FEP 9.03.15 Retinal Prosthesis

Effective Date: July 15, 2018

Related Policies:

Retinal Prosthesis

Description

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 patients 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. Only the Argus II system has been cleared for use by the U.S. Food and Drug Administration.

FDA REGULATORY STATUS

In 2013, the Argus® II Retinal Prosthesis System (Second Sight Medical) was cleared for marketing by the U.S. Food and Drug Administration through a humanitarian use device exemption. This exemption is limited to devices that treat or diagnose fewer than 4000 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 history of the ability to see forms. Patients must also be willing and able to receive the recommended postimplant clinical follow-up, device fitting, and visual rehabilitation. Food and Drug Administration product code: NBF.

Other devices in development, none of which are approved or cleared by the U.S. Food and Drug Administration, 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 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 (38×40 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.

POLICY STATEMENT

Retinal prostheses are considered **investigational**.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

The investigational device exemption limited the use of this device to 6 centers in the United States.

RATIONALE

Summary of Evidence

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 U.S. Food and Drug Administration 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 Food and Drug Administration–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 Food and Drug Administration–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 vs 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 the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

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POLICY HISTORY

Date	Action	Description
March 2012	New Policy	
June 2013	Update Policy	Policy statement revised from investigational to not medically necessary. Device became FDA approved in early 2013. Rationale revised. References added and removed.
June 2015	Update Policy	Policy was updated with literature review, adding reference 4, 5, 10 & 11. No changes were made to the policy statement.
September 2016	Update Policy	Policy updated with literature review, references 2 and 5 added. Policy statement unchanged.
June 2018	Update Policy	Policy updated with literature review through January 8, 2018; references 1, 3, and 8 added. Policy statement unchanged except “not medically necessary” corrected to “investigational” based on HDE FDA status.