

## PROVINCIAL FUNDING SUMMARY

### Trametinib (Mekinist) for Metastatic Melanoma (pCODR 10030)

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: Nov 6, 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, 2016	BRAF V600 mutation-positive unresectable or metastatic melanoma. Previously untreated or as second line treatment for patients previously treated with first line pembrolizumab or ipilimumab or nivolumab. Only one BRAF/MEK targeted treatment will be funded (daBRAFeinib, trametinib, or combination). ECOG 0 to 1. Adequate hematological, hepatic and renal function. If brain metastases are present, patients should be asymptomatic or stable. A BCCA "Compassionate Access Program" request with appropriate clinical information for each patient must be approved prior to treatment.
AB	Funded	Oct 18, 2016	Criteria updated Oct. 30, 2018: Trametinib and/or Dabrafenib 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.  Trametinib is not approved in patients who have progressed on prior BRAF inhibitor therapy.

PROVINCE	STATUS	DECISION DATE	FUNDING CRITERIA
MB	Funded	Oct 16, 2014	<p>For monotherapy treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma (either previously untreated or treated with chemotherapy) with ECOG performance of 0 or 1. If brain metastases are present, they should be stable. Treatment should continue until disease progression or the development of unacceptable toxicity.</p> <p>Exclusions: Mekinist is not approved in patients who have progressed on a prior BRAF inhibitor therapy.</p>
ON	Funded	Aug 19, 2014	<p>1st Line Setting Initial requests:</p> <ul style="list-style-type: none"> <li>• As monotherapy for the first (1st) line treatment of patients with BRAF V600 mutation-positive unresectable melanoma or metastatic disease.</li> <li>• If brain metastases are present, they should be stable.</li> </ul> <p>Recommended Dose: 2 mg once daily until disease progression or development of unacceptable toxicity requiring discontinuation of trametinib Approval duration: 6 months (Patients should have their disease status assessed at least every 3 months) Requests for Mekinist for patients who have initiated another BRAF therapy (i.e. Zelboraf, Tafinlar) and who have not had disease progression will be considered on a case by case basis</p> <p>2nd Line Setting Initial requests:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• If brain metastases are present, they should be stable</li> </ul> <p>Recommended Dose: 2 mg once daily until disease progression or development of unacceptable toxicity requiring discontinuation of trametinib Approval duration: 6 months (Patients should have their disease status assessed at least every 3 months)</p> <p>Exclusion Criteria:</p> <ul style="list-style-type: none"> <li>• BRAF V600 negative, or wild type tumors, or unknown status will not be funded</li> <li>• Trametinib will not be considered for funding in patients who have progressed on a prior BRAF inhibitor therapy</li> <li>• Combination therapy with Tafinlar will not be considered for funding</li> </ul>

PROVINCE	STATUS	DECISION DATE	FUNDING CRITERIA
NS	Under provincial consideration*		
NB	Funded	Oct 3, 2014	<ul style="list-style-type: none"> <li>• 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 stable.</li> <li>• 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 stable.</li> </ul> <p>Clinical Notes:</p> <ul style="list-style-type: none"> <li>• Recommended Dose: 2 mg once daily until disease progression or development of unacceptable toxicity requiring discontinuation of trametinib.</li> <li>• Trametinib will not be reimbursed in patients who have progressed on a prior BRAF therapy.</li> </ul> <p>Claim Notes:</p> <ul style="list-style-type: none"> <li>• Initial approval duration: 6 months</li> <li>• Renewal approval duration: 6 months</li> </ul>
NL	Funded	Aug 1, 2014	<p>As monotherapy treatment for patients with BRAF V600 mutation-positive unresectable or metastatic melanoma (either previously untreated or treated with chemotherapy) with ECOG performance of 0 or 1. If brain metastases are present, patients should be stable. Treatment should continue until disease progression or the development of unacceptable toxicity.</p> <p>Note: MEKINIST is not approved in patients who have progressed on a prior BRAF inhibitor therapy</p>
PEI	Funded	Oct 29, 2018	<p>Melanoma - Advanced (Unresectable 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.</p>

*\*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.