CADTH | pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

PROVINCIAL FUNDING SUMMARY

Venetoclax (Venclexta) in combo Rituximab for Chronic Lymphocytic Leukemia (pCODR 10162)

pERC Recommendation: Recommends with conditions

For further details, please see pERC Final Recommendation

Notification to Implement Issued by pCODR: June 17, 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	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
BC	Funded	Jan 1, 2020	Relapsed/refractory chronic lymphocytic leukemia or small lymphocytic lymphoma with or without chromosome 17p deletion, who have received at least one prior line of therapy • Symptomatic disease requiring systemic therapy • Patients who responded to anti-CD20 therapy (rituximab or obinutuzumab) and with a treatment-free interval of 12 months or longer. • Patients may be re-treated with ULYVENETOR if they responded to and completed 2 years of ULYVENETOR with at least 12 months of progression-free interval (remission). • Patients currently receiving and responding to venetoclax monotherapy (ULYVENTO) but without achieving an adequate response. Venetoclax therapy is funded to a maximum of 2 years from the time when rituximab is added. • A Compassionate Access Program (CAP) approval is required prior to the initiation of treatment (please refer to https://cap.phsa.ca/).
AB	Funded	Apr 10, 2020	In combination with rituximab for the treatment of patients with chronic lymphocytic leukemia (CLL) who have received at least one prior therapy, irrespective of their 17p deletion status. Patients should have good performance status and treatment should continue until disease progression or unacceptable toxicities, up to a maximum of 2 years. Sequencing options for venetoclax + rituximab and ibrutinib in the second or third line setting are open, providing patients have not received prior treatment with either option and meet all other criteria. Retreatment

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
			with venetoclax + rituximab is allowed in patients who responded to and completed 24 months of therapy, after progression free interval of at least 12 months. Addition of rituximab is allowed for patients currently receiving and responding to venetoclax monotherapy, but who have not achieved an adequate response. The funded duration of venetoclax therapy from the point of rituximab addition will be up to a maximum of 2 years".
SK	Funded	Mar 1, 2020	•In combination with Rituximab for the treatment of adult patients with chronic lymphocytic leukemia (CLL) who have received at least one prior therapy, irrespective of their 17p deletion status •Patients may be continued on Venetoclax until disease progression or unacceptable toxicity up to a maximum of two years, whichever comes first Notes: •Eligible patients should have good performance status, usually interpreted as ECOG 0-2 •Patients who were previously treated with and responded to an anti-CD20 containing therapy (e.g., FCR, BR, Chlorambucil-Obinutuzumab) must have had a progression-free interval of 12 months or longer since the last anti-CD20 therapy to be eligible for the combination of Venetoclax plus Rituximab; patients remain eligible for second-line Ibrutinib followed by third-line Venetoclax monotherapy in cases where the progression-free interval following anti-CD20 containing therapy is less than 12 months •Patients currently receiving and responding to Venetoclax monotherapy (initiated after at least one prior therapy and who have failed a B-cell receptor inhibitor [e.g., Ibrutinib, Idelalisib]), but who have not achieved an adequate response are eligible to have Rituximab added to Venetoclax; Venetoclax therapy is funded to a maximum of 2 years from the time when Rituximab is added •Addition of Rituximab to Venetoclax is not approved in patients who are experiencing disease progression on Venetoclax monotherapy •Re-treatment with Venetoclax plus Rituximab is funded as an option at the time of relapse if the progression-free interval was at least 12 months for patients who responded and completed 2 years of Venetoclax therapy •Venetoclax plus Rituximab may be used as a third-line treatment option if Ibrutinib is chosen as a second-line therapy provided all other funding eligibility criteria is met; conversely, Ibrutinib may be used as a third-line treatment

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
			option if Venetoclax plus Rituximab is chosen as a second-line therapy provided all other funding eligibility criteria is met
MB	Funded	Apr 2, 2020	• Venetoclax in combination with rituximab for the treatment of adult patients with chronic lymphocytic leukemia (CLL) who have received at least one prior therapy, irrespective of their 17p deletion status. • Treatment should be continued until disease progression or unacceptable toxicity up to a maximum of two years*, whichever comes first.
ON	Under provincial consideration		
NS	Funded	Jul 1, 2020	In combination with rituximab for the treatment of adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) who have received at least one prior therapy, irrespective of their 17p deletion status. Treatment should be continued until disease progression or unacceptable toxicity up to a maximum of two years, whichever comes first. Clinical Notes: Patients who were previously treated with and responded to an anti-CD20 therapy (rituximab or obinutuzumab) will be eligible for treatment with the combination of venetoclax plus rituximab if they had a progression-free interval of 12 months or longer. Patients currently receiving and responding to venetoclax monotherapy, and who have not achieved an adequate response are eligible to have rituximab added to venetoclax. Note: Venetoclax therapy is funded to a maximum of two years from the time rituximab is added. Patients may be retreated with venetoclax plus rituximab if they responded to and completed two years of therapy with at least 12 months of progression-free interval. Patients will be eligible for treatment with either ibrutinib, or idelalisib with rituximab following progression on venetoclax with rituximab if they have not received before and otherwise meet eligibility criteria.
NB	Funded	Jul 16, 2020	In combination with rituximab for the treatment of patients with chronic lymphocytic leukemia/small lymphocytic lymphoma who have received at least one prior therapy. Renewal criteria: • Written confirmation that the patient has responded to treatment and there is no evidence of disease progression. Clinical Notes: 1. Patient must have a good performance status. 2.

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
			Treatment should be continued until disease progression or unacceptable toxicity, up to a maximum of 2 years. Claim Notes: • Requests will not be considered for patients previously treated with anti-CD20 therapy who have a treatment-free interval of less than 12 months since the last anti-CD20 treatment. • Requests for re-treatment with venetoclax in combination with rituximab within the same line of therapy will be considered for patients who responded to and completed 2 years of therapy and have had a progression-free interval of at least 12 months. • Initial approval period: 1 year. • Renewal approval period: 1 year.
NL	Funded	Sep 2, 2020	In combination with rituximab for the treatment of adult patients with chronic lymphocytic leukemia (CLL) who have received at least one prior therapy, irrespective of their 17p deletion status. Renewal Criteria: • Written confirmation that the patient has responded to treatment and there is no evidence of disease progression or unacceptable toxicity Clinical Notes: 1. Patients must have a good performance status. 2. Treatment may be continued until disease progression or unacceptable toxicity, up to a maximum of two years. 3. Addition of Rituximab is allowed for patients currently receiving and responding to Venetoclax monotherapy, but who have not achieved an adequate response. The funded duration of Venetoclax therapy from the point of rituximab addition will be up to a maximum of 2 years. 4. Re-treatment with Venetoclax plus Rituximab is funded as an option at the time of relapse if the progression-free interval was at least 12 months for patients who responded and completed 2 years of Venetoclax therapy. Claim Notes: • Initial approval period: 1 year • Renewal approval period: 1 year
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.