Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Brentuximab Vedotin - In Combination with Chemotherapy for Previously Untreated Peripheral T-cell Lymphoma (PTCL)

(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 treatment of previously untreated adult patients with systemic anaplastic large cell lymphoma (sALCL), peripheral T-cell lymphoma not otherwise specified (PTCL-NOS) or angioimmunoblastic T-cell lymphoma (AITL), whose tumours express CD30, in combination with cyclophosphamide, doxorubicin, and prednisone (CHP).
- Patients with anaplastic lymphoma kinase (ALK) positive sALCL must have an International Prognostic Index (IPI) score of equal or greater than 2.

☐ Yes

3. Baseline Information

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

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

c. If yes, how many cycles did the patient have prior to transitioning to public funding?
○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7

d. PTCL subtype
- ○ Peripheral T-cell lymphoma not otherwise specified (PTCL-NOS)
- ○ Angioimmunoblastic T-cell lymphoma (AITL)
- ○ Systemic anaplastic large cell lymphoma (sALCL)
- ○ Other (prior approval required)

e. If other, please submit as a prior approval request and include the most recent clinic note and pathology report confirming CD30 positivity.
- ○ Adult T-cell leukemia or lymphoma (ATLL)
- ○ Enteropathy-associated T-cell lymphoma (EATL)
- ○ Other (please specify in prior approval request)

4. Funded Dose

Brentuximab vedotin 1.8 mg/kg intravenously (IV) once on day 1 with each cycle of CHP, or in combination with cyclophosphamide, etoposide, and prednisone (CEP).

Treatment should be continued for six to eight cycles, until disease progression or unacceptable toxicity, whichever comes first.

[ST-QBP regimen codes: CHP+BREN or CEP+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 180 mg).
2. Brentuximab vedotin must be started with either CHP or CEP chemotherapy in order to be eligible for funding.

6. FAQs

i. **My patient is currently receiving brentuximab vedotin (in combination with chemotherapy) 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 up to eight cycles of brentuximab vedotin, regardless of funding source.

ii. **My patient has started front-line chemotherapy but I would prefer to switch my patient to brentuximab vedotin (in combination with chemotherapy). Will NDFP fund the switch?**

Yes, provided all other funding criteria are met, NDFP can accommodate a switch to brentuximab vedotin (in combination with CHP or CEP chemotherapy) for patients currently on front-line chemotherapy and who have not progressed. Please submit as a prior approval request including the most recent clinic note (and response to therapy, if able to assess) along with the pathology report confirming CD30 positivity.

iii. **My patient with anaplastic lymphoma kinase (ALK) positive sALCL has a low IPI score (0 or 1). Will NDFP fund brentuximab vedotin (in combination with chemotherapy) for this subgroup of patients?**

NDFP will only fund brentuximab vedotin (in combination with chemotherapy) for ALK positive sALCL patients with an IPI score of equal or greater than 2.

iv. **Will my patient be eligible for brentuximab vedotin retreatment at the time of disease progression after front-line chemotherapy?**

NDFP will fund brentuximab vedotin monotherapy in a subsequent line of therapy if the patient has had a disease-free interval (DFI) of six months or greater from completion of prior brentuximab vedotin therapy. Retreatment with brentuximab vedotin (in combination with chemotherapy) will not be funded.

v. **What treatment alternatives may be funded through NDFP if my patient relapsed after or is refractory to front-line brentuximab vedotin (in combination with chemotherapy)?**

Provided all other funding criteria are met, patients will be eligible for one of pralatrexate or romidepsin. Patients who have previously received brentuximab vedotin will be eligible for retreatment as monotherapy if there has been a DFI of six months or greater from completion of prior brentuximab vedotin therapy.

7. Supporting Documents

A copy of the pathology report confirming CD30 positivity and the peripheral T-cell lymphoma (PTCL) subtype must be submitted to NDFP prior to the start of treatment to be eligible for reimbursement.

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

- Clinic note indicating the patient's treatment history.

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

....
Day Month Year

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