DRAFT Medical Coverage Policy | Retinal Prosthesis

EFFECTIVE DATE: 09|01|2023
POLICY LAST UPDATED: 05|03|2023

OVERVIEW
A retinal prosthesis replaces lost photoreceptor function by transmitting external images to an array of electrodes or via light sensors placed in the epiretinal or subretinal space. The artificial retina could restore sight to individuals with blindness secondary to retinal diseases, such as retinitis pigmentosa, hereditary retinal degeneration, and some forms of age-related macular degeneration. Several models of retinal prostheses are in development in the United States, Europe, and Asia.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
Retinal prostheses are not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products
Retinal prostheses are considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

BACKGROUND
Two approaches are being explored to develop an artificial retina that could 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. The first is implantation of electrode arrays in the epiretinal or subretinal space to stimulate retinal ganglion cells. A second approach is the implantation in the subretinal space of light-sensitive multi photodiode arrays, which stimulate the remaining photoreceptors in the inner retina. Use of a multi photodiode 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 United States began with a first-generation, 16-electrode device (eg, the Argus 16; Second Sight Medical Products), which permitted the distinction between the presence and absence of light. 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 National Science Foundation. They collaborated to provide grant funding, support for material design, and other basic research for the project.

Devices in development, none of which are approved or cleared by the U.S. Food and Drug Administration(FDA), include the following:

- The Alpha IMS was developed at the University of Tübingen, and has an electronic chip design provided by the Institute for Microelectronics, Stuttgart. 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 multi photodiode array with 1500 elements that moves with the eye, senses incident light, and applies a constant-voltage signal at the respective 1500electrodes. The multi photodiode array transforms visual scenes into corresponding spatial patterns (38x40 pixels) of light-intensity-dependent electric stimulation pulses with a maximum visual field of 15°.

- The Boston Retinal Implant Project 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 Boston Retinal Implant Project is a joint effort of the Massachusetts Institute of Technology, the Massachusetts Eye and Ear Infirmary, the Veterans Affairs Boston Healthcare System, and Cornell University.
- EPIRET3 retinal implant (Philipps-University Marburg, Germany) is a wireless system that consists of a semiconductor camera on the frame of a pair of glasses 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 micro cable.
- Intelligent Retinal Implant System (Pixium Vision, Paris, France) uses an external camera 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.
- Learning Retinal Implant (Intelligent Medical Implants, Zug, Switzerland) uses an external camera on the frame of a pair of glasses and wireless data and power transfer. Receiver electronics connect via a scleral tunnel to an epiretinal implant. A retinal encoder with 100 to 1000 tunable spatiotemporal filters simulates the filtering operations performed by the ganglion cell and allows individual calibration to improve each patient's visual perception.
- The Microelectrode-STS (suprachoroidal-transretinal stimulation) system (Osaka University, Japan) places its 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, because the electrodes do not touch the retina.

For individuals who have blindness secondary to retinal diseases who receive a retinal prosthesis, the evidence includes a prospective single-arm study evaluating the device approved by the FDA and a systematic review of studies on various devices. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. A 2016 systematic review included studies on the FDA-approved retinal prosthesis as well as devices unavailable in the United States; the overall conclusion was that the evidence on retinal prostheses is insufficient on all outcomes of interest. One study with 30 patients has evaluated the single FDA approved device (Argus II); numerous articles on this study have been published. Primary outcomes included 3 computer-based visual acuity tests. At 3- and 5-year follow-up visits, patients performed significantly better on the 3 computer tasks with the device on versus off. Performance on the most difficult task (grating discrimination) was still relatively low with the device on. Subgroup studies have tested performance on more practical tasks. These studies have tended to find significantly better performance with the device on but differences between groups may not be clinically meaningful. The same 30 patients have been evaluated multiple times and as a result of multiple testing, their performance may differ from other individuals with the device. Additional prospective studies and additional evaluations of the ability to perform practical tasks that have a clinically meaningful impact on health outcomes are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

COVERAGE

Medicare Advantage Plans and Commercial Products

The following code(s) are considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

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 intraocular 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

C1841 Retinal prosthesis, includes all internal and external components (Code deleted 1/01/2023)

C1842 Retinal prosthesis, includes all internal and external components; add-on to C1841 (Code deleted 1/01/2023)

L8608 Miscellaneous external component, supply or accessory for use with the Argus II Retinal Prosthesis System

RELATED POLICIES

None

PUBLISHED

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REFERENCES

1. Fontanarosa J, Treadwell JR, Samson DJ, et al. Retinal Prostheses in the Medicare Population (AHRQ Technology Assessment). Rockville, MD: Agency for Healthcare Research and Quality; 2016.
2. Humayun MS, Dorn JD, da Cruz L, et al. Interim results from the international trial of Second Sight's visual prosthesis. Ophthalmology. Apr 2012; 119(4): 779-88. PMID 22244176
3. da Cruz L, Dorn JD, Humayun MS, et al. Five-Year Safety and Performance Results from the Argus II Retinal Prosthesis System Clinical Trial. Ophthalmology. Oct 2016; 123(10): 2248-54. PMID 27453256
4. Ho AC, Humayun MS, Dorn JD, et al. Long-Term Results from an Epiretinal Prosthesis to Restore Sight to the Blind. Ophthalmology. Aug 2015; 122(8): 1547-54. PMID 26162233
5. Geruschat DR, Richards TP, Arditi A, et al. An analysis of observer-rated functional vision in patients implanted with the Argus II Retinal Prosthesis System at three years. Clin Exp Optom. May 2016; 99(3): 227-32. PMID 26804484
6. da Cruz L, Coley BF, Dorn J, et al. The Argus II epiretinal prosthesis system allows letter and word reading and long-term function in patients with profound vision loss. Br J Ophthalmol. May 2013; 97(5): 632-6. PMID 23426738
7. Kotecha A, Zhong J, Stewart D, et al. The Argus II prosthesis facilitates reaching and grasping tasks: a case series. BMC Ophthalmol. May 23 2014; 14: 71. PMID 24885164