Bosutinib (Bosulif) for Chronic Myeloid Leukemia (pCODR RFA 0002)

pERC Recommendation: Recommends with conditions For further details, please see <u>pERC RFA Final Recommendation</u>

Notification to Implement Issued by pCODR: August 2, 2019

This information is current as of October 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	STATUS	FUNDING DATE	FUNDING CRITERIA
ВС	Under provincial consideration		
АВ	Funded	Jul 30, 2020	For the treatment of patients with chronic, accelerated, of blast phase Philadelphia chromosome positive (Ph+ve) chronic myelogenous leukemia (CML) who have resistance or intolerance to prior TKI therapy.
SK	Under provincial consideration		
МВ	Funded	Jul 16, 2020	For the treatment of patients with chronic, accelerated, or blast phase Philadelphia chromosome- positive (Ph+) chronic myelogenous leukemia (CML) in adult patients with resistance or intolerance to prior TKI therapy.
ON	Funded	Sep 3, 2020	Initial EAP Criteria: For the treatment of patients with Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) in patients meeting the following criteria; 1. 18 years of age or older; AND 2. Diagnosis of (Ph+) chronic phase, accelerated phase, or blast phase CML; AND 3. Bosutinib is used in one of the following clinical situations: i) As second line therapy after experiencing disease progression on imatinib, dasatinib, or nilotinib1 in first line: OR ii) as third line therapy after experiencing disease progression to imatinib, dasatinib, nilotinib1, or ponatinib in second line; OR iii) In patients who have not progressed on one or more prior TKIs but who have documented mutational drug resistance to imatinib, dasatinib, and/or nilotinib1 which make them clinically inappropriate treatment choices; OR iv) In patients who have not progressed on one or more TKIs but have experienced unacceptable intolerance or toxicity to one prior TKI (i.e. imatinib, dasatinib, or nilotinib1) Exclusion Criteria: 1. Bosutinib will not be funded in combination with

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PROVINCE	STATUS	FUNDING DATE	FUNDING CRITERIA
			another oral TKI (e.g. imatinib, nilotinib, dasatinib, or ponatinib) 2. Bosutinib will not be funded as 4th line treatment for CML or beyond. 1Note that nilotinib is not funded in blast phase CML, therefore, considerations will only be applied for imatinib and dasatinib in patients with blast phase CML Renewal criteria: Renewal of funding will be considered upon confirmation from the patient's clinician that the patient has experienced hematologic and/or cytogenic response and is expected to continue to do so Recommended Dosing: 500mg per day Approval period for initials & renewals: 1 year
NS	Under provincial consideration		
NB	Funded	Aug 20, 2020	For the treatment of adult patients with chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) who have resistance or intolerance to prior tyrosine kinase inhibitor therapy. Clinical Note: • Patients must have a good performance status. Claim Notes: • Initial approval period: 1 year. • Renewal approval period: 1 year.
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.