Auditory Brainstem Implantation for Adults With Neurofibromatosis 2 or Severe Inner Ear Abnormalities: Recommendation

FINAL RECOMMENDATION

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

- Auditory brainstem implantation for adults with neurofibromatosis 2 who are not candidates for cochlear implantation
- Auditory brainstem implantation for adults with severe inner ear abnormalities who are not candidates for cochlear implantation

RATIONALE FOR THE RECOMMENDATION

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

The committee was particularly influenced by the relatively small budget impact of publicly funding auditory brainstem implantation for adults with neurofibromatosis 2 or severe inner ear abnormalities. The committee noted that the budget impact of funding this technology in both populations was small, and that the technology offers the possibility of quality-of-life improvements in an extremely small population for whom there is no alternative treatment option. Publicly funding auditory brainstem implantation in Ontario would lead to additional costs of between $130,000 and $260,000 annually.

The committee also recommended that the Ontario Cochlear Implant Program discuss realistic expectations of clinical outcomes with patients when determining their candidacy, ensure equitable access for Ontarians living outside large cities, and explore the feasibility of developing a program for children in Ontario.

Public Comment: Held April 17 to May 7, 2019.

Decision Determinants for Auditory Brainstem Implantation in Adults With Neurofibromatosis 2

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, ABI allows any degree of improvement in sound recognition (GRADE: High), in speech perception in conjunction with lip-reading (GRADE: High), and provides subjective benefits of hearing (GRADE: High). It likely allows any degree of improvement in speech perception when used alone (GRADE: Moderate) and may improve quality of life in adults with NF2 (GRADE: Low).
	Safety How safe is the health technology/intervention likely to be?	The ABI procedure is reasonably safe. The rate of cerebrospinal fluid leak, infection, and meningitis in adults with NF2 was 3% to 15%, 10% to 13%, and 2% to 3%, respectively.
	Burden of illness What is the likely size of the burden of illness pertaining to this health technology/intervention?	It is estimated that fewer than 5 adults per year will need ABI in Ontario.
	Need How large is the need for this health technology/intervention?	ABI is the only treatment option to restore partial functional hearing for adults with NF2 who are not candidates for cochlear implantation.
Consistency with expected patient, societal, and ethical values[a] How likely is adoption of the health technology/intervention to be congruent with patient, societal, and ethical values?	**Patient values** How likely is the adoption of the health technology/intervention to be congruent with expected patient values?	Participants reported that ABI restored some level of hearing, resulting in better quality of life and improved activities of daily living.
	Societal values How likely is adoption of the health technology/intervention to be congruent with expected societal values?	Because participants report feeling that ABI improves overall health and reduces the impact of hearing loss, publicly funding ABI is likely congruent with societal values of independence and empowerment. Given the extremely small population in which this technology will be used, paying a relatively high price per patient is likely consistent with societal values.
	Ethical values How likely is adoption of the health technology/intervention to be congruent with expected ethical values?	Because ABI helps reduce the impact of hearing loss, publicly funding ABI is likely to be congruent with the ethical values of autonomy, justice, non-maleficence, and beneficence.
Cost-effectiveness How efficient is the health technology/ intervention likely to be?	**Economic evaluation** How efficient is the health technology/intervention likely to be?	We did not identify any published economic studies on ABI or any utilities for people with ABI. In addition, the outcomes identified in our clinical evidence review were difficult to translate into measures appropriate for health economic modelling. Therefore, we were unable to determine the cost-effectiveness of ABI in Ontario.
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 estimated annual net budget impact of publicly funding ABI for 1 to 3 adults with NF2 in Ontario would range from $65,000 to $200,000 over the next 5 y.
	Organizational feasibility How organizationally feasible is it to implement the health technology/intervention?	The infrastructure is in place to make implementation feasible.

Abbreviations: ABI, auditory brainstem implantation; GRADE, Grading of Recommendations Assessment, Development, and Evaluation; NF2, neurofibromatosis 2.
[a]The anticipated or assumed common patient, societal, and ethical 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 patient, societal, and ethical values, the expected values are considered.

Decision Determinants for Auditory Brainstem Implantation in Adults With Severe Inner Ear Abnormalities

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, ABI likely allows any degree of improvement in sound recognition (GRADE: Moderate) and in speech perception when used alone (GRADE: Moderate). It may allow any degree of improvement in speech perception when used in conjunction with lip-reading (GRADE: Low), provide subjective benefits of hearing (GRADE: Low), and improve quality of life (GRADE: Low) in adults with severe inner ear abnormalities.
	Safety How safe is the health technology/intervention likely to be?	The ABI procedure is reasonably safe. The rate of cerebrospinal fluid leak, infection, and meningitis in adults with severe inner ear abnormalities was 2%, 2% to 4%, and 4%, respectively.
	Burden of illness What is the likely size of the burden of illness pertaining to this health technology/intervention?	It is estimated that fewer than 5 adults per year will need ABI in Ontario.
	Need How large is the need for this health technology/intervention?	ABI is the only treatment option to restore partial functional hearing for adults with severe inner ear abnormalities who are not candidates for cochlear implantation.
Consistency with expected patient, societal, and ethical values[a] How likely is adoption of the health technology/intervention to be congruent with patient, societal, and ethical values?	**Patient values** How likely is the adoption of the health technology/intervention to be congruent with expected patient values?	Participants reported that ABI restored some level of hearing, resulting in better quality of life and improved activities of daily living.
	Societal values How likely is adoption of the health technology/intervention to be congruent with expected societal values?	Because participants reported feeling that ABI improves overall health and reduces the impact of hearing loss, publicly funding ABI is likely to be consistent with societal values of independence and empowerment. Given the extremely small population in which this technology will be used, paying a relatively high price per patient is likely consistent with societal values.
	Ethical values How likely is adoption of the health technology/intervention to be congruent with expected ethical values?	Because ABI helps reduce the impact of hearing loss, publicly funding ABI is likely to be congruent with the ethical values of autonomy, justice, non-maleficence, and beneficence.
Cost-effectiveness How efficient is the health technology/ intervention likely to be?	**Economic evaluation** How efficient is the health technology/intervention likely to be?	We did not identify any published economic studies on ABI or any utilities for people with ABI. In addition, the outcomes identified in our clinical evidence review were difficult to translate into measures appropriate for health economic modelling. Therefore, we were unable to determine the cost-effectiveness of ABI in Ontario.
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 estimated annual net budget impact of publicly funding ABI for one adult with bilateral deafness due to severe inner ear abnormalities in Ontario would be around $65,000 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: ABI, auditory brainstem implantation; GRADE, Grading of Recommendations Assessment, Development, and Evaluation.
[a]The anticipated or assumed common patient, societal, and ethical 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 patient, societal, and ethical values, the expected values are considered.

REFERENCE

(1) Ontario Health (Quality). Auditory brainstem implantation for adults with neurofibromatosis 2 or severe inner ear abnormalities: a health technology assessment. Ont Health Technol Assess Ser [Internet]. 2020 Mar;20(4): 1–85. Available from: https://www.hqontario.ca/evidence-to-improve-care/health-technology-assessment/reviews-and-recommendations/auditory-brainstem-implantation-for-adults-with-neurofibromatosis-2-or-severe-inner-ear-abnormalities

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