Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Brentuximab Vedotin - Consolidation Post-Autologous Stem Cell Transplant (ASCT) for 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

a. The patient meets the following criteria:

- Brentuximab vedotin will be used for the post-autologous stem cell transplant (ASCT) consolidation treatment of patients with Hodgkin lymphoma (HL) at increased risk of relapse or progression*. ☐ Yes

- *Patients with increased risk of relapse or progression as defined in the pivotal trial:
  - Refractory to frontline therapy or;
  - Relapsed less than 12 months from frontline therapy or;
  - Relapse 12 months or greater after frontline therapy with extranodal disease.

3. Baseline Information

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

b. Number of previous salvage therapies for HL ○ One ○ Two or more

c. High-risk feature associated with an increased risk of relapse or progression
- ○ Refractory to frontline therapy
- ○ Relapsed < 12 months from frontline therapy
- ○ Relapse >= 12 months after frontline therapy with extranodal disease

4. Funded Dose

Brentuximab vedotin 1.8 mg/kg intravenously (IV) once every 3 weeks until a maximum of 16 cycles, disease progression or unacceptable toxicity, whichever comes first [ST-QBP regimen code: BREN(CONS)].

Consolidation treatment should be initiated within four to six weeks post-ASCT or upon recovery from ASCT.

5. Notes

1. Patients who are not ASCT candidates are not eligible for brentuximab vedotin funding under this policy.
2. The funding of brentuximab vedotin under this policy is not for pre-ASCT use.
3. 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.
4. NDFP will fund brentuximab vedotin monotherapy in a subsequent line of therapy if the patient has had a disease-free interval (DFI) of 12 months or greater from completion of prior brentuximab vedotin.

6. FAQs

i. ***My patient is currently receiving brentuximab vedotin as consolidation treatment through non-publicly funded means. 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 for 16 total cycles of brentuximab vedotin regardless of funding source.

ii. ***My patient is at high risk of disease progression or relapse post-ASCT with features not captured in the pivotal trial's definition of high risk. Would they be eligible for brentuximab vedotin funding post-ASCT as consolidative therapy through NDFP?***

There is currently insufficient evidence to consider a broader definition of increased risk beyond those high-risk subgroups defined in the pivotal trial. NDFP funding will align with the high-risk subgroups as per the pivotal trial and outlined in the 'Eligibility Criteria' section.

7. Supporting Documents

None required at the time of enrolment.

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

- Clinic notes indicating treatment history, including the date of the ASCT, and the pathology report confirming CD30 positivity.

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

....
Day Month Year