Pigmented Lesion Assay for Suspected Melanoma Lesions: Recommendation

Final Recommendation

- Ontario Health, based on guidance from the Ontario Health Technology Advisory Committee, recommends against publicly funding pigmented lesion assay for people with suspected melanoma lesions

Rationale for the Recommendation

The Ontario Health Technology Advisory Committee has reviewed the findings of the health technology assessment[1] and the recommendation of a subcommittee, the Ontario Genetics Advisory Committee.

Ontario Health Technology Advisory Committee members noted that there is uncertainty because of low quality evidence for the diagnostic accuracy of pigmented lesion assay (sensitivity of 79% and specificity of 80% using biopsy as the reference standard). The committee considered the nature of melanoma and the need for a diagnostic test to have a high sensitivity to minimize the chance of missing melanoma and optimize patient outcomes through early diagnosis. In Ontario, usual care is for clinicians to use visual inspection to determine which moles suspicious for melanoma require biopsy. The committee felt that the risk of missing a true case of melanoma is too high (false negative rate: 2.5%) with pigmented lesion assay.

The committee also considered the lived experience of people with melanoma who expressed preference for a non-invasive test option to skin biopsy, but only if accuracy was sufficiently high.

The committee also noted there is considerable uncertainty about the cost-effectiveness of the pigmented lesion assay at this time; in part because of the limited health economic evidence that was identified. The lack of good-quality clinical evidence precludes the ability to create an economic model.

Public Comment: Held February 4–24, 2021

Decision Determinants for Pigmented Lesion Assay for Suspected Melanoma Lesions

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)?	The evidence suggests pigmented lesion assay has a sensitivity of 79% (95% confidence interval [CI] 58%–93%) and specificity of 80% (95% CI 73%–85%). The negative predictive value was 97.3%, using an estimated melanoma prevalence of 12%. The evidence is uncertain about the effect of pigmented lesion assay when directly compared to visual inspection alone. We did not identify any evidence of the direct impact of pigmented lesion assay testing on patient health outcomes. The evidence is uncertain if pigmented lesion assay has an impact on clinical decision making.
	Safety How safe is the health technology/intervention likely to be?	There are no concerns about patient safety with the use of the pigmented lesion assay adhesive patch.
	Burden of illness What is the likely size of the burden of illness pertaining to this health technology/ intervention?	Melanoma accounts for approximately 3% of all new cancer cases in Canada. In 2017, 7,250 Canadians were diagnosed with melanoma, of whom 1,250 died. Early detection is key for survival with a 5-year survival rate of 97% for melanoma patients diagnosed in the earliest stage, compared to 15–20% survival for those diagnosed at the most advanced stage of melanoma.
	Need How large is the need for this health technology/intervention?	The current standard of care is skin biopsy. Pigmented lesion assay proposes—if effective—to offer a non-invasive alternative to skin biopsy for ruling out melanoma.

Decision Criteria	Subcriteria	Decision Determinants Considerations
Patient preferences and values How likely is adoption of the health technology/intervention to be congruent with patient preferences and values and with ethical or legal standards?	**Patient preferences and values** Do patients have specific preferences, values, or needs related to the health condition, health technology/intervention, or life impact that are relevant to this assessment? (Note: The preferences and values of family members and informal caregivers are to be considered as appropriate.)	Patients value early detection of melanoma and see potential benefits to using the pigmented lesion assay as a non-invasive alternative to skin biopsy. Patients also value test accuracy as a key characteristic of a diagnostic test for melanoma.
	Autonomy, privacy, confidentiality, and/or other relevant ethical principles as applicable Are there concerns regarding accepted ethical or legal standards related to patient autonomy, privacy, confidentiality, or other ethical principles that are relevant to this assessment? (Note: The preferences and values of the public are to be considered as appropriate.)	There are no concerns about patient privacy or confidentiality regarding the use of pigmented lesion assay. To support patient autonomy regarding their preferences and values for their care, the accuracy of pigmented lesion assay to rule out melanoma should be discussed with patients.
Equity and patient care How could the health technology/ intervention affect equity of access and coordination of patient care?	**Equity of access or outcomes** Are there disadvantaged populations or populations in need whose access to care or health outcomes might be improved or worsened that are relevant to this assessment?	Not all primary care providers will perform a skin biopsy, and availability and access to dermatologists across the province may vary. A non-invasive alternative to skin biopsy to rule out melanoma has the potential to reduce the number of patients requiring access to a clinician who can conduct skin biopsy.
	Patient care Are there challenges in the coordination of care for patients or other system-level aspects of patient care (e.g., timeliness of care, care setting) that might be improved or worsened that are relevant to this assessment?	The wait time for access to a dermatologist in Ontario is estimated to be on average less than 3 months. This time period is within guideline recommendations for follow-up period for suspicious melanoma lesions and therefore not considered to be unreasonably lengthy.

Decision Criteria	Subcriteria	Decision Determinants Considerations
Cost-effectiveness How efficient is the health technology/ intervention likely to be?	**Economic evaluation** How efficient is the health technology/intervention likely to be?	There is a lack of published economic evidence demonstrating that pigmented lesion assay is cost-effective. We only identified one published health economic study, and after assessment, it was determined to have potentially serious limitations. A primary economic evaluation was not conducted because (1) there is low to very low quality clinical evidence about test characteristics and relevant patient outcomes, and (2) the potential avoidance of skin biopsy and specialist referrals with the use of pigmented lesion assay were estimated in the budget impact analysis.
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?	Assuming a very low uptake, the 5-year budget impact is estimated to be about $3.44 million if pigmented lesion assay is used by primary care providers and $2.56 million if pigmented lesion assay is used by specialists.
	Organizational feasibility How organizationally feasible is it to implement the health technology/intervention?	Pigmented lesion assay results are processed at a laboratory in California, USA. Minimal training is required for clinicians to use the pigmented lesion assay test.

Reference

(1) Ontario Health. Pigmented lesion assay for suspected melanoma lesions: a health technology assessment. Ont Health Technol Assess Ser [Internet]. 2021 June;21(5):1–81. Available from: https://www.hqontario.ca/evidence-to-improve-care/health-technology-assessment/reviews-and-recommendations/pigmented-lesion-assay

Disclaimer

About Ontario Health

About the Ontario Health Technology Advisory Committee

How to Obtain Recommendation Reports

Ontario Health
130 Bloor Street West, 10th Floor
Toronto, Ontario
M5S 1N5
Tel: 416-323-6868
Toll Free: 1-866-623-6868
Fax: 416-323-9261
Email: EvidenceInfo@hqontario.ca
www.hqontario.ca

ISBN 978-1-4868-5312-0 (PDF)

Citation

Ontario Health. Pigmented lesion assay for suspected melanoma lesions: recommendation [Internet]. Toronto (ON): Queen's Printer for Ontario; 2021 June. 5 pp. Available from: https://www.hqontario.ca/evidence-to-improve-care/health-technology-assessment/reviews-and-recommendations/pigmented-lesion-assay