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 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 are able to transmit the visual information to the optic nerve.

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 2 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 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.

- 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).

MEDICAL POLICY CRITERIA

Subconjunctival retinal prostheses are considered investigational for all indications.

SCIENTIFIC EVIDENCE

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, long-term clinical trials that study the following:

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

**Literature Appraisal**

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**

- Second Sight Medical Products reported that the Argus I (a 16 electrode device) was implanted in 6 subjects with RP between 2002 and 2004; the study is ongoing with 5 of 6 subjects wearing the retinal prosthesis at home.[1] No outcomes data have been published from this study.
- In 2010, Ahuja and colleagues published findings from a small feasibility study of the Argus II (a 60-electrode device).[2] 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 6-month) results from the Argus II feasibility trial were reported by Humayun et al. in 2012.[3] Devices were individually programmed and the subjects received training with the device for activities of daily living. Evaluations were scheduled for day 1, weeks 1, 2, and 4, and months 3, 6, 9, 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 were able to 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.

**Learning Retina Implant**

No reports of this device have been identified in the peer-reviewed literature.

**EPIRET3**

Initial results from the EPIRET3 were reported in 6 legally blind subjects with retinitis pigmentosa in 2011.[4] The device was activated on 3 occasions to record visual sensations and then removed at day 28, per the study protocol. During the 1-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 6 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

In 2011, functional testing of the STS system was reported in 2 subjects with retinitis pigmentosa.[5] 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 3 subjects with hereditary retinal dystrophy (retinitis pigmentosa and choroideraemia) who received a Tubingen subretinal implant.[6] The subjects, who previously had only limited light perception, were able to locate bright objects on a dark table. One subject was able to 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. A follow-up study with the next-generation system (Alpha IMS) is ongoing (registered at online site www.clinicaltrials.gov as NCT01024803).

Clinical Practice Guidelines

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

Summary

There is insufficient data at this time to reach scientific conclusions concerning whether retinal prostheses result in improved useful vision. These devices are in the early phases of testing, and current evidence is limited to small, short-term feasibility trials. In addition, there are currently no clinical practice guidelines from U.S. professional societies that recommend the use of any retinal prosthesis. Therefore, the use of retinal prostheses is considered investigational.

REFERENCES


**CROSS REFERENCES**

None

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<tr>
<th>CODES</th>
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<td>Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy</td>
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