

## PROVINCIAL FUNDING SUMMARY

Ipilimumab (Yervoy) for Metastatic Melanoma, first-line

pERC Recommendation: Recommend with condition on the cost-effectiveness being improved to an acceptable level For further details, please see <u>pERC Final Recommendation</u>.

Notification to Implement Issued by pCODR: January 14, 2015

This information is current as of June 30, 2016.

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.

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PROVINCE	STATUS	DECISION DATE	FUNDING CRITERIA
ВС	Funded	July 1, 2015	<ul> <li>Unresectable stage IIIC or stage IV melanoma:</li> <li>ECOG 0 or 1</li> <li>Adequate hepatic and renal function</li> <li>Life expectancy of at least 4 months</li> <li>Access to a treatment centre with expertise to manage immune-mediated adverse reactions of ipilimumab</li> <li>A BCCA "Compassionate Access Program" request with appropriate clinical information for each patient must be approved prior to treatment</li> </ul>
АВ	Funded	Mar 30, 2015	Ipilimumab for the first line treatment of advanced (unresectable or metastatic) melanoma dosed at 3 mg/kg every 3 weeks for 4 doses. Only patients with a documented response maintained for 6 months are eligible for retreatment.
SK	Funded	May 1, 2015	First line treatment of adult patients with stage IIIC or IV melanoma, regardless of BRAF mutation status, who have an ECOG performance status of 0 or 1, and are not currently receiving immunosuppressive therapy.
МВ	Funded	Mar 5, 2015	Inclusion criteria: - Primary unresectable stage IIIC or IV melanoma - ECOG performances status of 0 or 1  Exclusion criteria: - Current immunosuppressive therapy - Unstable CNS metastases - Pregnant or lactating females  Approved dosing schedule: 3 mg/kg intravenously every 3 weeks for 4 doses



PROVINCE	STATUS	DECISION DATE	FUNDING CRITERIA
ON	Funded	Apr 1, 2015	For the first line treatment of patients who are at least 18 years old with advanced melanoma (i.e. primary cutaneous unresectable state IIIC or IV melanoma or metastatic melanoma), regardless of BRAF mutation status, who have an ECOG PS score less than or equal to 1, and are not currently receiving immunosuppressive therapy If a patient has brain metastasis, then he or she must be asymptomatic or stable. Dosage Regimen: - 3mg/kg every three weeks for four doses. Exclusion Criteria: - Requests for dose escalation up to 10 mg/kg will not be considered - Maintenance or reinduction requests in the 1st line setting will not be considered - Patients who have used ipilimumab for advanced/ metastatic melanoma in the 1st line setting are not eligible for funding in the 2nd line setting
NS	Funded	Apr 1, 2015	As a single agent for the treatment of primary cutaneous unresectable stage IIIC or IV melanoma in patients (regardless of BRAF mutation status) as first line therapy or who have received at least one prior systemic treatment (excluding ipilimumab) for advanced melanoma , have an ECOG performance status (PS) ≤ 1 and are not currently receiving imunosuppressive therapy. If brain metastases are present, patients should be asymptomatic or stable.
NB	Funded	Jul 15, 2015	Initial treatment: As a single agent for the first line treatment of primary cutaneous unresectable stage IIIC or IV melanoma in patients (regardless of BRAF mutation status) or who have received at least one prior systemic treatment (excluding ipilimumab) for advanced melanoma, have an ECOG performance status (PS) ≤ 1 and are not currently receiving imunosuppressive therapy. If brain metastases are present, patients should be asymptomatic or stable.  Re-induction: At the time of disease progression, the patient has had stable disease for at least three months or has previously experienced a complete or partial response to ipilimumab. The
NL	Under provincial consideration*		patient has an ECOG ≤ 1.



PROVINCE	STATUS	DECISION DATE	FUNDING CRITERIA
PEI	Funded		First line treatment of adult patients with stage IIIC or IV melanoma, regardless of BRAF mutation status, who have an ECOG performance status of 0 or 1, and are not currently receiving immunosuppressive therapy.  - If brain metastases are present, patients should be asymptomatic or stable  - Ipilimumab induction is funded for four (4) doses at 3 mg/kg administered every 3 weeks  - Induction therapy is discontinued if 4 doses cannot be administered within 16 weeks  Note: re-induction with a further 4 doses may be considered in patients who remain ECOG 0 or 1 and who experienced clinical benefit (e.g., partial/complete response or stable disease) for a minimum of 3 months following first induction or who achieved a partial or complete response to first induction.

\*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.