

Polaris Cell Cycle Progression Test for Localized Prostate Cancer: OHTAC Recommendation

ONTARIO HEALTH TECHNOLOGY ADVISORY COMMITTEE RECOMMENDATION

- The Ontario Health Technology Advisory Committee recommends against publicly funding the Polaris cell cycle progression test for treatment selection in men with newly diagnosed low- or intermediate-risk localized prostate cancer.

RATIONALE FOR THE RECOMMENDATION

After considering the available evidence on clinical utility, budget impact, and lived experience,¹ as well as patient preferences and values,² the committee reached consensus that there is uncertainty about the potential clinical benefits of this test. The clinical evidence is limited, there is uncertainty about its generalizability, and there remains an important gap in information on how adding this test to clinical practice in Ontario would affect patient-important outcomes, such as quality of life or mortality. In addition, the test is expensive, both on an individual basis and in terms of the total budget impact.

Decision Determinants for Prolaris Cell Cycle Progression Test for Localized Prostate Cancer

Decision Criteria	Subcriteria	Decision Determinants Considerations
Overall clinical benefit How likely is the health technology/intervention to result in high, moderate, or low overall benefit?	Effectiveness How effective is the health technology/intervention likely to be (taking into account any variability)? Safety How safe is the health technology/intervention likely to be? Burden of illness What is the likely size of the burden of illness pertaining to this health technology/intervention? Need How large is the need for this health technology/intervention?	No evidence was found demonstrating the impact of treatment decisions informed by the Prolaris CCP test on patient-important clinical outcomes. The limited evidence currently available shows that the CCP test appears to provide information that, when considered in addition to clinical risk stratification, may change the treatment plan (GRADE: Very low) or actual treatment (GRADE: Very low) of some low- and intermediate-risk prostate cancer patients. The Prolaris CCP test does not pose safety concerns to the patient. There may be safety concerns associated with over- and undertreatment of prostate cancer patients. Prostate cancer is the most common cancer in Canadian men, with an incidence in Ontario of about 8,500 cases per year. An estimated 90% of new diagnoses are localized prostate cancer. Prostate cancer patients are grouped at diagnosis based on risk, as determined by the D'Amico classification scheme, into low, intermediate, or high risk. Serum prostate-specific antigen level, Gleason grade, and tumour stage form the basis of clinical risk stratification. Clinical risk assessment is beneficial, but further information about the aggressiveness of an individual patient's cancer could be very helpful.
Consistency with expected societal and ethical values^a How likely is adoption of the health technology/intervention to be congruent with societal and ethical values?	Societal values How likely is adoption of the health technology/intervention to be congruent with expected societal values? Ethical values How likely is adoption of the health technology/intervention to be congruent with expected ethical values?	In interviews, patients did not raise concerns about the Prolaris CCP test being incongruent with social or ethical values. Patients view the information the CCP test provides as valuable to help make decisions about what treatment they ought to receive. Patients feel that adoption of the health technology could lead to better informed decision-making. However, patients feel that there is uncertainty about whether the information the test provides would change their treatment decision.
Value for money How efficient is the health technology/intervention likely to be?	Economic evaluation How efficient is the health technology/intervention likely to be?	The value for money of the CCP test is unknown because its cost-effectiveness could not be determined based on the evidence currently available.
Feasibility of adoption into health system How feasible is it to adopt the health technology/intervention into the Ontario health care system?	Economic feasibility How economically feasible is the health technology/intervention? Organizational feasibility How organizationally feasible is it to implement the health technology/intervention?	Given the large cost per CCP test and large size of the target population, the total budget impact would be relatively large. The CCP test would make use of the same biopsy tissue used for diagnosis; a prepared sample is sent for analysis. Relative to current practice, an additional health care visit with a specialist would be required to discuss results of the CCP test and select a treatment.

Abbreviations: CCP, cell cycle progression.

^aThe anticipated or assumed common ethical and societal values held in regard to the target condition, target population, and/or treatment options. Unless there is evidence from scientific sources to corroborate the true nature of the ethical and societal values, the expected values are considered.

REFERENCES

- (1) Health Quality Ontario. Prolaris cell cycle progression test for localized prostate cancer: a health technology assessment. Ont Health Technol Assess Ser [Internet]. 2017 May;17(6):1-75. Available from: <http://www.hqontario.ca/Evidence-to-Improve-Care/Journal-Ontario-Health-Technology-Assessment-Series>
- (2) Kandasamy S, Khalid AF, Majid U, and Vanstone M. Prostate cancer patient perspectives on the use of information in treatment decision-making: a systematic review and qualitative meta-synthesis. Ont Health Technol Assess Ser [Internet]. 2017 May;17(7):1-32. Available from: <http://www.hqontario.ca/Evidence-to-Improve-Care/Journal-Ontario-Health-Technology-Assessment-Series>

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Citation

Health Quality Ontario. Prolaris Cell cycle progression test for localized prostate cancer: OHTAC recommendation [Internet]. Toronto (ON): Queen's Printer for Ontario; 2017 May. 3 p. Available from: <http://www.hqontario.ca/evidence-to-improve-care/recommendations-and-reports/OHTAC/cell-cycle-progression>