PROVINCIAL FUNDING SUMMARY

Dabrafenib (Tafinlar) for Metastatic Melanoma (pCODR 10025)

pERC Recommendation: Recommends 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: December 20, 2013

This information is current as of June 3, 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	STATUS	DECISION DATE	FUNDING CRITERIA
BC	Funded	Dec 1, 2014	For BRAF V600 mutation-positive unresectable or metastatic melanoma patients with ECOG 0 or 1; If brain metastases are present, patients should be asymptomatic or stable. BCCA "Compassionate Access Program" request with appropriate clinical information for each patient must be approved prior to treatment. Note: only one anti-BRAF therapy will be funded
AB	Funded	Mar 30, 2015	Criteria updated Oct. 30, 2018: Dabrafenib and/or trametinib for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600 mutation. Not to be used after progression on an alternate BRAF inhibitor and/or MEK inhibitor.
SK	Funded	Sep 15, 2014	Monotherapy treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma (either previously untreated or treated with chemotherapy) with an ECOG performance status of 0 or 1; if brain metastases are present, patients should be asymptomatic or stable. Dabrafenib is not approved in patients who have progressed on prior BRAF inhibitor therapy.
MB	Funded	Oct 16, 2014	For monotherapy treatment of patients with BRAF V600 mutuation-positive unresectable or metastic melanoma (either previously untreated or treated with chemotherapy) with ECOG performance of 0 or 1. If brain metastases are present, patients should be asymptomatic or stable. Treatment should continue until disease progression or the development of unacceptable toxicity. Exclusions: Tafinlar is not approved in patients who have progressed on a prior BRAF inhibitor therapy.

PROVINCE	STATUS	DECISION DATE	FUNDING CRITERIA
ON	Funded	Aug 19, 2014	1st Line Setting Initial requests: •As monotherapy for the first (1st) line treatment of patients with BRAF V600 mutation-positive unresectable melanoma or metastatic disease. •If brain metastases are present, they should be asymptomatic or stable. Recommended Dose: 150 mg twice daily until disease progression or development of unacceptable toxicity requiring discontinuation of dabrafenib Approval duration: 6 months (Patients should have their disease status assessed at least every 3 months). Requests for Tafinlar for patients who have initatied another BRAF therapy (i.e. Zelboraf, Mekinist) and who have not had disease progression will be considered on a case by case basis 2nd Line Setting Initial requests: •As monotherapy, for the second (2nd) line treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma for patients who have progressed after receiving chemotherapy treatment in the first line setting. •If brain metastases are present, they should be asymptomatic or stable Recommended Dose: 150 mg twice daily until disease progression or development of unacceptable toxicity requiring discontinuation of dabrafenib Approval duration: 6 months (Patients should have their disease status assessed at least every 3 months) Exclusion Criteria: •BRAF V600 negative, or wild type tumors, or unknown status will not be funded •Dabrafenib will not be considered for funding in patients who have progressed on a prior BRAF inhibitor therapy •Combination therapy with Mekinist will not be considered for funding
NS	Under provincial consideration*		

PROVINCE	STATUS	DECISION DATE	FUNDING CRITERIA
NB	Funded	Oct 3, 2014	• As monotherapy for the first line treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma with ECOG performance status of 0 or 1. If brain metastases are present, patients should be asymptomatic or stable. • As monotherapy for the second line treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma for patients who have progressed after receiving chemotherapy treatment in the first line setting with ECOG performance status of 0 or 1. If brain metastases are present, patients should be asymptomatic or stable. Clinical Notes: • Recommended Dose: 150 mg twice daily until disease progression or development of unacceptable toxicity requiring discontinuation of dabrafenib. • Dabrafenib will not be reimbursed in patients who have progressed on a prior BRAF therapy. Claim Notes: • Initial approval duration: 6 months • Renewal approval duration: 6 months
NL	Funded	Aug 1, 2014	Monotherapy treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma (either previously untreated or treated with chemotherapy) with ECOG performance status of 0 or 1. If brain metastases are present, patients should be asymptomatic or stable. Treatment should continue until disease progression or the development of unacceptable toxicity. Note: TAFINLAR is not approved in patients who have progressed on a prior BRAF inhibitor therapy.
PEI	Funded	Oct 29, 2018	Melanoma – Advanced (Unresctable or Metastatic) -For the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma. Clinical Notes: 1. Patients must have an ECOG performance status of 0 or 1. 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. Patients must apply for coverage under the High-Cost Drug Program. If written by an oncologist, this medication does not require the submission of a Pharmacare Special Authorization form.

**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 Pricing 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.