CADTH | pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

PROVINCIAL FUNDING SUMMARY

Inotuzumab Ozogamicin (Besponsa) for Acute Lymphoblastic Leukemia (pCODR 10121)

pERC Recommendation: Recommends with conditions

For further details, please see pERC Final Recommendation

Notification to Implement Issued by pCODR:

This information is current as of August 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	Jun 1, 2019	Adult patients with relapsed or refractory pre-B cell acute lymphoblastic leukemia (ALL) with positive CD-22 expression: • Philadelphia chromosome positive (Ph+): after at least one standard multi-drug chemotherapy induction and one second-generation or third-generation tyrosine kinase inhibitor • Philadelphia chromosome negative (Ph-): after at least one standard multi-drug chemotherapy induction • ECOG performance status 0-2 • Total bilirubin less than or equal to 1.5 x upper limit of normal (ULN), ALT less than or equal to 2.5 x ULN, serum creatinine less than or equal to 1.5 x ULN • Prescribed by Leukemia/BMT Program physicians and delivered at Vancouver General Hospital • Only one of blinatumomab or inotuzumab ozogamicin will be funded • For patients proceeding to HSCT, maximum of 3 cycles will be funded. For patients not proceeding to HSCT, maximum of 6 cycles will be funded. • NOTE: A BC Cancer "Compassionate Access Program" request with appropriate clinical information for each patient must be approved prior to treatment (please refer to https://cap.phsa.ca/).
AB	Under provincial consideration		

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
SK	Funded	Sep 3, 2019	Treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). Eligible patients include Philadelphia chromosome (Ph)-positive and (Ph)-negative relapsed or refractory B-cell precursor ALL. Treatment may be continued until unacceptable toxicity or disease progression, up to a maximum of 3 cycles for patients proceeding to hematopoietic stem cell transplant (HSCT); for patients not proceeding to HSCT who achieve a complete response or complete response with incomplete count recovery (CR/CRi) and minimal residual disease negativity, treatment may be continued for a maximum of 6 cycles.
MB	Funded	Jun 26, 2019	For the treatment of relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) - Eligible patients include Philadelphia (Ph)-chromosome positive and Ph- chromosome negative relapsed or refractory B cell precursor ALL with good performance status. - For patients with Ph-positive ALL, failure with at least one second-generation or third-generation tyrosine kinase inhibitor and standard multi-drug induction chemotherapy is required before treatment with inotuzumab ozogamicin. - Treatment should be continued until unacceptable toxicity or disease progression, up to a maximum of three cycles, for those patients proceeding to hematopoietic stem cell transplant (HSCT). For patients not proceeding to HSCT who achieve a complete response or complete response with incomplete count recovery (CR/CRi) and minimal residual disease negativity, treatment may be continued for a maximum of six cycles.
ON	Funded	Jul 18, 2019	For the treatment of Philadelphia chromosome (Ph) positive and negative patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) who have good performance status. For patients with Ph+ ALL, failure with at least one second-generation or third-generation tyrosine kinase inhibitor (TKI) and standard multi-drug induction chemotherapy is required before treatment with inotuzumab ozogamicin. Update (February 25, 2020): Sequencing of blinatumomab and inotuzumab ozogamicin in curative situations for relapsed Ph+ BCP-ALL. Curative situation is defined as a goal to take the patient to transplant if response can be achieved.

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
NS	Funded	Feb 1, 2020	As a single agent treatment option in adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). Eligible patients include Philadelphia chromosome (Ph) - positive and (Ph)-negative relapsed or refractory B cell precursor ALL with a good performance status. For patients with (Ph)-positive ALL, failure with at least one second-generation or third-generation tyrosine kinase inhibitor (TKI) and standard multi-drug induction chemotherapy is required before treatment with inotuzumab ozogamicin. Treatment should be continued until unacceptable toxicity or disease progression, up to a maximum of three cycles, for those patients proceeding to hematopoietic stem cell transplant (HSCT). For patients not proceeding to HSCT who achieve a complete response or complete response with incomplete count recovery (CR/Cri) and minimal residual disease negativity, treatment may be continued for a maximum of six cycles.
NB	Funded	Nov 1, 2019	For the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia. Patients with Philadelphia chromosome positive (Ph+) disease must have failed at least one second-generation or third-generation tyrosine kinase inhibitor and standard multi-drug induction chemotherapy. Patients must have a good performance status. Treatment should be discontinued upon disease progression or unacceptable toxicity. For patients proceeding to hematopoietic stem cell transplant (HSCT), treatment is for a maximum of 3 cycles. For patients not proceeding to HSCT who achieve a complete response (CR) or complete response with incomplete count recovery (CRi) and minimal residual disease negativity, treatment is for a maximum of 6 cycles. If CR/CRi is not achieved after 3 cycles, discontinue treatment.
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.