CADTH | pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

PROVINCIAL FUNDING SUMMARY

Cobimetinib (Cotellic) for Metastatic Melanoma (pCODR 10070)

pERC Recommendation: Recommends with conditions

For further details, please see pERC Final Recommendation

Notification to Implement Issued by pCODR: July 18, 2016

This information is current as of July 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	Sept 1, 2017	In combination with vemurafenib for Previously untreated BRAF V600 mutation-positive unresectable or metastatic melanoma stage III or IV: • Good performance status • 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 Note: only one BRAF/MEK targeted treatment will be funded (daBRAFenib, trametinib, or combination)
AB	Funded	Nov 28, 2017	Criteria updated Oct. 30, 2018: For the treatment of patients with unresectable or metastatic melanoma with BRAF V600 mutation in combination with vemurafenib Not to be used if progression on treatment with alternative BRAF inhibitor and/or MEK inhibitor.
SK	Funded	Sept 1, 2017	In combination with Vemurafenib, for the treatment of patients with previously untreated BRAF V600 mutation-positive unresectable stage Ill or stage IV melanoma who have a good performance status.

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
MB	Funded	Oct 19, 2017	In combination with Zelboraf (vermurafenib), for the treatment of patients with previously untreated BRAF V600 mutation-positive unresectable stage III or stage IV melanoma who have a good performance status. Treatment should continue until unacceptable toxicity or disease progression. If brain metastases are present, patients should be asymptomatic or have stable symptoms.
ON	Funded	Nov 17, 2017	Initial requests: For the treatment of patients with previously untreated BRAF V600 mutation-positive unresectable stage Ill or stage IV melanoma who have a good performance status (ECOG ≤ 2). As first-line combination therapy with vemurafenib; AND If brain metastases are present, they should be asymptomatic or stable Recommended Dose as combination dual therapy with Vemurafenib: Cobimetinib 60mg once daily for 21 days, followed by seven days off treatment; AND Vemurafenib 960mg twice daily for 28 days. Both drugs are given until disease progression or unacceptable toxicity. Renewal requests: Combination dual therapy may be continued until evidence of disease progression or development of unacceptable toxicity requiring discontinuation. Letter from physician outlining radiological and clinical benefit requiring continuation of the drug and verification of no disease progression or development of unacceptable toxicity must be submitted. Requests in patients who have initiated another BRAF and/or MEK inhibitor as monotherapy or combination therapy will be considered on a case-by-case basis ONLY IF there has been no disease progression.
NS	Funded	Jun 1, 2020	In combination with vemurafenib for patients with previously untreated BRAFV600 mutation-positive unresectable stage III or stage IV melanoma. Patients should have a good performance status. If brain metastases are present, patients should be asymptomatic or have stable symptoms. Treatment should continue until unacceptable toxicity or disease progression. Use of the combination of cobimetinib and vemurafenib precludes the use of any other BRAF targeted therapy as a subsequent line of therapy following disease progression. Exceptions will be considered in cases of intolerance without progression. For BRAF-positive patients, BRAF-targeted therapy and immunotherapy (including nivolumab plus ipilimumab combination therapy) may be sequenced in either order upon treatment failure, based on clinician assessment.

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
NB	Funded	Sept 22, 2017	For the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma, when used as first line therapy, in combination with vemurafenib. Renewal criteria: Written confirmation that the patient has responded to treatment and there is no evidence of disease progression. Clinical Notes: 1. Patients must have a good performance status. 2. If brain metastases are present, patients should be asymptomatic or have stable symptoms. 3. Treatment should be discontinued upon disease progression or unacceptable toxicity. Claim Notes: Cobimetinib will not be reimbursed in patients who have progressed on BRAF targeted therapy. Initial approval duration: 6 months Renewal approval duration: 6 months.
NL	Funded	Jun 1, 2017	In combination with vemurafenib, for the treatment of patients with previously untreated BRAF V600 mutation-positive unresectable stage III or stage IV melanoma who have a good performance status. Treatment should continue until unacceptable toxicity or disease progression. If brain metastases are present, patients should be asymptomatic or have stable symptoms.
PEI	Funded	Aug 1, 2018	In combination with vemurafenib, for the treatment of patients with previously untreated BRAF V600 mutation-positive unresectable stage III or stage IV melanoma who have a good performance status. Treatment should continue until unacceptable toxicity or disease progression. If brain metastases are present, patients should be asymptomatic or have stable symptoms. Approvals are for a maximum daily dose of 60mg during 21 consecutive days per 28 day cycle. 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.

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.