Anthem

Medical Policy

Subject: Artificial Retinal Devices
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Description/Scope

This document addresses artificial retinal devices that include various artificial retinas used as a method to restore sight for those who have experienced blindness as a result of degenerative retinal diseases (RD).

Position Statement

Investigational and Not Medically Necessary:

The use of artificial retinal devices is considered **investigational and not medically necessary** for all indications.

Rationale

In February 2013, the United States Food and Drug Administration (FDA) granted a humanitarian device exemption (HDE) to the Argus® II system (Second Sight® Medical Products, Inc., Sylmar, CA). An HDE exempts the device from a review of clinical effectiveness. The FDA concluded the Argus II Retinal Prosthesis System will not expose blind individuals with severe outer retinal degeneration to an unreasonable or significant risk of illness or injury. The FDA concluded the initial data demonstrated a probable benefit which outweighed the risks of the device.

In a pilot safety and feasibility study, 6 participants with vision loss as a result of retinitis pigmentosa (RP) underwent implantation of an artificial silicone retina (ASR®, Optobionics, Glen Ellyn, IN) microchip within the subretinal space in the right eye (Chow, 2004). For this study, the left eye was maintained as the control. Intraocular pressure (IOP) to greater than 25 mm Hg was the only common adverse event reported within the immediate postoperative period. This occurred in 3 of the 6 cases within the first week of the procedure. All received treatment with medication, and the IOP returned to preoperative value. Within the follow-up period of 6 to 18 months, visual improvement was reported in all study group participants as well as surprising visual changes in the retinal area surrounding the implant. There were no severe adverse safety events reported in the study. The author explained that further study is needed to validate these findings and determine the group of individuals that will benefit from the ASR device.

De Balthasar and colleagues (2008), reported on 6 blind participants due to retinitis pigmentosa who underwent retinal prosthesis implantation. The study protocol received approval by the FDA as a clinical trial under the investigational device exemption (IDE). The study looked at the perceptual threshold in retinal prostheses.

Ahuja and colleagues (2011) reported a multicenter study in which 27 blind participants with severe to profound RP underwent implantation of the Argus II prosthesis in an attempt to partially restore vision. All participants were reported to have some degree of bare light perception (BLP) prior to implantation of the prosthesis or upon clinical follow-up. None of the participants had a reportable visual acuity prior to the procedure. Square localization tasks were used to evaluate the participant's ability to localize and touch a high contrast square target on a touch screen monitor. The author reported that 96% of implanted participants studied had responses that were significantly more accurate and 93% had responses that were more repeatable with the system "on" compared with the system "off."

> For the subjects who showed significant improvement in accuracy with the system on compared with the system off, the factor of improvement ranged from 1.25 to 4.63. This range was largely due to the variability in performance with the system off. (The standard deviation of the mean accuracy across all subjects was 86.3 pixels with system off compared with 51.4 with the system on.) In other words, the rare cases of only marginal improvement in accuracy with the system on were due to the fact that a few subjects had enough light perception and eye-hand coordination to perform the task with their native vision. This limited the possible range of improvement with the system on.

This study provides promising initial results for the Argus II prosthesis and suggests it may be able to provide partial vision restoration in blinded individuals, although ongoing research is needed to validate the outcomes.

Humayun and colleagues (2012) reported interim results from an ongoing feasibility trial of Second Sight's visual prosthesis (Argus II). This single-arm, prospective study evaluated the Argus II Retinal Prosthesis System in blind participants with severe retinitis pigmentosa or other outer retinal degeneration. Thirty participants (30% females and 70% males) in the United States and Europe were implanted with the device, median age of implantation 57.5 ± 9.9 years. Additional entry criteria included bare or no light perception and a prior history of some useful form of vision. A total of 27 of 28 participants (96%) were able to perform object location better with the system on versus system off. For motion discrimination, 16 of 28 participants (57%) performed better with the system on, and for discrimination of oriented grating 23% performed better with the system on. After the surgery, 11 of 30 participants experienced a total of 23 serious adverse events, which included erosion of the conjunctiva, dehiscence over the extraocular implant, retinal detachment, inflammation, and hypotony (low intraocular pressure). Although the interim results show promise, the study sample size was small with limited duration of follow-up (minimum of 6 months up to 2.6 years) and outcome measures were limited to visual tasks in a laboratory setting. Additional research is needed to validate these preliminary findings.

In 2015, Ho and colleagues reported long-term safety results in 29 of 30 participants included in the Argus II study. At 36 months post implantation, a total of 23 adverse events were reported in 11 study participants. The most frequently reported adverse events were conjunctival erosion (n=4), hypotony (n=4), conjunctival dehiscence (n=3), and presumed endophthalmitis (n=3).

In 2016, da Cruz et al. reported 5-year performance and safety results in the Argus II study. Out of the original 30 participants enrolled, 24 remained with functioning devices at 5 years post-implantation. The authors reported that visual function assessment results at 5 years were similar to those at 3 years and continued to show efficacy of the Argus II. The square localization assessment resulted in 81% of participants performing better with the device on; while the direction of motion assessment resulted in 50% of participants performing better with the device on; and the grating visual acuity resulted in 38% of participants performing better with the device on. The safety results showed that only one new serious adverse event developed between 3 to 5 years. A

rhegmatogenous retinal detachment was identified in the implanted eye of 1 participant. Three devices were explanted: one at 14 months, another at 3.5 years, and the most recent at 4.3 years. One individual experienced chronic hypotony and ptosis and 2 other individuals experienced recurrent conjunctival erosion. Participants in the original study will be followed for 10 years to gather data on the safety and efficacy of the device. The authors concluded the Argus II continues to serve as an option for individuals with RP and may improve some basic visual functions.

In 2016, the Agency for Healthcare Research and Quality (AHRQ) conducted a Technology Assessment on retinal prostheses systems (RPS) in the Medicare population with retinitis pigmentosa and age-related macular degeneration leading to visual loss. The authors concluded that “future studies of RPS devices should make an effort to report valid and reliable measures of important outcomes, especially day-to-day function and quality of life using the FLORA, IADL-VLV, and IVI.”

In 2022, Second Sight ceased manufacturing for all Argus II devices. The FDA was notified and subsequently approved discontinuation of the post-approval study of the Argus II Retinal Prosthesis System (NCT01860092).

The following are RPS in development outside the United States, although none have received FDA approval or clearance:

- The Alpha IMS (Retinal Implant AG, Reutlingen, Germany)
- EPIRET3 Retinal Implant (Phillips-University Marburg, Germany)
- Intelligent Retinal Implant System (Pixum Vision, Paris, France)
- The Alpha IMS (Retinal Implant AG, Reutlingen, Germany)
- The Microelectrode-STS (suprachoroidal-transretinal stimulation) system (Osaka University, Japan)

Background/Overview

The retina is a light-sensitive, layered tissue located inside the eye that delivers visual messages via the optic nerve to the brain. Also, there are blood vessels that nourish the retina in an under layer of the eye called the choroid. Another blood supply to the outer aspect of the retina layer is the retinal pigment epithelium (RPE). Visual impairment or blindness can occur as a result of a variety of retinal diseases including retinitis pigmentosa (RP) and some forms of age-related macular degeneration (AMD). According to the National Eye Institute (NEI), there are approximately 2.07 million Americans 50 years and over who are currently blind, and an estimated 2.1 percent of adults aged 50 and older have AMD and experience visual impairments. By 2050, the estimated number of individuals with AMD is expected to double, with white Americans to account for the majority of cases (NEI, 2022).

There are two types of retinal implant systems currently under study. Epiretinal implants are positioned on the surface of the retina and receive light signals from an electronic camera mounted in the frame of eyeglasses. These electronic images are transmitted to a microchip implanted in the retina. Subretinal implants are positioned behind the retina and receive light directly from the environment. The subretinal implant is a silicone based device containing several thousand micro-electrode tipped microphotodiodes powered by incoming light. The electrical charge produced by these microphotodiodes is designed to alter the membrane potentials of adjacent retinal neurons and simulate how light would normally activate these cells to form visual images. An intact optic nerve pathway is necessary for these devices to function.

Definitions

Age-Related Macular Degeneration (AMD): A slowly progressive, painless disease affecting the macula that blurs the sharp, central vision needed for "straight-ahead" activities such as reading, sewing, and driving.

Artificial Retina: A device intended to restore vision loss caused by retinal disorders. The device is purported to replace or improve the natural retina function by transmitting images from a small eye-glass-mounted camera wirelessly to a microelectrode implanted on an individuals damaged retina, which sends electrical signals via the optic nerve to the brain so it may interpret an image.

Retinitis pigmentosa (RP): A group of hereditary retinal diseases that results in a progressive deterioration of specialized, light-absorbing cells found in the retina, and is characterized by advanced visual field loss.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:

CPT

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

L8608	Miscellaneous external component, supply or accessory for use with the Argus II retinal prosthesis system

ICD-10 Procedure

08H005Z	Insertion of epiretinal visual prosthesis into right eye, open approach
08H105Z	Insertion of epiretinal visual prosthesis into left eye, open approach

ICD-10 Diagnosis

	All diagnoses

References

Peer Reviewed Publications:

1. 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(4):539-543.
2. Chow AY, Chow VY, Packo KH, et al. The artificial silicon retina microchip for the treatment of vision loss from retinitis pigmentosa. Arch Ophthalmol. 2004; 122(4):460-469.
3. 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. 2017; 45(2):152-159.
4. da Cruz L, Dorn JD, Humayun MS, et al. Argus II study group. Five-year safety and performance results from the Argus II retinal prosthesis system clinical trial. Ophthalmology. 2016; 123(10):2248-2254.
5. de Balthasar C, Patel S, Roy A, et al. Factors affecting perceptual thresholds in epiretinal prostheses. Invest Ophthalmol Vis Sci. 2008; 49(6):2303-2314.
6. Ho AC, Humayun MS, Dorn JD, et al. Long-term results from an epiretinal prosthesis to restore sight to the blind. Ophthalmology. 2015; 122(8):1547-1554.
7. 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):779-788.
8. Mahadevappa M, Weiland JD, Yanai D, et al. Perceptual thresholds and electrode impedance in three retinal prosthesis subjects. IEEE Trans Neural Syst Rehabil Eng. 2005; 13(2):201-206.
9. 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.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Agency for Healthcare Research and Quality. Retinal prostheses in the Medicare population. Technology Assessment Report. September 30, 2016. Project ID: RPST0515. Available at: https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id103TA.pdf. Accessed on January 4, 2024.
2. American Academy of Ophthalmologists (AAO). Retinal Panel, Preferred Practice Patterns Committee. Age-related macular degeneration. January 2015. For additional information visit the AAO website at: http://one.aao.org/CE/PracticeGuidelines/PPP.aspx. Accessed on January 4, 2024.
3. Second Sight Medical Products. New enrollment post-approval study of the Argus® II retinal prosthesis system. NLM Identifier: NCT01860092. Last updated December 23, 2021. Available at: https://clinicaltrials.gov/ct2/show/NCT01860092?term=ARGUS+II+retina&rank=5. Accessed on January 4, 2024.
4. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness: Argus II Retinal Prosthesis System Humanitarian Device Exemptions No.H110002. Rockville, MD: FDA. Available at: http://wayback.archive-it.org/7993/20170112091520/http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm343162.htm. Accessed on January 4, 2024.

Websites for Additional Information

1. Centers for Disease Control and Prevention. Prevalence of age-related macular degeneration (AMD). Last reviewed October 31, 2022. Available at: Prevalence Estimates | Vision and Eye Health Surveillance System | Vision Health Initiative (VHI) | CDC. Accessed on January 4, 2024.
2. National Eye Institute. Age-related macular degeneration (AMD) data and statistics. Last reviewed June 15, 2022. Available at: https://www.nei.nih.gov/learn-about-eye-health/resources-for-health-educators/eye-health-data-and-statistics/age-related-macular-degeneration-amd-data-and-statistics. Accessed on January 4, 2024.
3. National Eye Institute. At a glance: Retinitis Pigmentosa. Last reviewed November 15, 2023. Available at: https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/retinitis-pigmentosa. Accessed on January 4, 2024.
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5. United States National Science Foundation. Artificial Retina Receives FDA approval. February 14, 2013. Available at: https://www.nsf.gov/news/news_summ.jsp?cntn_id=126756. Accessed on January 4, 2024.

Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Definitions, References, and Website sections.
Reviewed	02/16/2023	MPTAC review. Updated Rationale, Background, References and Websites sections.
	12/28/2022	Updated Coding section with 01/01/2023 HCPCS updates; removed C1841, C1842 deleted 12/31/2022.
Reviewed	02/17//2022	MPTAC review. Updated References and Websites sections.
Reviewed	02/11/2021	MPTAC review. Updated References and Websites sections.
Reviewed	02/20/2020	MPTAC review. Updated Background, References and Websites Sections.
Reviewed	03/21/2019	MPTAC review. Updated Rationale and References sections.
	12/27/2018	Updated Coding section with 01/01/2019 HCPCS changes; added L8608.

Reviewed	05/03/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Rationale and References sections.
Reviewed	05/04/2017	MPTAC review. Updated Rationale and References sections. Updated Coding section with 07/01/2017 CPT changes.
	01/01/2017	Updated Coding section with 01/01/2017 HCPCS changes.
Reviewed	05/05/2016	MPTAC review. Updated Rationale, Background, and References sections. Removed ICD-9 codes from Coding section.
Reviewed	05/07/2015	MPTAC review. Description. Rationale, Background and Websites sections updated.
Reviewed	05/15/2014	MPTAC review. Rationale and Websites sections updated.
	10/01/2013	Updated Coding section with 10/01/2013 HCPCS and ICD-9 procedure code changes.
Reviewed	05/09/2013	MPTAC review. Updated Rationale and Websites.
Reviewed	05/10/2012	MPTAC review. Rationale, Reference and Website sections updated.
Reviewed	05/19/2011	MPTAC review. References and Websites updated.
Reviewed	05/13/2010	MPTAC review. Background and references updated.
New	05/21/2009	MPTAC review. Initial document development.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.