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

PROVINCIAL FUNDING SUMMARY

Nivolumab (Opdivo) in combo with Ipilimumab (Yervoy) for Metastatic Melanoma (pCODR 10098)

pERC Recommendation: Recommends with conditions For further details, please see pERC Final Recommendation

Notification to Implement Issued by pCODR: December 15, 2017

This information is current as of August 1, 2019.

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	Apr 1, 2019	 Unresectable stage III or stage IV melanoma ECOG 0 - 1 Adequate hepatic and renal function No prior systemic therapy for advanced disease with the exception of BRAF and/or MEK inhibitors for BRAF mutant metastatic melanoma Patients on or completed anti-PD-1 monotherapy for advanced disease without progression, particularly if at high risk for disease progression Patients who relapse after a response > 2 years with ipilimumab started prior to 1 April 2019 for advanced disease Access to a treatment centre with expertise to manage immune-mediated adverse reactions of immunotherapy checkpoint inhibitors A BC Cancer "Compassionate Access Program" request with appropriate clinical information for each patient must be approved prior to treatment Note: No replacement of nivolumab with pembrolizumab in the maintenance phase 	
AB	Funded	Jul 16, 2019	Nivolumab in combination with Ipilimumab for the treatment of patients with unresectable or metastatic melanoma, regardless of BRAF status, with good performance status and with stable brain metastases, if present. Treatment should continue until unacceptable toxicity or disease progression. Treatments will be limited to tertiary centres only.	

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
SK	Funded	Apr 15, 2019	Combination use of Nivolumab plus Ipilimumab followed by Nivolumab maintenance for patients with unresectable or metastatic melanoma regardless of BRAF status who are treatment naïve, or may have received treatment with BRAF-targeted therapy, with ECOG performance status of 0-1 and with stable brain metastases, if present. Treatment should continue until unacceptable toxicity or disease progression.
MB	Funded	Apr 15, 2019	For patients with unresectable or metastatic melanoma regardless of BRAF status who are treatment-naive, with ECOG performance status C to 1 and with stable brain metastases, if present. Treatment should continue until acceptable toxicity. Note: Patients currently on 1st line treatment for BRAF positive unresectable or metastatic melanoma with BRAF (+/-) MEK inhibitor can have access to Nivolumab and Ipilimumab upon progression of the BRAF (+/-) MEK inhibitor.
ON	Funded	Apr 4, 2019	Combination nivolumab plus ipilimumab is used for the treatment of unresectable or metastatic melanoma regardless of BRAF status, who are treatment naïve or may have received prior treatment with BRAF-targeted therapy, with ECOG performance status of 0 or 1 and with stable brain metastases (if present). • Treatment with combination nivolumab plus ipilimumab (followed by nivolumab maintenance) should be continued until unacceptable toxicity of confirmed disease progression. • Patients with BRAF mutation may be initiated on BRAF targeted therapy or immunotherapy. Upon disease progression, the patient may be switched to the other treatment modality as a subsequent line of therapy. • For patients who stop nivolumab maintenance without disease progression, continuation of maintenance nivolumab will be funded provided that no other treatment is given in between.
NS	Funded	Jul 1, 2019	As combination use of nivolumab plus ipilimumab for the treatment of patients with unresectable o metastatic melanoma regardless of BRAF status who are treatment naïve, or may have received prior treatment with BRAF-targeted therapy, with an ECOG performance status of 0-1 and with stable brain metastases, if present. Treatment should continue until unacceptable toxicity or disease progression.

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PROVINCE	FUNDING STATUS		FUNDING DATE	FUNDING CRITERIA	
NB	Funded		Jun 28, 2019	For the treatment of patients with unresectable or metastatic melanoma, regardless of BRAF status, who are treatment naïve or have received prior treatment with BRAF-targeted therapy. Patients must have an ECOG performance status of 0 or 1 and, if present, stable brain metastases. Treatment should be discontinued upon disease progression or unacceptable toxicity.	
NL	Funded		Jul 16, 2019	Combination of Ipilimumab and Nivolumab, followed by Nivolumab maintenance for patients with unresectable or metastatic melanoma regardless of BRAF status. Patients must be treatment-naïve, however BRAF mutation positive patients may have received prior first-line treatment with BRAF-targeted (+/- MEK inhibitor) therapy. Patients must have ECOG performance status 0-2. If present, brain metastases must be stable.	
PEI		provincial eration			

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.