Clinical Policy: Artificial Retina

Reference Number: HNCA.CP.MP.349
Last Review Date: 6/20

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
The Argus II Retinal Prosthesis System was approved by the United States Food and Drug Adminstration (FDA) under the humanitarian device exemption (HDE) application in February 2013. This system is intended to provide electrical stimulation of the retina to induce visual perception in patients with severe to profound retinitis pigmentosa (RP).

Policy/Criteria

I. It is the policy of Health Net of California that the Argus II Retinal Prosthesis System is medically necessary under the FDA HDE for the patients with severe to profound RP who meet the following criteria:
   A. Adults, age ≥ 25 years
   B. Bare light or no light reception in both eyes with evidence of intact inner layer retina function
   C. Previous history of useful form vision
   D. Aphakic or pseudophakic or the if phakic, the natural lens will be removed during the implant procedure
   E. Patients must be willing to participate in the recommended post implant clinical follow-up, device fitting and visual rehabilitation

II. It is the policy Health Net of California that the Argus II Retinal Prosthesis System is not medically necessary for any other circumstances than those specified above.

Background
RP includes a group of inherited conditions that cause progressive retinal degeneration and affect the photoreceptors and retinal pigment epithelium. Loss of visual field is progressive, starting in the midperiphery and progressing more peripherally, resulting in a constricted visual field. Although there is no cure for RP, treatments are available for managing some aspects of its clinical manifestations. New treatments, involving gene therapy, transplantation, and implanted electrical devices, are in active development.

The Argus II Retinal Prosthesis System is a device implanted in and on the eye, which electrically stimulates the retina. This system includes a small video camera, a transmitter mounted on a pair of eyeglasses, a video processing unit and an implanted retinal prosthesis or artificial retina. This device converts the video images captured from the video camera into a series of small electrical impulses that are wirelessly transmitted to an array of 60 electrodes on the retina. While the Argus II Retinal Prosthesis System will not restore vision to patients, it

replaces the function of degenerated cells in the retina and may improve a patient's ability to perceive images, detect light and dark in the environment and it may help them in identifying the location or movement of objects or people.

Studies and clinical trials have noted that Argus II Retinal Prosthesis System has an acceptable risk profile and is a beneficial therapy for profoundly blind patients with RP. They have also shown that individuals implanted with this device were able to perform a motion detection task they could not do with their native vision, confirming that electrical stimulation of the retina provides spatial information from synchronized activation of multiple electrodes.

After an FDA-convened panel of 19 experts voted unanimously that the benefits outweighed the risks of the Argus II System, the FDA approved the System for market under the Humanitarian Device Exemption in the United States.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2017, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	Description
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-hyphenocular 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-hyphenocular 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 Codes	Description
C1841	Retinal prosthesis, includes all internal and external components
C1842	Retinal prosthesis, includes all internal and external components; add-hyphenon to C1841

HCPCS Codes	Description
L8608	Miscellaneous external component, supply or accessory for use with the argus ii retinal prosthesis system

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
H35.52	Pigmentary retinal dystrophy

Reviews, Revisions, and Approvals	Date	Approval Date
Policy Adopted from Health Net NMP#349 Artificial Retina	6/17	
Added references	6/18	6/18
Added CPT and HCPCS codes and references	6/19	6/19
Reviewed, no changes	6/20	6/20

References

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12. Seitz IP, Achberger K, Liebau S, Fischer MD. Stem cells for retina replacement. Klin Monbl Augenheilkd. 2016;233(12):1350-1356.
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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.