



# MASSACHUSETTS

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## Medical Policy Retinal Prosthesis

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### Policy Number: 606

BCBSA Reference Number: 9.03.15 (For Plan internal use only)

NCD/LCD: N/A

### Related Policies

N/A

### Policy

#### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

Retinal prostheses are INVESTIGATIONAL.

### Prior Authorization Information

#### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed inpatient.

#### Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed outpatient.

|                                       | Outpatient                            |
|---------------------------------------|---------------------------------------|
| Commercial Managed Care (HMO and POS) | This is <b>not</b> a covered service. |
| Commercial PPO and Indemnity          | This is <b>not</b> a covered service. |
| Medicare HMO Blue <sup>SM</sup>       | This is <b>not</b> a covered service. |
| Medicare PPO Blue <sup>SM</sup>       | This is <b>not</b> a covered service. |

### CPT Codes / HCPCS Codes / ICD Codes

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

The following codes are included below for informational purposes only; this is not an all-inclusive list

The following CPT and HCPCS codes are considered investigational for **Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue, and Medicare PPO Blue:**

### CPT Codes

| CPT codes: | Code Description  |
|------------|---|
| 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 intra-ocular 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 intra-ocular 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  |

### HCPCS Codes

| HCPCS codes: | Code Description  |
|--------------|---|
| L8608        | Miscellaneous external component, supply or accessory for use with the argus ii retinal prosthesis system |

### Description

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 (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.

Numerous retinal prosthesis have been developed or are in various stages of preclinical or clinical development; however, with the exception of Argus II, none are approved or cleared by the U.S. Food and Drug Administration (FDA).

### Summary

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

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.

## Policy History

| Date           | Action  |
|----------------|---|
| 5/2024         | Annual policy review. Policy updated with literature review through January 22, 2024; no references added. Policy statement unchanged.                  |
| 5/2023         | Annual policy review. Description, summary, and references updated. Policy statements unchanged.  |
| 1/2023         | Annual policy review. PA information section clarified to include Medicare.   |
| 1/2023         | Clarified coding information.   |
| 4/2022         | Annual policy review. Policy statements unchanged.  |
| 4/2021         | Annual policy review. Summary updated. Policy statements unchanged.   |
| 1/2021         | Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference. |
| 5/2020         | Annual policy review. Description, summary, and references updated. Policy statements unchanged.  |
| 4/2019         | Annual policy review. Description, summary, and references updated. Policy statements unchanged.  |
| 1/2019         | Clarified coding information.   |
| 7/2017         | Clarified coding information.   |
| 4/2017         | Annual policy review. New references added.   |
| 4/2016         | Annual policy review. New references added.   |
| 3/2015         | Annual policy review. New references added.   |
| 5/2014         | Annual policy review. New references added.   |
| 3/2014         | Annual policy review. New references added.   |
| 10/2013        | Updated to add new HCPCS code C1841.  |
| 4/2013         | Annual policy review. New references added.   |
| 11/2011-4/2012 | Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.   |
| 5/2011         | New policy effective 5/10/2011 describing ongoing non-coverage.   |

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

## 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
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® II retinal prosthesis system. *Clin Exp Ophthalmol*. Mar 2017; 45(2): 152-159. PMID 27495262