CADTH | pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

PROVINCIAL FUNDING SUMMARY

Pembrolizumab (Keytruda) for Metastatic Melanoma (pCODR 10058)

pERC Recommendation: Recommends

For further details, please see pERC Final Recommendation

Notification to Implement Issued by pCODR: December 1, 2015

This information is current as of August 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	June 1, 2016	Unresectable stage 3 or stage 4 metastatic melanoma in patients: - Ipilimumab naïve, regardless of BRAF V600 mutation status - ECOG 0 - 1 - Adequate hepatic and renal function - access to a treatment centre with expertise to manage immune-mediated adverse reactions of pembrolizumab - A BCCA "Compassionate Access Program" request with appropriate clinical information for each patient must be approved prior to treatment - Patients are eligible to receive pembrolizumab or ipilimumab or nivolumab but not sequential use of these agents
AB	Funded	July 15, 2016	Criteria updated Oct.30, 2018: Pembrolizumab for the treatment of patients with unresectable or metastatic melanoma regardless of BRAF status Treatment should be in patients with good performance status who have stable brain metastases (if present), using 2 mg/kg dose every 3 weeks for maximum of 200 mg for 24 months or until disease progression, whichever occurs first.Patients who stop therapy prior to progression or completed 2 years of therapy retreatment as per studies may be considered for up to 1 year. Time limited for patients who failed on ipilimumab if started on ipilimumab prior to pembrolizumab listing date (July 2016)

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PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
SK	Funded	May 20, 2016	Treatment of patients with advanced (unresectable or metastatic) melanoma as a single agent at a dose of 2 mg/kg every 3 weeks for 24 months or until disease progression, according to the following criteria: • First line checkpoint inhibitor immunotherapy in patients naïve to Ipilimumab treatment (patients with BRAF mutation positive tumors may or may not have received BRAF targeted therapy) • After failure of Ipilimumab (and may have also failed BRAF targeted therapy) only for patients who received Ipilimumab before the effective funding date of Pembrolizumab (May 2016) • Treatment in either setting is for patients with an ECOG performance status of 0 or 1, and who have stable brain metastases (if present)
MB	Funded	May 30, 2016	i) For the treatment of patients with unresectable or metastatic melanoma who have not received prior treatment with ipilimumab. Patients with BRAF V600 mutation positive melanoma may have received prior BRAF inhibitor or MEK inhibitor. ii) For the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab therapy and, if BRAF V600 mutation positive, following a BRAF or MEK inhibitor. Eligibility will be for patients who received ipilimumab prior to May 30th, 2016. iii) Patients require to have an Eastern Cooperative Oncology Group performance status of 0 or 1.

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PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
ON	Funded	June 2, 2016	For the treatment of patients with advanced melanoma (unresectable or metastatic melanoma) for the following: - Patients who are naive to ipilimumab treatment (patients with BRAF mutation positive may or may not have received BRAF targeted therapy) - Patients have failed ipilimumab*, and if BRAF mutation positive, have also failed BRAF mutation therapy - Treatment in either setting should be in patients with an ECOG performance status of 0 or 1, and who have stable brain metastasis. Treatment should be continued until disease progression or to a maximum of 24 months of equivalent therapy, whichever comes first. Update (April 4, 2019): For patients treated with anti-PD-1 monotherapy (instead of combination nivolumab plus ipilimumab) in the metastatic setting, ipilimumab monotherapy will be funded as a subsequent line of therapy provided that funding criteria are met. Update (June 10, 2020): Pembrolizumab retreatment, for up to an additional 12 months' worth of therapy, can be considered at the point of confirmed disease progression.
NS	Funded	June 2, 2016	As a single agent treatment option for patients with advanced melanoma (unresectable or metastatic melanoma) for the following indications: Ipilimumab Naïve: Patients who are naïve to ipilimumab treatment (patients with BRAF mutation positive may or may not have received BRAF targeted therapy). OR Progression Post Ipilimumab (legacy patients only*): Patients who have failed ipilimumab and if BRAF mutation positive have also failed BRAF mutation therapy.(*pertains to eligible patients prior to funding of pembrolizumab) Patients in either setting should have an ECOG PS 0 or 1 and if present stable brain metastases. Treatment duration in either patient population can continue for 24 months or until disease progression, whichever comes first. Sequencing of anti-CTLA-4 immunotherapy agents (eg ipilimumab) post PD-1 inhibitors is not funded.

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PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
NB	Funded	June 2, 2016	For the treatment of unresectable or metastatic melanoma (stage III or IV) in patients who are naïve to ipilimumab (Yervoy™) treatment. Patients who are BRAF mutation positive may or may not have received BRAF mutation targeted therapy. Patients initiated on ipilimumab (Yervoy™) therapy prior to June 2nd, 2016 are eligible to receive pembrolizumab upon treatment failure or disease progression. Patients who are BRAF mutation positive must have also failed BRAF mutation targeted therapy. Treatment in either setting should be in patients with an ECOG performance status of 0 or 1 and stable brain metastases (if present). The funded dose is pembrolizumab 2 mg/kg intravenously every 3 weeks for 24 months or until disease progression, whichever occurs first.
NL	Funded	June 2, 2016	Treatment of patients with advanced melanoma (unresectable or metastatic melanoma) for the following indications: - Patients who are naïve to ipilimumab treatment (patients with BRAF mutation positive may or may not have received BRAF targeted therapy). - Patients who have failed ipilimumab and, if BRAF mutation positive, have also failed BRAF mutation therapy. - Sequential use of ipilimumab (i.e. pembrolizumab first followed by ipilimumab) will not be funded. - Treatment should be in patients with an ECOG performance status 0 or 1, and who have stable brain metastases (if present). - Duration of therapy will be 24 months or until disease progression, whichever occurs first.
PEI	Funded	Sept 1, 2016	Treatment of patients with advanced (unresectable or metastatic) melanoma as a single agent at a dose of 2 mg/kg every 3 weeks for 24 months or until disease progression, whichever occurs first, with the following criteria: •First line checkpoint inhibitor immunotherapy in patients naïve to Ipilimumab treatment (patients with BRAF mutation positive tumors may or may not have received BRAF targeted therapy) •Treatment in either setting if for patients with an ECOG performance status of 0 or 1 and who have stable brain metastases (if present) NOTE: Pembrolizumab is not funded for patients who have disease progression after Nivolumab. Re-treatment with Pembrolizumab is not funded. •Not to be used sequentially with ipilimumab

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