Implantable Devices for Single-Sided Deafness and Conductive or Mixed Hearing Loss: Recommendation

FINAL RECOMMENDATION

The Quality business unit at Ontario Health, based on guidance from the Ontario Health Technology Advisory Committee, recommends publicly funding:

- Cochlear implantation for adults and children with single-sided deafness
- Bone-conduction implantable devices for adults and children with single-sided deafness who have a contraindication to cochlear implantation
- Bone-conduction implantable devices for adults and children with conductive or mixed hearing loss

RATIONALE FOR THE RECOMMENDATION

The Ontario Health Technology Advisory Committee reviewed and accepted the findings of the health technology assessment.¹

The committee determined that cochlear implantation improves objective and subjective benefits of hearing and provides good value in people with single-sided deafness.

In contrast, committee members noted considerable uncertainty with respect to the costeffectiveness estimates for bone-conduction implantable devices for adults and children with single-sided deafness and conductive or mixed hearing loss, and also the relatively unfavourable estimate of the incremental cost-effectiveness ratio in individuals who have singlesided deafness and a contraindication to cochlear implantation. The committee considered the need for this technology when a cochlear implant or other forms of non-implantable sound amplification could not be used, the small number of people who would use this technology, the small budget impact associated with public funding, and the low likelihood of high-quality evidence emerging in the next few years. After considerable deliberation, a majority of committee members voted in favour of public funding, for both indications.



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)?	Compared with no intervention, cochlear implantation likely results in a large improvement in sound localization (GRADE: Moderate), likely improves tinnitus (GRADE: Moderate), likely improves quality of life (GRADE: Moderate), and likely improves speech perception in noise in adults and children with single-sided deafness. It also likely improves speech and language development in children (GRADE: Moderate).
	Safety How safe is the health technology/ intervention likely to be?	The cochlear implantation procedure is generally safe. Existing evidence showed an overall complication rate of 16% to 20%; about 5% of major complications required surgical revision.
	Burden of illness What is the likely size of the burden of illness pertaining to this health technology/intervention?	The Ontario Cochlear Implant Program estimated the clinical needs of cochlear implantation for adults and children with single-sided deafness to be 24 devices per year.
	Need How large is the need for this health technology/intervention?	There is a significant unmet need for adults and children with single-sided deafness whose opposite ear is at risk of deafness and for those who have experienced failure with all forms of non-implantable sound amplification devices.
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?	Providing cochlear implantation to adults and children with single-sided deafness who are unable to benefit from non- implantable sound amplification devices and are committed to the lengthy training period required is likely congruent with societal values.
	Ethical values How likely is adoption of the health technology/intervention to be congruent with expected ethical values?	Providing cochlear implantation to adults and children with single-sided deafness was noted to improve the ability to hear in both ears, the ability to localize sounds, and safety. Parents of children with single-sided deafness also reported improvements in development and learning after their children received cochlear implants. These findings are likely congruent with ethical values.
Cost-effectiveness How efficient is the health technology/ intervention likely to be?	Economic evaluation How efficient is the health technology/ intervention likely to be?	Compared with no intervention, cochlear implantation may be cost-effective in adults and children with single-sided deafness (ICER: \$17,783–\$18,148/QALY). About 70% of simulations were considered cost-effective at a willingness- to-pay of \$100,000 per QALY.
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 a cochlear implant device is estimated to be approximately \$25,000. For people with single-sided deafness, publicly funding cochlear implants in Ontario would result in an estimated additional cost of \$2.8 million to \$3.6 million over the next 5 years.
	Organizational feasibility How organizationally feasible is it to implement the health technology/ intervention?	The infrastructure is in place to make implementation feasible.

Decision Determinants for Cochlear Implantation in Single-Sided Deafness

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; ICER, incremental cost-effectiveness ratio; 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.

Decision Determinants for Bone-Conduction Implantable Devices in Single-Sided Deafness

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)?	Compared with no intervention, bone-conduction implantable devices likely result in a large improvement in hearing thresholds (GRADE: Moderate), likely improve quality of life (GRADE: Moderate), and likely improve speech perception in noise (GRADE: Moderate), but likely do not improve sound localization (GRADE: Moderate) in adults and children with single-sided deafness who are contraindicated for cochlear implantation.
	Safety How safe is the health technology/ intervention likely to be?	Surgery to implant bone-conduction devices currently in clinical use is generally safe. Existing evidence showed a lack of major complications, and most minor complications resolved on their own or could be treated medically without surgical intervention.
	Burden of illness What is the likely size of the burden of illness pertaining to this health technology/ intervention?	The Ontario Cochlear Implant Program estimated the clinical needs of bone-conduction implantable devices for adults and children with single-sided deafness contraindicated for cochlear implantation to be 11 devices per year.
	Need How large is the need for this health technology/intervention?	For adults and children with single-sided deafness contraindicated for cochlear implantation who could not benefit from non-implantable sound amplification devices, bone-conduction implantable devices are the only treatment option to restore hearing.
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?	Providing bone-conduction implantable devices to adults and children with single-sided deafness who are unable to benefit from non-implantable sound amplification devices or cochlear implants and are committed to the lengthy training period required is likely congruent with societal values.
	Ethical values How likely is adoption of the health technology/intervention to be congruent with expected ethical values?	Providing bone-conduction implantable devices to adults and children with single-sided deafness was noted to improve the ability to hear in noisy environments and to improve quality of life. These findings are likely congruent with ethical values.
Cost-effectiveness How efficient is the health technology/ intervention likely to be?	Economic evaluation How efficient is the health technology/ intervention likely to be?	Compared with no intervention, bone-conduction implantable devices are unlikely to be cost-effective in adults and children with single-sided deafness (ICER: \$402,899– \$408,350/QALY). About 38% of simulations were considered cost-effective at a willingness-to-pay of \$100,000 per QALY.
Feasibility of adoption	Economic feasibility	Bone-conduction implantable devices are estimated to cost approximately \$9,000–\$11,000. For people with single-sided deafness, publicly funding bone-conduction implantable devices in Ontario would result in an estimated additional cost of \$0.8 million over the next 5 years.
into health system How feasible is it to adopt the health technology/intervention into the Ontario health care system?	How economically feasible is the health technology/intervention?	
	Organizational feasibility How organizationally feasible is it to implement the health technology/ intervention?	The infrastructure is in place to make implementation feasible.

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; ICER, incremental cost-effectiveness ratio; 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.

Decision Determinants for Bone-Conduction Implantable Devices in Conductive or Mixed Hearing Loss

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)?	Compared with no intervention, bone-conduction implantable devices likely result in a large improvement in hearing thresholds (GRADE: Moderate), likely improve quality of life (GRADE: Moderate), and likely improve speech perception in noise (GRADE: Moderate) in adults and children with conductive or mixed hearing loss.
	Safety How safe is the health technology/ intervention likely to be?	Surgery to implant bone-conduction devices currently in clinical use is generally safe. Existing evidence showed a lack of major complications, and most minor complications resolved on their own or could be treated medically without surgical intervention.
	Burden of illness What is the likely size of the burden of illness pertaining to this health technology/ intervention?	The Ontario Cochlear Implant Program estimated the clinical needs of bone-conduction implantable devices for adults and children with conductive or mixed hearing loss to be 57 devices per year.
	Need How large is the need for this health technology/intervention?	There is a significant unmet need for adults and children with conductive or mixed hearing loss who cannot benefit from non-implantable sound amplification devices.
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?	Providing bone-conduction implantable devices to adults and children with conductive or mixed hearing loss unable to benefit from non-implantable sound amplification devices is likely congruent with societal values.
	Ethical values How likely is adoption of the health technology/intervention to be congruent with expected ethical values?	Providing bone-conduction implantable devices to adults and children with conductive or mixed hearing loss was noted to improve their quality of life, which is likely congruent with ethical values.
Cost-effectiveness How efficient is the health technology/ intervention likely to be?	Economic evaluation How efficient is the health technology/ intervention likely to be?	Compared with no intervention, bone-conduction implantable devices may be cost-effective in adults and children with conductive or mixed hearing loss (ICER: \$74,155– \$87,580/QALY). About 50% to 55% of simulations were considered cost-effective at a willingness-to-pay of \$100,000 per QALY.
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?	Bone-conduction implantable devices are estimated to cost approximately \$9,000–\$11,000. For people with conductive or mixed hearing loss, publicly funding bone-conduction implantable devices in Ontario would result in an estimated additional cost of \$3.1 million to \$3.3 million over the next 5 years.
	Organizational feasibility How organizationally feasible is it to implement the health technology/ intervention?	The infrastructure is in place to make implementation feasible.

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; ICER, incremental cost-effectiveness ratio; 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.

REFERENCE

(1) Ontario Health (Quality). Implantable devices for single-sided deafness and conductive or mixed hearing loss: a health technology assessment. Ont Health Technol Assess Ser [Internet]. 2020 Mar;20(1):1–165. Available from: <u>https://www.hqontario.ca/Evidence-to-Improve-Care/Health-Technology-Assessment/Reviews-And-Recommendations/Implantable-Devices-for-Single-Sided-Deafness-and-Conductive-or-<u>Mixed-Hearing-Loss</u></u>

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