CADTH | pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

PROVINCIAL FUNDING SUMMARY

Cabozantinib (Cabometyx) for Renal Cell Carcinoma Resubmission (pCODR 10163)

pERC Recommendation: Recommends with conditions

For further details, please see pERC Final Recommendation

Notification to Implement Issued by pCODR: March 7, 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	Metastatic renal cell carcinoma • Any histology or IMDC risk group • As second or third-line therapy after failure of first-line tyrosine kinase inhibitor therapy (SUNItinib, SORAfenib, or PAZOpanib) OR after first-line immunotherapy followed by second-line tyrosine kinase inhibitor OR after everolimus (UGUEVER) or axitinib (UGUAXI), if intolerant to these drugs* • A BC Cancer Compassionate Access Program (CAP) request with appropriate clinical information for each patient must be approved prior to treatment * Patients are eligible to receive everolimus (UGUEVER) OR axitinib (UGUAXIT) OR cabozantinib (UGUCABO) but not sequential use of these agents except for intolerance or contraindications.
AB	Under provincial consideration		
SK	Funded	Mar 1, 2020	• Treatment of patients with advanced renal cell carcinoma (RCC) who have received at least one prior vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) therapy. • Treatment may continue until clinically meaningful disease progression or unacceptable toxicity Notes: • Patients with both clear cell and non-clear cell histologies are eligible • For patients treated with a VEGF TKI (e.g., Sunitinib, Pazopanib) in the first-line setting, Cabozantinib is funded as an option either second-line before Nivolumab or third-line after Nivolumab

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
			• Either Axitinib or Cabozantinib are funded for third-line treatment of advanced RCC for intermediate or poor risk patients previously treated with Nivolumab plus Ipilimumab first-line and a VEGF TKI (Sunitinib or Pazopanib) second-line.
MB	Funded	Apr 2, 2020	For the treatment of patients with advanced renal cell carcinoma (RCC) who have received at least one prior vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) therapy and treatment should continue until clinically meaningful disease progression or unacceptable toxicity.
ON	Funded	May 6, 2020	EAP Criteria Cabozantinib (Cabometyx) will be reimbursed as monotherapy treatment of patients with advanced renal cell carcinoma (RCC) meeting one of the following situations: 1. As monotherapy, second line therapy in a Patient with any risk category (i.e. good, intermediate or poor risk) of advanced RCC after progression on at least one prior vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) therapy (e.g. Sunitinib, Pazopanib). If used in this second line setting, only one of Cabometyx or axitinib or nivolumab will be funded; 2. As monotherapy, third line therapy in a Patient with any risk category (i.e. good, intermediate or poor risk) of advanced RCC after progression on at least one prior vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) therapy (e.g. Sunitinib, Pazopanib) in first line and nivolumab in second line. 3. As monotherapy, third line therapy in a Patient with intermediate or poor risk advanced RCC after progression on an ipilimumab-nivolumab combination in first line and a vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) therapy (e.g. Sunitinib, Pazopanib) in second line. If used in this third line setting, only one of Cabometyx or axitinib will be funded Exclusion Criteria: 1. Patients who have experienced progression to cabozantinib for advance RCC will not be considered for EAP reimbursement for retreatment with cabozanitinib in a subsequent line. 2. Cabozantinib will not be funded in combination with another treatment for advance RCC. 3. Cabozantinib will not be funded as first line therapy. 4. Cabozantinib will not be funded for patients when used as in fourth line or later therapy.1 1Case-by-case consideration may be provided for patients who have experienced disease progression or intolerance to everolimus or temsirolimus or sorafenib used for advanced or

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
			metastatic RCC. Renewals will be considered until clinically meaningful disease progression or the patient has experienced unacceptable toxicity. Recommended dose: 60 mg daily. Requests for 20mg and 40mg tablets should include reasons why the lower dosed tablets are required. Approval duration: 1 year (for initial and renewal requests)
NS	Funded	Jun 1, 2020	For the treatment of patients with advanced or metastatic renal cell carcinoma (RCC) who have received at least one prior vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) therapy. Treatment may continue until clinically meaningful disease progression or unacceptable toxicity.
NB	Funded	Jul 16, 2020	For the treatment of patients with advanced or metastatic renal cell carcinoma who have received at least one prior vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) therapy when used as: • second-line therapy following disease progression on sunitinib or pazopanib; or • third-line therapy following disease progression on immunotherapy and VEGF TKI (i.e., sunitinib or pazopanib), used in any sequence. Renewal Criteria: Written confirmation that the patient has responded to treatment and there is no evidence of clinically meaningful disease progression. Clinical Note: Treatment should be discontinued upon clinically meaningful disease progression or unacceptable toxicity. Claim Notes: • Requests for cabozantinib will not be considered for patients who experience disease progression on everolimus or axitinib monotherapy. • Initial approval period: 1 year. • Renewal approval period: 1 year.
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.