

Brentuximab Vedotin – Systemic Anaplastic Large Cell Lymphoma

This is a renamed version of *Brentuximab - Systemic Anaplastic Large Cell Lymphoma* policy.

(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:

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2. Eligibility Criteria

The patient meets the following criteria:

- Brentuximab vedotin will be used as monotherapy in patients with systemic anaplastic large cell lymphoma who have failed at least one prior multi-agent chemotherapy regimen and who have an ECOG performance status of 0 or 1. Yes

3. Funded Dose

Brentuximab vedotin 1.8 mg/kg IV every 3 weeks until disease progression or unacceptable toxicity.

4. Notes

1. A pathology report confirming CD30+ve systemic anaplastic large cell lymphoma and a clinic note outlining the patient's treatment history must be submitted to CCO prior to the start of treatment.
2. Treatments beyond 16 cycles require documentation showing continued evidence of benefit (i.e., a clinic note and CT scan confirming that there is no evidence of disease progression). The documentation can be submitted with the treatment claims.
3. Use of brentuximab vedotin in the first line setting or as a bridge to allogeneic stem cell transplant will not be funded.
4. As per the manufacturer's product monograph, the maximum dose that can be administered is based on a weight of 100kg.
5. Romidepsin (or pralatrexate) funding is also available for patients with the CD30+ systemic anaplastic large cell lymphoma subtype of peripheral T-cell lymphoma, provided funding criteria are met. No evidence exists to inform the optimal sequencing for brentuximab vedotin versus pralatrexate or romidepsin. The choice in sequencing should be based on a discussion between the treating hematologist and patient.
6. 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 (in combination with chemotherapy). Retreatment with brentuximab vedotin (in combination with chemotherapy) will not be funded.

5. Supporting Documents

To ensure reimbursement of your claim, both the completed enrolment form and a copy of the required documentation (where applicable) must be submitted through CCO e-Claims.

1. Clinic note detailing treatment history
2. Pathology report confirming CD30+ve systemic anaplastic large cell lymphoma
3. Documentation showing continued evidence of benefit (for treatments beyond 16 cycles)

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

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Day Month Year

Form 851