

PROVINCIAL FUNDING SUMMARY

Pembrolizumab (Keytruda) for Melanoma Adjuvant Treatment (pCODR 10168)

pERC Recommendation: Recommends with conditions

For further details, please see [pERC Final Recommendation](#)

Notification to Implement Issued by pCODR: August 19, 2019

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	<p>Cutaneous or mucosal melanoma stage IIIA to IV NED (AJCC 8th edition). Disease metastasized to the regional nodes (if stage IIIA and only one node involved then metastatic deposit > 1 mm), in-transit metastases or distant metastases must be completely surgically resected.</p> <ul style="list-style-type: none"> Brain metastases must be completely resected (or definitively treated with stereostatic radiation) Adequate baseline hematological, renal and liver functions
AB	Funded	Sep 15, 2020	<p>For the adjuvant treatment of patients with stage IIIA (with node metastases greater than or equal to 1 mm), stage IIIB/C/D and stage IV cutaneous melanoma. Disease must be completely resected including in-transit metastases; however presence of regional lymph nodes with micro metastases after sentinel lymph node biopsy alone is allowed. Patients must have good performance status. Treatment should continue up to a maximum of 18 doses (every 3 weeks of equivalent) or until unacceptable toxicity or disease recurrence. Dosing should be 2 mg/kg up to a maximum dose of 200 mg every 3 weeks</p>
SK	Funded	May 1, 2020	<ul style="list-style-type: none"> Adjuvant treatment of patients with stage IIIA (limited to lymph node metastases of >1 mm) to stage IIID, and stage IV melanoma (based on 8th edition of the American Joint Committee on Cancer [AJCC] melanoma staging system) Disease must be completely resected including in-transit metastases; however, presence of regional lymph nodes with micrometastases after sentinel lymph node biopsy alone is allowed Eligible patients may continue treatment until disease progression or a maximum of one year, whichever comes first <p>Melanoma - Adjuvant Funding Notes -Patients with either cutaneous or</p>

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
			<p>mucosal melanoma are included in the eligibility criteria; patients with ocular melanoma are not eligible for SCA funded Pembrolizumab as adjuvant treatment -Patients should have good performance status -Treatment should start within 12 weeks from surgery -For patients who have dose interruptions and subsequently resume therapy, Pembrolizumab may continue up to a maximum of 12 months from the time of treatment initiation -Therapy should be discontinued prior to 12 months if there is confirmation of local disease progression or development of metastatic disease -Patients should be assessed for disease recurrence at least every 3 months, or more frequently as clinically indicated -Patients currently receiving adjuvant Interferon may be switched to Pembrolizumab for up to 12 months of Pembrolizumab treatment provided they meet all other funding criteria -If a patient is BRAF mutation positive, a one-time switch to the combination of Dabrafenib and Trametinib is allowed within the first 3 months of Pembrolizumab treatment; the total duration of adjuvant therapy that is funded is 12 months of immunotherapy and BRAF targeted therapy combined -Patients will be eligible for all immunotherapy options in the advanced or metastatic setting only if there has been at least a 6 month progression-free interval between completion of adjuvant Pembrolizumab (or Nivolumab) and confirmation of disease progression.</p>
MB	Funded	May 4, 2020	<p>For the treatment of patients with stage IIIA (limited to lymph node metastases of greater than 1mm) to stage IIID (8th edition of the American Joint Committee on Cancer [AJCC] staging system) cutaneous melanoma. Disease must be completely resected; however, presence of regional lymph nodes with micro metastases after sentinel lymph node biopsy alone is allowed. Patients should have good performance status. Treatment will be for a maximum of 1 year (1 cycle given every 3 weeks for a total of 18 cycles).</p>

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
ON	Funded	Aug 4, 2020	Pembrolizumab is used for the adjuvant treatment of adult patients with completely resected stage IIIA (with node metastases >1mm), IIIB, IIIC, IIID or stage IV melanoma and; the disease must be completely resected including in-transit metastases; however, presence of regional lymph nodes with micrometastases after sentinel lymph node biopsy alone is allowed. Treatment should be continued until disease progression or unacceptable toxicity up to a maximum of 12 months (or equivalent therapy), whichever comes first.
NS	Funded	May 1, 2020	For the adjuvant treatment of patients with cutaneous melanoma with completely resected Stage IIIA (limited to lymph node metastases of \geq 1 mm) to Stage IV (8th edition of the American Joint Committee on Cancer [AJCC] melanoma staging system), regardless of BRAF status. Disease must be completely resected including in-transit metastases; however, presence of regional lymph nodes with micrometastases after sentinel lymph node biopsy alone is allowed. Patients should have a good performance status and brain metastases, if present, must be completely resected (or definitively treated with stereotactic radiation). Eligible patients should continue treatment until disease progression or a maximum of 1 year, whichever comes first. Patients with mucosal melanoma will be eligible for adjuvant treatment with pembrolizumab.
NB	Funded	Jul 16, 2020	For the adjuvant treatment of adult patients with completely resected stage IIIA (with lymph node metastases greater than 1mm) IIIB, IIIC, IIID and stage IV melanoma, based on the 8th edition of the American Joint Committee on Cancer (AJCC) melanoma staging system. Disease must be completely resected including in-transit metastases; however, presence of regional lymph nodes with micrometastases after sentinel node biopsy alone is allowed. Patients must have a good performance status. Treatment should be discontinued upon disease progression, unacceptable toxicity or a maximum of 1 year of adjuvant therapy, whichever occurs first.

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
NL	Funded	Jun 1, 2020	<ul style="list-style-type: none"> Adjuvant treatment of patients with stage IIIA (limited to lymph node metastases of > 1 mm)/IIIB/IIIC/IIID and resected stage IV cutaneous or mucosal melanoma - Patients must have good performance status (ECOG 0-2) Treatment should continue until disease recurrence or unacceptable toxicity, up to a maximum of 18 administrations
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.