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. 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

<table>
<thead>
<tr>
<th>Decision Criteria</th>
<th>Subcriteria</th>
<th>Decision Determinants Considerations</th>
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<tbody>
<tr>
<td><strong>Overall clinical benefit</strong></td>
<td>Effectiveness</td>
<td>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</td>
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<td>Safety</td>
<td>At 1 year after implantation, there had been 18 serious adverse events in 10 out of 30 patients</td>
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<td>Burden of illness</td>
<td>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</td>
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<td>Need</td>
<td>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</td>
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<td><strong>Consistency with expected societal and ethical values</strong></td>
<td>Societal values</td>
<td>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</td>
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<td>Ethical values</td>
<td>The 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.</td>
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<td><strong>Value for money</strong></td>
<td>Economic evaluation</td>
<td>Argus II would be cost-effective only if the willingness to pay were greater than $207,616 per QALY</td>
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<td><strong>Feasibility of adoption into health system</strong></td>
<td>Economic feasibility</td>
<td>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</td>
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<td>Organizational feasibility</td>
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Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; QALY, quality-adjusted life-year.

*The 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


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About OHTAC

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