CADTH | pCODR PAN-CANADIAN ONCOLOGY DRUG REVIEW

PROVINCIAL FUNDING SUMMARY

Enzalutamide (Xtandi) for non-metastatic Castration-Resistant Prostate Cancer (pCODR 10149)

pERC Recommendation: Recommends with conditions

For further details, please see pERC Final Recommendation

Notification to Implement Issued by pCODR: April 10, 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	Under provincial consideration		
AB	Funded	Jul 30, 2020	In combination with androgen deprivation therapy (ADT) for the treatment of patients with non-metastatic castration resistant prostate cancer (nmCRPC) who are at high risk of developing metastases. High risk is defined as prostate specific antigen doubling time (PSADT) of < l0 months during continuous ADT. Patients may receive only one of these agents (apalutamide or enzalutamide) in this setting and switching only if intolerant to one agent.
SK	Funded	Jun 1, 2020	• In combination with androgen deprivation therapy (ADT) for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastases • High risk is defined as a prostate-specific antigen doubling time (PSADT) of ≤ 10 months during continuous ADT • Patients should have good performance status and no risk factors for seizures; treatment may continue until unacceptable toxicity or radiographic disease progression Notes (nmCRPC): • Patients should have histologically or cytologically confirmed adenocarcinoma of the prostate without neuroendocrine differentiation, signet cell features, or small cell features -Patients should have no detectable distant metastases by either CT, MRI or technetium-99m bone scan • Patients with presence of CNS, vertebral or meningeal involvement are not eligible; however, patients with pelvic lymph nodes <2

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PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
			cm in short axis (N1) located below the common iliac vessels are eligible • Castrate levels of testosterone (<1.7 nmol/L) must be demonstrated prior to treatment initiation • Castration-resistant prostate cancer must be demonstrated during continuous ADT, and is defined as 3 PSA rises, at least 1 week apart, with the last PSA >2 mcg/L • Patients who are receiving a first generation anti-androgen (e.g., Bicalutamide) must show a further rise in PSA measured at least 6 weeks after discontinuing the anti-androgen to be eligible • In case of biochemical progression (rising PSA) while on Enzalutamide, appropriate clinical evaluation and/or investigations for metastatic disease should be conducted in a timely manner
MB	Funded	Jul 16, 2020	Non-metastatic castration-resistant prostate cancer: ● In combination with androgen deprivation therapy (ADT) for the treatment of patients with non- metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastases. ● High risk is defined as a prostate-specific antigen doubling time (PSADT) of ≤ 10 months during continuous ADT. Patients should have good performance status and no risk factors for seizures. Treatment should continue until unacceptable toxicity or radiographic disease progression.
ON	Funded	June 1, 2020	Initial Criteria: For the treatment of high risk non-metastatic castration resistant prostate cancer (nmCRPC) in patients who meet all the following criteria: 1. Patient using Xtandi in combination with androgen deprivation therapy (ADT); AND 2. Has no detectable distant metastases as determined by CT, MRI, or technetium-99m bone scan; AND 3. Patient has castrate resistant disease based on meeting all the following indicia observed while on continuous ADT treatment or post orchiectomy: • Castrate serum testosterone levels: AND • Biochemical progression defined as Three (3) prostate-specific antigen (PSA) rises at least 1 week apart, with the last PSA greater than 2ng/mL; and 4. Patient is at high risk for developing metastatic disease based on a Prostate-specific antigen doubling time (PSADT) of less than or equal to 10 months during continuous ADT. 5. Has an Eastern Cooperative

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PROVINCE	FUNDING STATUS	FUNDING DATE	FUNDING CRITERIA
			Oncology Group (ECOG) Performance Status less than or equal to 2. Approval Duration: 1 year Exclusion Criteria: • The patient received prior chemotherapy for the treatment of prostate cancer, unless it was in the adjuvant or neoadjuvant setting. • The patient has experienced disease progression on prior treatment with Erleada (apalutamide). • The patient has risk factors for seizures. Approved Dosage: 160mg (four 40mg capsules) administered orally once daily Notes: • The Ministry will fund only one of Erleada (apalutamide) or Xtandi in patients with non-metastatic castrate resistant prostate cancer. • Patients who have progressed on Xtandi for nmCRPC will not be eligible for Xtandi in metastatic castrate resistant prostate cancer (mCRPC). • Requests for Xtandi in patients who initiated Erleada therapy in the nmCRPC setting and who have not had disease progression will be considered on a case-by-case basis. Renewal Criteria: Renewals will be considered in patients without evidence of radiographic disease progression or unacceptable toxicity while on Xtandi therapy. Approval Duration: 1 year
NS	Under provincial consideration		
NB	Under provincial consideration		
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.

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