

Osseointegrated Prosthetic Implants for People With Lower-Limb Amputation: Health Quality Ontario Recommendation

DRAFT RECOMMENDATION

- Health Quality Ontario, under the guidance of the Ontario Health Technology Advisory Committee, recommends against publicly funding osseointegrated prosthetic implants for people with lower-limb amputation

RATIONALE FOR THE RECOMMENDATION

The Ontario Health Technology Advisory Committee has reviewed the findings of the health technology assessment.¹ While committee members agreed that osseointegrated prosthetic implants may improve functional outcomes, they were also concerned about the frequency and severity of serious adverse events (e.g., osteomyelitis) and were very uncertain that the anticipated benefits outweigh the risks.

Committee members considered the lived experience of patients with osseointegrated prosthetic implants and patients interested in using the technology, as well as caregivers of those who had received an osseointegrated prosthetic implant. The patients whose experiences were described in the health technology assessment reported an improved quality of life after receiving the implant, but committee members noted that these patients would not represent the full spectrum of experiences and outcomes of people with lower-limb amputation.

Committee members were also aware that osseointegrated prosthetic implants do not have Health Canada approval and, typically, this means the technology would first be provided in a research setting and funded by research grants.

After deliberation, there was consensus among members of the committee to recommend against publicly funding osseointegrated prosthetic implants for people with lower-limb amputation at this time.

Public Comment: TBA

Decision Determinants for Osseointegrated Prosthetic Implants for People with Lower-Limb Amputation

Decision Criteria	Subcriteria	Decision Determinants Considerations
<p>Overall clinical benefit</p> <p>How likely is the health technology/intervention to result in high, moderate, or low overall benefit?</p>	<p>Effectiveness</p> <p>How effective is the health technology/intervention likely to be (taking into account any variability)?</p>	<p>Functional outcomes improved with osseointegrated prosthetic implants (GRADE: Low).</p>
	<p>Safety</p> <p>How safe is the health technology/intervention likely to be?</p>	<p>Osseointegrated prosthetic implants can lead to serious adverse events such as bone infection, bone fracture, and implant extraction in some patients, which may require additional surgeries (GRADE: High).</p>
	<p>Burden of illness</p> <p>What is the likely size of the burden of illness pertaining to this health technology/intervention?</p>	<p>Osseointegrated prosthetic implants can be an option when the cause of amputation is nonvascular (e.g., trauma, cancer, or congenital defects). In Canada, 6% of lower-limb amputations are due to trauma, 1.8% to cancer, and 0.6% to congenital defects. Each year about 69 people will have above-the-knee amputations due to nonvascular causes in Ontario.</p>
	<p>Need</p> <p>How large is the need for this health technology/intervention?</p>	<p>Some people with lower-limb amputation have chronic skin problems and pain with the socket prosthesis, which may limit their use of the prosthesis and their activity level.</p>
<p>Consistency with patient values, and expected societal and ethical values^a</p> <p>How likely is adoption of the health technology/intervention to be congruent with patient, societal and ethical values?</p>	<p>Patient values</p> <p>How likely is adoption of the health technology/intervention to be congruent with expected patient values?</p>	<p>Patients with a functional disability value being able to walk better and feel more independent. They value the perceived improvement in their health they feel osseointegrated prosthetic implants may be able to provide.</p>
	<p>Societal values</p> <p>How likely is adoption of the health technology/intervention to be congruent with expected societal values?</p>	<p>The adoption of osseointegrated prosthetic implants, if benefits exceed harms, would be consistent with a societal value to maximize the health and independence of people with a physical disability. Not adopting osseointegrated prosthetic implants may be consistent with societal values to prevent harm.</p>
	<p>Ethical values</p> <p>How likely is adoption of the health technology/intervention to be congruent with expected ethical values?</p>	<p>The adoption of osseointegrated prosthetic implants may be consistent with the ethical values of autonomy, justice, fairness, and beneficence. However, the ethical value of balancing benefit and harm is also a consideration.</p>
<p>Cost-effectiveness</p> <p>How efficient is the health technology/intervention likely to be?</p>	<p>Economic evaluation</p> <p>How efficient is the health technology/intervention likely to be?</p>	<p>The economic evaluation determined that the best estimate of the incremental cost-effectiveness ratio is \$94,987 per quality-adjusted life-year (QALY) gained. However, there was substantial uncertainty in this estimate. We estimated that the probability of osseointegrated prosthetic implants being cost-effective compared with continued use of a poorly fitting socket prosthesis is 54% at a willingness-to-pay value of \$100,000 per QALY gained.</p>

Decision Criteria	Subcriteria	Decision Determinants Considerations
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?	The cost of an osseointegrated prosthetic implant device (i.e. internal and external components) is approximately \$36,500. In addition, costs related to surgeries, professional fees, rehabilitation, and complications are expected over time. We estimated that the annual net budget impact of publicly funding osseointegrated prosthetic implants in Ontario over the next 5 years would range from \$1.5 million in year 1 to \$0.6 million in year 5, with 20 people being treated in years 1 and 2, and approximately 7 being treated in each following year.
	Organizational feasibility How organizationally feasible is it to implement the health technology/intervention?	Some training would be required for surgeons, central purchasing of devices would need to be established, and experts indicated that one or two centres should be selected to conduct these surgeries.

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; QALY, quality-adjusted life-year.

^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.

Patient values have been informed from the patient preferences and values information obtained through the patient partnering activities completed for the health technology assessment.

REFERENCE

(1) TBA

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