

Brentuximab Vedotin - Previously Treated Primary Cutaneous Anaplastic Large Cell Lymphoma or Mycosis Fungoides

(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 (m²): * 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:

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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 adult patients with CD30-positive primary cutaneous anaplastic large cell lymphoma (pcALCL) or mycosis fungoides (MF) who have had prior systemic therapy and have good performance status. Yes

Patients with MF must have received at least one prior systemic therapy and patients with pcALCL must have at least one prior systemic therapy or prior radiation therapy.

3. Baseline Information

- a. ECOG Performance Status at the time of enrolment 0 1 2
- b. Is the patient transitioning from a private pay or 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 12 13 14 15

4. Funded Dose

Brentuximab vedotin 1.8 mg/kg intravenously (IV) once on day 1 of each 21-day cycle.

Treatment should be continued until disease progression, unacceptable toxicity, or up to a maximum of 16 cycles, whichever comes first.

ST-QBP regimen code: [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. Patients with subtypes of cutaneous T-cell lymphoma that are not pcALCL or MF (including Sezary Syndrome) are not eligible for brentuximab vedotin funding under this policy.
3. Brentuximab vedotin is only funded as monotherapy under this policy.
4. Upon disease relapse, patients may be funded for up to an additional 16 cycles of brentuximab vedotin retreatment if there was no disease progression within 6 months of the last dose of brentuximab vedotin and all other funding criteria are met. Claims should be submitted under the same enrolment form used for initial treatment.

6. FAQs

i. My patient is currently receiving brentuximab vedotin through non-publicly funded means for pcALCL or MF. 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 16 cycles of brentuximab vedotin, regardless of funding source.

ii. My patient has already initiated second line therapy for pcALCL or MF. Can I switch my patient to brentuximab vedotin?

Patients who have initiated second line therapy for pcALCL or MF may be considered for brentuximab vedotin upon disease progression on their second line therapy or if the patient experiences unacceptable toxicity to the second line therapy.

Supporting Documents

Pathology report confirming pcALCL or MF diagnosis with CD30 positivity $\geq 10\%$ must be uploaded at the time of enrolment.

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

- Clinic note containing treatment history

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

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Day Month Year