



**Kaiser Foundation Health Plan of Washington**

**Clinical Review Criteria  
Retinal (Implant) Prosthesis System**

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**Criteria**

**For Medicare Members**

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, <b>Retinal (Implant) Prosthesis System</b> for medical necessity determinations. Refer to the non-Medicare criteria below.

**For Non-Medicare Members**

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

**If requesting this service, please send the following documentation to support medical necessity:**

- Last 6 months of clinical notes from requesting provider &/or consulting specialist.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

**Background**

Retinitis pigmentosa (RP) comprises a group of hereditary eye diseases characterized by progressive degeneration of retinal photoreceptors; usually starting in the midperiphery of the fundus and advancing towards the macula and fovea. This field loss is progressive and usually does not reduce central vision until late in the disease resulting in severe visual loss that may lead to legal blindness. Like other areas of the mammalian central nervous system, neurons of the retina are not replaced following degeneration (Musarelle 2011, Petrs-Silva 2014, Rayapudi 2013)

Currently, there is no proven therapy for retinitis pigmentosa. However, there are worldwide efforts to develop new therapies for preserving or improving the retinal function. Therapeutic strategies that may potentially restore vision to patients who only retain light perception, or even no light perception vision, include optogenetics and retinal chip implants. Transcorneal electrostimulation is another technique that might help patients with retinitis pigmentosa who still have functional vision. Optogenetics uses light sensors to induce some cells to be reactive to light. The activated light sensor creates an electric current that can stimulate or inactivate a particular cell. Retinal chips on the other

hand, use transducers to create electricity to replace the electrical stimulation that would normally be created by the photoreceptors. Eyes with retinitis pigmentosa respond to electrical stimulation from the retinal chip because the disease destroys the photoreceptors but leaves a significant percentage of inner retinal cells (ganglion and bipolar cells) intact and functional. The chip implants stimulate these remaining functional cells, thus bypassing the need for functioning photoreceptor cells. In order to restore visual function, chip implants have to detect light, convert light energy into electrical signal and deliver it to retinal neurons other than photoreceptors to elicit activity that is interpreted as vision (Garg 2013, Wieland 2011).

Retinal implants or prosthesis can be categorized according to the location of the stimulating electrodes. In clinical trials the electrodes were placed epiretinally, subretinally, suprachoroidally, or inside the optic nerve. In earlier feasibility studies the stimulating electrodes were placed temporarily (acute implantation). Chronic implantation on the other hand, refers to leaving the device in the subjects for a length of time. This requires considerable engineering to manufacture the device. Chronic retinal prosthesis can be divided into uncontrolled/passive stimulation devices or controlled /active stimulation devices, based on whether the electrical stimulation pattern can be controlled via software or just by light activation without the need for an external power source. Some of the major challenges for bioelectronic implants include long-term stable performance of the implanted electronics as well as a safe surgical implantation procedure (Weiland 2011).

Argus II retinal prosthesis system (Second Sight Medical Products Inc.) consists of an implantable device that is surgically implanted on and in the eye, and an external unit worn by the user. The implanted portion consists of a receiving and transmitting coil, a sealed electronic case fixed to the sclera outside the eye, and an electrode array (a 6 x 10 array of 60 electrodes) that is secured to the surface of the retina (epiretinal) inside the eye by a retinal tack. The electrode array is connected to the electronics by a metalized polymer cable that penetrates the sclera in the pars plana. The external unit consists of a small camera and transmitter mounted on a pair of sunglasses and a video processing unit (VPU) and battery that can be worn on a belt or shoulder strap. The camera captures a video and sends the information to the processor, which converts the image to electronic signals that are then sent to the transmitter on the glasses. The implanted receiver wirelessly receives these data and sends the signal to the electrode array via a small bus, where electric stimulation pulses are emitted. The controlled electrical stimulation of the retina induces cellular responses in retinal ganglion cells that travel through the optic nerve to the visual cortex and results in visual percepts. It is reported that positioning of the epiretinal array remains a challenge, since poor positioning was shown to lead to higher stimulus thresholds. In addition, object recognition including letter reading tasks generally requires head movement to move the camera. An implanted or an external camera coupled to eye movement may allow a more natural viewing experience for users (Weiland 2011, Lauritzen 2012, Dorn 2013).

Epiretinal implants have the advantage of their direct attachment to the ganglion cells which are the cells that need to be stimulated to generate a visual signal that is sent to the brain. A potential disadvantage of this however, is the unwanted stimulation for the retinal ganglion cells that can result in less distinct and /or wanted visual stimuli (Garg 2013).

## Medical Technology Assessment Committee (MTAC)

### *Argus II Retinal Prosthesis System*

#### **04/21/2014: MTAC REVIEW**

**Evidence Conclusion:** There is insufficient published evidence to determine the safety and efficacy of Argus II retinal prosthesis system in patients with profound visual loss due to retinitis pigmentosa. Argus II retinal prosthesis was evaluated in a small, multicenter, case series with no control group (evidence table1). The study enrolled 30 patients between June 2007 and August 2009. The primary performance endpoint was visual function as assessed by several visually guided tasks and orientation and mobility tasks. The primary safety endpoint was the number, severity, and relation of all adverse events. The study enrolled 30 blind patients 50 years or older (18 or older in some clinical sites) with a diagnosis of retinitis pigmentosa (or other outer retinal degeneration at some sites), with remaining vision of bare or no light perception in both eyes, and with a history of useful form vision. All participants received an Argus II implant and were regularly evaluated for a duration of 36 months. 28 of the 30 participants were available for testing. The results indicate that all 28 were able to perceive light during the postoperative stimulation of the implant. 57% were able to see the motion of a white bar moving across a black background, and many were able to identify some 3-4.5 cm letters on a high contrast background. The best vision was 20/1262. Adverse events associated with the Argus II system included conjunctival dehiscence or erosion over the extraocular implant in 16% of cases, endophthalmitis (10%), and hypotony (10%). There was one intraoperative retinal tear, and two postprocedural retinal detachment. The adverse effects were treated in all patients except for one in whom the device had to be explanted.

**Articles:** The literature search revealed only one small observational study with no control or comparison group. The study was published in a number of journals articles and was critically appraised.

[Evidence Table](#). Ahuja AK, Dorn JD, Caspi A, et al. Blind subjects implanted with the Argus II retinal prosthesis are able to improve performance in a spatial-motor task. *Br J Ophthalmol*. 2011;95:539-543. 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*. 2013;97:632-636. Dorn JD, Ahuja AK, Caspi A, et al. The Detection of Motion by Blind Subjects with the Epiretinal 60-Electrode (Argus II) Retinal Prosthesis. *JAMA Ophthalmol*. 2013;131:183-189. Parikh N, Itti L, Humayun M, et al. Performance of visually guided tasks using simulated prosthetic vision and saliency-based cues. *J Neural Eng*. 2013;10 (2):026017. doi: 10.1088/1741-2560/10/2/026017.

The use of Argus II Retinal Prosthesis System does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

## Applicable Codes

### Considered Not Medically Necessary:

CPT® Codes	Description
0100T	Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy

**\*Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

\*\*To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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Date Created	Date Reviewed	Date Last Revised
05/06/2014	05/06/2014 <sup>MPC</sup> , 03/03/2015 <sup>MPC</sup> , 01/05/2016 <sup>MPC</sup> , 11/01/2016 <sup>MPC</sup> , 09/05/2017 <sup>MPC</sup> , 07/10/2018 <sup>MPC</sup> , 07/09/2019 <sup>MPC</sup> , 07/07/2020 <sup>MPC</sup> , 07/06/2021 <sup>MPC</sup> , 07/05/2022 <sup>MPC</sup>	07/06/2021

<sup>MPC</sup> Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L35008
07/07/2020	Added Medicare LCA (A57642) for non-covered services
07/06/2021	Removed retired Medicare LCD (L35008) and LCA (A57642) for non-covered services. Added Kaiser Permanente Medical Policy statement for Medicare.