Clinical Policy: Artificial Retina
Reference Number: HNCA.CP.MP.349
Last Review Date: 6/21

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 Administration (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 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**

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<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>0100T</td>
<td>Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy</td>
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<tr>
<td>0472T</td>
<td>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</td>
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<tr>
<td>0473T</td>
<td>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</td>
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<th>HCPCS Codes</th>
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<tr>
<td>C1841</td>
<td>Retinal prosthesis, includes all internal and external components</td>
</tr>
<tr>
<td>C1842</td>
<td>Retinal prosthesis, includes all internal and external components; add-hyphenon to C1841</td>
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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

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<thead>
<tr>
<th>ICD-10-CM Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>H35.52</td>
<td>Pigmentary retinal dystrophy</td>
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Reviews, Revisions, and Approvals

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<thead>
<tr>
<th>Description</th>
<th>Date</th>
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<tr>
<td>Policy Adopted from Health Net NMP#349 Artificial Retina</td>
<td>6/17</td>
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<tr>
<td>Added references</td>
<td>6/18</td>
<td>6/18</td>
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<tr>
<td>Added CPT and HCPCS codes and references</td>
<td>6/19</td>
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<tr>
<td>Reviewed, no changes</td>
<td>6/20</td>
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<tr>
<td>Updated references, no change</td>
<td>6/21</td>
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References

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.

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**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](http://www.cms.gov) for additional information.

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