BC Cancer Protocol Summary for Adjuvant Treatment of Non-Small Cell Lung Cancer Using 6-Weekly Pembrolizumab

Protocol Code	*LUAJPMB6*
Tumour Group	*Lung*
Contact Physician	*LU Systemic Therapy*

ELIGIBILITY:

Patients must have:

- Stage IB (T2a greater than or equal to 4 cm), II or IIIA non-small cell lung cancer,
- PD-L1 TPS score less than 50%
- Undergone complete surgical resection with no clinical or radiographic evidence of disease,
- Received prior adjuvant platinum-based chemotherapy without progression

Patients should have:

- Start date within 12 weeks of completion of platinum-based chemotherapy,
- Good performance status,
- Adequate hepatic and renal function, and
- Access to a treatment centre with expertise to manage immune-mediated adverse reactions of pembrolizumab

Notes:

- CAP approval is not required to switch between LUAJPMB6 and LUAJPMB

EXCLUSION:

Patient must not have:

- Received neoadjuvant treatment for the current malignancy
- Prior treatment with any immunomodulating drugs

CAUTIONS:

- Active, known or suspected autoimmune disease
- Use with caution in 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, 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 child-bearing 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:

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 **6 weeks** until disease progression, unacceptable toxicity, or a maximum of 1 year of treatment, whichever comes first (including doses given as LUAJPMB)

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

REFERENCES:

1. O'Brien M, Paz-Ares L, Marreaud S et al. Pembrolizumab Versus Placebo as Adjuvant Therapy for Completely Resected Stage IB-IIIA Non-Small-Cell Lung Cancer (PEARLS/KEYNOTE-091): an Interim Analysis of a Randomised, Triple-Blind, Phase 3 Trial. Lancet Oncol 2022; 23: 1274-86.
2. Pembrolizumab (Keytruda) Canada's Drug Agency (CDA-AMC) Reimbursement Recommendation. Canadian Journal of Health Technologies. February 2025; 5(2): 1-25.

Appendix. Dose Bands

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**
265.5	284.49	**275**
285.5	332.49	**300**
333.5	374.49	**350**
374.5	400	**400**