CADTH **PCODR** PAN-CANADIAN ONCOLOGY DRUG REVIEW

## **PROVINCIAL FUNDING SUMMARY**

Pembrolizumab (Keytruda) for Advanced Non-Small Cell Lung Carcinoma (First Line) (pCODR 10101)

## pERC Recommendation: Recommends with conditions For further details, please see <u>pERC Final Recommendation</u>

## Notification to Implement Issued by pCODR: September 8, 2017

This information is current as of October 1, 2020.

Note: Funding criteria as listed on the decision date. Please refer to the provincial drug programs for the most recent funding criteria and program eligibility.

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
BC	Funded	Feb 1, 2018	<ul> <li>Previously untreated advanced non-small cell lung cancer</li> <li>Tumour characteristics confirmed by an accredited laboratory: <ul> <li>PD-L1 expression positive (&gt;50%)</li> <li>For non-squamous carcimona:</li> <li>EGFR mutation-negative</li> <li>ALK mutation-negative</li> </ul> </li> <li>ECOG 0-1</li> <li>Adequate hepatic and renal function</li> <li>Access to a treatment centre with expertise to manage immune-mediated adverse reactions of pembrolizumab</li> <li>BC Cancer Compassionate Access Program (CAP) approval must be obtained</li> </ul>
AB	Funded	Feb 16, 2018	Criteria Updated: Pembrolizumab monotherapy for the treatment of locally advanced or previously untreated metastatic non-small cell lung cancer (NSCLC) or for patients previously treated with durvalumab in the adjuvant setting where a six month interval has passed after completion or durvalumab therapy with no disease recurrence while on durvalumab. For use in patients whose tumors express the PDL-1 (Tumour Proportions Score (TPS) $\geq$ 50%) as determined by a validated test and who do not harbor a sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) translocation. Patients with locally advanced disease (stage IIIB) should be eligible if they are not eligible for potentially curative concurrent chemoradiotherapy. Patients should have good performance status. Treatment should continue until confirmed disease progression or unacceptable toxicity or to a maximum of two years (35 cycles) whichever comes first. Patients are eligible for re-treatment for up to 17 cycles if

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
			patient received 35 cycles and stopped treatment after 35 cycles for reasons other than disease progression, intolerability, or if patient attained a complete response and stopped treatment.
SK	Funded	Dec 7, 2017	Treatment of locally advanced (Stage IIIB, not eligible for potentially curative concurrent chemoradiotherapy) or previously untreated metastatic non-small cell lung cancer (NSCLC) in patients whose tumours express PD-L1 Tumour Proportion Score (TPS) ≥50% as determined by a validated test and who have a good performance status, and who do not harbour a sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) translocation o Treatment should continue until confirmed disease progression or unacceptable toxicity, or to a maximum of two years (35 cycles), whichever comes first o Pembrolizumab may be re-started and continued for up to 12 additional months at the time of confirmed radiographic disease progression (according to immune-related response criteria) after initial Pembrolizumab therapy was stopped due to either completion of two years of therapy (35 cycles) or at physician discretion before 2 years in the setting of maximum response.
MB	Funded	Dec 15, 2017	Treatment of locally advanced or previously untreated metastatic non-small cell lung cancer (NSCLC) in patients whose tumors express PD-L1 Tumor Proportion Score equal to or greater than 50% as determined by a validated test and who do not harbour a sensitizing epidermal growth factor (EGFR) mutation or anaplastic lymphoma kinase (ALK) translocation Patients with locally advanced disease (stage IIIB) are eligible for funding if they are not eligible for potentially concurrent chemoradiotherapy Patients should have good performance status - Patients can receive up to an additional 12 months of pembrolizumab if they experience radiographic disease progression, according to immune-related response criteria, after previously stopping their initial treatment with pembrolizumab due to a confirmed complete response or having received 35 administriions (cycles), whichever comes first.

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
ON	Funded	Jan 17, 2018	<ul> <li>For the treatment of locally advanced or previously untreated metastatic non-small cell lung cancer (NSCLC) in patients whose tumours express PD-L1 (Tumour Proportion Score [TPS] ≥ 50%) as determined by a validated test and who do not harbour a sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) translocation. Patients should have good performance status.</li> <li>Patients who have locally advanced (stage IIIB) disease cannot be eligible for potentially curative concurrent chemoradiotherapy.</li> <li>Pembrolizumab will be funded until confirmed disease progression or unacceptable toxicity or to a maximum of two years (35 cycles), whichever comes first.</li> <li>Patients who complete 35 cycles without disease progression if the treating physician deems the patient eligible for retreatment.</li> </ul>
NS	Funded	May 24, 2018	As a single agent treatment option for the treatment of locally advanced (Stage IIIB, not eligible for potentially curative concurrent chemoradiotherapy) or previously untreated metastatic non-small cell lung cancer (NSCLC) in patients whose tumours express PD-L1 Tumour Proportion Score (TPS) $\geq$ 50% as determined by a validated test and who do not harbor a sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) translocation. Patients should have a good performance status. Treatment should continue until confirmed disease progression or unacceptable toxicity, or to a maximum of two years (35 cycles), whichever comes first. Patients who complete 2 years of therapy (35 cycles), or before 2 years in the setting of maximum response, may receive up to an additional 12 months (17 cycles) at the point of confirmed disease progression if the treating physician deems the patient eligible for treatment.

CADTH PAN-CANADIAN ONCOLOGY DRUG REVIEW			
PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
NB	Funded	May 2, 2018	For the treatment of locally advanced (stage IIIB, not eligible for potentially curative concurrent chemoradiotherapy) or previously untreated metastatic non-small cell lung cancer (NSCLC) in patients whose tumors express PD-L1 (Tumor Proportion Score [TPS] greater than or equal to 50%) as determined by a validated test and, who do not harbor a sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) translocation. Patients must have a good performance status. Treatment should be discontinued upon disease progression, unacceptable toxicity or, a maximum of 2 years (i.e., 35 cycles), whichever occurs first.
NL	Funded	May 30, 2018	Treatment of locally advanced or previously untreated metastatic non-small cell lung cancer in patients whose tumours express PD-L1 (TPS ≥ 50%) as determined by a validated test and who do not harbour a sensitizing EGFR mutation or ALK translocation with good performance status. Patients with locally advanced disease (stage IIIB) are eligible for funding if they are not eligible for potentially curative concurrent chemo- radiotherapy. Treatment should continue until confirmed disease progression or unacceptable toxicity or to a maximum of two years (35 cycles), whichever comes first. Pembrolizumab is given as a single agent and dosed at 2mg/kg up to a maximum of 200 mg.

CADTH PAN-CANADIAN ONCOLOGY DRUG REVIEW			REVIEW	
PROVINCE	FUNDI	NG STATUS	FUNDING DATE	FUNDING CRITERIA
PEI	Funde	d	Aug 1, 2019	Treatment of locally advanced or previously untreated metastatic non-small cell lung cancer (NSCLC) in patients whose tumours express PD-L1 (Tumour Proportion Score [TPS] equal to or greater than 50%) as determined by a validated test and who do not harbour a sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) translocation. • Patients with locally advanced disease (stage IIIB) should be eligible for funding if they are not eligible for potentially curative concurrent chemoradiotherapy. Funding should be for patients who have good performance status. • Patients could receive up to 12 months of pembrolizumab if they experienced an investigator-determined confirmed radiographic disease progression, according to immune-related response criteria after stopping their initial treatment with pembrolizumab due to achievement of a confirmed complete response or having experienced 35 administrations of pembrolizumab. • Treatment should continue until confirmed disease or unacceptable toxicity or to a maximum of two years (35 cycles), whichever comes first.