

Health Quality Ontario

The provincial advisor on the quality of health care in Ontario

Retinal Prosthesis System for Advanced Retinitis Pigmentosa: OHTAC Recommendation

ONTARIO HEALTH TECHNOLOGY ADVISORY COMMITTEE RECOMMENDATIONS

- OHTAC recommends against publicly funding the Argus II retinal prosthesis system for advanced retinitis pigmentosa.
- OHTAC recommends that Health Quality Ontario review the evidence for retinal prosthesis systems in 1 year to re-evaluate the clinical effectiveness.

BACKGROUND

Retinitis pigmentosa is a group of hereditary outer retinal degenerative diseases that involves the progressive breakdown and loss of photoreceptors. It can result in profound vision loss. A surgical implantable device is now available to potentially improve functional vision in patients with bare or no light perception as a result of advanced retinitis pigmentosa. The Argus II Retinal Prosthesis System is the only retinal prosthesis licenced by Health Canada.

SUMMARY OF FINDINGS

The health technology assessment completed by Health Quality Ontario is available separately.¹ A completed decision determinants framework is included in this report.

The key findings of the health technology assessment were:

- Based on available evidence of moderate quality, the Argus II retinal prosthesis system improved visual function, functional outcomes and quality of life in patients with severe vision loss from advanced retinitis pigmentosa at 3-year follow-up
- There was a trend toward an improved safety profile of the Argus II retinal prosthesis system as the technology evolves and the surgeons refine their skills
- The Argus II retinal prosthesis system would be cost-effective only if the “willingness to pay” were more than \$207,616 per quality-adjusted life year (QALY) gained
- The budget impact of funding the Argus II retinal prosthesis system at one Ontario centre would range from \$800,404 to \$837,596 over the next 5 years
- Patients described the Argus II retinal prosthesis system as enabling perception of light/dark and shapes/objects, having a positive impact on quality of life

OHTAC DELIBERATIONS

The Ontario Health Technology Advisory Committee (OHTAC) accepted the findings of the health technology assessment.

OHTAC recognized that the Argus II retinal prosthesis system is a rapidly evolving technology. However, despite the moderate quality of the available evidence on its effectiveness and safety at 3-year follow-up, OHTAC found that there were insufficient long-term patient data on the magnitude of improvement conferred to support public funding at present. Given the ongoing development of the technology, OHTAC agreed to review the topic again when more published evidence becomes available.

Decision Determinants for the Retinal Prosthesis System for Advanced Retinitis Pigmentosa

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?	The following visual outcomes were significantly improved when the Argus II retinal prosthesis system was on vs. off (GRADE moderate): object localization; direction of motion; grating visual acuity; orientation and mobility; eye-hand coordination; spatial resolution At 1 year after implantation, there had been 18 serious adverse events in 10 out of 30 patients Approximately 4,000 patients in Ontario have some form of retinitis pigmentosa. Based on expert opinion, approximately 100–300 patients would be eligible for the Argus II retinal prosthesis system in Ontario The Argus II retinal prosthesis system is the only currently available implantable device that has been shown to improve visual function in patients with severe visual loss from advanced retinitis pigmentosa
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 the adoption of the health technology/intervention to be congruent with expected societal values? Ethical values How likely is the adoption of the health technology/intervention to be congruent with expected ethical values?	People with retinitis pigmentosa have a good quality of life, but are significantly impacted by their condition as a result of accessibility issues Argus II improves the quality of life of people with retinitis pigmentosa by providing some of the fundamental elements of sight
Value for money How efficient is the health technology likely to be?	Economic evaluation How efficient is the health technology/intervention likely to be?	Argus II would be cost-effective only if the willingness to pay were greater than \$207,616 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? Organizational feasibility How organizationally feasible is it to implement the health technology/intervention?	The University Health Network has assembled a specialized team capable of implanting the Argus II retinal prosthesis system and providing the requisite screening, follow-up, visual training and rehabilitation

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.

REFERENCE

- (1) Health Quality Ontario. Retinal prosthesis system for advanced retinitis pigmentosa: a health technology assessment. Ont Health Technol Assess Ser [Internet]. 2016 June;16(14):1-63. Available from: <http://www.hqontario.ca/evidence-to-improve-care/journal-ontario-health-technology-assessment-series>.

Permission Requests: All inquiries regarding permission to reproduce any content in Health Quality Ontario reports should be directed to EvidenceInfo@hqontario.ca.

About Health Quality Ontario

About OHTAC

How to Obtain OHTAC Recommendation Reports From Health Quality Ontario

Health Quality Ontario
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

© Queen's Printer for Ontario, 2016

Citation

Health Quality Ontario. Retinal prosthesis system for advanced retinitis pigmentosa: OHTAC recommendation [Internet]. Toronto (ON): Queen's Printer for Ontario; 2016 June; 4 pp. Available from: <http://www.hqontario.ca/evidence-to-improve-care/recommendations-and-reports/OHTAC/retinal-prosthesis>.