

## PROVINCIAL FUNDING SUMMARY

### Dabrafenib & Trametinib (Tafinlar & Mekinist) in combo Melanoma Adjuvant Therapy (pCODR 10152)

pERC Recommendation: Recommends with conditions  
For further details, please see [pERC Final Recommendation](#)

Notification to Implement Issued by pCODR: May 21, 2019

This information is current as of June 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	Nov 1, 2019	<p>Cutaneous melanoma stage IIIA to IV NED (AJCC 8th edition). Disease metastasized to the regional nodes (if stage IIIA and only one node involved then metastatic deposit &gt; 1 mm), intransit metastases or distant metastases must be completely surgically resected.</p> <ul style="list-style-type: none"> <li>▪ Brain metastases must be completely resected (or definitively treated with stereostatic radiation)</li> <li>▪ BRAF mutation (all BRAF V600 mutations)</li> <li>▪ Adequate baseline hematological, renal and liver functions</li> <li>▪ BC Cancer Compassionate Access Program (CAP) must be obtained.</li> <li>▪ * Patients can receive one year of either adjuvant nivolumab OR combination dabrafenib/trametinib. Patients with BRAF mutated melanoma who are unable to tolerate up to a 3-month trial of combination dabrafenib/trametinib due to toxicities can apply for adjuvant nivolumab and complete a total of one year of therapy. A switch to combination cobimetinib/vemurafenib is not funded.</li> </ul>
AB	Funded	Apr 10, 2020	<p>For the adjuvant treatment of patients with stage IIIA (limited to lymph node metastases of greater than or equal to 1 mm) to stage IIID (8th edition of American Joint Committee on Cancer (AJCC) staging system) BRAF mutated (all BRAF V600 mutations) cutaneous melanoma. Disease must be completely resected including in-transit metastases, however presence of regional lymph nodes with micro metastases after sentinel lymph node biopsy is allowed. Patients must have good performance status. Treatment should continue until disease recurrence, unacceptable toxicity,</p>

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
			or up to a maximum of 12 months. Retreatment with BRAF targeted therapy is allowed if the treatment free interval is greater than or equal to 6 months from the completion of adjuvant BRAF therapy”, for addition to the Alberta Outpatient Cancer Drug Benefit Program.
SK	Funded	Jan 1, 2020	<ul style="list-style-type: none"> <li>•Adjuvant treatment of patients with stage IIIA (limited to lymph node metastases of &gt; 1 mm) to stage IIID BRAF-mutated (all BRAF V600 mutations) cutaneous melanoma (based on 8th edition of the American Joint Committee on Cancer [AJCC] staging system)</li> <li>•Disease must be completely resected including in-transit metastases; however, presence of regional lymph nodes with micrometastases after sentinel lymph node biopsy alone is allowed</li> <li>•Patients must have a good performance status</li> <li>Additional clarifications for use and funding of the combination of Dabrafenib and Trametinib for adjuvant treatment of melanoma are noted below:               <ul style="list-style-type: none"> <li>•Patients with mucosal or ocular melanoma are not eligible for the combination of Dabrafenib and Trametinib</li> <li>•Treatment should start within 12 weeks from surgery</li> <li>•Treatment should continue until disease recurrence, unacceptable toxicity, or a maximum duration of 12 months from treatment initiation</li> <li>•For patients who have dose interruptions and subsequently resume therapy, Dabrafenib and Trametinib may continue up to a maximum of 12 months from the time of treatment initiation</li> <li>•Treatment should be discontinued prior to 12 months if there is confirmation of local disease progression or development of metastatic disease</li> <li>•Patients should be assessed for disease recurrence at least every 3 months, or more frequently as clinically indicated</li> <li>•Patients currently receiving adjuvant Interferon who are BRAF mutation positive may be switched to the combination of Dabrafenib and Trametinib for up to 12 months of BRAF targeted therapy provided they meet all other funding criteria</li> <li>•A one-time switch to adjuvant Nivolumab is allowed within the first 3 months of combination Dabrafenib and Trametinib treatment; the total duration of adjuvant therapy that is funded is 12 months of BRAF targeted therapy and immunotherapy combined</li> <li>•Switching to the combination of Vemurafenib and Cobimetinib is not funded for patients who experience intolerance or disease progression on</li> </ul> </li> </ul>

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
			<p>the combination of Dabrafenib and Trametinib</p> <ul style="list-style-type: none"> <li>•Retreatment with BRAF targeted therapy for recurrent or metastatic disease is allowed if the progression-free interval from the completion of adjuvant Dabrafenib and Trametinib is &gt;6 months</li> <li>•All immunotherapy treatment options are available for patients relapsing on or any time after completion of combination Dabrafenib and Trametinib</li> </ul>
MB	Funded	Mar 2, 2020	<p>Inclusion Criteria:</p> <ul style="list-style-type: none"> <li>• For the treatment of patients with stage IIIA (limited to lymph node metastases of greater than 1 mm) to stage IIID (8th edition of the American Joint Committee on Cancer [AJCC] staging system) BRAF-mutated (all BRAF V600 mutations) cutaneous melanoma.</li> <li>• Disease must be completely resected including in-transit metastases. However, presence of regional lymph nodes with micrometastases after sentinel lymph node biopsy alone is allowed.</li> <li>• Patients must have a good performance status.</li> </ul> <p>Exclusion Criterion:</p> <ul style="list-style-type: none"> <li>• Ocular Melanoma</li> </ul>
ON	Under provincial consideration		
NS	Funded	Apr 23, 2020	<p>For the adjuvant treatment of patients with stage IIIA (limited to lymph node metastases of &gt; 1 mm) to stage IIID (8th edition of American Joint Committee on Cancer [AJCC] staging system) BRAF- mutated cutaneous melanoma. Disease must be completely resected including in-transit metastases; however, presence of regional lymph nodes with micrometastases after sentinel lymph node biopsy alone is allowed. Patients must have a good performance status. Treatment with dabrafenib plus trametinib should continue until disease recurrence, unacceptable toxicity, or up to a maximum of 12 months.</p>

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
NB	Funded	Apr 23, 2020	For the adjuvant treatment of patients with cutaneous melanoma who meet all of the following criteria: • Stage IIIA (limited to lymph node metastases of greater than 1 mm) to stage IIID disease (AJCC 8th edition) • BRAF V600-mutation positive • Completely resected disease including in-transit metastases Clinical Notes: 1. Patients must have a good performance status. 2. Treatment should continue until disease recurrence, unacceptable toxicity, or up to a maximum of 12 months. Claim Notes: • Requests will be considered for patients with regional lymph nodes with micrometastases after sentinel lymph node biopsy. • Requests will not be considered for patients who received adjuvant immunotherapy for greater than three months. Patients may switch to BRAF targeted therapy within the first three months of initiating immunotherapy to complete a total of 12 months of adjuvant treatment. • Approval period: Up to 12 months.
NL	Under provincial consideration		
PEI	Under provincial consideration		

*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.