient evidence to support funding under this policy for patients under 18 years of age based on the pivotal trial.
5. As the Health Canada approved indication is specific to patients with stage IV disease, patients with stage III (or earlier stage) HL will not be eligible for funding under this policy.

6. FAQs

i. **My patient is currently receiving brentuximab vedotin through non-publicly funded means for HL. Can my patient be transitioned over to receive funding through the New Drug Funding Program (NDFP)?**

Provided the funding criteria were met at the time of treatment initiation and the patient's disease has not progressed, your patient may be eligible for continued coverage of brentuximab vedotin through NDFP. Funding is up to a maximum of six cycles of brentuximab vedotin, in combination with AVD, regardless of funding source.

ii. **Will my patient be eligible for brentuximab vedotin retreatment?**

Brentuximab vedotin retreatment or as consolidation post-autologous stem cell transplant (ASCT) is funded as subsequent lines of therapy for patients whose disease is not refractory to brentuximab vedotin (e.g., the patient has sustained a response and has remained disease free for at least 12 months following the last dose of brentuximab received), provided all other funding criteria are met.

iii. **My patient has initiated front-line treatment with doxorubicin, bleomycin, vinblastine, and dacarbazine (ABVD) and has not progressed. Is my patient eligible for a switch to brentuximab vedotin in combination with AVD?**

Yes, provided all other funding criteria are met, NDFP can accommodate a switch to brentuximab vedotin, in combination with AVD, for patients currently on front-line chemotherapy who have not progressed. Please submit as a prior approval request and include the most recent clinic note (specifying response to therapy, if able to assess, along with the rationale for the switch). Switches may also be considered for patients who initiate ABVD and cannot tolerate bleomycin.

Supporting Documents

None required at the time of enrolment.

In the event of an audit, the following should be available to document eligibility:

- Clinic note indicating the patient's treatment history, staging, and the pathology report confirming CD30 positivity.

Signature of Attending Physician (MRP-Most Responsible Physician): .....

....
Day Month Year