CADTH | pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

PROVINCIAL FUNDING SUMMARY

Regorafenib (Stivarga) for Unresectable Hepatocellular Carcinoma (HCC) (pCODR 10119)

pERC Recommendation: Recommends with conditions

For further details, please see pERC Final Recommendation

Notification to Implement Issued by pCODR: May 3, 2018

This information is current as of May 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	Jul 1, 2019	Advanced hepatocellular carcinoma with disease progression on Sorafenib. • Tolerated Sorafenib dose at least 400 mg/day for 20 of 28 days • Not amenable to surgery or other local therapy ▫ ECOG 0-1 • Child-Pugh A liver function • No major surgery within 14 days of administration of therapy • A BC Cancer "Compassionate Access Program" request with appropriate clinical information for each patient must be approved prior to treatment ▫ Caution in 1) Asian patients, 2) patients with mild or moderate hepatic impairment, 3) patients 65 years or older, 4) hypertension
AB	Funded	Nov 18, 2019	Criteria Updated: For patients with unresectable hepatocellular carcinoma (HCC) who have been previously treated with, and progressed on sorafenib or lenvatinib. To be eligible patients should have ECOG performance status of 0 to 1, have a Child-Pugh class status of A, have tolerated previous sorafenib or lenvatinib, and otherwise meet the RESORCE trial criteria. Treatment should continue until disease progression.
SK	Funded	Sep 3, 2019	Treatment of patients with unresectable hepatocellular carcinoma (HCC) who have been previously treated with Sorafenib; treatment may continue until disease progression. Eligible patients should have an ECOG performance status of 0 to 1, a Child-Pugh class status of A, and be able to tolerate Sorafenib as defined in the RESORCE trial criteria (>400 mg/day for >20 days of the last 28 days of treatment).

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
MB	Funded	Mar 2, 2020	Inclusion Criteria: • For patients with unresectable hepatocellular carcinoma who have been previously treated with sorafenib. • Patients should have an ECOG performance status of 0 to 1, a Child-Pugh class status of A, be able to tolerate sorafenib as defined in the RESORCE trial (patients who have tolerated sorafenib at a dose of at least 400mg per day for 20 days of a 28 days cycle in most recent cycle)and otherwise meet the RESORCE trial criteria. Treatment should continue until disease progression.
ON	Under provincial consideration		
NS	Funded	Nov 1, 2019	For the treatment of patients with unresectable hepatocellular carcinoma (HCC) who have experienced disease progression on sorafenib and meet all of the following criteria: ECOG performance status of 0 or 1, Child-Pugh class status of A, tolerated sorafenib at a dose of at least 400mg per day for at least 20 days of the last 28 day cycle. Treatment should continue until disease progression or unacceptable toxicity.
NB	Funded	Nov 7, 2019	For the treatment of patients with unresectable hepatocellular carcinoma (HCC) who have had disease progression on sorafenib and meet all of the following criteria: • ECOG performance status of 0 or 1 • Child-Pugh class status of A • Tolerated sorafenib at a minimum dose of 400 mg per day for at least 20 of the last 28 days of treatment Renewal Criteria: • Written confirmation that the patient has responded to treatment and there is no evidence of disease progression. Clinical Note: • Treatment should be discontinued upon disease progression or unacceptable toxicity. Claim Notes: • Initial approval period: 4 months. • Renewal approval period: 6 months.
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.