Cancer Care Ontario
Action Cancer Ontario | eClaims

Eligibility Form

Pembrolizumab - Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck

(This form must 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
- ○ 9-Supplemental doses requested
- ○ 10-COVID-19 pandemic: In instances where treatment becomes palliative or where platinum use is perceived to be contraindicated
- ○ 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 for the first-line treatment of metastatic or unresectable recurrent head & neck squamous cell carcinoma (HNSCC):
  - As monotherapy for patients whose tumours have PD-L1 expression combined positive score (CPS) greater than or equal to 1, or
  - In combination with platinum and 5-fluorouracil (5-FU) chemotherapy regardless of PD-L1 expression level.

○ Monotherapy
○ Combination

3. Baseline Information

a. ECOG performance status at the time of enrolment ○ 0 ○ 1 ○ 2

b. PD-L1 expression using CPS
○ Less than 1%
○ Between 1% and less than 20%
○ Equal to or greater than 20%

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 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		

e. If 'combination' is selected in '2' above, specify the chemotherapy backbone to be used with pembrolizumab.
○ 5-FU/cisplatin
○ 5-FU/carboplatin
○ Paclitaxel/carboplatin
○ Other (prior approval required)

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.

When used as combination therapy, pembrolizumab must be given with 5-FU and platinum (cisplatin or carboplatin) for up to 6 cycles, followed by pembrolizumab maintenance [ST-QBP regimen codes: CISPFU+PEMB, CRBPFU+PEMB or CRBPPACL+PEMB for the induction phase, PEMB(MNT) for the maintenance phase].

When used as monotherapy, the ST-QBP regimen code is PEMB.

5. Notes

1. Patients will also be considered for funding under this policy if carboplatin and paclitaxel is used as the chemotherapy backbone with pembrolizumab as outlined in the ‘Funded Dose’ section.
2. Ontario Health will fund one line of pembrolizumab or nivolumab for recurrent or metastatic squamous cell carcinoma of the head and neck.
3. Patients with a primary cutaneous squamous cell carcinoma are not eligible for pembrolizumab.
4. For patients who temporarily stop pembrolizumab without disease progression, continuation of pembrolizumab (to complete 2 years’ worth of treatment) will be funded provided that no other systemic treatment is given in between.
5. Patients who complete 2 years’ worth of treatment without disease progression may receive up to an additional 1 years’ worth of treatment with pembrolizumab monotherapy 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 form used for the initial course of treatment.

6. FAQs

i. **My patient is currently receiving pembrolizumab for metastatic or unresectable recurrent HNSCC 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 pembrolizumab through NDFP. Of note, patients enrolled in the manufacturer's Patient Support Program (PSP) will continue to receive treatment through the PSP until August 10, 2021. After this date, eligible patients may transition to NDFP funding for the remainder of their treatment course. Please submit as a prior approval request in eClaims including the most recent clinic note (outlining the response to treatment, if able to assess).

   Please note that the NDFP funded dose is 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), and the funding is for a total of 2 years' worth of treatment for the initial course, regardless of funding source.

ii. **My patient is currently on platinum and 5-FU (or alternate platinum doublet) chemotherapy and is being treated with palliative intent. Can I add pembrolizumab to the treatment regimen?**

   Patients who have already initiated therapy with platinum and 5-FU (or alternate platinum doublet) given with palliative intent, as of the effective funding date, may add pembrolizumab to the treatment regimen provided all funding criteria for pembrolizumab are met. Please submit as a prior approval request in eClaims including the most recent clinic note (outlining the treatment(s) to date and response to treatment, if able to assess).

   Patients who have already completed platinum doublet chemotherapy as of the effective funding date will not be eligible for pembrolizumab but may be eligible for nivolumab in a subsequent line of therapy.

iii. **My patient may not be able to tolerate both pembrolizumab and platinum/5-FU (or alternate platinum doublet) upfront. Can I start my patient with pembrolizumab or platinum doublet and add the other part later?**

   Patients whose tumours have PD-L1 expression using CPS = 1 are eligible to receive pembrolizumab monotherapy. Patients with PD-L1 expression using CPS < 1 are only eligible for pembrolizumab if it is given in combination with a platinum doublet.

iv. **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 the time of enrolment.

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

- CT scans every 3 to 6 months, 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 the subsequent CT scan confirming no disease progression.
- Pathology report confirming squamous cell carcinoma of the H&N.
- PD-L1 CPS testing result.

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

....
Day Month Year

Form 960