

## Corporate Medical Policy

### Retinal Prosthesis

**File Name:** retinal\_prosthesis  
**Origination:** 6/2011  
**Last CAP Review:** NA  
**Next CAP Review:** 6/2012  
**Last Review:** 6/2011

#### Description of Procedure or Service

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A retinal prosthesis is a device that replaces lost photoreceptor function by transmitting computer-processed video images to an array of electrodes placed on the retinal surface.

There is ongoing research interest in developing an artificial retina that could potentially 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. As currently investigated, the artificial retina consists of a small external video camera, held on eyeglass frames, that captures images that are then processed by an externally worn microcomputer. These signals are transmitted to an electrode array implanted in the back of the eye, which in turn stimulates the optic nerve.

Research has begun with a first generation, 16-electrode device (e.g., the Argus™ 16), which is expected to permit the distinction between the presence and absence of light, and the second generation (e.g., Argus™ II), which has 60 electrodes. It is hoped that further generation devices, containing more than 1,000 electrodes, will provide more useful vision. The first and second generation devices are currently being studied in 2 Investigational New Device Trials approved by the U.S. Food and Drug Administration (FDA). Second Sight Medical Products and the National Institutes of Health are partnering sponsors for these feasibility studies. At the present time, no device has received final FDA approval.

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

#### Policy

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**Retinal prostheses are considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.**

#### Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

#### When Retinal Prosthesis is covered

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Not applicable.

# Retinal Prosthesis

## When Retinal Prosthesis is not covered

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Retinal Prostheses are considered **investigational**. BCBSNC does not provide coverage for investigational services or procedures.

## Policy Guidelines

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Second Sight Medical Products reports that the Argus 16 was implanted in 6 subjects with retinitis pigmentosa between 2002 and 2004; the study is ongoing with 5 of 6 subjects wearing the retinal prosthesis at home. The company is currently recruiting 30 subjects for a National Institutes of Health-sponsored Phase II multicenter safety and effectiveness study of the second generation Argus II Retinal Stimulation System.

No device has final U.S. Food and Drug Administration (FDA) approval. This treatment is considered investigational.

## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: 0100T*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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Feasibility Study of a Chronic Retinal Stimulator in Retinitis Pigmentosa. Available online at: <http://clinicaltrials.gov/ct2/show/NCT00279500?term=NCT00279500&rank=1> . Last accessed September 2009.

Argus™ II Retinal Stimulation System Feasibility Protocol. Available online at: <http://clinicaltrials.gov/show/NCT00407602> . Last accessed September 2009.

BCBSA Medical Policy Reference Manual [Electronic]. 9.03.15, 2/10/2011

Specialty Matched Consultant Panel Review- 6/2011

Medical Director review 6/2011

## Policy Implementation/Update Information

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7/1/2011 New policy implemented. Retinal Prostheses are considered **investigational**. BCBSNC does not provide coverage for investigational services or procedures. Medical director review 6/2011. (lpr)

# Retinal Prosthesis

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.