Medical Policy Manual   Surgery, Policy No. 194

Retinal Prosthesis

Effective: September 1, 2023

Next Review: May 2024
Last Review: July 2023

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

A retinal prosthesis is a device that replaces lost photoreceptor function by transmitting computer-processed video images to an array of electrodes or via light sensors placed on the retinal surface. This device may also be referred to as an artificial retina.

MEDICAL POLICY CRITERIA

Subconjunctival retinal prostheses are considered **investigational** for all indications.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

None

BACKGROUND

A retinal prosthesis is a device that replaces lost photoreceptor function by transmitting computer processed video images to an array of electrodes or via light sensors placed on the retinal surface. This device may also be referred to as an artificial retina.

There is ongoing research interest in developing an artificial retina that could potentially restore sight to patients with blindness secondary to retinal diseases, such as retinitis pigmentosa (RP), hereditary retinal degeneration, and some forms of age-related macular degeneration. As currently investigated, the artificial retina consists of a small external video camera, held on eyeglass frames, that captures images then processed by an externally worn microcomputer. These signals are transmitted to an electrode array implanted in the back of the eye, which in turn stimulates the optic nerve.

REGULATORY STATUS

In February 2013, Second Sight received humanitarian device exemption (HDE) approval from the U.S. Food and Drug Administration (FDA) for use of their second-generation Argus® device, the Argus® II Retinal Prosthesis System, in select adult patients with severe retinitis pigmentosa. A miniature video camera housed in glasses frames sends video to a small patient-worn processing unit. The processed signals are sent to a 60-electrode array which stimulates undamaged retinal cells that can transmit the visual information to the optic nerve. FDA product code: NBF.

No other devices have received full FDA approval. Other devices in development include:

The Argus™ I, formerly called the Argus 16, was the first-generation retinal prosthesis which included a 16-electrode device. Second Sight Medical Products and the National Institutes of Health are partnering sponsors of two investigational new device (IDE) trials that have been approved by the FDA to study the first and second generation Argus devices. A third generation model with 200 electrodes is in the preclinical testing phase of development.

The Boston Retinal Implant (Retinal Implant Research Group) uses an external camera mounted on a pair of glasses and a 100-electrode array. The image obtained by the external camera is translated into an electromagnetic signal transmitted from the external primary data coil mounted on a pair of glasses to the implanted secondary data coil attached to the cornea. Most of the volume of the implant lies outside the eye, with transscleral cables connected to a subretinal electrode array. The Retinal Implant Project is a joint effort of MIT, the Massachusetts Eye and Ear Infirmary, the VA Boston Healthcare System, and the NanoScale Science & Technology Facility at Cornell University.

The Learning Retinal Implant (Intelligent Medical Implants AG), which uses an extraocular retinal encoder with 100 to 1,000 individually tunable spatiotemporal filters on the frame of a pair of glasses. The processing of the retinal encoder simulates the filtering operations performed by the ganglion cell. The output is transmitted via a wireless signal and energy transmission system to an implanted retinal stimulator.

The EPIRET3 retinal implant (Philipps-University Marburg), a wireless system that consists of a semiconductor camera in glasses frames and a transmitter coil outside the eye which sends electromagnetic signals to a receiver coil in the anterior vitreous (similar to an intraocular lens), which passes them on to a receiver microchip. A stimulator chip then generates the stimulation pulses and activates a selection of 25 electrodes placed on the epiretinal surface via a connecting microcable.

Intelligent Retinal Implant System (IRIS, Pixium Vision) uses an external camera that is integrated with a pair of glasses and linked by wire to a pocket computer. Receiver electronics

connect via a scleral tunnel to an electrode array on the surface of the retina. Pixium Vision is also developing PRIMA, which uses a subretinal implant.

The Microelectrode-STS (suprachoroidal-transretinal stimulation) system (Osaka University Graduate School of Medicine) places the 9-electrode retinal prosthesis in a scleral pocket with a reference electrode in the vitreous cavity. A video camera is used to detect a visual object. A proposed advantage of the STS prosthesis over epi- or subretinal prostheses is the safety of the surgical procedure, since the electrodes do not touch the retina. However, because the electrodes are at a greater distance from the retina, the resolution of the image may be lower than other devices.

The Tubingen retinal implant (University of Tubingen) is an externally powered subretinally implanted multiphotodiode array, with 1,500 elements, that senses incident light and applies a constant-voltage signal at the respective electrode. The multiphotodiode array transforms visual scenes into corresponding spatial patterns (38 x 40 pixels) of light intensity-dependent electric stimulation pulses. The implant also contains 16 hard-wired electrodes for light-independent direct-stimulation experiments. A second generation device (Alpha IMS) is now produced by Retina Implant AG (Germany).

EVIDENCE SUMMARY

The most clinically relevant outcome for the use of a retinal prosthesis is partial restoration of vision sufficient to significantly improve functioning and quality of life in patients with blindness due to retinal disease. Thus, assessment of the safety and effectiveness of retinal prostheses requires evidence from sufficiently large prospective, studies that evaluate the following:

- Ability of the device to restore sight in patients with blindness secondary to retinal diseases;
- Durability of any beneficial treatment effects; and
- Safety, including complications related to surgical implantation of the device.

Literature on various subconjunctival retinal prostheses is limited to small case series (n<50) mainly focusing on device safety or feasibility.

ARGUS I AND ARGUS II

The Agency for Healthcare Research and Quality (AHRQ) published a technology assessment in 2016 that included a systematic review of the literature on retinal prostheses.[1] Reviewers included studies on the Argus II, as well as other retinal prostheses. Outcomes of interest were visual function, visual acuity, laboratory-based visual performance measures, day-to-day function, and quality of life. In their qualitative summary of the literature on retinal prostheses, reviewers concluded that the strength of evidence was insufficient for all outcomes.

da Cruz (2016) reported three- and five-year safety and performance outcomes for 30 patients with the Argus II.[2] Primary outcome was safety and secondary outcome was visual performance. One adverse event was reported between three and five years after implant. The authors stated the Argus II is safe and effective for patients with retinal pigmentosa.

Dagnelie (2016) evaluated performance on three functional tasks in 28 of 40 study participants who had been implanted with the device between six months and three years previously.[3] The three tasks were intended to have real-world value. Performance was compared with the

retinal prosthesis device on and off. Task one was sock sorting, sorting a mixed pile of socks into piles of pure white, pure black and grey socks. The sock task was performed four times; with the device on versus off and the surface of the table covered in a known color of cloth, and on versus off on a bare table. Task two was sidewalk tracking. Subjects were asked to walk along three six-meter stretches of sidewalk (straight, curved, or angled) within one meter of the edge without stepping off the pavement. No canes or other mobility aids were used. The task was scored by the number of times the subject moved out of bounds (i.e. moved off the pavement or more than one meter from the edge). Task three was walking direction discrimination. Subjects were seated and markers were placed 10 feet away in either direction. Initially a tester was placed at each marker. During the test, every 15 seconds there was an audible beep and a tester passed in front of the subject who guessed which direction they were walking.

On all three tasks, subjects performed significantly better with the device on versus off (p<0.05). (For the sock sorting task, results were presented in figures and precise numbers/percentages were not available). With a cloth-covered table, subjects sorted approximately 70% of the socks correctly with the device on and 30% correct with the device off. With a bare table, subjects sorted approximately 50% of socks correctly with the device and 30% with the device off. For the sidewalk task, subjects walked out of bounds a mean of 6.85 times with the device off and a mean of 4.93 times with the device on. For the walking direction discrimination task, 15 (56%) of 27 subjects performed significantly better than chance with the device on and four performed significantly better than chance with the device off. Although statistically significant, clinical significance of the differences in performance on the three tasks is more uncertain.

Ahuja (2010) published findings from a small feasibility study of the Argus II (a 60-electrode device).[4] Blind subjects (with some level of bare light perception) were implanted with the Argus II prosthesis. High-contrast square stimuli were displayed in random locations on a touch screen located in front of the subjects. The subjects were instructed to locate and touch the square center with the system turned on and then turned off, and the positions were recorded. Twenty-six of 27 (96%) subjects showed a significant improvement in accuracy and 93% (25/27) showed a significant improvement in repeatability with the system on compared with the system off (p<0.05).

Interim (minimum six-month) results from the Argus II feasibility trial were reported by Humayun in 2012.[5] Devices were individually programmed and the subjects received training with the device for activities of daily living. Evaluations were scheduled for day one, weeks one, two, and four, and months three, six, nine, 12, 18, 24, 30, and 36. There were three types of visual acuity tasks using a computer and two types of real-world utility tests. Performance on three of the computer tasks (square localization, direction of motion, and grating discrimination) was improved with the system on compared with off. With the system on, subjects had a 54% success rate in finding a door compared to 27% success with the device off, and had 68% success in following a white line on a dark floor compared to 23% success with the device off. Although all subjects could perceive light when the system was on, the Argus II did not affect full-field light perception. Seventeen serious adverse events that were considered to be device or surgery related occurred in 30% of subjects, and one device was explanted. Most of the serious adverse events occurred earlier in the study before the device and surgical procedures were modified.

Gerushat (2016) reported functional outcomes at three years.[6] Functional ability was assessed using the Functional Low-Vision Observer Rated Assessment (FLORA) instrument, which is an observer-rated assessment of the ability to complete common activities. The instrument assesses 35 tasks in four domains (Visual Orientation, Mobility, Daily Life, and Interaction With Others). Tasks were performed with the device in the on and off positions. Twenty-six (87%) of the 30 enrolled patients were included in the analysis at a mean of 36 months (range, 18-44 months) after device implantation. Twenty-four (69%) of tasks had significantly better scores with the device turned on than off. Two (6%) tasks were significantly worse with the device turned on, and the remaining nine (26%) tasks showed no significant difference with the device on or off.

Long-term safety results in 29 of the 30 patients included in the Argus II study were reported by Ho (2015).[7] At three years postimplantation, 23 serious adverse events (SAEs) were reported in 11 patients. The most common SAEs were conjunctival erosion (n=4), hypotony (n=4), conjunctival dehiscence (n=3), and presumed endophthalmitis (n=3).

LEARNING RETINA IMPLANT

No studies were identified in the peer-reviewed literature.

EPIRET3

Initial results from the EPIRET3 were reported in six legally blind subjects with retinitis pigmentosa in 2011.[8] The device was activated on three occasions to record visual sensations and then removed at day 28, per the study protocol. During the one-hour sessions the current amplitude, pulse duration, pulse frequency, number of pulses per stimulus, and stimulated electrodes were varied. Although the same stimulation patterns were used, they elicited different sensations in the six subjects. Most visual sensations were described as bright colors such as red, green, blue and yellow, but some subjects also reported seeing dark or black patterns. Some of the subjects reported seeing geometric patterns that corresponded to different stimulation patterns and/or could discriminate the stimulus orientation.

SUPRACHOROIDAL-TRANSRETINAL STIMULATION (STS) SYSTEM

Ayton (2014) reported on the outcomes of suprachoroidal implantation of a retinal prosthesis in three subjects with profound visual loss due to retinitis pigmentosa.[9] At 12 months' follow-up, the intraocular array remained stable. Light localization was significantly improved compared to chance in all three subjects with correct response rates between 66.6% and 97.5%. Visual acuity and vision processing were also significantly improved compared to "system off" scores. Adverse events included one infection of the percutaneous connector occurred and was treated successfully with IV antibiotics without disruption or explantation of the device. In the future, this percutaneous connector will be fully implantable and wireless, which is expected to significantly decrease the infection risk. All three subjects had transient subretinal and suprachoroidal hemorrhage 3-4 days postoperatively, causing a small fibrovascular scar in one patient. The authors recommended caution in interpreting the visual acuity scores of the Landolt C optotype recognition tests because they only provide estimates of acuity and cannot be directly compared with the acuity tests in normally sighted individuals.

In 2011, functional testing of the STS system was reported in two subjects with retinitis pigmentosa.[10] Visual acuity consisted of light perception; an eye mask was placed over both eyes during the testing. Both subjects performed better than chance for object detection and

object discrimination using a video camera. One patient scored better than chance in detecting the direction of motion of an object and grasping objects. The device was removed 5-7 weeks after implantation.

TUBINGEN SUBRETINAL IMPLANT

The ability to recognize complex spatial percepts with subretinal implantation of a microchip was reported in 2011 in three subjects with hereditary retinal dystrophy (retinitis pigmentosa and choroideraemia) who received a Tubingen subretinal implant.[11] The subjects, who previously had only limited light perception, could locate bright objects on a dark table. One subject could correctly describe and name objects like a fork or knife on a table, geometric patterns, different kinds of fruit, and to read large simplified letters. The authors concluded that while this study provides proof-of-concept, further development is needed to provide long-term stability, improve contrast and spatial resolution, and increase field size through implantation of multiple chips.

PRACTICE GUIDELINE SUMMARY

No clinical practice guidelines were identified that address the use of retinal prostheses.

SUMMARY

There is not enough research to show that subconjunctival retinal prosthesis improves health outcomes for people with lost photoreceptor function or any indication. No clinical practice guidelines, based on research recommend the use of retinal prostheses for any indication. Therefore, the use of retinal prostheses is considered investigational.

REFERENCES

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CODES

Codes	Number	Description
CPT	0100T	Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy
	0472T	Device evaluation, interrogation, and initial programming of intraocular retinal electrode array (eg, retinal prosthesis), in person, with iterative adjustment of the implantable device to test functionality, select optimal permanent programmed values with analysis, including visual training, with review and report by a qualified health care professional
	0473T	Device evaluation and interrogation of intra-ocular retinal electrode array (eg, retinal prosthesis), in person, including reprogramming and visual training, when performed, with review and report by a qualified health care professional
HCPCS	~~C1841~~	~~Retinal prosthesis, includes all internal and external components~~ (Deleted 01/01/2023)
	~~C1842~~	~~Retinal prosthesis, includes all internal and external components; add-on to C1841~~ (Deleted 01/01/2023)
	L8608	Miscellaneous external component, supply or accessory for use with the argus ii retinal prosthesis system

Date of Origin: *July 2005*