

Corporate Medical Policy

Retinal Prosthesis

File Name:	retinal_prosthesis
Origination:	6/2011
Last CAP Review:	6/2019
Next CAP Review:	6/2020
Last Review:	6/2019

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 or via light sensors placed in the epiretinal or subretinal space.

Two different 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 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 United States began with a first generation, 16-electrode device (e.g., the Argus™ 16), which is expected to permit the distinction between the presence and absence of light.

Devices in development include, 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, Tübingen, 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 (38x40 pixels) of light intensity-dependent electric stimulation pulses with a maximum visual field of 15°.

Boston Retinal Implant (Retinal Implant Research Group, Boston) 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.

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

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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.

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.

Learning Retinal Implant (Intelligent Medical Implants AG) uses an external camera on the frame of a pair of glasses and wireless data and power transfer. Receiver electronics connect via a sclera 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.

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.

Regulatory Status

In 2013, The U.S. Food and Drug (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 per year. The Argus II Retinal Prosthesis 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.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

Retinal prostheses are considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Retinal Prosthesis is covered

Not applicable.

When Retinal Prosthesis is not covered

Retinal prostheses are considered **investigational**. BCBSNC does not provide coverage for investigational services or procedures.

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Policy Guidelines

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

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 Food and Drug Administration (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 also 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 compared with off. Performance on the most difficult task (grating discrimination) was still relatively low with the device on. Substudies 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 0100T, 0472T, 0473T, C1841, C1842, L8608, L8698

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Feasibility Study of a Chronic Retinal Stimulator in Retinitis Pigmentosa. Available online at: <http://clinicaltrials.gov/ct2/show/NCT00279500?term=NCT00279500&rank=1> . Last accessed September 2009.

Argus™ II Retinal Stimulation System Feasibility Protocol. Available online at: <http://clinicaltrials.gov/show/NCT00407602> . Last accessed September 2009.

BCBSA Medical Policy Reference Manual [Electronic]. 9.03.15, 2/10/2011

Specialty Matched Consultant Panel Review- 6/2011

Medical Director review 6/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.15, 2/9/12

Specialty Matched Consultant Advisory Panel review- 6/2012

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BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.15, 2/14/13
Specialty Matched Consultant Advisory Panel review- 6/2013
BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.15, 2/13/14
Specialty Matched Consultant Advisory Panel review- 6/2014
BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.15, 2/12/15
Specialty Matched Consultant Advisory Panel review- 6/2015
BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.15, 3/10/16
Specialty Matched Consultant Advisory Panel review- 6/2016
BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.15, 3/9/17
Specialty Matched Consultant Advisory Panel review- 6/2017
BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.15, 3/8/18
Specialty Matched Consultant Advisory Panel review- 6/2018
BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.15, 3/14/19
Specialty Matched Consultant Advisory Panel review- 6/2019
Medical Director review 6/2019

Policy Implementation/Update Information

7/1/2011 New policy implemented. Retinal Prostheses are considered **investigational**. BCBSNC does not provide coverage for investigational services or procedures. Medical director review 6/2011. (lpr)

7/10/12 Specialty Matched Consultant Advisory Panel review meeting 6/20/2012. Description section extensively revised. Policy guidelines updated. No change to policy statement. Reference added. (lpr)

4/1/13 Revised Description section and Policy Guidelines section. Reference added. No change to policy statement. Medical director review 3/2013. (lpr)

7/16/13 Specialty Matched consultant advisory panel review 6/19/2013. No change to policy statement. (lpr)

10/1/13 Added HCPCS code C1841 to Billing/Coding section for coding update. (lpr)

4/1/14 Reference updated. Regulatory status updated. No change to policy statement. (lpr)

7/15/14 Specialty matched consultant advisory panel review meeting 6/24/2014. No change to policy statement. (lpr)

3/31/15 Updated Description section. Reference added. (lpr)

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- 7/28/15 Specialty Matched Consultant Advisory Panel review 6/24/2015. No change to policy statement. (lpr)
- 4/29/16 Updated Description and Policy Guidelines sections. Reference added. No change to policy statement. (lpr)
- 7/26/16 Specialty Matched Consultant Advisory Panel review 6/29/2016. No change to policy statement. (lpr)
- 12/30/16 Added HCPCS code C1842 to Billing/Coding section for effective date 1/1/2017. (lpr)
- 4/28/17 Updated Policy Guidelines section. Added CPT codes 0472T, 0473T to the Billing/Coding section for effective date 7/1/17. Reference added. No change to policy statement.(lpr)
- 7/28/17 Specialty Matched Consultant Advisory Panel review 6/28/2017. No change to policy statement. (lpr)
- 8/10/18 Updated Description section. Reference added. Specialty Matched Consultant Advisory Panel review 6/2018. No change to policy statement. (lpr)
- 12/31/18 Added HCPC codes L8608 and L8698 to Billing/Coding section effective 1/1/19. (lpr)
- 7/16/19 Updated Description section. Reference added. Specialty Matched Consultant Advisory Panel review 6/19/2019. No change to policy statement. Medical Director review 6/2019. (lpr)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.