CADTH | pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

PROVINCIAL FUNDING SUMMARY

Osimertinib (Tagrisso) for Non-Small Cell Lung Cancer (first line) (pCODR 10137)

pERC Recommendation: Recommends with conditions

For further details, please see pERC Final Recommendation

Notification to Implement Issued by pCODR: January 21, 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	Locally advanced or metastatic non-small cell lung cancer • EGFR mutation-positive tumour with exon 19 deletion or L858R mutation confirmed by accredited laboratory • First-line monotherapy • ECOG 0-2 • Stable and asymptomatic brain metastases • BC Cancer Compassionate Access Program (CAP) approval must be obtained
AB	Funded	Apr 10, 2020	Osimertinib for the first line treatment of patients with locally advanced (not amenable to curative intent therapy) or metastatic non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) mutations (exon l9 deletions (exon l9 del) or exon 21 (L858R). Patients should be previously untreated in the locally advanced or metastatic setting and have a good performance status. Treatment should continue until clinically meaningful disease progression or unacceptable toxicity
SK	Funded	Mar 1, 2020	•First-line treatment of patients with locally advanced (not amenable to curative intent therapy) or metastatic non-small cell lung cancer (NSCLC) whose tumors have the following epidermal growth factor receptor (EGFR) mutations - exon 19 deletions [exon 19 del] or exon 21 [L858R] mutations; eligible patients should be previously untreated in the locally advanced or metastatic setting and have a good performance status •Treatment may continue until clinically meaningful disease progression or unacceptable toxicity Notes:

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
			• Patients currently receiving alternate first-line EGFR TKI's (e.g., Erlotinib, Gefitinib, Afatinib) whose tumors have the noted EGFR mutations (exon 19 del or L858R) may be switched to Osimertinib provided they meet all other funding criteria and have not experienced disease progression • Patients in whom chemotherapy was initiated prior to receiving results of their tumor's EGFR mutation status may be switched to Osimertinib if eligible (exon 19 del, L858R, T790M mutations identified) • Patients that experience disease progression while receiving Osimertinib, either first or second-line, are not eligible for any funded subsequent treatment with alternate EGFR TKI's
MB	Funded	Apr 2, 2020	Inclusion criteria: • For the first-line treatment of patients with locally advanced (not amenable to curative intent therapy) or metastatic NSCLC whose tumors have epidermal growth factor receptor (EGFR) mutations (exon 19 deletions [exon 19 del] or exon 21 [L858R]). • Eligible patients should be previously untreated in locally advanced or metastatic setting and have a good performance status. • Treatment should continue until clinically meaningful disease progression or unacceptable toxicity.

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
ON	Funded	Jan 10, 2020	Initiation: For the treatment of locally advanced (not amenable to curative therapies) or metastatic non-small cell lung cancer (NSCLC) in individuals meeting the following criteria: 1. Previously untreated1 NSCLC in a patient with tumours that are documented to have Epidermal Growth Factor Receptor (EGFR) exon 19 deletions (exon 19 del) or exon 21 (L858R) substitution mutations (either alone or in combination with other EGFR mutations) OR Previously treated NSCLC in a patient who has experienced disease progression on one EGFR tyrosine kinase inhibitor (TKI) therapy (i.e. afatinib, gefitinib or erlotinib) with tumours that are documented to have EGFR T790M resistance mutations2; AND 2. Has a good performance status; AND 3. Osimertinib is being used as monotherapy. Exclusion: • Patients with EGFR wild-type mutations • Patients with EGFR unknown mutations • Osimertinib will not be funded as a third-line TKI • Patients with EGFR exon 19 deletions (exon 19 del) or exon 21 (L858R) substitution mutations who receive afatinib or gefitinib in first line are not eligible for osimertinib in the 2nd line NSCLC setting.3,4 Note: 1 Eligible patients should be previously untreated in the locally advanced or metastatic setting. 2 Patients with de novo EGFR 790M mutations may be considered case-by-case. 3Time-limited consideration will be provided for patients meeting all the above criteria who are currently on a first-, or second-generation EGFR TKI (i.e. gefitinib, afatinib, erlotinib) who have not experienced disease progression or patients who are currently on chemotherapy and are found to harbour a sensitizing or resistance mutation who wish to switch to osimertinib therapy. 4Patients who progress on osimertinib in the first line, will not be considered for another targeted TKI therapy (i.e. gefitinib or afatinib) for NSCLC Renewal of funding of osimertinib will be considered in patients who continue to derive benefit from treatment. (i.e. until clinically meaningful progression occurs or development of unacceptable toxicities.) Recommended dose: 80 mg per day orally (Note that 40mg tablets are approved on a case-by-case basis to ensure cost-effectiveness of the funded strength.) Duration of Approval for Initial and Renewal requests: 6 months
NS	Under provincial consideration		

PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
NB	Funded	Mar 19, 2020	For the first-line treatment of patients with locally advanced (not amenable to curative intent therapy) or metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations. Renewal Criteria: Written confirmation that the patient is responding to treatment. Clinical Note: Treatment should be discontinued upon clinically meaningful disease progression or unacceptable toxicity.
NL	Funded	Feb 20, 2020	For the first-line treatment of patients with locally advanced (not amenable to curative therapy) or metastatic epidermal growth factor receptor (EGFR) non-small cell lung cancer (NSCLC) (exon 19 deletions [exon 19 del] or exon 21 [L858R]). Eligible patients should be previously untreated in the locally advanced or metastatic setting. Renewal Criteria: Written confirmation that the patient is responding to treatment. Clinical Notes: 1. Patients must have a good performance status. 2. Treatment should be discontinued upon clinically meaningful disease progression or unacceptable toxicity. 3. Prior treatment with EGFR TKI therapy is not required in patients with de novo T790M mutation-positive NSCLC.
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.