CADTH | pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

PROVINCIAL FUNDING SUMMARY

Nivolumab (Opdivo) for Melanoma Adjuvant Therapy (pCODR 10147)

pERC Recommendation: Recommends with conditions

For further details, please see pERC Final Recommendation

Notification to Implement Issued by pCODR: March 22, 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	Nov 1, 2019	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. ▪ Brain metastases must be completely resected (or definitively treated with stereotactic radiation) ▪ Adequate baseline hematological, renal and liver functions ▪ Access to a treatment centre with expertise in managing immunotherapy mediated toxicities ▪ BC Cancer Compassionate Access Program (CAP) must be obtained. * Patients can receive one year of either adjuvant nivolumab OR combination dabrafenib/trametinib. Patients with BRAF mutated melanoma who are unable to tolerate up to a 3-month trial of combination dabrafenib/trametinib due to toxicities can apply for adjuvant nivolumab and complete a total of one year of therapy. A switch to combination cobimetinib/vemurafenib is not funded.
AB	Funded	Apr 10, 2020	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 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. Treatment until disease progression or a maximum of 1 year, whichever comes first Dosing should be 3 mg/kg up to maximum of 240 mg every 2 weeks or 6 mg/kg up to a maximum dose of 480 mg ever 4 weeks.

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
SK	Funded	Jan 1, 2020	•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 Additional clarifications for use and funding of Nivolumab for adjuvant treatment of melanoma are noted below: •Patients with either cutaneous or mucosal melanoma are included in the eligibility criteria; patients with ocular melanoma are not eligible for SCA funded Nivolumab as adjuvant treatment •Treatment should start within 12 weeks from surgery •For patients who have dose interruptions and subsequently resume therapy, Nivolumab 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 Nivolumab for up to 12 months of Nivolumab 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 Nivolumab 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 Nivolumab and confirmation of disease progression •Patients that experience disease progression while receiving, or within 6 months of receiving adjuvant Nivolumab will be eligible for single agent Ipilimumab

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
MB	Funded	Jan 15, 2020	For the adjuvant treatment of patients with: - completely resected stage IIIA (with node metastases greater than 1mm), IIIB, IIIC, IIID and stage IV disease (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 micro metastases after sentinel lymph node biopsy is allowed. Eligible patients should continue treatment until disease progression or a maximum of one year, whichever comes first. Treatment should start within 12 weeks from surgery.
ON	Funded	Jan 20, 2020	• Nivolumab 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. 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. Staging is based on the 8th edition of the American Joint Committee on Cancer (AJCC) melanoma staging system. • Nivolumab 3 mg/kg (up to a maximum dose of 240 mg) intravenously (IV) once every 2 weeks (or nivolumab 6 mg/kg (up to a maximum dose of 480 mg) intravenously (IV) once every 4 weeks) until disease progression or a maximum of one year of equivalent therapy, whichever comes first. • Patients whose disease relapses at least 6 months after completing adjuvant nivolumab may be eligible for combination ipilimumab & nivolumab in the metastatic setting. If the patient is unfit for combination immunotherapy, they may be eligible for single agent immunotherapy. • Patients with BRAF mutated melanoma who initiated treatment with adjuvant immunotherapy or adjuvant dabrafenib and trametinib may switch once between adjuvant therapies within 3 months of initiation of therapy. Funded therapy will be limited to a total of 12 months of adjuvant treatment, regardless of funding source.
NS	Funded	Apr 1, 2020	For the adjuvant treatment of patients with cutaneous or mucosal melanoma with completely resected Stage IIIA (limited to lymph node metastases of ≥ 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

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
			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.
NB	Funded	Apr 6, 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 completed resected including in-transit metastases; however, presence of regional lymph nodes with micrometastases after sentinel node biopsy alone is allowed. Treatment should be discontinued upon disease progression, unacceptable toxicity or a maximum of 1 year of adjuvant therapy, whichever occurs first.
NL	Under provincial consideration		
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.