MEDICAL POLICY

POLICY TITLE	RETINAL PROSTHESIS
POLICY NUMBER	MP 6.060

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**3/1/2024**

POLICY
RATIONALE
DISCLAIMER
POLICY HISTORY
PRODUCT VARIATIONS
DEFINITIONS
CODING INFORMATION
DESCRIPTION/BACKGROUND
BENEFIT VARIATIONS
REFERENCES

I. POLICY

Retinal prostheses are considered **investigational**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-reference:

MP 9.011 Corneal Transplant, Endothelial Keratoplasty, and Keratoprosthesis

II. PRODUCT VARIATIONS

TOP

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

III. DESCRIPTION/BACKGROUND

TOP

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 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; 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, with 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 subrationally 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) was 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 twenty-five 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.

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 (FDA) through a humanitarian use device exemption (HDE). This exemption is limited to devices that treat or diagnose fewer than four thousand 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. FDA product code: NBF.

IV. RATIONALE

TOP

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 thirty patients has evaluated the single Food and Drug Administration-approved device (Argus II); numerous articles on this study have been published. Primary outcomes included three computer-based visual acuity tests. At 3- and 5-year follow-up visits, patients performed significantly better on the three 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 thirty 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.

V. DEFINITIONS

TOP

NA

VI. BENEFIT VARIATIONS

TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

TOP

Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Retinal prosthesis is considered investigational and therefore not covered:

Procedure Codes								
0100T	0472T	0473T	L8608					

IX. REFERENCES

TOP

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):779-788. 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):2248-2254. 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):1547-1554. 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):227-232. PMID 26804484*
6. *da Cruz L, Coley BF, Dorn J, et al. The Argus sII 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):632-636. 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. 2014;14:71. PMID 24885164*
8. *Dagnelie G, Christopher P, Arditi A, et al. Performance of real-world functional vision tasks by blind subjects improves after implantation with the Argus(R) II retinal prosthesis system. Clin Exp Ophthalmol. Aug 06 2016. PMID 27495262*
9. *Ozmert E, Arslan U. Retinal Prostheses and Artificial Vision. Turk J Ophthalmol 2019 Sep 3;49(4):213-219*
10. *Blue Cross Blue Shield Association Medical Policy Reference Manual 9.03.15,Retinal Prosthesis.April 2023*

X. POLICY HISTORY

TOP

MP 6.060	**CAC 05/23/2017** New policy adopting BCBSA. Retinal prostheses are considered investigational. Coding reviewed.
	03/02/2018 Consensus review. No change to the policy statement. Rationale updated. No new references.
	01/04/2019 Admin Update: Added new code L8608 effective 1/1/19.
	02/20/2019 Consensus review. No change to the policy statement. References reviewed. Rationale revised.
	02/26/2020 Consensus review. Policy updated with literature updated. Policy statement unchanged.
	04/09/2021 Consensus review. No change to policy statement. Background updated.
	04/04/2022 Consensus review. No change to policy statement. Coding table format updated. Product Variations updated.
	11/29/2022 Admin update. Deleted Codes C1841 & C1842.
	7/14/2023 Consensus review. No change to policy statement. References reviewed and updated. Coding reviewed.
	1/19/2024 Administrative update. Clinical benefit added.

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Top