Ontario Santé Health Ontario | eClaims Demandes de remboursement en ligne

Eligibility Form

Brentuximab Vedotin - In Combination with Chemotherapy for Pediatric High-Risk 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)

.....

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

Brentuximab vedotin is used for the treatment of pediatric and adolescent patients (aged 2 years or older) with previously untreated high-risk* Hodgkin lymphoma (HL) in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide (AVEPC). ☐ Yes

*High-risk disease is defined as stage IIB with bulk tumour, stage IIIB, IVA, or IVB according to the Ann Arbor staging system.

3. Baseline Information

a. Is the patient transitioning from a private payer or compassionate program? ○ Yes ○ No

b. If yes, please indicate the funding source
○ Private payer
○ Manufacturer patient support program

c. If yes, how many doses of brentuximab vedotin did the patient receive prior to the transition? ○ 1 ○ 2 ○ 3 ○ 4

4. Funded Dose

Brentuximab vedotin 1.8 mg/kg given intravenously (IV) every 3 weeks, in combination with AVEPC.

Treatment should continue until disease progression or unacceptable toxicity, up to a maximum of 5 cycles, whichever comes first.

5. Notes

1. As per the Health Canada 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 180 mg).

2. Brentuximab vedotin is only funded when used with AVEPC chemotherapy.

3. Patients with nodular lymphocyte-predominant Hodgkin lymphoma, cerebral or meningeal disease (including signs and symptoms of progressive multifocal leukoencephalopathy), neurologic disease affecting activities of daily living, or severe sensory or motor peripheral neuropathy are not eligible for funding under this policy.

6. FAQs

1. **My patient is currently receiving brentuximab vedotin through non-publicly funded means (e.g., patient support program, private insurance). Can my patient be transitioned to receive funding through the New Drug Funding Program (NDFP)?**

   Provided the eligibility 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 through the NDFP.

2. **What is the process for transitioning my patient from a non-publicly funded program to NDFP funding?**

   If your patient meets all of the eligibility criteria outlined in this policy, please submit as a regular eClaims enrolment. Prior approval requests are reserved for instances where there is clinical uncertainty on eligibility. In these circumstances, please specify your reason(s) for uncertainty and upload the following:

   - A clinic note and imaging (if applicable) from treatment initiation, and
   - The most recent clinic note and imaging (if applicable).

3. **My patient recently started an alternate chemotherapy regimen. Can I switch them to BV-AVEPC?**

   On a time-limited basis and provided patients meet all other funding criteria, patients who initiated an alternate chemotherapy regimen for previously untreated high-risk HL may switch to brentuximab vedotin with AVEPC provided there is no disease progression on the current chemotherapy regimen . Please submit requests as prior approvals with confirmation of high-risk HL and the most recent clinic note.

Supporting Documents

None required at time of enrolment.

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

- Pathology report confirming high-risk Hodgkin Lymphoma
- Clinic notes outlining patient and treatment history/response.
- CT scans demonstrating no disease progression.

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

....
Day Month Year

Form 1093