BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES
SECTION: VISION

ORIGINAL EFFECTIVE DATE: 04/19/05
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ARTIFICIAL RETINA

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

The artificial retina has been investigated as a device to restore vision for individuals afflicted with blindness secondary to retinitis pigmentosa, hereditary retinal degeneration and age-related macular degeneration. Images are obtained by a small video camera worn externally on glasses, processed by externally worn microcomputers and transmitted to electrodes implanted within a subconjunctival retinal prosthesis to stimulate the optic nerve. The Argus™ 16 and second generation Argus™ II are being investigated in clinical trails. In 2013, the FDA approved a humanitarian use device exemption (HDE) for the Argus II retinal prosthesis for use in individuals with severe to profound retinitis pigmentosa.

ARTIFICIAL RETINA (cont.)

Criteria:

- Artificial retina is considered ***experimental or investigational*** based upon:

1. Lack of final approval from the Food and Drug Administration, and
2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
3. Insufficient evidence to support improvement of the net health outcome, and
4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
5. Insufficient evidence to support improvement outside the investigational setting.

Resources:

1. 9.03.15 BCBS Association Medical Policy Reference Manual. Retinal Prosthesis. Re-issue date 02/13/2014, issue date 04/01/2005

2. Javaheri M, Hahn DS, Lakhanpal RR, Weiland JD, Humayun MS. Retinal prostheses for the blind. Ann Acad Med Singapore. 2006 Mar 2006;35(3):137-144

FDA Humanitarian Device Exemption for Argus II:

- The HDE allows Second Sight Medical Products, Inc., to market the above device for the use in patients with severe to profound retinitis pigmentosa who meet the following criteria:

  - Adults, age 25 years or older
  - Bare light or not light perception in both eyes. (If the patient has no residual light perception, then evidence of intact inner layer retina function must be confirmed.)
  - Previous history of useful form vision.
  - Aphakic or pseudophakic. (If the patient is phakic prior to implant, the natural lens will be removed during the implant procedure.)
  - Patients who are willing and able to receive the recommended post-implant clinical follow-up, device fitting, and visual rehabilitation.