



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

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Coverage Policy Number 0457

Subject Artificial Retinal Devices

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Hyperlink to Related Coverage Policies

- Bevacizumab (Avastin®)
- Photocoagulation Laser Treatment of Macular Drusen
- Photodynamic Therapy for Ocular Conditions
- Proton Beam Therapy for Ocular Melanoma, Ocular Hemangiomas and Macular Degeneration
- Transpupillary Thermal Therapy (TTT)

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of CIGNA. Copyright ©2011 CIGNA

Coverage Policy

CIGNA does not cover an artificial retinal device for any indication because it is considered experimental, investigational or unproven.

General Background

Artificial retinal devices, also called retinal implants or prostheses, have been developed to act as a replacement for degenerated photoreceptor cells (i.e., rods and cones). The retinal prosthesis has been proposed as a potential treatment for diseases such as age-related macular degeneration (AMD) and retinitis pigmentosa (RP) that are limited primarily to the outer retina. Management options for AMD include antioxidant vitamins and mineral supplements, intravitreal injection of anti-vascular endothelial growth factor (VEGF) agents, photodynamic therapy (PDT), and laser photocoagulation surgery (American Academy of Ophthalmologists [AAO], 2008). Available treatments for RP are not highly effective and, like AMD, there is no cure.

Two types of prostheses are being investigated: epiretinal implants, which are positioned on the surface of the retina, and subretinal implants placed between the outer retina and the retinal pigment epithelium. Epiretinal implants receive electrical signals via a camera located outside of the body. Light signals are initially received by a microchip within the camera. This microchip deciphers the signals and relays them to a second microchip on

the surface of the retina, which in turn stimulates the retinal ganglion cells. Signals are then sent to the optic nerve and transmitted to the visual cortex of the brain. The cortex generates phosphenes or perceptible flashes of light. A vitrectomy is required to implant the intraocular component of this prosthesis. The Argus™ II, developed by Second Sight Medical Products Inc. (Sylmar, CA), is an example of an epiretinal implant.

Subretinal implants contain a network of microphotodiodes (i.e., solar cells) attached to microelectrodes. A subretinal prosthesis receives ambient light and converts it to electrical signals that stimulate the remnant sensory layers of the retina. Subretinal prostheses are fully implanted and require no external optics. Surgical access to the subretina is gained either by scleral incision or through the vitreous cavity and retina. The Artificial Silicon Retina™ (ASR™) (Optobionics, Wheaton, IL), a subretinal microchip, is 2 mm in diameter and 25 microns thick. It contains approximately 5000 microphotodiodes each with its own stimulating electrode.

U.S. Food and Drug Administration (FDA)

Currently, there are no retinal prosthetic devices approved by the U.S. FDA.

Literature Review

Ahuja et al. (2011) reported on a clinical trial of 27 patients with severe to profound RP who were implanted the Argus II retinal prosthesis. The study aimed to determine to what extent subjects implanted with the Argus II retinal prosthesis improved performance compared to residual native vision in a spatial-motor task. Significant improvement in accuracy was reported in 96% of subjects and 93% of subjects showed a significant improvement in repeatability with the system on compared with off (p<0.05).

Early clinical trials of retinal prostheses include a feasibility study by Chow et al. (2004) evaluating the ASR microchip implanted in the eyes of patients with RP (n=6). No significant safety-related adverse effects were reported in six to 18 months of follow-up.

Professional Societies/Organizations

The American Academy of Ophthalmologists (AAO) has not issued a position on artificial retinal devices.

Summary

The investigation of various retinal prosthetic devices is ongoing and in the early stages of clinical study. As a result, available data in the published peer-reviewed medical literature is limited. Potential problems with retinal implants include availability of an adequate power source, surgical complications, and long- term durability. Additional research is needed to refine the technology, explore these issues, and establish the safety and efficacy of these devices. Artificial retinas are investigational at present, as there is insufficient evidence to support their use in the treatment of retinal diseases.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered:

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

ICD-9-CM Diagnosis Codes	Description
362.50-362.57	Degeneration of macula and posterior pole
362.74	Pigmentary retinal dystrophy

*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.

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Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	6/15/2008	0457	Artificial Retinal Devices

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