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Originated Department	Clinical Operations

Retinal Prosthesis

Audience

Providers, Members, Brokers, MHC

Purpose

Medical policy provides general guidance for applying Mountain Health CO-OP benefit plans (for purposes of medical policy, the terms “benefit plan” and “member contract” are used interchangeably). Coverage decisions must reference the member specific benefit plan document. The terms of the member specific benefit plan document may be different than the standard benefit plan upon which this medical policy is based. If there is a conflict between a member specific benefit plan and the Mountain Health CO-OP’s standard benefit plan, the member specific benefit plan supersedes this medical policy. Any person applying this medical policy must identify member eligibility, the member specific benefit plan, and any related policies or guidelines prior to applying this medical policy, including the existence of any state or federal guidance that may be specific to a line of business. Mountain Health CO-OP medical policies are designed for informational purposes only and are not an authorization, explanation of benefits or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the member specific benefit plan coverage. Mountain Health CO-OP reserves the sole discretionary right to modify all its policies and guidelines at any time. This medical policy does not constitute medical advice.

Definition

Policy/Procedure

Commercial Plans
Mountain health Co-Op considers retinal prostheses as investigational, experimental and unproven unless specifically indicated as covered.

1. Section 1862(a)(1)(A) of the Social Security Act is the basis for denying payment for types of care, specific items, services, or procedures, not excluded by any other statutory clause, meeting all technical requirements for coverage, but are determined to be any of the following:

- 1.1** Not generally accepted in the medical community as safe and effective in the setting and for the condition for which it is used,
 - 1.2** Not proven to be safe and effective based on peer review or scientific literature
 - 1.3** Experimental
 - 1.4** Not medically necessary in the particular case
 - 1.5** Furnished at a level, duration or frequency that is not medically appropriate
 - 1.6** Not furnished in accordance with accepted standards of medical practice, or
 - 1.7** Not furnished in a setting appropriate to the patient's medical needs and condition.
- 2.** Items and services must be established as safe and effective to be considered medically necessary. That is, the items and services must be:
- 2.1** Consistent with the symptoms or diagnosis of the illness or injury under treatment; and
 - 2.2** Necessary for, and consistent with, generally accepted professional medical standards of care (e.g., not experimental or investigational);and
 - 2.3** Not furnished primarily for the convenience of the patient, the provider or supplier; and
 - 2.4** Furnished at the most appropriate level that can be provided safely and effectively to the patient.

Medical devices that are not approved for marketing by the Food and Drug Administration (FDA) are considered investigational by Medicare and are not considered reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve functioning of a malformed body member. Mountain Health Co-Op payments, therefore, may not be made for medical procedures and services performed using devices that have not been approved for marketing by the FDA or for those not included in an FDA-approved investigational (IDE) trial.

3. Background

- 3.1** Two approaches are being explored to develop an artificial retina that 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. The first is implantation of electrode arrays in the epiretinal or subretinal space to stimulate retinal ganglion cells. A second approach is the implantation in the subretinal space of light-sensitive multiphotodiode arrays, which stimulate the remaining photoreceptors in the inner retina. Use of a multiphotodiode array does not require external image processing. The latter approach is being evaluated for degenerative retinal diseases such as retinitis pigmentosa, in which outer retinal cells deteriorate, but inner retinal cells remain intact for years. Research in the United States began with a first-generation, 16-electrode device (e.g., the Argus 16; Second Sight Medical Products), which permitted the distinction between the presence and absence of light. Three government organizations provided support for the development of the Argus II: the Department of Energy, National Eye Institute at the National Institutes of Health,

and National Science Foundation. They collaborated to provide grant funding, support for material design, and other basic research for the project.

3.2 Devices in development, none of which are approved or cleared by the U.S. Food and Drug Administration (FDA), include the following.

- a)** The Alpha IMS was developed at the University of Tübingen, and has an electronic chip design provided by the Institute for Microelectronics, Stuttgart. The second-generation Alpha IMS device has wireless power and signal transmission and is produced by Retina Implant AG (Germany). The microchip is implanted subretinally and receives input from a multiphotodiode array with 1500 elements that moves with the eye, senses incident light, and applies a constant-voltage signal at the respective 1500 electrodes. The multiphotodiode array transforms visual scenes into corresponding spatial patterns (38 ´ 40 pixels) of light-intensity-dependent electric stimulation pulses with a maximum visual field of 15°.
- b)** The Boston Retinal Implant Project uses an external camera mounted on a pair of glasses and a 100-electrode array. The image obtained by the external camera is translated into an electromagnetic signal transmitted from the external primary data coil mounted on a pair of glasses to the implanted secondary data coil attached to the cornea. Most of the volume of the implant lies outside the eye, with transscleral cables connected to a subretinal electrode array. The Boston Retinal Implant Project is a joint effort of the Massachusetts Institute of Technology, the Massachusetts Eye and Ear Infirmary, the Veterans Affairs Boston Healthcare System, and Cornell University.
- c)** EPIRET3 retinal implant (Philipps-University Marburg, Germany) is a wireless system that consists of a semiconductor camera on the frame of a pair of glasses and a transmitter coil outside the eye, which sends electromagnetic signals to a receiver coil in the anterior vitreous (similar to an intraocular lens), which passes them on to a receiver microchip. A stimulator chip then generates the stimulation pulses and activates a selection of 25 electrodes placed on the epiretinal surface via a connecting micro cable.
- d)** Intelligent Retinal Implant System (Pixium Vision, Paris, France) uses an external camera integrated with a pair of glasses and linked by wire to a pocket computer. Receiver electronics connect via a scleral tunnel to an electrode array on the surface of the retina. Pixium Vision is also developing PRIMA, which uses a subretinal implant.
- e)** Learning Retinal Implant (Intelligent Medical Implants, Zug, Switzerland) uses an external camera on the frame of a pair of glasses and wireless data and power transfer. Receiver electronics connect via a scleral tunnel to an epiretinal implant. A retinal encoder with 100 to 1000 tunable spatiotemporal filters simulates the filtering operations performed by the ganglion cell and allows individual calibration to improve each patient's visual perception.
- f)** The Microelectrode-STs (suprachoroidal-transretinal stimulation) system (Osaka University, Japan) places its 9-electrode retinal prosthesis in a scleral pocket with a reference electrode in the vitreous cavity. A video camera is used to detect a visual object. Because the electrodes are at a greater distance from the retina, the resolution of the image may be lower than other devices. A

proposed advantage of the STS prosthesis over epi- or subretinal prostheses is the safety of the surgical procedure, because the electrodes do not touch the retina.

4. Regulatory Status

4.1 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.

5. Rationale

- 5.1** This evidence review was created in April 2005 and has been updated regularly using searches of the PubMed database. The most recent literature update was performed through December 19, 2022. Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.
- 5.2** To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice. The following is a summary of the key literature to date.
- 5.3** Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.)

will continue when reflective of language used in publications describing study populations.

6. Clinical Context and Therapy Purpose

6.1 The purpose of implanting a retinal prosthesis in individuals who have blindness due to retinal diseases is to provide a treatment option that is an alternative to or an improvement on existing therapies.

6.2 The question addressed in this evidence review: Does the use of a retinal prosthesis in individuals who have blindness due to retinal diseases improve net health outcomes?

The following PICO was used to select literature to inform this review.

7. Populations

7.1 The relevant population(s) of interest is individuals with blindness secondary to retinal diseases, such as retinitis pigmentosa, hereditary retinal degeneration, and some forms of age-related macular degeneration.

8. Interventions

8.1 The treatment being considered is the use of a retinal prosthesis. The Argus II Retinal Prosthesis System (Argus II) is the second-generation device, which has 60 electrodes. The retinal prosthesis, with the electrode array, is surgically implanted in and on the eye. The system's external components include a small external video camera, held on eyeglass frames, that captures images then processed by an externally worn microcomputer. These signals are transmitted to an antenna in the prosthesis, an electronics package in the superior temporal quadrant and an electrode array implanted in the back of the eye, which in turn stimulates the optic nerve. It has been suggested that future-generation devices, containing more than 1000 electrodes, will provide more detailed vision.

9. Comparators

9.1 Standard treatment of retinal diseases; medical therapies in early stage of some conditions and adaptive interventions.

10. Outcomes

10.1 The general outcomes of interest are symptoms, change in disease status, functional outcomes and quality of life. More specific outcomes include: visual function, visual acuity, laboratory-based visual performance measures, and day-to-day function.

10.2 Follow-up of at least 6 months would be desirable to assess outcomes.

10.3 Study Selection Criteria

10.4 Methodologically credible studies were selected using the following principles:

- a)** To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- b)** In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- c)** To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Studies with duplicative or overlapping populations were excluded.

11. Review of Evidence

- 11.1** A 2016 technology assessment prepared for the Agency for Healthcare Research and Quality included a systematic review of the literature on retinal prostheses.¹ Reviewers included studies on the Argus II, the only retinal prosthesis cleared for marketing in the United States, as well as other retinal prostheses. Outcomes of interest were visual function, visual acuity, laboratory-based visual performance measures, day-to-day function, and quality of life. In their qualitative summary of the literature on retinal prostheses, reviewers concluded that the strength of evidence was insufficient for all outcomes. One single-arm study with 30 patients (NCT00407602) has evaluated the Argus II retinal prosthesis; numerous articles have been published on its findings and on subgroup studies conducted on some or all of the participants. The study was prospective and multicenter, with sites in the United States and Europe. It included patients with retinitis pigmentosa (United States) or outer retinal degeneration (Europe) who had bare light perception or no light perception in both eyes. Articles based on this study are described next.
- 11.2** Humayun et al (2012) reported on interim (minimum 6-month) results on 3 types of visual acuity tasks using a computer and 2 types of real-world utility tests. 2, The computer tasks included square localization (locating a high-contrast white square of light on a black background), direction of motion (indicating the direction of a high-contrast bar moving across the screen), and grating discrimination (discriminating among square-wave gratings of different spatial frequencies presented on a monitor). Patients performed better on all 3 computer tasks with the system on than off. In terms of the 2 real-world utility tests, with the system on, subjects had a 54% success rate in finding a door compared with a 27% success rate with the device off and a 68% success rate in following a white line on a dark floor compared with a 23% success rate with the device off. Although all subjects were able to perceive light when the system was stimulated, Argus II did not affect full-field light perception. Da Cruz et al (2016) reported on 3- and 5-year results of the visual acuity tests. 3, Patients performed significantly better on the 3 computer tasks with the device on than off. For the simplest task, square localization, 89% (25/28) of patients tested did better with the device on and, at year 5, 81% (17/21) of patients tested did better with the device on. For grating discrimination, the most difficult assessment, 33% (9/27) of patients tested at year 3 did better with the device on and 38% (8/21) of patients tested at year 5 did better with the device on. Ho et al (2015) reported on safety up to 3 years. 4, At 3 years post-implantation, 23 serious adverse events were reported in 11 patients; the most commonly reported were conjunctival erosion (n=4), hypotony (n=4), conjunctival dehiscence (n=3), and presumed endophthalmitis (n=3). Five-year safety was reported by da Cruz et al (2016). 3, As reported by da Cruz, only 1 additional serious adverse event, a case of a rhegmatogenous retinal detachment, occurred after the 3-year follow-up (>4.5 years).³ Three devices were explanted, one each at 14 months, 3.5 years, and 4.3 years after implantation. Two patients experienced recurrent conjunctival erosion and the third experienced chronic hypotony and ptosis. Several publications have reported on additional functional outcomes in patients participating in the Argus II study. Patients served as their own controls; performance was compared with the device in the on vs off position. Geruschat et al (2016) reported on observer-rated

assessments of visual function using the multicomponent Functional Low-Vision Observer Rated Assessment, which evaluates performance of 35 tasks.⁵ Tasks were grouped into 4 domains: visual orientation, mobility, daily life, and interaction with others. Twenty-six (87%) of the 30 enrolled patients were included in the analysis at a mean of 36 months (range, 18-44 months) after device implantation. All patients performed significantly better ($p < 0.05$) in each of the 4 domains with the device on versus off, ranging from 19% to 38% improvement. Twenty-four (69%) of 35 tasks had statistically significant improvements in outcomes (i.e., they were easier to perform) with the device turned on versus off. A 2013 study reported on letter and word reading at 20 months in 21 patients participating in the Argus II study.⁶ Correct letter reading ranged from 51.7% to 72.3% with the device on, compared with 15.3% to 17.7% with the device off. The average time to correctly identify letters with the device ranged from 47.7 to 68.6 seconds. Subjects who successfully completed the letter identification task proceeded to the next task. Six subjects were able consistently to read letters of reduced size. The smallest letter identified was 0.9 cm for 1 subject, but the preferred letter size was as much as 22.6 cm. Four subjects were able to correctly identify 2-, 3-, and 4-letter words. Kotecha et al. (2014) reported on further testing of 6 patients from one of the Argus II study sites that had at least 3 years of follow-up; reaching and grasping outcomes were assessed.⁷ The test consisted of picking up a white cube from a table covered with black felt and illuminated from above, and was conducted with the electrode array on, array off, and scrambled (i.e., array stimulated with a random, scattered input), in a random order. Also randomized was the location of the object, which could be placed in 1 of 4 positions. To eliminate the use of any residual vision among participants, certain patients had both eyes taped shut during the test. After 4 to 6 weeks, patients were retested to examine repeatability of performance. The percentage of successful grasps was significantly higher with the device on (69%) compared with off (0%); this finding was maintained at the second visit. With the signal scrambled, success rates were 59% at the first visit and 28% at the second visit. There were no significant differences between “on” or “scrambled” conditions for movement onset, time to object contact, or path deviation ratio, which was defined as the “deviation of the movement trajectory from a straight route between the starting and object contact wrist positions.” Dagnelie et al. (2017) evaluated performance on several functional tasks in 28 of 30 study participants who had been implanted with the device between 6 months and 3 years earlier.⁸ The 3 tasks were intended to have real-world applications. Performance was compared with the retinal prosthesis device on and off. Task 1 was sock sorting; task 2 was sidewalk tracking; and task 3 was walking direction discrimination. On all 3 tasks, subjects performed significantly better with the device on than off ($p < 0.05$). (For the sock sorting task, results were presented in figures, hence precise data were not available.) With a cloth-covered table, subjects sorted approximately 70% of the socks correctly with the device on and 30% correctly with the device off. With a bare table, subjects sorted approximately 50% of socks correctly with the device and 30% with the device off. For the sidewalk task, subjects walked out of bounds a mean of 6.85 times with the device off and a mean of 4.93 times with the device on. For the walking direction discrimination task, 15 (56%) of 27 subjects performed

significantly better than chance with the device on and 4 performed significantly better than chance with the device off. Although statistically significant, the clinical significance of the differences in performance on the 3 tasks is uncertain.

12. Summary of Evidence

12.1 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 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 a 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.

12.2 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.

13. Supplemental Information

13.1 The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

14. Practice Guidelines and Position Statements

14.1 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.

14.2 No guidelines or statements were identified.

15. U.S. Preventive Services Task Force Recommendations

15.1 Not applicable.

16. Medicare National Coverage

16.1 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.

17. Ongoing and Unpublished Clinical Trials

17.1 Some currently ongoing and unpublished trials that might influence this review are listed in

Table 1.

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
Unpublished			
NCT01864486 ^a	Restoring Vision With the Intelligent Retinal Implant System (IRIS V1) in Patients With Retinal Dystrophy (Title in France: Compensation of Vision With the Intelligent Retinal Implant System (IRIS V1) in Patients With Retinal Dystrophy)	20	Oct 2017 (updated 10/17/17)
NCT02303288 ^a	Post-Market Study of the Argus® II Retinal Prosthesis System - France	18	Nov 2018 (updated 06/22/20)

Table 1. Summary of Key Trials

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

18. Essential Health Benefits

18.1 The Affordable Care Act (ACA) requires fully insured non-grandfathered individual and small group benefit plans to provide coverage for ten categories of Essential Health Benefits (“EHBs”), whether the benefit plans are offered through an Exchange or not. States can define EHBs for their respective state.

18.2 States vary on how they define the term small group. In Idaho, a small group employer is defined as an employer with at least two but no more than fifty eligible employees on the first day of the plan or contract year, the majority of whom are employed in Idaho. Large group employers, whether they are self-funded or fully insured, are not required to offer EHBs, but may voluntarily offer them.

18.3 The ACA requires any benefit plan offering EHBs to remove all dollar limits for EHBs.

19. Applicable Coding

19.1 The following codes and coding guidance are provided for general reference purposes only and may not be all-inclusive. The inclusion of a code does not guarantee or imply any right to member coverage or provider reimbursement, nor does its exclusion represent or imply that coverage or reimbursement is unavailable. All benefit coverage determinations are subject to the member-specific benefit plan documentation as well as additional terms and conditions, including but not limited to the written coverage position set forth in this medical policy, legal requirements, and other policies and guidelines, as applicable.

CPT 0100T	Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy
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0472T	Device evaluation, interrogation, and initial programming of intra-ocular retinal electrode array (e.g., 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-ocular retinal electrode array (e.g., retinal prosthesis), in person, including reprogramming and visual training, when performed, with review and report by a qualified health care professional
HCPCS	
L8608	Miscellaneous external component, supply or accessory for use with the Argus II Retinal Prosthesis System
V2799	Vision item or service, miscellaneous
ICD-10-CM	Investigational for all relevant diagnoses
H35.31 10- H35.3194	Nonexudative age-related macular degeneration code range
H35.50	Unspecified hereditary retinal dystrophy
H35.52	Pigmentary retinal dystrophy
ICD-10-PCS	ICD-10-PCS codes are only used for inpatient services. There is no specific ICD-10-PCS code for this procedure.
08H005Z, 08H105Z	Surgical, eye, insertion, epiretinal visual prosthesis code range, codes for right and left eye
08UE0JZ, 08UE3JZ, 08UF0JZ, 08UF3JZ	Surgical, eye, supplement, synthetic substitute, code by body part (right retina or left retina) and approach (open or percutaneous)

Vendors

- **Personify**
- **HPS**

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8. Dagnelie G, Christopher P, Arditi A, et al. Performance of real-world functional vision tasks by blind subjects improves after implantation with the Argus® II retinal prosthesis system. *Clin Exp Ophthalmol*. Mar 2017; 45(2): 152-159. PMID 27495262

Review/Revision/Approval History

Date	Description
06/27/2024	New Policy
04/27/2026	Reviewed and approved by Mountain Health CO-OP Policy Committee

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