PROVINCIAL FUNDING SUMMARY

Vemurafenib (Zelboraf) for Advanced Melanoma (pCODR 10006)

pERC Recommendation: Recommend with condition on the cost-effectiveness being improved to an acceptable level

For further details, please see pERC Final Recommendation

Notification to Implement Issued by pCODR: June 18, 2012

This information is current as of November 9, 2018.

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	STATUS	DECISION DATE	FUNDING CRITERIA
BC	Funded	Oct 1, 2012	Unresectable stage III or stage IV melanoma; BRAF V600 mutation-positive; ECOG 0-2; life expectancy of at least 3 months; 18 years and older (for patients younger than 18 years old, CAP will review the eligibility on a case-by-case basis); adequate hematological, hepatic and renal function; if brain metastases are present, they must have been previously treated and be stable. A BCCA "Compassionate Access Program" request with appropriate clinical information for each patient must be approved prior to treatment
AB	Funded	Oct 19, 2012	Criteria updated Oct. 30, 2018: For the treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma alone or in combination with cobimetinib. Not to be used if progression on treatment with an alternate BRAF inhibitor and/or MEK inhibitor.
SK	Funded	Sep 4, 2012	Melanoma - Advanced: - Completion of the SCA Treatment Evaluation Program (STEP) request form for each patient is required for treatment approval, - First line treatment of patients with BRAF V600 mutation-positive advanced melanoma (unresectable stage IIIC or metastatic) with a good performance status (ECOG 0 or 1), - Interim eligibility as a second or subsequent line of therapy for patients with BRAF V600 mutation-positive advanced melanoma (unresectable stage IIIC or metastatic) with a good performance status (ECOG 0 or 1) who did not receive Vemurafenib in the first line setting.

PROVINCE	STATUS	DECISION DATE	FUNDING CRITERIA
MB	Funded	Sep 24, 2012	For the treatment of patients: With unresectable or metastatic (Stage IIIC or IV) melanoma AND With an Eastern Cooperative Oncology Group (ECOG) performance status of 1 or less AND With anticipated life expectancy of more than 3 months AND Who have received at least one line of systemic therapy for advanced melanoma OR With intolerance to a previous line of systemic therapy for advanced melanoma.

PROVINCE	STATUS	DECISION DATE	FUNDING CRITERIA
ON	Funded	Aug 31, 2012	1st Line Setting Initial requests: As monotherapy for the first (1st) line treatment of patients with BRAF V600 mutation-positive unresectable stage IIIC or IV melanoma or metastatic disease. Recommended Dose: 960 mg twice daily until disease progression or development of unacceptable toxicity requiring discontinuation of vemurafenib. Patients should have their disease status assessed at least every 3 months. Approval duration: 6 months Renewal requests: Vemurafenib 960 mg orally twice daily may be continued until evidence of disease progression* or development of unacceptable toxicity requiring discontinuation of vemurafenib. *Documentation from physician outlining the radiological and clinical benefit requiring continuation of the drug and verifiying that there has been no disease progression or development of unacceptable toxicity. Approval duration: 6 months 2nd Line Setting Initial requests: As monotherapy, for the second (2nd) line treatment of patients with BRAF V600 mutation-positive unresectable stage IIIC or IV melanoma or for patients with metastatic disease who have progressed after receiving treatment in the first line setting. Recommended Dose: 960 mg twice daily until disease progression or development of unacceptable toxicity requiring discontinuation of vemurafenib Patients should have their disease status assessed at least every 3 months. Approval duration: 6 months Renewal requests: Vemurafenib 960 mg orally twice daily may be continued until evidence of disease progression* or development of unacceptable toxicity requiring discontinuation of vemurafenib. *Documentation from physician outlining the radiological and clinical benefit requiring continuation of the drug and verifiying that there has been no disease progression or development of unacceptable toxicity Approval duration: 6 months Exclusion Criteria: BRAF V600 negative, or wild type tumors, or unknown mutation status will not be funded
NS	Funded	Mar 4, 2013	As a first line, single agent for the treatment of BRAF V600 mutation positive unresectable or metastatic melanoma in patients with an ECOG performance status (PS) of ≤ 1. For BRAF V600 mutation positive patients who have progressed after first line treatment prior to vemurafenib availability, funding of vemurafenib as a second line agent may be considered.

PROVINCE	STATUS	DECISION DATE	FUNDING CRITERIA
NB	Funded	Sep 11, 2013	1) For the first line treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma who have an ECOG status performance of ≤1. 2) For the second line treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma who have an ECOG performance status of ≤1 and did not receive vemurafenib as first line treatment.
NL	Funded	Dec 20, 2013	As a first-line therapy for patients presenting with BRAF V600 mutation-positive unresectable stage IIIC or IV melanoma or for patients who develop metastatic disease. Patients should have good performance status (ECOG ≤ 1), and, if brain metastases are present, the metastases must have been previously treated and be stable. As a second-line therapy for patients with BRAF V600 mutation-positive unresectable stage IIIC or IV melanoma and good performance status (ECOG ≤ 1), who have progressed on first-line therapy before vemurafenib was available. Approval Period: 6 months Recommended Dose: 960 mg twice daily until disease progression or development of unacceptable toxicity requiring discontinuation of vemurafenib. Renewals will be considered for patients who do not have evidence of disease progression AND who have not developed unacceptable toxicities that require discontinuation of vemurafenib.
PEI	Funded	Apr 27, 2015	As a first line, single agent for the treatment of BRAF V600 mutation positive unresectable or metastatic melanoma in patients with an ECOG performance status (PS) of 0 or 1. For BRAF V600 mutation positive patients who have progressed after first line treatment prior to vemurafenib availability, funding or vemurafenib as a second line agent may be considered. The request for coverage must be made and the medication prescribed by a specialist in haematology or medical oncology, or a general practitioner acting under the direction of those specialists.