CADTH | pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

PROVINCIAL FUNDING SUMMARY

Lenvatinib (Lenvima) for Hepatocellular Carcinoma (pCODR 10175)

pERC Recommendation: Recommends with conditions

For further details, please see pERC Final Recommendation

Notification to Implement Issued by pCODR: August 9, 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	Jul 1, 2020	Patients with hepatocellular carcinoma not amenable for local regional therapy • First line therapy or in sorafenib intolerant patients • ECOG 0-1 • Child-Pugh A liver function • Adequately controlled: blood pressure, renal and liver function
AB	Funded	Apr 10, 2020	For the first line treatment of adult patients with unresectable hepatocellular carcinoma (HCC). To be eligible patients should have: Child-Pugh class status A,ECOG status of 0 to 1, less than 50% liver involvement, and no invasion or the bile duct or portal vein, brain metastases or liver transplantion. Treatment should continue until confirmed disease progression or unacceptable toxicity. Not to be used in patients that have progressed on sorafenib; may be used in patients who are intolerant to sorafenib.
SK	Funded	Mar 1, 2020	•First-line treatment of adult patients with unresectable hepatocellular carcinoma (HCC) with Child-Pugh A liver function who have an ECOG performance status of 0-1 and who would otherwise meet the inclusion criteria of the REFLECT trial •Treatment may continue until confirmed disease progression or unacceptable toxicity Notes: •Diagnosis of HCC should be confirmed histologically or cytologically, or confirmed clinically in accordance with the American Association for the Study of Liver Diseases criteria •Patients must have one or more measurable target lesions (lesions previously treated with radiotherapy or locoregional therapy must show radiographic evidence of disease progression to be deemed target lesions) based on mRECIST criteria

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
			•Patients must have Barcelona Clinic Liver Cancer (BCLC) stage B or C category •Patients must have <50% liver involvement with no invasion of the bile duct or main portal vein •Patients with prior liver transplantation, brain or leptomeningeal involvement are not eligible •Lenvatinib is not approved for maintenance therapy or as a bridge to transplant •Patients coinfected with hepatitis and patients with intermediate-stage HCC who are unable to receive TACE (provided they have Child-Pugh A liver function) are eligible •Patients should have controlled blood pressure and adequate organ function before treatment initiation •Lenvatinib may be used in patients unable to tolerate Sorafenib, but who have not experienced disease progression, provided all other funding criteria are met; conversely, patients unable to tolerate Lenvatinib may be switched to Sorafenib if there is no disease progression and all other funding criteria for Sorafenib are met •Regorafenib is funded as a second-line option after treatment failure with either Lenvatinib or Sorafenib, provided all funding criteria for Regorafenib are met
MB	Funded	Apr 2, 2020	• For the first line treatment of adult patients with unresectable hepatocellular carcinoma with Child-Pugh A liver function. • Patients should have an ECOG performance status of 0 to 1 and would meet the inclusion criteria of the REFLECT trial. • Treatment should continue until confirmed disease progression or unacceptable toxicity.
ON	Funded	Mar 5, 2020	For the treatment of unresectable advanced1 hepatocellular carcinoma (HCC) in adult patients who meet ALL the following criteria prior to starting treatment with lenvatinib; • Patient is 18 years of age or older; AND • Lenvatinib will be used as monotherapy for HCC; AND • Patient has good performance status with Eastern Cooperative Oncology Group (ECOG) Performance status less than or equal to 2; AND • Has a Child-Pugh class A liver function. 1 Patients with Stage B HCC, based on the Barcelona Clinic Liver Cancer (BCLC) Staging System will be considered for lenvatinib if they have progressed on transarterial chemoembolization (TACE). Case-by-case consideration will be provided for Stage B HCC patients who are not suitable for the TACE procedure. In such situations, please provide additional information to support why the patient is not suitable for TACE. Exclusion Criteria:

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
			Patients meeting any of the following criteria will not be funded. • Patients with Child-Pugh score greater than 6 (i.e. Child-Pugh class B or C) will not be funded. • Patients who have progressed on sorafenib for HCC will not be funded for lenvatinib Only one of sorafenib or lenvatinib for the treatment of HCC will be funded in the first line. Patients will be permitted to switch from sorafenib to lenvatinib if they experience intolerance and have not progressed on sorafenib. Recommended Dosage: The recommended daily dose of lenvatinib is 8mg once daily for patients with a body weight of <60kg and 12 mg once daily for patients with a body weight of ≥60 kg Renewals will be considered for patients who have not experienced unacceptable toxicities to lenvatinib or until disease progression. Please provide radiographic results, scan results or both indicating no progression. Progression evaluation will be in accordance with modified Response Evaluation Criteria in Solid Tumors (mRECIST) or RECIST 1.1 criteria. . Approval duration for initials and approvals : 3 months
NS	Funded	Aug 1, 2020	For the first-line treatment of adult patients with unresectable or metastatic hepatocellular carcinoma who meet all the following criteria: o Child-Pugh class status of A. o ECOG performance status of 0 or 1. o Less than 50% liver involvement and no invasion of the bile duct or main portal vein. o No brain metastases or prior liver transplantation. Clinical Notes: ▫ Treatment should be continued until disease progression or unacceptable toxicity. ▫ Patients who are unable to tolerate lenvatinib may be switched to sorafenib if there is no disease progression and provided all other funding criteria are met. ▫ Patients with disease progression on lenvatinib are not eligible for reimbursement of sorafenib.

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
NB	Funded	Jul 16, 2020	Advanced Hepatocellular Carcinoma For the first-line treatment of adult patients with unresectable hepatocellular carcinoma who meet all of the following criteria: • Child-Pugh class status of A • ECOG performance status of 0 or 1 • Less than 50% liver involvement and no invasion of the bile duct or main portal vein • No prior liver transplant • No brain metastases 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: • Requests for lenvatinib will not be considered for patients who have progressed on sorafenib. • Initial approval period: 6 months. • Renewal approval period: 1 year.
NL	Funded	Sep 2, 2020	For the first line treatment of adult patients with unresectable hepatocellular carcinoma (HCC) who meet all of the following criteria: • Child-Pugh class status of A • ECOG performance status of 0 or 1 • Less than 50% liver involvement and no invasion of the bile duct or main portal vein • No prior liver transplant • No brain metastases 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: • Requests for lenvatinib will not be considered for patients who have progressed on sorafenib. • Initial approval period: 6 months. • 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.