Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Pembrolizumab (Adult and Pediatric) - Relapsed Classical Hodgkin Lymphoma Post-Autologous Stem Cell Transplant 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 (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

The patient must meet the following criteria:

Pembrolizumab is used as monotherapy in adult and pediatric patients* with refractory or relapsed classical Hodgkin lymphoma (cHL) who have failed autologous stem cell transplant (ASCT) or who are not candidates for multi-agent salvage chemotherapy and ASCT. ☐ Yes

Treatment is for patients with good performance status.

*Eligible patients include those who:

1. have failed to achieve a response or progressed after ASCT;
2. are not eligible to receive an ASCT due to chemotherapy-resistant disease, advanced age, or any significant coexisting medical condition that may have a negative impact on tolerability of ASCT.

3. Baseline Information

a. Has the patient received prior brentuximab vedotin?
○ Yes ○ No ○ Not applicable, enrolment is for a pediatric patient

b. ECOG Performance Status (PS) at the time of enrolment for adult patients:
○ 0 ○ 1 ○ 2 ○ Not applicable

c. Karnofsky (for patients 16 years old and older) or Lansky (for patients under 16 years old) PS for pediatric patients:
○ 50 ○ 60 ○ 70 ○ 80 ○ 90 ○ 100 ○ Not applicable

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

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

f. If yes to 3e, was the patient on an every 3 week dosing schedule of pembrolizumab?
○ Yes ○ No

g. If yes to 3f, how many cycles of every 3 week pembrolizumab did the patient have prior to transitioning to public funding?

○ 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		

h. If no to 3f, how many cycles of every 6 week pembrolizumab did the patient have prior to transitioning to public funding?

○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7	○ 8	○ 9
○ 10	○ 11	○ 12	○ 13	○ 14	○ 15	○ 16	○ 17	

4. Funded Dose

Pembrolizumab 2 mg/kg, up to a maximum of 200 mg, every three weeks as an intravenous (IV) infusion (adult and pediatric),
or
Pembrolizumab 4 mg/kg, up to a maximum of 400 mg, every six weeks as an IV infusion (adult patients only).

Treatment should be continued until disease progression or unacceptable toxicity, or to a maximum of 2 years (or equivalent therapy), 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.
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 on 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. Please submit as a prior approval request in eClaims including the most recent clinic note outlining the response to treatment, if able to assess, and the number of cycles of pembrolizumab received to date.

Please note that the NDFP funded dose is 2 mg/kg given every 3 weeks, up to a maximum of 200 mg per dose, or 4 mg/kg given every 6 weeks, 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 due to chemotherapy-resistant disease, advanced age, or any significant coexisting medical condition(s) that may have a negative impact on tolerability of ASCT.

iii. **My patient with relapsed/refractory cHL is currently receiving brentuximab vedotin (BV). Would they be eligible to switch to pembrolizumab?**

Patients should continue to receive BV if they are responding well to treatment and have not experienced disease progression. Provided funding criteria are met, patients who have failed ASCT and BV may be eligible for downstream pembrolizumab* (or nivolumab).

*Please enrol under the *Pembrolizumab (Adult Who Failed Prior Brentuximab Vedotin) - Relapsed Classical Hodgkin Lymphoma Post-Autologous Stem Cell Transplant or ASCT Ineligible* policy.

iv. **My transplant ineligible patient with relapsed or refractory cHL responded to pembrolizumab and was able to proceed to transplant. The patient has subsequently relapsed. Is my patient eligible for pembrolizumab retreatment?**

Patients who end up responding to pembrolizumab and proceed to transplant would not be eligible for subsequent anti-PD-1 therapy.

v. **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).

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 progression post-ASCT or ASCT ineligible rationale.
- 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): .....

....
Day Month Year

Form 933