CADTH | pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

PROVINCIAL FUNDING SUMMARY

Bosutinib (Bosulif) for Chronic Myeloid Leukemia

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: May 6, 2015

This information is current as of December 6, 2016.

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	FUNDING DATE	FUNDING CRITERIA
BC	Funded	Dec 1, 2016	• Chronic or accelerated Philadelphia chromosome positive chronic myelogenous leukemia (Ph+ CML) resistant to at least two prior lines of TKI. • Chronic or accelerated Philadelphia chromosome positive chronic myelogenous leukemia (Ph+ CML) intolerant to imatinib, nilotinib and dasatinib. • Good performance status. • A Compassionate Access Program (CAP) approval is required prior to the initiation of treatment (please refer to https://cap.phsa.ca/). • May be used in combination with hydroxyurea, and/or prednisone.
AB	Funded	Feb 3, 2016	Bosutinib for the treatment of patients with chronic, accelerated, or blast phase Philadelphia chromosome positive (Ph+ve) chronic myelogenous leukemia (CML) who have resistance or intolerance to prior TKI therapy, and for whom subsequent treatment with imatinib, nilotinib, and dasatinib is not clinically appropriate
SK	Funded	Dec 28, 2015	Treatment patients with chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) who have resistance/disease progression or intolerance to prior tyrosine kinase inhibitor (TKI) therapy.

PROVINCE	STATUS	FUNDING DATE	FUNDING CRITERIA
MB	Funded	Apr 18, 2016	For the treatment of patients with Chronic Myelogenous Leukemia (Chronic Phase, Accelerated Phase, Blast Phase) with: • An Eastern Cooperative Oncology Group Performance Status of 2 or less AND • Disease resistant to at least one prior tyrosine kinase inhibitor therapies with imatinib, dasatinib, or nilotinib OR • Intolerance to prior tyrosine kinase inhibitor therapy and in whom subsequent therapy with imatinib, dasatinib, or nilotinib is not clinically appropriate.

ON	Funded	Feb 26, 2016	Chronic Phase chronic myelogenous leukemia: i) For the treatment of patients with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in chronic phase with documented resistance/disease progression to 2 (two) prior oral tyrosine kinase inhibitors (TKI) (imatinib, dasatinib or nilotinib), where bosutinib would be the third line TKI; OR ii) For the treatment of patients with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in chronic phase with documented intolerance to 1 (one) prior oral TKI (imatinib, dasatinib or nilotinib) where subsequent treatment with an alternative oral TKI (imatinib, dasatinib or nilotinib) is not clinically appropriate. Dosing recommendation: 500 mg per day Renewals will be considered upon confirmation from the clinician that the patient has experienced hematologic and/or cytogenic response and is expected to continue to do so. Dosing recommendation: 500 mg per day Accelerated Phase chronic myelogenous leukemia: i) For the treatment of patients with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in accelerated phase with documented resistance/disease progression to 2 (Two) prior oral TKIs (imatinib, dasatinib or nilotinib), where bosutinib would be the third line TKI; OR ii) For the treatment of patients with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in accelerated phase with documented intolerance to 1(One) prior oral TKI (imatinib, dasatinib or nilotinib) where subsequent treatment with an alternative oral TKI (imatinib, dasatinib or nilotinib) is not clinically appropriate. Dosing recommendation: 500 mg per day Renewals will be considered upon confirmation from the clinician that the patient has experienced hematologic and/or cytogenic response and is expected to continue to do so. Dosing recommendation: 500 mg per day Blast Phase chronic myelogenous leukemia: i) For the treatment of patients with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in blast phase with documented resistance/disease progression to 2(two) prior oral TKIs (imatinib or dasatinib), where bosutinib would be the third line TKI; OR ii) For the treatment of patients with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in blast phase with documented intolerance to 1 (One) prior oral TKI (imatinib or dasatinib) where subsequent treatment with an alternative oral TKI (imatinib or dasatinib) is not clinically appropriate. Dosing recommendation: 500 mg per day Renewals will be considered upon confirmation from the clinician that the patient has experienced hematologic and/or cytogenic response and is expected to continue to do so. Dosing recommendation: 500 mg per day

PROVINCE	STATUS	FUNDING DATE	FUNDING CRITERIA
NS	Funded	May 2, 2016	As a treatment option for patients with chronic, accelerated or blast phase Philadelpha chromosome positive (Ph+) chronic myelogenous leukemia (CML) who have resistance/disease progression or intolerance to prior tyrosine kinase inhibitor (TKI) therapy and for whom subsequent treatment with imatinib, nilotinib and dasatinib is not clinically appropriate.
NB	Funded	Apr 12, 2016	For the treatment of patients with chronic, accelerated or blast phase Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) who: · have resistance/disease progression after prior use of two tyrosine kinase inhibitors (TKIs) where bosutinib would be the third line therapy, or · have resistance or intolerance to prior TKI therapy and for whom subsequent treatment with imatinib, nilotinib and dasatinib is not clinically appropriate. Clinical Notes: 1. Patients must have an ECOG performance status of 0-2. 2. Patients may be considered inappropriate for dasatinib or nilotinib if they have a genetic mutation that predicts reduced efficacy or if patients have co-morbidities that may predispose them to a drug-related adverse event.
NL	Funded	Feb 1, 2016	For the treatment of patients with chronic, accelerated or blast phase Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) who have resistance/disease progression or intolerance to prior tyrosine kinase inhibitor (TKI) therapy, and for whom subsequent treatment with imatinib, nilotinib and dasatinib is not clinically appropriate. Renewals will be considered for patients who are responding to treatment AND who have not developed unacceptable toxicities that require discontinuation of bosutinib.
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.