Retinal Prosthesis

Policy Number: 9.03.15  Last Review: 7/2014

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for retinal prosthesis. This is considered investigational.

When Policy Topic is covered
Not Applicable

When Policy Topic is not covered
Retinal prostheses are considered investigational.

Description of Procedure or Service
A retinal prosthesis is a device that replaces lost photoreceptor function by transmitting external images to an array of electrodes placed in the epiretinal or subretinal space.

Background
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, hereditary retinal degeneration, and some forms of age-related macular degeneration. Two different approaches are being developed. The first is implantation of electrode arrays in the epiretinal space in order to stimulate retinal ganglion cells. A second approach is the implantation in the subretinal space of light-sensitive multiphotodiode arrays which stimulate the remaining photoreceptors in the inner retina. Use of a multiphotodiode array does not require external image processing. The latter approach is being evaluated for degenerative retinal diseases such as retinitis pigmentosa, in which outer retinal cells deteriorate, but inner retinal cells remain intact for years.

Research in the U.S. has begun with a first generation, 16-electrode device (e.g., the Argus™ 16, Second Sight Medical Products), which is expected to permit the distinction between the presence and absence of light, and the second generation (e.g., Argus™ II), which has 60 electrodes. The Argus artificial retina consists of a small external video camera, held on eyeglass frames, that captures images that are then processed by an externally worn microcomputer. These signals are transmitted to a coil on the globe, an electronics package in the superior temporal quadrant and an electrode array implanted in the back of the eye, which in turn stimulates the optic nerve. It is hoped that further generation devices, containing more than 1,000 electrodes, will provide more detailed vision. Three government organizations provided support for the development of the Argus II. The Department of Energy, National Eye Institute at the National Institutes of Health and the National Science Foundation collaborated to provide grant funding, support for material design and other basic research for the project.

Other devices in development include:
Learning Retinal Implant (Intelligent Medical Implants AG) 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.

EPIRET3 retinal implant (Philipps-University Marburg, Marburg, Germany) is 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. A second generation wireless implant is being developed with a greater number of electrodes.

Microelectrode-STS (suprachoroidal-transretinal stimulation) system (Osaka University Graduate School of Medicine, Osaka, Japan) 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. Because the electrodes are at a greater distance from the retina, the resolution of the image may be lower than other devices. 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.

Alpha-IMS was developed at the University of Tubingen, Tubingen, Germany with the electronic chip design provided by the Institute for Microelectronics, Stuttgart (IMS) Germany. The second-generation Alpha-IMS device has wireless power and signal transmission and is produced by Retina Implant AG (Germany). The microchip is implanted subretinally and receives input from a multiphotodiode array with 1500 elements, that moves with the eye, senses incident light, and applies a constant-voltage signal at the respective 1500 electrodes. The multiphotodiode array transforms visual scenes into corresponding spatial patterns (38 x 40 pixels) of light intensity-dependent electric stimulation pulses with a maximum visual field of 15°.

Regulatory Status
The Argus II device received commercial approval in Europe in March 2011. In 2013, the U.S. Food and Drug Administration (FDA) approved a humanitarian use device exemption (HDE) for the Argus II retinal prosthesis by Second Sight Medical. HDE approval is limited to those devices that treat or diagnose fewer than 4,000 people in the United States each year. The Argus II system is intended for use in adults, age 25 years or older, with severe to profound retinitis pigmentosa who have bare light perception (can perceive light, but not the direction from which it is coming) or no light perception in both eyes, evidence of intact inner layer retina function, and a previous history of the ability to see forms. Patients must also be willing and able to receive the recommended post-implant clinical follow-up, device fitting, and visual rehabilitation.

Rationale
This policy was created in 2005 and updated periodically using the MEDLINE database. The most recent literature update was performed through January 3, 2014.

Argus I and Argus II
Second Sight Medical Products reports that the Argus 16 was implanted in 6 subjects with retinitis pigmentosa between 2002 and 2004; the study is ongoing with 5 of 6 subjects wearing the retinal prosthesis at home.(1) The company has also recruited 30 subjects for a National Institutes of Health-sponsored Phase II multicenter safety and effectiveness study of the second-generation Argus II Retinal Stimulation System.(2) Interim (minimum 6-month) results from this trial were reported by Humayan et al in 2012. (3) Thirty subjects with retinal degeneration and bare or no light perception were implanted with the 60-electrode array. 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. Eight subjects had reached 24-month follow-up at the time of data analysis. There were 3 types of visual acuity tasks using a computer and 2 types of real-world utility tests. Performance on 3 of the computer tasks (square localization, direction of
motion, grating discrimination) was improved with the system on compared to off. With the system on, subjects had a 54% success rate in finding a door compared with 27% success with the device off, and had 68% success in following a white line on a dark floor compared with 23% success with the device off. Although all subjects were able to perceive light when the system was stimulated, the Argus II did not affect full-field light perception. There were 17 serious adverse events that were considered to be device or surgery related, and 1 device was explanted. Most of the serious adverse events occurred earlier in the study before the device and surgical procedures were modified.

Twenty-one subjects were tested for letter and word reading at an average 19.9-month follow-up (range, 8.6-34.8).(4) Correct letter reading ranged from 51.7% to 72.3% with the device on, compared with 15.3% to 17.7% with the device off. The average time for correctly identified letters ranged from 47.7 seconds to 68.6 seconds. Subjects who successfully completed the letter identification task proceeded to the next task. Six subjects were able to consistently read letters of reduced size. The smallest letter identified was 0.9 cm for 1 subject, but preferred letter size was as much as 22.6 cm. Four subjects were able to correctly identify 2-, 3-, and 4-letter words.

In a 2009 summary of their work, Chader et al reported that the 60-electrode device is in a phase II/III clinical trial (registered at online site www.ClinicalTrials.gov as NCT00407602), a 250-electrode unit is “on the drawing board,” and functional vision with a 1000-electrode prosthesis could potentially be achieved within 5 to 10 years.(5) The Argus II received FDA approval for marketing through a humanitarian use device exemption in 2013.

Learning Retina Implant

An acute trial began in 2003 with 20 patients who underwent electrical stimulation lasting 45 minutes.(6) Nineteen of the subjects described sensations of phosphenes (small spots of light) during stimulation. Chronic studies in human subjects began in 2005, and a multicenter clinical trial is proposed in Europe. (registered at online site www.ClinicalTrials.gov as NCT00427180)

EPIRET3

Initial results from the EPIRET3 were reported in 6 legally blind subjects with retinitis pigmentosa in 2011.(7) 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.

STS System

In 2011, functional testing of the STS system was reported in 2 subjects with retinitis pigmentosa.(8) 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 to 7 weeks after implantation.

alpha-IMS Subretinal Implant

The ability to recognize complex spatial percepts with subretinal implantation of a 1500 electrode microchip was reported in 3 subjects with hereditary retinal dystrophy (retinitis pigmentosa and choroideraemia) in 2011.(9) In 2013, short-term outcomes with the next-generation alpha-IMS system were reported from 9 subjects with subfoveal placement and from 12 subjects with parafoveal placement (registered at online site www.ClinicalTrials.gov as NCT01024803 and NCT00515814,
Preoperatively, 8 of 9 subjects with subfoveal implantation had light perception without localization and 1 had complete blindness. During surgery of the first subject, the tip of the implant touched the optic nerve, leading to failure of light perception and exclusion of this subject. Another patient developed postoperative subretinal bleeding and, in several other patients, the observation period was limited by technical instability and removal of the implant. On standardized testing, 8 of 8 subjects had light perception, 7 had light localization, 5 had motion detection, 6 had grating acuity up to 3.3 cycles per degree, and 2 subjects had visual acuity of 20/546 with the system turned on. Identification, localization, and discrimination of objects improved over time for these 8 subjects with up to 9-month follow-up. Five subjects with subfoveal implantation reported useable visual experiences in daily life that included object recognition ranging from table top items to movement of cars. Parafoveal implantation was found to be inferior to subfoveal implantation.

Summary

Several models of retinal prostheses are in development in the U.S., Europe, and Asia. Although the Phase II/III investigational device exemption trial of the Argus II system has reported short-term improvements in completion of visual acuity tasks in the research setting, the impact on patient functional status, quality of life, and/or other relevant outcomes has not yet been determined. Additional study, along with Food and Drug Administration approval for other devices, is needed. This treatment is considered investigational.

References

Billing Coding/Physician Documentation Information
0100T Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy

Additional Policy Key Words
N/A

Policy Implementation/Update Information
7/1/08  New policy; considered investigational.
1/1/09  No policy statement changes.
7/1/09  No policy statement changes.
1/1/10  No policy statement changes. “Subconjunctival” removed from title.
7/1/10  No policy statement changes.
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