Retinal Prosthesis

Description

A retinal prosthesis replaces lost photoreceptor function by transmitting external images to an array of electrodes or via light sensors placed in the epiretinal or subretinal space. The artificial retina 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. Several models of retinal prostheses are in development in the United States, Europe, and Asia. Only the Argus II system has been cleared for use by the U.S. Food and Drug Administration.

OBJECTIVE

The objective of this evidence review is to determine whether retinal prostheses improve the net health outcome in patients with blindness secondary to retinal diseases.

POLICY STATEMENT

Retinal prostheses are considered investigational.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
**BENEFIT APPLICATION**

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

The investigational device exemption limited the use of this device to 6 centers in the United States. Therefore, out-of-network referral may be requested.

**FDA REGULATORY STATUS**

In 2013, the Argus II Retinal Prosthesis System (Second Sight Medical) was cleared for marketing by the U.S. Food and Drug Administration through a humanitarian use device exemption. This exemption is limited to devices that treat or diagnose fewer than 4000 people in the United States each year. The Argus II system is intended for use in adults, age 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 history of the ability to see forms. Patients must also be willing and able to receive the recommended postimplant clinical follow-up, device fitting, and visual rehabilitation. Food and Drug Administration product code: NBF.

**RATIONALE**

**Summary of Evidence**

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 U.S. Food and Drug Administration 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 Food and Drug Administration-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 Food and Drug Administration-approved device (Argus II); numerous articles on this study have 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 vs off. Performance on the most difficult task (grating discrimination) was still relatively low with the device on. Subgroup studies 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 evidence is insufficient to determine the effects of the technology on health outcomes.

**SUPPLEMENTAL INFORMATION**

**Practice Guidelines and Position Statements**

No guidelines or statements were identified.

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.
REFERENCES


POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>June 2013</td>
<td>Replace policy</td>
<td>Policy was updated with literature review, adding reference 4, 5, 10 &amp; 11. No changes were made to the policy statement.</td>
</tr>
<tr>
<td>June 2015</td>
<td>Replace policy</td>
<td>Policy updated with literature review, references 2 and 5 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>September 2016</td>
<td>Replace policy</td>
<td>Policy updated with literature review through January 8, 2018; references 1, 3, and 8 added. Policy statement unchanged except &quot;not medically necessary&quot; corrected to &quot;investigational&quot; based on HDE FDA status.</td>
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<tr>
<td>June 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through February 28, 2019; no references added. Policy statement unchanged.</td>
</tr>
<tr>
<td>June 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through February 28, 2019; no references added. Policy statement unchanged.</td>
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