BC Cancer Protocol Summary for Adjuvant Treatment of Squamous Cell Carcinoma of the Head and Neck Using Pembrolizumab

Protocol Code	*HNAJPMB*
Tumour Group	*Head and Neck*
Contact Physician	*HN Systemic Therapy*

ELIGIBILITY:

Patients must have:

- Resected locally advanced squamous cell carcinoma of the head and neck (HNSCC) with low risk of recurrence,
- PD-L1 CPS score greater than or equal to 1%,
- Completed neoadjuvant treatment with HNNAPMB prior to resection

Patients should have:

- Access to a treatment centre with expertise to manage immune-mediated adverse reactions of pembrolizumab

EXCLUSIONS:

Patient must not have:

- Stage T4b and/or N3 locally advanced HNSCC
- Distant metastases
- Tumours outside the oropharynx, larynx, hypopharynx or oral cavity

CAUTIONS:

- Active, known or suspected autoimmune disease
- Patients with long term immunosuppressive therapy or systemic corticosteroids (requiring more than 10 mg predniSONE/day or equivalent)

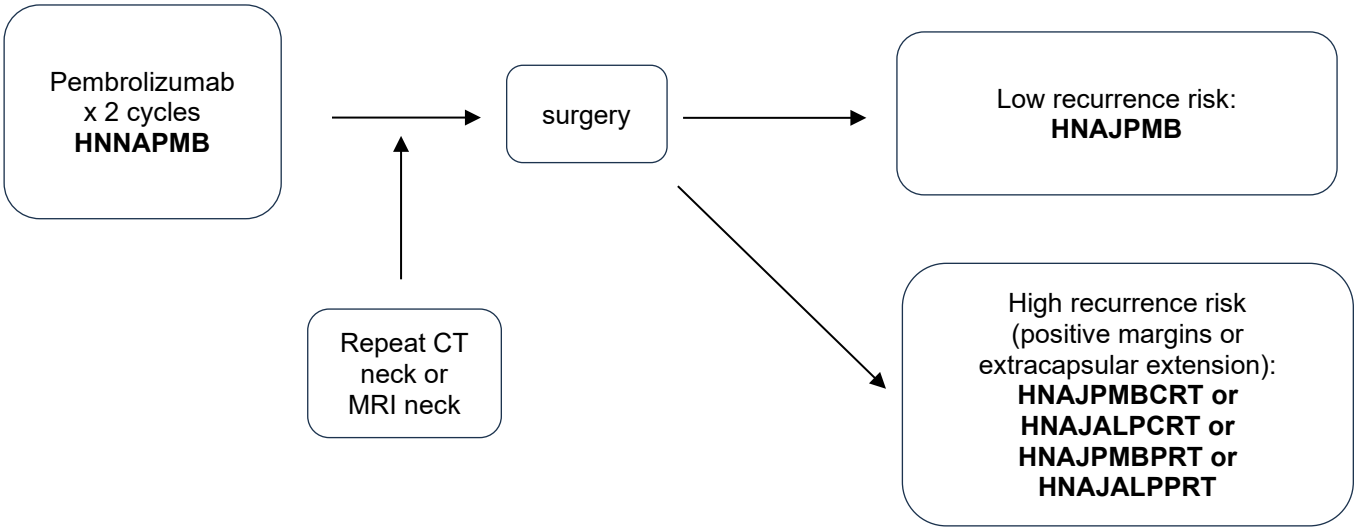
TESTS:

- Baseline: CBC & Diff, creatinine, alkaline phosphatase, ALT, total bilirubin, LDH, sodium, potassium, TSH, morning serum cortisol, serum or urine HCG (required for women of childbearing potential if pregnancy suspected), chest x-ray
- Before each treatment: CBC & Diff, creatinine, alkaline phosphatase, ALT, total bilirubin, LDH, sodium, potassium, TSH
- If clinically indicated: chest x-ray, morning serum cortisol, lipase, random glucose, serum or urine HCG (required for women of childbearing potential if pregnancy suspected), free T3 and free T4, serum ACTH levels, testosterone, estradiol, FSH, LH, ECG
- Weekly telephone nursing assessment for signs and symptoms of side effects while on treatment (optional).

PREMEDICATIONS:

- Antiemetics are not usually required
- If required, antiemetic protocol for low emetogenicity (see SCNAUSEA)
- If prior infusion reactions to pembrolizumab: diphenhydrAMINE 50 mg PO, acetaminophen 325 to 975 mg PO, and hydrocortisone 25 mg IV 30 minutes prior to treatment

TREATMENT SCHEMA:



TREATMENT:

Cycle 1 to 3:

Drug	Dose	BC Cancer Administration Guideline
pembrolizumab	2 mg/kg* (maximum 200 mg)	IV in 50 mL NS over 30 minutes using a 0.2 micron in-line filter

* Select dose per Dose Banding Table (appendix).

- Cycles 1 to 3 to be given alongside radiation therapy (radiation therapy typically delivered over 6 to 6.5 weeks), every 21 days

Cycles 4 and onwards: starts 21 days after Cycle 3

Drug	Dose	BC Cancer Administration Guideline
pembrolizumab	2 mg/kg* (maximum 200 mg)	IV in 50 mL NS over 30 minutes using a 0.2 micron in-line filter

*Select dose per Dose Banding Table (appendix).

- Repeat every 21 days until disease progression, unacceptable toxicity up to a maximum of 17 cycles of 3-weekly dosing (or equivalent combination of 3-weekly and 6-weekly doses), including doses given as part of HNNAPMB. Patients may have treatment breaks for reasons other than progression (e.g. toxicities).

OR

Drug	Dose	BC Cancer Administration Guideline
pembrolizumab	4 mg/kg* (maximum 400 mg)	IV in 50 mL NS over 30 minutes using a 0.2 micron in-line filter

*Select dose per Dose Banding Table (appendix).

- Repeat every 42 days until disease progression, unacceptable toxicity up to a equivalent maximum of 17 cycles of 3-weekly dosing (equivalent combination of 3-weekly and 6-weekly doses), including doses given as part of HNNAPMB. Patients may have treatment breaks for reasons other than progression (e.g. toxicities).

DOSE MODIFICATIONS:

No specific dose modifications. Toxicity managed by treatment delay and other measures (see SCIMMUNE protocol for management of immune-mediated adverse reactions to checkpoint inhibitors immunotherapy).

PRECAUTIONS:

1. **Serious immune-mediated reactions**: can be severe to fatal and usually occur during the treatment course, but may develop months after discontinuation of therapy. They may include enterocolitis, intestinal perforation or hemorrhage, hepatitis, dermatitis, neuropathy, endocrinopathy, pneumonitis, as well as toxicities in other organ systems. Early diagnosis and appropriate management are essential to minimize life-threatening complications (**see SCIMMUNE protocol for management of immune-mediated adverse reactions to checkpoint inhibitors immunotherapy**).
2. **Infusion-related reactions:** isolated cases of severe infusion reactions have been reported. Discontinue pembrolizumab with severe reactions (Grade 3 or 4). Patients with mild or moderate infusion reactions may receive pembrolizumab with close monitoring, reduced rates of administration and use of premedication.

Contact the HN Systemic Therapy physician at your regional cancer centre or the HN Systemic Therapy Chair with any problems or questions regarding this treatment program.

REFERENCES:

1. Uppaluri R, Haddad RI, Tao Y et al. Neoadjuvant and Adjuvant Pembrolizumab in Locally Advanced Head and Neck Cancer. N Engl J Med 2025;393:37-50.
2. Pembrolizumab (Keytruda) Canada's Drug Agency (CDA-AMC) Reimbursement Recommendation. Canadian Journal of Health Technologies. October 2025; 5(10): 1-21.

Appendix. Dose Bands

PEMBROLIZUMAB DOSE BANDING TABLE (2 mg/kg capped 200 mg)

Ordered Dose (mg)		Rounded dose (mg)
From:	To:	
Less than 70		**Pharmacy prepares specific dose**
70	80.49	**75**
80.5	92.49	**85**
92.5	110.49	**100**
110.5	137.49	**125**
137.5	162.49	**150**
162.5	187.49	**175**
187.5	200	**200**

PEMBROLIZUMAB DOSE BANDING TABLE (4 mg/kg capped 400 mg)

Ordered Dose (mg)		Rounded dose (mg)
From:	To:	
Less than 137.5		**Pharmacy prepares specific dose**
137.5	162.49	**150**
162.5	187.49	**175**
187.5	221.49	**200**
221.5	242.49	**225**
242.5	264.49	**250**
264.5	284.49	**275**
284.5	332.49	**300**
332.5	374.49	**350**
374.5	400	**400**