



# Geisinger Health Plan Policies and Procedure Manual

**Policy: MP169**

**Section: Medical Benefit Policy**

**Subject: Retinal Prosthesis**

**Applicable line of business:**

<b>Commercial</b>	<b>x</b>	<b>Medicaid</b>	<b>x</b>
<b>Medicare</b>	<b>x</b>	<b>ACA</b>	<b>x</b>
<b>CHIP</b>	<b>x</b>		

**I. Policy:** Retinal Prosthesis

**II. Purpose/Objective:**

To provide a policy of coverage regarding Retinal Prosthesis

**III. Responsibility:**

- A. Medical Directors
- B. Medical Management

**IV. Required Definitions**

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

**Commercial**

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

**Medicare**

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

**CHIP**

Geisinger Health Plan Kids (GHP Kids) is a Children’s Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

**Medicaid**

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

## V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

### Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

### DESCRIPTION:

Two types of microelectronic implanted retinal prosthetics are currently in development as a means of restoring vision in patients blinded by retinal degenerative diseases such as retinitis pigmentosa and macular degeneration. Epiretinal implants positioned on the retinal surface transmit electrical data gathered by external cameras directly to the ganglion and bipolar cells. Subretinal implants are positioned behind the retina and convert light from the environment into electrical signals stimulating remnant cell layers in the retina.

### MEDICARE BUSINESS SEGMENT

The ArgusM II Retinal Prosthesis System (CPT Code 0100T) has been approved by the FDA for marketing under the humanitarian device exemption (HDE) application when all of the following criteria are met:

- Adults, age 25 years or older.
- Bare light or no light perception in both eyes. (If the patient has no residual light perception, then evidence of intact inner layer retina function must be confirmed.)
- Previous history of useful vision.
- Aphakic or pseudophakic. (If the patient is phakic prior to implant, the natural lens will be removed during the implant procedure.)
- Patients who are willing and able to receive the recommended post-implant clinical follow-up, device fitting, and visual rehabilitation.

In addition, the Argus II implant is intended to be implanted in a single eye, typically the worse seeing eye.

### EXCLUSIONS:

Unless coverage is mandated, the Plan does **NOT** provide coverage for the use of artificial retinas because it is considered **unproven**. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

### Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

**Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.**

**CODING ASSOCIATED WITH:** Artificial Retinas

***The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider***

**reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at [www.cms.gov](http://www.cms.gov) or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.**

0100T – Placement of 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 intraocular 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 intraocular 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

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL.

#### **LINE OF BUSINESS:**

**Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.**

#### **REFERENCES:**

Palanker D, Vankov A, Huie P, Baccus S. Design of a high-resolution optoelectronic retinal prosthesis. *Journal of Neural Engineering* 2005;2:S105-S120.

Walter P, Kisvárdy ZF, Görtz M, et. al. Cortical activation via an implanted wireless retinal prosthesis. *Investigative Ophthalmology & Visual Science*. 2005;46:1780-1785.

Chowdhury V, Morley JW, Coroneo MT. Feasibility of extraocular stimulation for a retinal prosthesis. *Canadian Journal of ophthalmology*. 2005;40:563-572.

Chowdhury V, Morley JW, Coroneo MT. Stimulation of the retina with a multielectrode extraocular visual prosthesis. *ANZ J. Surgery*. 2005 August;75(8):697-704.

American Academy of Ophthalmology. Rapid Clinical Report. Microelectronic retinal implants. Aug. 2000. <http://www.aaopt.org/education/library/rapid/retinal.cfm> Accessed 11/18/05.

Lee PJ. ARMD, retinal electronic prosthesis and RPE transplantation. *eMedicine*. Oct.4, 2004. <http://www.emedecine.com/oph/topic763.htm> Accessed 11/18/05.

Optoelectronic implants to treat visual diseases. *Optic report* Sept. 01, 2001. <http://www.opticsreport.com/content/printable.php?id=1007&command=article> Accessed 11/18/05.

Retinal Prosthesis Provides Hope for Restoring Sight. *Research Highlights. Science & Technology. Lawrence Livermore National Library*. <http://www.llnl.gov/str/November03/Davidson.html> Accessed 11/18/05.

Chiang A, Haller JA. Vitreoretinal disease in the coming decade. *Curr Opin Ophthalmol*. 2010;21(3):197-202

Hayes Inc. Online. *Hayes Medical Technology Directory*, (May 17, 2011) "The Argus II Retinal Prosthesis System ("Argus II"; Second Sight Medical Products Inc." Retrieved Dec. 22, 2011.

Humayun MS, Dorn JD, da Cruz L, et al. Interim results from the international trial of Second Sight's visual prosthesis. *Ophthalmology*. 2012; 119(4):779-78

Chuang AT, Margo CE, Greenberg PB. Retinal implants: A systematic review. *Br J Ophthalmol*. 2014;98(7):852-856.

Stronks HC, Dagnelie G. The functional performance of the Argus II retinal prosthesis. *Expert Rev Med Devices*. 2014;11(1):23-30.

da Cruz, L., Dorn, J., Humayun, M., Dagnelie, G., Handa, J., Barale, P., et. al., (2016) Five-Year Safety and Performance Results from the Argus II Retinal Prosthesis System Clinical Trial. American Academy of Ophthalmology. 2016.06.049 1-7.

Ho, A., Humayun, M., Dorn, J., da Cruz, L., Dagnelie, G., Handa, J., et. al., (2015, August) Long-term results from an epiretinal prosthesis to restore sight to the blind. Ophthalmology; 2015;122(8): 1547-1554.

Geruschat, D., Richards, T., Ardit, A., da Cruz, L., Dagnelie, G., Dorn, J., et al. An analysis of observer-rated functional vision in patients implanted with the Argus II retinal prosthesis system at three years. Clinical and Experimental Optometry 2016; 99 (3), 227-232

Dagnelie, G, Christopher, P, Ardit, A, et al. Performance of real-world functional vision tasks by blind subjects improves after implantation with the Argus(R) II retinal prosthesis system. Clinical & experimental ophthalmology. 2017 Mar;45(2):152-9.

Duncan JL, Richards TP, Ardit A, et al. Improvements in vision-related quality of life in blind patients implanted with the Argus II Epiretinal Prosthesis. Clin Exp Optom. 2017;100(2):144-150.

Cheng DL, Greenberg PB, Borton DA. Advances in retinal prosthetic research: A systematic review of engineering and clinical characteristics of current prosthetic initiatives. Curr Eye Res. 2017;42(3):334-347.

Farvardin M, Afarid M, Attarzadeh A, et al. The Argus-II retinal prosthesis implantation; from the global to local successful experience. Front Neurosci. 2018;12:584

Im M, Kim SW. Neurophysiological and medical considerations for better-performing microelectronic retinal prostheses. J. Neural Eng. 2020;17 033001

Yue L, Wuyyuru V, Gonzalez-Calle A, et al. Retina-electrode interface properties and vision restoration by two generations of retinal prostheses in one patient-one in each eye. J Neural Eng. 2020; 17(2):026020.

Centers for Medicare & Medicaid Services. A53044 Billing and Coding: ArgusM II Retinal Prosthesis System

This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 12/29/05

**Revised:** 12/21 (Added Medicare Segment)

**Reviewed:** 12/06, 12/07, 12/08, 12/09, 12/10, 1/12, 1/13, 1/14, 1/15, 1/16; 1/17, 12/17, 12/18, 12/19, 12/20, 12/22, 12/23, 12/24; 12/25 (Update Unproven language)

**CMS UM Oversight Committee Approval:** 12/23, 2/25, 2/26

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Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.

