# Corporate Medical Policy

## Retinal Prosthesis

**File Name:** retinal_prosthesis
**Origination:** 6/2011
**Last Review:** 6/2024

## Description of Procedure or Service

A retinal prosthesis is a device that replaces lost photoreceptor function by transmitting external images to an array of electrodes or via light sensors placed in the epiretinal or subretinal space.

Two different 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 in order 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 (e.g., the Argus™ 16), which is expected to permit the distinction between the presence and absence of light.

There are numerous devices in various stages of preclinical or clinical development, however, none are approved or cleared by the U.S. Food and Drug Administration.

**Regulatory Status**
In 2013, The U.S. Food and Drug (FDA) approved a humanitarian use device exemption (HDE) for the Argus II retinal prosthesis by Second Sight Medical. HDE approval is limited to those devices that treat or diagnose fewer than 4,000 people in the United States per year. The Argus II Retinal Prosthesis is intended for use in adults aged 25 years or older, with severe to profound retinitis pigmentosa who have bare light perception (can perceive light but not the direction from which it is coming) or no light perception in both eyes, evidence of intact inner layer retina function, and a previous history of the ability to see forms. Patients must also be willing and able to receive the recommended post-implant clinical follow-up, device fitting, and visual rehabilitation.

******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

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

## Benefits Application

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

Not applicable.

## When Retinal Prosthesis is not covered

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

## Policy Guidelines

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

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 Food and Drug Administration (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 also 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 compared with off. Performance on the most difficult task (grating discrimination) was still relatively low with the device on. Substudies 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 scientific evidence of the safety and effectiveness is insufficient to determine the effects of the technology on health outcomes or for restoring vision.

## Billing/Coding/Physician Documentation Information

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. They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes*: *0100T, 0472T, 0473T, L8608*

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

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

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.15, 2/9/12

Specialty Matched Consultant Advisory Panel review- 6/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.15, 2/14/13

Specialty Matched Consultant Advisory Panel review- 6/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.15, 2/13/14

Specialty Matched Consultant Advisory Panel review- 6/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.15, 2/12/15

Specialty Matched Consultant Advisory Panel review- 6/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.15, 3/10/16

Specialty Matched Consultant Advisory Panel review- 6/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.15, 3/9/17

Specialty Matched Consultant Advisory Panel review- 6/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.15, 3/8/18

Specialty Matched Consultant Advisory Panel review- 6/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.15, 3/14/19

Specialty Matched Consultant Advisory Panel review- 6/2019

Medical Director review 6/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.15, 3/12/20

Specialty Matched Consultant Advisory Panel review- 6/2020

Medical Director review 6/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.15, 3/11/21

Specialty Matched Consultant Advisory Panel review- 6/2021

Medical Director review 6/2021

Specialty Matched Consultant Advisory Panel review- 6/2022

Medical Director review 6/2022

Specialty Matched Consultant Advisory Panel review- 6/2023

Medical Director review 6/2023

American Academy of Ophthalmology - Preferred Practice Patterns – Retinal Prosthesis, 2023
https://www.aao.org/education/preferred-practice-pattern/corneal-retinal-prosthesis-ppp-2023

Specialty Matched Consultant Advisory Panel review- 6/2024

Medical Director review 6/2024

## Policy Implementation/Update Information

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)

7/10/12 Specialty Matched Consultant Advisory Panel review meeting 6/20/2012. Description section extensively revised. Policy guidelines updated. No change to policy statement. Reference added. (lpr)

4/1/13 Revised Description section and Policy Guidelines section. Reference added. No change to policy statement. Medical director review 3/2013. (lpr)

7/16/13 Specialty Matched consultant advisory panel review 6/19/2013. No change to policy statement. (lpr)

10/1/13 Added HCPCS code C1841 to Billing/Coding section for coding update. (lpr)

4/1/14 Reference updated. Regulatory status updated. No change to policy statement. (lpr)

7/15/14 Specialty matched consultant advisory panel review meeting 6/24/2014. No change to policy statement. (lpr)

3/31/15 Updated Description section. Reference added. (lpr)

7/28/15 Specialty Matched Consultant Advisory Panel review 6/24/2015. No change to policy statement. (lpr)

4/29/16 Updated Description and Policy Guidelines sections. Reference added. No change to policy statement. (lpr)

7/26/16 Specialty Matched Consultant Advisory Panel review 6/29/2016. No change to policy statement. (lpr)

12/30/16 Added HCPCS code C1842 to Billing/Coding section for effective date 1/1/2017. (lpr)

4/28/17 Updated Policy Guidelines section. Added CPT codes 0472T, 0473T to the Billing/Coding section for effective date 7/1/17. Reference added. No change to policy statement. (lpr)

7/28/17 Specialty Matched Consultant Advisory Panel review 6/28/2017. No change to policy statement. (lpr)

8/10/18 Updated Description section. Reference added. Specialty Matched Consultant Advisory Panel review 6/2018. No change to policy statement. (lpr)

12/31/18 Added HCPC codes L8608 and L8698 to Billing/Coding section effective 1/1/19. (lpr)

7/16/19 Updated Description section. Reference added. Specialty Matched Consultant Advisory Panel review 6/19/2019. No change to policy statement. Medical Director review 6/2019. (lpr)

6/30/20 Specialty Matched Consultant Advisory Panel review 6/17/2020. Reference added. No change to policy statement. Medical Director review 6/2020. (lpr)

7/13/21 Specialty Matched Consultant Advisory Panel review 6/16/2021. Reference added. Medical Director review 6/2021. No change to policy statement. (lpr)

7/26/22 Specialty Matched Consultant Advisory Panel review 6/2022. Removed HCPCS code L8698 from Billing/Coding section. Medical Director review 6/2022. (lpr)

12/30/22 Deleted CPT codes C1841, C1842 from Billing/Coding section effective 1/1/2023. (lpr)

7/18/23 Specialty Matched Consultant Advisory Panel review 6/21/2023. Medical Director review 6/2023. No change to policy statement. (lpr)

7/17/24 Specialty Matched Consultant Advisory Panel review 6/19/2024. Updated description section and added reference. Medical Director review 6/2024. No change to policy statement. (lpr)