Ontario Health / Santé Ontario

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Eligibility Form

Pembrolizumab (Adult Who Failed Prior Brentuximab Vedotin) - Relapsed Classical Hodgkin Lymphoma Post-Autologous Stem Cell Transplant or ASCT Ineligible

This is a renamed version of *Pembrolizumab - Relapsed Classical Hodgkin Lymphoma (cHL) Post-Autologous Stem Cell Transplant (ASCT) or ASCT Ineligible*.

(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 (comple 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:

- Pembrolizumab is used as monotherapy for the treatment of adult patients with refractory or relapsed classical Hodgkin lymphoma (cHL) who have failed autologous stem cell transplant (ASCT) and brentuximab vedotin (BV), or who are not candidates for ASCT and have failed BV. ☐ Yes

3. Baseline Information

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

b. Has the patient had a prior ASCT? ○ Yes ○ No

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

d. 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	○ 16	○ 17	○ 18
○ 19	○ 20	○ 21	○ 22	○ 23	○ 24	○ 25	○ 26	○ 27
○ 28	○ 29	○ 30	○ 31	○ 32	○ 33	○ 34		

4. Funded Dose

Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 21 days; or
Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 42 days.

Treatment should continue until confirmed disease progression or unacceptable toxicity to a maximum of 2 years (up to 35 doses given every 3 weeks or 18 doses given every 6 weeks), whichever comes first.

[ST-QBP regimen code: PEMB]

5. Notes

1. Patients will be eligible for either pembrolizumab or nivolumab for refractory or relapsed classical Hodgkin lymphoma (cHL), but not both. Please enroll in the policy entitled *Pembrolizumab (Adult and Pediatric) - Relapsed Classical Hodgkin Lymphoma Post-Autologous Stem Cell Transplant or ASCT Ineligible* for patients with relapsed cHL who are brentuximab vedotin naïve if criteria are met.

2. For patients who stop pembrolizumab without disease progression, resumption of treatment (to complete two total years) will be funded provided no other treatment is given in between.

3. Pembrolizumab is not funded for patients who have progressed during or within 6 months of completion of treatment with a prior PD-1 or PD-L1 inhibitor.

4. Patients who complete 2 years' worth of treatment without disease progression may receive up to an additional 1 years' worth of treatment with pembrolizumab at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment and provided that no other systemic treatment is given in between. Claims should be submitted under the same enrolment form used for initial treatment.

6. FAQs

i. **My patient is currently receiving pembrolizumab through non-publicly funded means for relapsed cHL. 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 pembrolizumab through NDFP.

   At the NDFP funded dose of 2 mg/kg (up to a maximum of 200 mg per dose) or 4 mg/kg (up to a maximum of 400 mg per dose), funding is for a total of 2 years' worth of treatment for the initial course, regardless of funding source.

ii. **My patient with relapsed/refractory classical Hodgkin lymphoma (cHL) is not a candidate for an autologous stem cell transplant (ASCT). Would they be eligible for pembrolizumab?**

   Patients with relapsed/refractory cHL who are not candidates for an ASCT would be eligible for pembrolizumab after failure of prior brentuximab vedotin.

iii. **My patient is currently receiving pembrolizumab on an every 3 week schedule. Can my patient be transitioned over to an every 6 week schedule?**

   The decision to switch should be based on a discussion between the clinician and patient. Switches between schedules (from every 3 weeks to every 6 weeks or vice versa) will be eligible for continued funding provided the patient's disease has not progressed. Please note that the funded duration remains the same (i.e., a maximum of two years for the initial treatment course plus one additional year of retreatment, if eligible).

7. Supporting Documents

None required at 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 (if eligible).
- CT scans every 3 to 6 months (or as clinically appropriate), along with clinic notes indicating no disease progression.
- In instances where there is pseudoprogression,
    - a clinic note documenting the assessment and decision to continue, AND
    - a confirmatory scan conducted preferably at 6 to 8 weeks but no later than 12 weeks after the initial disease progression to confirm the absence of true progression.

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

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Day Month Year

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