

# BC Cancer Protocol Summary for Neoadjuvant Treatment of Squamous Cell Carcinoma of the Head and Neck with Pembrolizumab

**Protocol Code**

*HNNAPMB*

**Tumour Group**

*Head and Neck*

**Contact Physician**

*HN Systemic Therapy*

## **ELIGIBILITY:**

Patients must have:

- Previously untreated locally advanced squamous cell carcinoma of the head and neck (HNSCC) amenable to curative surgery, and one of the following:
  - stage III oropharyngeal p16-positive HNSCC that is T4, N0-N2, M0
  - stage III or IVA oropharyngeal p16-negative HNSCC
  - stage III or IVA larynx, hypopharynx, oral cavity HNSCC (independent of p16)
- PD-L1 CPS score greater than or equal to 1%,
- Planned concomitant radiation or chemoradiation following surgery

Patient should have:

- Good performance status
- Adequate hematologic, hepatic and renal function
- 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
- Prior radiation or systemic therapy for the current malignancy

## **CAUTIONS:**

- Active uncontrolled autoimmune disease
- Known active hepatitis B, C or HIV
- Patients with long term immunosuppressive therapy or systemic corticosteroids (requiring more than 10 mg predniSONE/day or equivalent)

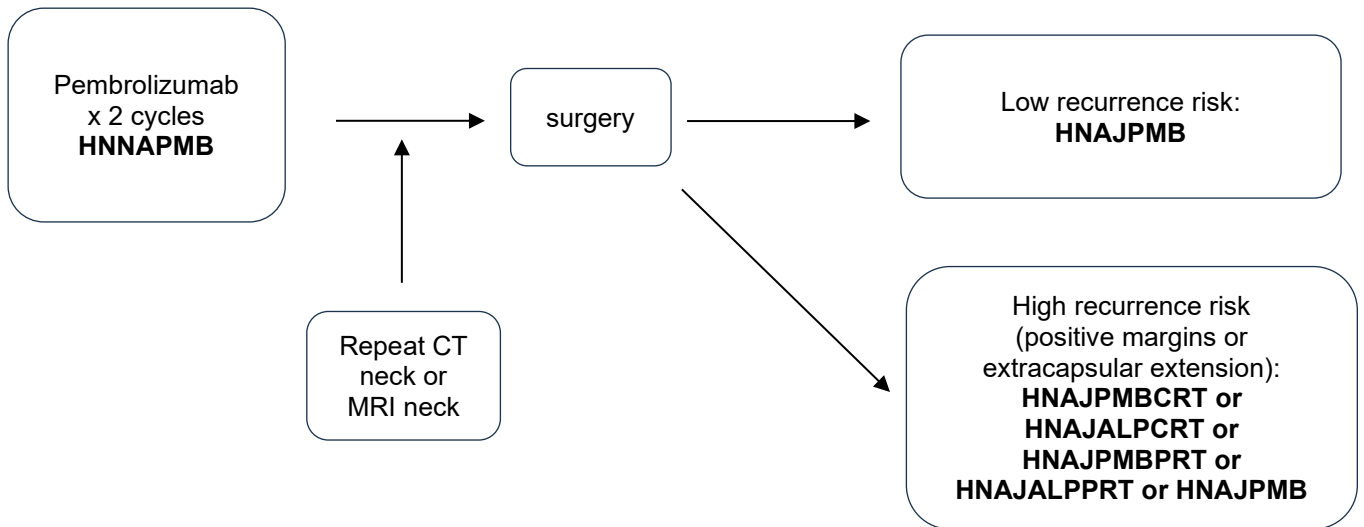
## TESTS:

- Baseline: CBC & Diff, creatinine, alkaline phosphatase, ALT, total bilirubin, LDH, sodium, potassium, TSH, morning serum cortisol, urea, albumin, magnesium, calcium, phosphate, 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:

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).

- Each cycle is 3 weeks (21 days) for 2 cycles
- After Cycle 2, prior to surgery, CT neck or MRI neck restaging is required (whichever was done as pre-treatment baseline)
- Adjuvant treatment to begin within 42 days of surgery; see HNAJPMB, HNAJPMBPRT, HNAJALPPRT, HNAJPMBCRT and HNAJALPCRT.

## 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 and use of premedication.

**Contact the HN Systemic Therapy physician at your regional 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	<b>75</b>
80.5	92.49	<b>85</b>
92.5	110.49	<b>100</b>
110.5	137.49	<b>125</b>
137.5	162.49	<b>150</b>
162.5	187.49	<b>175</b>
187.5	200	<b>200</b>