Clinical Commissioning Policy: Argus II retinal prosthesis for retinitis pigmentosa

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Contact Details for further information	england.specialisedcommissioning@nhs.net

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Clinical Commissioning Policy: Argus II retinal prosthesis for retinitis pigmentosa

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Contents

Policy Statement

NHS England will not routinely commission the argus II prosthesis system for retinal pigmentosa in accordance with the criteria outlined in this document. In creating this policy NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources. This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality Statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

Plain Language Summary

About retinitis pigmentosa

Retinitis pigmentosa is the name for a group of eye conditions. The conditions are often inherited and cause loss of sight that gets worse over time:

- Patients may first have an area of lost vision and night vision problems.
- This then slowly leads to the loss of all vision around the centre (called 'peripheral' vision).
- Central vision is usually kept until late stages - but can be lost earlier if the condition is severe.

About current treatments

Treatments are aimed at early identification and treatment of complications such as cataract (a clouding of the lens of the eye) or macular oedema (swelling at the back of the eye).

About the new treatment

The Argus II retinal prosthesis system is an artificial system that can be used help restore vision:

- A video camera is fitted to a pair of glasses (spectacles).
- An implant is placed surgically in the back of the eye where the light-sensitive cells are located (called the 'retina').
- The camera then sends messages wirelessly to the implant - this stimulates the retina electronically.
- The brain is able to interpret the messages as patterns of light.

What we decided

NHS England has carefully reviewed the evidence to treat retinitis pigmentosa with the Argus II retinal prosthesis system. Based on the recommendation by the Rare Diseases Advisory Group (RDAG), an application will be made for further evaluation before making the treatment available at this time.

1 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.

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 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.

2 Definitions

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

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.

3 Aims and Objectives

This policy proposition aims to define NHS England's commissioning position on Argus II retinal prosthesis as part of the treatment pathway for adult patients with end stage retinitis pigmentosa.

The objective is to ensure commissioning takes account of current evidence on the safety and efficacy of insertion of epiretinal prosthesis (Argus II) for retinitis pigmentosa.

4 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 may 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 people per annum would be eligible for the procedure.

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

5 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 Argus II study group has studied a cohort of 30 patients and published several papers. A total of 29 of 30 subjects had functioning Argus II Systems implants 3 years after implantation. Eleven subjects experienced a total of 23 serious device- or surgery-related adverse events. All were treated with standard ophthalmic care. As a

group, subjects performed better with the system on than off on all visual function tests and functional vision assessments but there is variation between patients and between tests.

In the real world assessment (FLORA) three years after implantation, 65% of 23 patients were graded ‘positive’ or ‘mildly positive’ (i.e. usually subjects who self-reported functional benefits that were not supported by assessors’ observations)’.

All patients had 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.

NICE Interventional procedure guidance (519) for Insertion of epiretinal prosthesis for retinitis pigmentosa (June 2015) https://www.nice.org.uk/guidance/ipg519 identified that the current evidence on the safety and efficacy of insertion of epiretinal prosthesis for retinitis pigmentosa is limited in quality and quantity, recommending that this procedure should only be used in the context of research. NICE recommended further research on this technology, including outcomes on the impact on quality of life and activities of day-to-day living, and durability of implants.

NICE Interventional procedure guidance (519) noted that insertion of an epiretinal prosthesis for retinitis pigmentosa is intended for patients with end-stage disease who have no useful sight and no other treatment options. It recognised that even minor improvements in vision may help these patients, but it wanted evidence that any changes in metrics of vision result in improvements in quality of life and activities of daily living.

In addition, it was recognised that the technology of epiretinal prostheses and related devices is evolving and that further developments may result in substantial changes to outcomes which may influence patient selection in the future. Careful patient selection, including psychological counselling to ensure that patients have realistic expectations was highlighted.

6 Documents which have informed this Policy

National Institute for Health and Care Excellence Interventional procedure guidance 519. Insertion of epiretinal prosthesis for retinitis pigmentosa. June 2015. https://www.nice.org.uk/guidance/ipg519

7 Date of Review

This document will be reviewed when information is received which indicates that the policy requires revision.

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