CADTH | pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

PROVINCIAL FUNDING SUMMARY

Lenvatinib (Lenvima) for Differentiated Thyroid Cancer (pCODR 10080)

pERC Recommendation: Recommends

For further details, please see pERC Final Recommendation

Notification to Implement Issued by pCODR: October 5, 2016

This information is current as of August 6, 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	Oct 1, 2017	Metastatic differentiated thyroid cancer refractory to radioiodine: • Treatment naïve or one prior TKI therapy (SORAfenib, SUNItinib, or PAZOpanib) • ECOG 0 to 2 • Adequately controlled: blood pressure, renal and liver function • TSH less than or equal to 0.5 mIU/L • A BCCA "Compassionate Access Program" form with appropriate clinical information for each patient must be submitted and approved prior to treatment.
AB	Funded	Nov 28, 2017	For the treatment of patients with locally recurrent or metastatic progressive radioactive iodine-refractory differentiated thyroid cancer (DTC) who have good performance status. Treatment should continue until disease progression or unacceptable toxicity.

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
SK	Funded	Aug 2, 2017	Treatment of patients with locally recurrent or metastatic, progressive, radioactive-iodine-refractory differentiated thyroid cancer (DTC). Treatment should be for patients with good performance status and who otherwise meet the eligibility criteria of the SELECT trial and should continue until disease progression or unacceptable toxicity. Eligibility for the SELECT trial is as follows: • Pathologically confirmed differentiated thyroid cancer (patients with anaplastic or medullary thyroid cancer are not eligible) • Evidence of iodine-131 refractory disease according to at least one of the following criteria: at least one measurable lesion without iodine uptake on any iodine-131 scan, at least one measurable lesion that had progressed according to RECIST criteria within 12 months after iodine-131 therapy despite iodine-131 avidity at the time of treatment, or total lifetime radioactive iodine dose greater than 600 mCi (millicurie); • Radiologic evidence of progression within the previous 13 months • No prior therapy with a tyrosine kinase inhibitor or have received one prior treatment regimen with a tyrosine kinase inhibitor.
MB	Funded	Oct 19, 2017	For treatment of patients with locally recurrent or metastatic, progressive, radioactive-iodine-refractory differentiated thyroid cancer (DTC). Treatment should be for patients with good performance status and who otherwise meet the eligibility criteria of the SELECT trial and should continue until treatment progression or unacceptable toxicity.
ON	Funded	Sept 12, 2017	For the treatment of patients with locally recurrent or metastatic, progressive, radioactive-iodine-refractory differentiated thyroid cancer (DTC) according to the following criteria: • Papillary or follicular subtypes of DTC that are histologically or cytologically confirmed; AND • Thyroid cancer is refractory or resistant to radioactive iodine; AND • DTC shows evidence of disease progression within the past 13 months; AND • Patient has good performance status with ECOG less than or equal to 2; AND • Lenvatinib is being used as monotherapy. Exclusion Criteria: • Patients with anaplastic or medullary thyroid cancer. • Patients who have received more than one prior therapy with a tyrosine kinase inhibitor.

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
NS	Funded	Apr 9, 2018	As a single agent treatment for patients with locally recurrent or metastatic, progressive, radioactive iodine refractory DTC. Treatment should be for patients with a good performance status and who otherwise meet eligibility criteria of the SELECT trial and should continue until disease progression or unacceptable toxicity. Eligiblity for the SELECT trial is as follows: Measurable, pathologically confirmed DTC (patients with anaplastic or medullary thyroid cancer are not eligible). Evidence of iodine-131 refractory disease according to at least one of the following criteria: at least one measurable lesion without iodine uptake on any iodine-131 scan, at least one measurable lesion that had progressed according to RESIST criteria within 12 months after iodine-131 therapy despite iodine-131 avidity at the time of treatment, or total lifetime radioactive iodine dose greater than 600 mCi and radiologic evidence of progression within previous 13 months. Eligible patients had received no prior therapy with a tyrosine kinase inhibitor (TKI) or have received one prior treatment regimen with a TKI.
NB	Funded	Dec 15, 2017	For the treatment of patients with locally recurrent or metastatic, progressive, differentiated thyroid cancer (DTC) who meet the following criteria: - Pathologically confirmed papillary or follicular thyroid cancer, and - Disease that is refractory or resistant to radioactive iodine therapy, and - Radiological evidence of disease progression within the previous 13 months, and - Previous treatment with no more than one tyrosine kinase inhibitor (TKI). Clinical Notes: 1. Patients must have a good performance status. 2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
NL	Funded	May 10, 2018	Treatment of patients with locally recurrent or metastatic, progressive, radioactive-iodine-refractory differentiated thyroid cancer (DTC). Treatment should be for patients with good performance status and who otherwise meet the eligibility criteria of the SELECT trial and should continue until treatment progression or unacceptable toxicity. Renewals will be considered for patients who do not have evidence of disease progression. AND who have not developed unacceptable toxicities that require discontinuation of lenvatinib. SELECT Trial Eligibility Criteria: Inclusion criteria: • 18 Years and older • Histologically or cytologically confirmed diagnosis of one of the following DTC subtypes: Papillary thyroid cancer (PTC) or follicular thyroid cancer (FTC). • Measurable disease according to (RECIST 1.1) and confirmed by central radiographic review. • 131 I-refractory/resistant disease. • Evidence of disease progression within 12 months prior to signing informed consent (+1 month screening window). • Prior treatment with 0 or 1 vascular endothelial growth-factor (VEGF) or vascular endothelial growth-factor receptors (VEGFR) targeted therapy. • Adequate renal, liver, bone marrow, and blood coagulation function, as defined in the protocol. Exclusion criteria: • Anaplastic or medullary carcinoma of the thyroid • 2 or more prior VEGF/ VEGFR-targeted therapies • Received any anticancer treatment within 21 days or any investigational agent within 30 days prior to the first dose of study drug.
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.