Clinical Commissioning Policy Proposition: Argus II retinal prosthesis

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1 Executive Summary

Equality Statement

NHS England has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. NHS England is committed to fulfilling this duty as to equality of access and to avoiding unlawful discrimination on the grounds of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, NHS England will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which NHS England is responsible, including policy development, review and implementation.

Plain Language Summary

The Argus II retinal prosthesis system consists of a video camera mounted on a pair of spectacles that communicates wirelessly with an implant placed surgically in the retina. The system stimulates the retina electronically, which the brain is able to interpret as patterns of light.

The system was considered by the Rare Diseases Advisory Group (RDAG) which recommended that further clinical evidence was required before the system could be considered for routine commissioning by NHS England. RDAG recommended that an application be made to the ‘Commissioning through Evaluation’ programme for the system.

The Argus II retinal prosthesis system is not routinely commissioned by NHS England.

2 Introduction

This document describes the evidence that has been considered by NHS England in formulating a proposal to not routinely commission the Argus II retinal prosthesis system.

For the purpose of consultation NHS England invites views on the evidence and other information that has been taken into account as described in this policy proposition.

A final decision as to whether the Argus II retinal prosthesis system will be routinely commissioned is planned to be made by NHS England by June 2016 following a recommendation from the Clinical Priorities Advisory Group.

3 Proposed Intervention and Clinical Indication

Retinitis pigmentosa is the encompassing term for a group of degenerative eye conditions that cause progressive loss of retinal photoreceptors. The disease is often inherited. Patients initially experience ring scotoma and night vision problems which, in most cases, slowly progress and lead to the loss of all peripheral vision. Central vision is usually preserved until late stages of the disease, but can be lost earlier with severe disease.

Conservative treatments are aimed at early identification and treatment of complications such as cataract or macular oedema. Some newer treatments aim to slow the progression of the condition. Surgical treatments are being developed, including subretinal and epiretinal prostheses, as well as optic nerve implants to restore basic sight.

Insertion of an epiretinal prosthesis aims to restore perception of light, movement and shapes by surgically implanting an array of electrodes onto the retina. The electrodes emit electrical impulses to stimulate the sensory neurons of surviving

retinal cells, which send visual information to the brain.
The Argus II Retinal Prosthesis System consists of a video camera mounted on a pair of spectacles that communicates wirelessly with an implant placed surgically in the retina. It is intended to provide electrical stimulation to the retina to induce visual perception in patients with inherited blindness as a result of retinitis pigmentosa. Retinitis Pigmentosa (RP) is the leading cause of inherited blindness.

It is estimated (from studies of patients with Retinitis Pigmentosa) that 20% of all RP patients have profound sight loss (less than 2.0 LogMAR) and are suitable for Argus II. There is currently no NHS treatment for patients with end stage RP.

4 Definitions

The Argus II retinal prosthesis system (RPS) consists of a video camera mounted on a pair of spectacles that communicates wirelessly with an implant placed surgically in the retina. The system stimulates the retina electrically with patterns that the brain is able to interpret as patterns of light.

Retinitis pigmentosa (RP) is the leading cause of inherited blindness, affecting 1 in 3,500 people.

5 Aims and Objectives

This policy proposition aims to set out the proposal for the non-routine commissioning of this intervention. The NICE Interventional procedure guidance (519) for Insertion of an epiretinal prosthesis for retinitis pigmentosa, issued June 2015 (https://www.nice.org.uk/guidance/ipg519) made the following recommendations:

Current evidence on the safety and efficacy of insertion of an epiretinal prosthesis for retinitis pigmentosa is limited in quality and quantity. Therefore, this procedure should only be used in the context of research.

NICE encourages further research on this technology. Outcomes should include the impact on quality of life and activities of day-to-day living, and durability of implants.

NICE may update the guidance on publication of further evidence.

6 Epidemiology and Needs Assessment

Retinitis pigmentosa (RP) is the leading cause of inherited blindness, affecting 1 in 3,500 people. The annual incidence of 6 per million suggests a total of 318 new cases in England per year.

It is estimated (from studies of patients with RP) that 20% of all RP patients have profound sight loss (less than 2.0 LogMAR) and are suitable for Argus II. It is estimated that approximately 100 referrals would be received annually but, due to eligibility, selection criteria for the procedure and patient choice, approximately 10 in England per annum would undergo the procedure.

There is currently no NHS treatment for patients with end stage RP.

7 Evidence Base

NHS England has concluded that there is not sufficient evidence to support a proposal for the routine commissioning of this treatment for the indication.

The clinical benefit associated with the Argus II RPS has been extensively studied in an orphan population of thirty patients suffering from advanced RP. There has been an international trial of the Argus II retinal prosthesis system (Argus II RPS) and 30 of these systems have been implanted worldwide. Of these, 10 were carried out in the UK – seven at Moorfields Eye Hospital (the first in April 2008) and three in Manchester.

All patients have been followed for a minimum of twelve months with the majority of patients having been followed for over 12 months (median = 22 months). The implant duration over all patients is in excess of 45 patient-years. The Argus II RPS is intended to provide electrical stimulation to the retina to induce visual perception in blind patients. At the most basic level, this performance was clearly

demonstrated. All 30 patients perceived visual phosphenes (the experience of seeing light without light actually entering the eye) when stimulated with the Argus II System.

At a higher level, the visual performance showed a clear measurable benefit for most patients when the system was activated. The objective measure of performance was variable across the 30 patients, and can be quantified in three groups of low vision tests of increasing difficulty.

In the first group, 29 out of 30 subjects (97%) successfully achieved localisation tasks. In the second group, 16 out of 30 subjects (57%) successfully achieved motion discrimination tasks, in addition to the localisation tasks. In the third group 7 out of 30 subjects (23%) achieved a repeatable acuity score with a grating visual acuity test, again in addition to improvements in both localisation and motion discrimination tasks.

This showed that, on average, patients with the Argus II RPS activated had an improved visual acuity from Bare Light Perception to at least Hand Motion detection, and possibly Counting Fingers, when the RPS was active. At baseline, or when the system was inactive, their visual acuity did not exceed Bare Light Perception. This was an important outcome since it was the first example of a device – or any therapy – that has demonstrated improved visual function in the extremely low-vision range (No Light Perception to Hand Motion detection) in this patient population.

The significant improvements in visual function corresponded to similar achievements in orientation and mobility, which was one measure of clinical utility. Consistent with how patients scored on the battery of low-vision tests, the “door” and “line” tests confirmed that patients were significantly better ($p<0.05$) at touching a door or walking on a white line when the System was ON versus when it was OFF. These data correctly correlated improvements in visual function with “real world” activities. This again was a significant achievement for patients who were bare light perception before implantation.

This benefit also translated into the patients' day to day lives. The activities of daily living survey (Massof Activity Inventory) was administered at baseline and 6, 12, 18, 24 and 36 months after starting to use the Argus II RPS. It showed that daily living activities became easier, and showed a continuing improvement in the main score - "Goals" starting at 6 months, becoming significant at 12 months, further improving to a very significant +0.5 logit for the cohort at 24 months. This Inventory also allowed break-down of the score in four sub-domains of activity (Visual Information, Visual Motor, Orientation- Mobility, and Reading). It showed that most of the improvement was gained on Visual Motor tasks (e.g. activities like avoiding cutting oneself, avoiding burning oneself, transferring liquids, etc). The three other sub-domains showed smaller improvements, at the limit of significance.

This improvement on functional vision was a large effect and approximately twice the size of a clinical meaningful change (3 ETDRS lines – 0.3 LogMAR), based on data collected on a benchmark of 3,000 visually challenged subjects with variable visual impairment. Translating this improvement in utility values obtained a range from 0.12 to 0.22.

This result was also confirmed by the results in utility values that may be derived from the visual acuity results. If considered that 23% of subjects achieved counting fingers or better vision (better than 2.9 LogMAR visual acuity), while the remainder achieved only hand motion or light perception vision with the Argus II, a utility value of 0.13 can be estimated. It has also been estimated that the average expected remaining life of patients eligible for the Argus II system would be 24 years. With this information the increase in Quality Adjusted Life Years afforded by the Argus II RPS intervention can be determined.

The QALY is at minimum 3.1 based on visual function gained by the Argus II RPS, while the QALY-based functional vision benefit ranges between 2.9 and 5.3.

This is likely to give a conservative estimate of the magnitude in quality of life improvements provided by the Argus II RPS: firstly because such improvements are

underestimated given the larger functional benefits of vision gains at the very low level of vision range; and secondly because the Argus II RPS is designed to be upgraded with new visual processing software that will further improve the functional benefits.

The cost effectiveness of the treatment based on per patient cost (£93,734) gives £26,133 per QALY. This is in a similar range to currently approved treatments in ophthalmology, but indicated for an orphan population.

The device has been safely and consistently implanted in patients' eyes and functions to give patients some improved stable vision. It is the only treatment that has demonstrated long term safety and performance record with over 45 patient-years of experience.

8 Proposed Criteria for Commissioning

NHS England does not routinely commission the Argus II retinal prosthesis system.

9 Proposed Patient Pathway

Not applicable.

10 Proposed Governance Arrangements

Not applicable.

11 Proposed Mechanism for Funding

NHS England will not routinely fund the Argus II retinal prosthesis system.

12 Proposed Audit Requirements

Not applicable.

13 Documents That Have Informed This Policy Proposition

Not applicable.

14 Date of Review

This document will lapse upon publication by NHS England of a clinical commissioning policy for the proposed intervention that confirms whether it is routinely or non-routinely commissioned (expected by May 2016).

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