

* 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:

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c. Intended regimen:

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d. Drug(s) to be held:

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e. Rationale for holding drug(s):

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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):

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h. Anticipated date of first treatment:

.....
Day Month Year

i. Additional comments:

2. Eligibility Criteria

Pembrolizumab will be used for the treatment of adult patients with resectable locally advanced (Stage III-IVA) head and neck squamous cell carcinoma (HNSCC) whose tumours express PD-L1 (combined positive score [CPS] ≥ 1), as determined by a validated test. Treatment will be administered as monotherapy in the neoadjuvant setting, followed by adjuvant treatment in combination with radiotherapy (RT) with or without cisplatin, and then again as monotherapy. Eligible patients must have a good performance status. Yes

Patients must not have:

- Stage T4b and/or N3 locally advanced HNSCC and/or distant metastases; OR
- Cancer outside of the oropharynx, larynx, and hypopharynx or oral cavity; OR
- Received prior therapy with an anti-PD-1, anti-PD-L1, anti-PD-L2 drug or with a drug directed to another co-inhibitory T-cell receptor; OR
- Received prior RT treatment or systemic anticancer therapy for head and neck cancer (see Note 1)

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, please indicate the funding source Private payer Manufacturer patient support program
- d. If yes, how many doses of pembrolizumab given every 3 weeks did the patient receive prior to the transition? N/A 1 2 3 4 5
 6 7 8 9 10 11
 12 13 14 15 16
- e. If yes, how many doses of pembrolizumab given every 6 weeks did the patient receive prior to the transition? N/A 1 2 3 4 5
 6 7 8
- f. If yes, please indicate the date of the last administered dose _____
Day Month Year

4. Funded Dose

In the neoadjuvant setting:

Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 3 weeks for 2 cycles, or 4 mg/kg IV (up to a maximum of 400 mg) every 6 weeks for 1 cycle.

In the adjuvant setting:

Pembrolizumab 2 mg/kg IV (up to a maximum of 200 mg) every 3 weeks for 3 cycles, or 4 mg/kg IV (up to a maximum of 400 mg) every 6 weeks for 2 cycles, in combination with RT (with or without cisplatin), then as monotherapy.

Funding is until disease progression or unacceptable toxicity or for a total maximum duration of 1 year or equivalent (i.e., 17 cycles of every 3-week dosing, or 9 cycles of every 6-week dosing), whichever comes first.

[ST-QBP regimen code(s): PEMB (for the neoadjuvant portion and after completion of RT), PEMB(RT), CISP(RT)+PEMB, CISP(RT-W)+PEMB, CRBP(RT-3W)+PEMB (for the adjuvant portion in combination with RT)].

5. Notes

1. Patients with recurrent resectable HNSCC who had a recurrence more than 6 months after initiation of prior systemic therapy may be eligible for pembrolizumab funding under this policy, provided all other funding criteria are met.
2. Patients who do not proceed to surgery or who are not eligible for adjuvant RT will not be eligible for continued funding of pembrolizumab under this policy.
3. Pembrolizumab will not be funded prior to completion of PD-L1 testing.
4. Patients who experience intolerance to cisplatin are eligible for continued pembrolizumab funding if carboplatin is used as an alternate radiosensitizer.
5. Patients whose disease recurs at least 6 months after the last dose of pembrolizumab may be funded for 1 line of immune checkpoint inhibitor therapy for advanced HNSCC.

6. FAQs

1. My patient is currently receiving pembrolizumab through non-publicly funded means (e.g., patient support program, private insurance). Can my patient be transitioned to receive funding through the New Drug Funding Program (NDFP)?

Provided the eligibility 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 through the NDFP.

2. What is the process for transitioning my patient from a non-publicly funded program to NDFP funding?

If your patient meets all of the eligibility criteria outlined in this policy, please submit as a regular eClaims enrolment.

Prior approval requests are reserved for instances where there is clinical uncertainty on eligibility. In these circumstances, please specify your reason(s) for uncertainty and upload the following:

- A clinic note and imaging (if applicable) from treatment initiation, and
- The most recent clinic note and imaging (if applicable).

Please note: Patients who meet the NDFP eligibility criteria and are enrolled in the manufacturer's patient support program (PSP) are eligible to receive continued drug supply through the PSP until April 22, 2026, inclusive.

After this date, patients who met the NDFP eligibility criteria at the point of treatment initiation are eligible to transition to NDFP funding for the remainder of their treatment course. Although sites may enroll their patient onto this policy at any time beforehand, any treatment claims submitted to eClaims that were given on or before the PSP transition date will be denied.

Based on the recommendations from Canada's Drug Agency, Ontario Health (Cancer Care Ontario) does not reimburse hospitals for pembrolizumab given as a fixed or flat dose under this policy. Regardless of the patient's prior funding source or prior dosing, NDFP will fund the weight-based dosing as indicated in the Funded Dose section above.

The NDFP will fund a total duration of 1 year (17 cycles if given every 3 weeks, 9 cycles if given every 6 weeks), regardless of funding source.

3. My patient did not receive neoadjuvant pembrolizumab, can they use pembrolizumab in the adjuvant setting?

Patients are only funded for pembrolizumab in the adjuvant setting if they received neoadjuvant pembrolizumab.

4. My patient is experiencing toxicity to cisplatin, can they use carboplatin with adjuvant radiotherapy?

Patients who experience toxicity to cisplatin may continue pembrolizumab with adjuvant radiotherapy and carboplatin.

Supporting Documents

None required at time of enrolment.

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

- Clinic notes outlining patient and treatment history/response.
- CT scans demonstrating no disease progression.
- PD-L1 testing results confirming PD-L1 CPS \geq 1.
- For instances where there is pseudoprogression:
 - Clinic note documenting the assessment and decision to continue, AND
 - 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