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

PROVINCIAL FUNDING SUMMARY

Pembrolizumab (Keytruda) for Metastatic Urothelial Carcinoma (pCODR 10117)

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

Notification to Implement Issued by pCODR: March 19, 2018

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	Jun 1, 2020	 Locally advanced or metastatic urothelial carcinoma Second-line therapy for disease progression on or after platinum-based chemotherapy or within 12 months of completing adjuvant or neoadjuvant platinumbased chemotherapy ECOG performance status 0-2 Adequate hepatic and renal function
AB	Funded	Sep 1, 2020	Pembrolizumab in the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy (or a non-platinum containing chemotherapy if contraindications to platinum based chemotherapy) or within 12 months of completing neoadjuvant or adjuvant platinum containing chemotherapy. Treatment should continue until confirmed disease progression or unacceptable toxicity or completion of two years of pembrolizumab therapy (35 cycles) whichever comes first. Patients may receive re-treatment of an additional year (I7 cycles) if they either stopped initial treatment after confirmed completed response and were treated with at least 24 weeks of pembrolizumab and received two treatment of pembrolizumab beyond initial completed response or had stable disease, partial response, or complete response and stopped treatment after 24 months for reasons other than disease progression or intolerability. Dosing is at 2 mg/kg to a maximum (cap) of 200 mg per dose. Pembrolizumab is not to be used by itself in sequence of other single agent PD-1 or PD-L1 therapy unless the other PD-1 or PD-L1 agent was received in a clinical trial in the (neo)-adjuvant setting (ie patients may receive only one PD-l or PD-L1 agent by itself in the advanced/metastatic setting).

PROVINCE	FUNDING STATUS	FUNDING DATE May 1, 2020	FUNDING CRITERIA
SK	Funded		Treatment of locally advanced or metastatic urothelial carcinoma (mUC) in patients who have disease progression during or following platinum- containing chemotherapy or within 12 months of completing neoadjuvant or adjuvant platinum- containing chemotherapy, and who have good performance status •Treatment may continue until confirmed disease progression or unacceptable toxicity, or after completing 2 years of Pembrolizumab therapy, whichever comes first Urothelial Carcinoma Funding Notes: -Eligible patients include those with urothelial carcinoma of the renal pelvis, ureter, bladder or urethra that display predominantly transitional-cell features on histologic testing -Patients that have disease suitable for local therapy with curative intent are not eligible -Patients with contraindications to platinum-containing chemotherapy for mUC are eligible; patients who have not received any chemotherapy for mUC are not eligible -If Pembrolizumab is stopped in the setting of maximum response/stable disease or after completion of 2 years of therapy, it may be re-started at the time of disease progression for an additional 1 year of therapy.
MB	Funded	Apr 22, 2020	For the treatment of patients with locally advanced or metastatic urothelial carcinoma (MUC) who have disease progression during or following platinum-containing chemotherapy or within 12 months of completing neoadjuvant or adjuvant platinum-containing chemotherapy. Patients should have good performance status. Treatment should continue until confirmed disease progression or unacceptable toxicity or after completing two years of pembrolizumab therapy, whichever comes first. Patients who are ineligible for a platinum-based chemotherapy (i.e. have contraindications to platinum therapy) and would receive an alternative chemotherapy regimen: These patients will be eligible for pembrolizumab in the relapsed setting. Retreatment: Patients who have stable disease, partial response or complete response and stop pembrolizumab treatment after 24 months (35 cycles) for reasons other than disease progression or intolerability will be allowed up to an additional year of pembrolizumab.

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA	
ON	Funded	Apr 24, 2020	Pembrolizumab is used for the treatment of patients with locally advanced or metastatic urothelial carcinoma (MUC) who have disease progression during or following platinum- containing chemotherapy or within 12 months of completing neoadjuvant or adjuvant platinum- containing chemotherapy. Treatment should be for patients with good performance status.	
NS	Funded	May 1, 2020	As a single agent treatment option for patients with locally advanced or metastatic urothelial carcinoma (MUC) who have disease progression during or following platinum-based chemotherapy or within 12 months of completing neoadjuvant or adjuvant platinum-based chemotherapy. Patients should have a good performance status. Treatment should continue until confirmed disease progression or unacceptable toxicity or to a maximum of 2 years of treatment. Patients that are ineligible for platinum-based chemotherapy, i.e. have a contraindication to platinum, and who would receive an alternative chemotherapy, will be eligible for pembrolizumab in the second-line setting. Patients who complete 2 years of therapy, or less than 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.	
NB	Funded	Jul 16, 2020	For the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or within 12 months of completing neoadjuvant or adjuvant platinum-containing chemotherapy. Patients must have a good performance status. Treatment should be discontinued upon confirmed disease progression, unacceptable toxicity or after completing two years of therapy, whichever occurs first.	
NL	Funded	Jun 1, 2020	 Patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or within 12 months of completing neoadjuvant or adjuvant platinum-containing chemotherapy Patients must have good performance status -Treatment should continue until disease progression or unacceptable toxicity, up to a maximum of 2 years (35 cycles) 	

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PROVINCE	FUNDI	NG STATUS	FUNDING DATE	FUNDING CRITERIA
PEI	Under provincial consideration			

Under provincial consideration means that the province is reviewing pCODR's recommendation. This may include the province working with the drug manufacturer to reach an agreement for a drug product that both parties can accept, in particular in cases where the pCODR Expert Review Committee has recommended that the drug be funded only on the condition of cost-effectiveness being improved to an acceptable level. This may occur before or after the pan-Canadian Pharmaceutical Alliance negotiations. Please contact the specific provincial drug program and/or cancer agency in your province for information about the status of a given drug product.