BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 9.03.15 Retinal Prosthesis

Effective Policy Date: July 1, 2023

Original Policy Date: March 2012

Related Policies:

None

Retinal Prosthesis

Description

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 individuals 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 (FDA).

OBJECTIVE

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

POLICY STATEMENT

Retinal prostheses are considered **investigational**.

POLICY GUIDELINES

None

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 FDA 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. FDA 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 (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 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 versus 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 that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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

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3. da Cruz L, Dorn JD, Humayun MS, et al. Five-Year Safety and Performance Results from the Argus II Retinal Prosthesis System Clinical Trial. Ophthalmology. Oct 2016; 123(10): 2248-54. PMID 27453256
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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
March 2012	New policy	
June 2013	Replace policy	Policy statement revised from investigational to not medically necessary. Device became FDA approved in early 2013. Rationale revised. References added and removed.
June 2015	Replace policy	Policy was updated with literature review, adding reference 4, 5, 10 & 11. No changes were made to the policy statement.
September 2016	Replace policy	Policy updated with literature review, references 2 and 5 added. Policy statement unchanged.
June 2018	Replace policy	Policy updated with literature review through January 8, 2018; references 1, 3, and 8 added. Policy statement unchanged except "not medically necessary, corrected to "investigational, based on HDE FDA status.
June 2019	Replace policy	Policy updated with literature review through February 26, 2019; no references added. Policy statement unchanged.
June 2020	Replace policy	Policy updated with literature review through January 13, 2020; no references added. Policy statement unchanged.
June 2021	Replace policy	Policy updated with literature review through December 13, 2020; no references added. Policy statement unchanged.
June 2022	Replace policy	Policy updated with literature review through December 20, 2021; no references added. Policy statement unchanged.
June 2023	Replace policy	Policy updated with literature review through December 19, 2022; no references added. Policy statement unchanged.