CADTH | pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

PROVINCIAL FUNDING SUMMARY

Ponatinib (Iclusig) for Chronic Myeloid Leukemia/ Acute Lymphoblastic Leukemia (pCODR 10056)

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: October 19, 2015

This information is current as of September 3, 2018.

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	Dec 1, 2016	• Chronic, accelerated or blast phase chronic myelogenous leukemia (CML), or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) resistant to at least two prior lines of TKI • Chronic or accelerated CML intolerant to imatinib, nilotinib, dasatinib and bosutinib. • Blast phase CML or Philadelphia positive ALL intolerant of imatinib and dasatinib • CML or Ph+ALL that is T315I mutation positive, independent of previous TKI therapy • 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	Oct 18, 2016	Ponatinib for the treatment of patients with chronic phase, accelerated phase, or blasé phase Chronic Myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (PH+ve ALL) for whom other tyrosine kinase inhibitors (TKI) therapy is not appropriate, including ML or PH+ve ALL that is T3151 mutation positive or where there is resistance or intolerance to prior TKI therapy. Funding should be for patients with ECOG performance status 0-2. Treatment should continue until unacceptable toxicity or disease progression.

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
SK	Funded	Aug 8, 2016	Treatment of patients with chronic phase CML who have resistance or disease progression after at least two prior lines of TKI therapy - Treatment of patients with accelerated phase or blast phase CML or Ph+ ALL who have resistance or disease progression after at least one second generation TKI therapy - Treatment of any patient with confirmed T315i mutation positive disease, independent of prior TKI therapy - Treatment of last resort for patients with intolerances or contraindications to Imatinib and all the second generation TKI's (Dasatinib, Nilotinib, Bosutinib).
MB	Funded	Jan 25, 2017	For the treatment of patients with chronic phase, accelerated phase or blast phase CML, or Philadelphia chromosome positive ALL who have resistance/disease progression after at least 2 prior lines of tyrosine kinase inhibitor(TKI) therapy where ponatinib would available as third line TKI option, or who have intolerance to prior TKI therapy OR For treatment of patients who have confirmed T315I mutation positive disease, independent of previous TKI therapy. The patient's ECOG performance status should be 0 to 2. Treatment should continue until unacceptable toxicity or disease progression.

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
ON	Funded	Aug 3, 2016	Chronic Phase CML: a) For the treatment of patients with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in chronic phase and documented T315i mutation; OR b) For the treatment of patients with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in chronic phase with documented resistance/disease progression or intolerance to at least 2 prior oral TKIs (imatinib, dasatinib or nilotinib), where ponatinib would be the third or fourth line TKI. Accelerated Phase CML: a) For the treatment of patients with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in accelerated phase and documented T315i mutation; OR c) For the treatment of patients with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in accelerated phase with documented resistance/disease progression or intolerance to at least 2 prior oral TKIs (imatinib, dasatinib or nilotinib), where ponatinib would be the third or fourth line TKI. Blast Phase CML: a) For the treatment of patients with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in blast phase and documented T315i mutation; OR b) For the treatment of patients with Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) in blast phase with documented resistance/disease progression or intolerance to at least 2 prior oral TKIs (imatinib and dasatinib), where ponatinib would be the third or fourth line TKI. For Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL): a) For the treatment of patients with Philadelphia chromosome positive acute lymphoblastic leukemia (Ph +ALL) and documented T315i mutation; OR b) For the treatment of patients with Philadelphia chromosome positive acute lymphoblastic leukemia (Ph +ALL) with documented resistance/disease progression or intolerance to imatinib and dasatinib, where ponatinib would be the third line TKI.
NS	Funded	Dec 1, 2016	For the treatment of patients with chronic phase, accelerated phase or blast phase chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) for whom other tyrosine kinase inhibitor (TKI) therapy is not appropriate, including CML or Ph+ ALL that is T315i mutation positive or where there is resistance or intolerance to prior TKI therapy. Funding should be for ECOG performance status 0-2. Treatment should continue until unacceptable toxicity or disease progression.

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
NB	Funded	Sept 29, 2016	For the treatment of patients with chronic, accelerated or blast phase chronic myelogenous leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ALL) who have: • resistance or intolerance to two or more tyrosine kinase inhibitors (TKIs), or • confirmed T315i mutation positive disease. Renewal criteria: • Written confirmation that the patient has responded to treatment and there is no evidence of disease progression. Clinical Notes: 1. Patients must have an ECOG performance status of 0-2. 2. Treatment should be discontinued upon disease progression or unacceptable toxicity. Claim Notes: • Initial approval duration: 1 year. • Renewal approval duration: 1 year.
NL	Funded	Jul 1, 2018	For the treatment of patients with chronic phase, accelerated phase or blast phase chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) and with ECOG performance status 0-2 for whom other tyrosine kinase inhibitor (TKI) therapy is not appropriate, including CML or Ph+ ALL that is T315i mutation positive or where there is resistance or intolerance to prior TKI therapy. Treatment should continue until unacceptable toxicity or disease progression. Other TKI therapy is not considered appropriate in the following circumstances: • for treatment of patients who have confirmed T315i mutation positive disease, independent of previous TKI therapy • for the treatment of patients with chronic phase, accelerated phase or blast phase CML, or Ph+ ALL who have resistance/disease progression after at least two prior lines of TKI therapy where Iclusig would be available as third line TKI option, or who have intolerance to prior TKI therapy.
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.