KAISER PERMANENTE® Mid-Atlantic States	**Eye Prostheses** **Medical Coverage Policy**

2024 New Policy

UTILIZATION * ALERT*

- Prior to use of this MCP for evaluation of medical necessity, benefit MUST be verified in the member's EOC or benefit document if it includes the optional rider.
- Please refer to CMS guidelines or National Coverage Determination (NCD) for Medicare members. If no NCD/LCD/LCA is found after searching the Medicare Coverage Database, then use the policy referenced above for coverage guidelines.

I. Procedure: Eye Prostheses

II. Scope: Ocular Prostheses and Retinal Prosthesis

The retinal prostheses addressed in this policy are limited to three regulatory-approved retinal prostheses. Soft contact lenses are not discussed in this policy.

III. Ocular prosthesis

An ocular prosthesis or artificial (prosthetic) eye is a device which simulates the appearance of a natural eye by maintaining the volume of the eye socket but does not restore lost vision. An ocular prosthesis is indicated when there is absence or shrinkage of an eye due a birth defect, trauma, or surgical removal.

A. Adjustment, Repair and Replacement

The following services are considered medically necessary and eligible for coverage if the following requirements are met:

1. **Initial enlargement or reduction** of ocular prosthesis.
2. **Additional enlargement or reduction** of the ocular prosthesis when there is medical documentation that clearly supports the need for additional prosthetic enlargement or reduction.
3. **Modification** to ocular prosthesis, when it has been > than 90 days after delivery of the prosthesis and modification to prosthesis is required due to a change in the patient's condition.

4. **Polishing and resurfacing** of an ocular prosthesis twice per year.
5. **Repair** to the ocular prosthesis due to extensive wear or accidental damage to the prosthesis will be covered unless the cost of repairs exceeds the estimated expense for a replacement prosthesis.
6. **Replacement** of an ocular prosthesis or prosthetic component because of loss or irreparable damage under the following circumstances.
   a. After the five (5) year reasonable useful lifetime of the ocular prosthesis; **or**
   b. Prior to five years if the prosthesis is irreparably damaged, lost or stolen; **and**
      i. There is appropriate medical documentation that supports the prosthesis as originally ordered still fills the medical need of the patient; **or**
      ii. There is documentation from the ocularist to substantiate that replacement prosthesis is necessary.

B. Limitation

An ocular prosthesis is considered not medically necessary for the following:

1. Any condition other than those cited in section III or section IV; **or**
2. Any item or service that does not meet the requirements specified in this policy unless there is documentation that clearly explain and justify the medical need of the patient; **or**
3. Follow-up visit that occurs > than 90 days after delivery of eye prosthesis that do not involve modification or repair of the prosthesis; **or**
4. Services considered as inclusive within the eye prosthesis global component and not eligible for separate coverage such as any of the following:
   a. Patient evaluation for eye prosthesis; **and**
   b. Pre-operative planning; **and**
   c. Cost of prosthesis materials; **and**
   d. Labor associated with fabrication and fitting of the prosthesis; **and**
   e. Modifications to prosthesis at the time of prosthesis delivery or within 90 days post prosthetic delivery; **and**
   f. Prosthesis repair due to normal wear or tear within 90 days of delivery; **and**
   g. Follow-up visits within 90 days of delivery of the prosthesis; **and**
   h. Trial scleral cover shells which are fashioned to allow the eye to grow accustomed to the direct contact of the prosthesis.

IV. Scleral Shells

A scleral shell cover is a thin, plastic ocular device that is fitted directly over a malformed or cosmetically blemished eye and fabricated over the existing eye, covering the entire exposed surface of the eye to restore its natural appearance.

A. Clinical Indication

A scleral shell cover is indicated when the patient meets **all** of the following criteria:

1. Diagnosed with **any** of the following conditions:
   - **a.** Phthisis bulbi; or
   - b. Evisceration surgery; **or**
   - c. Microphthalmia; **or**
   - d. A full-sized disfigured eye; **and**
2. The scleral shell is intended for the treatment of **any** of the following:
   - a. An eye that is rendered sightless and shrunken by injury, illness, congenital anomaly, or inflammatory disease; **or**
   - b. "Dry eye" where the scleral shell serves as a substitute for the function of the diseased lacrimal gland; **and**
3. Condition of the afflicted eye:
   - **a.** The afflicted eye is stable and pain free; **and**
   - b. The afflicted eye is smaller than the undamaged companion eye; **and**

B. Adjustment, Repair, Replacement and Limitation

See section III, A and B

V. Prosthetic Replacement of the Ocular Surface Ecosystem (PROSE)

A. Clinical Indication:

PROSE is a prosthetic device system that provides therapeutic use and will be considered once the patient has failed the rigid gas permeable, hybrid and scleral lenses and need to meet the following conditions:

1. Irregular cornea

- a. As a refractive treatment for individuals with corneal conditions that cause irregular astigmatism or large asymmetric refractive errors.

- **b.** For the management of a distorted corneal surface (from corneal degenerations, corneal dystrophies, and corneal scarring from surgery, infection, or trauma), providing

an ideal microenvironment that allows constant lubrication of the ocular surface and protection from desiccation and mechanical trauma from the eyelids.

i. Neurotrophic keratitis; **or**
ii. Corneal exposure; **or**
iii. Corneal ectasia (i.e. keratoconus, keratoglobus, post-keratoplasty, post-radial keratotomy); **or**
iv. Corneal degenerations (such as Salzmann's nodular degeneration and Terrien's degeneration, as well as corneal dystrophies; **or**
v. Ocular surface disease from any of the following:
    1) Dry eye; **or**
    2) Limbal stem cell deficiency; **or**
    3) Disorders of the skin such as ectodermal dysplasia; **or**
vi. Post-surgical corneas

2. Ocular Surface Disease

a. To protect and support the ocular surface to promote healing, reduce symptoms, and prevent ocular surface breakdown for any of the following:
    i. Keratoconjunctivitis sicca; **or**
    ii. Stevens-Johnson syndrome; **or**
    iii. Ocular cicatricial pemphigoid; **or**
    iv. Sjogren's syndrome; **or**
    v. Rheumatoid arthritis; **or**
    vi. Ocular graft-versus-host disease

b. For the treatment of any of the following:
    i. Non-specific dry eye; **or**
    ii. Corneal neuropathy; **or**
    iii. Neurotrophic keratitis; **or**
    iv. Exposure keratopathy; **or**
    v. Descemetocele; **or**
    vi. Limbal stem cell deficiency; **or**
    vii. Aniridic keratopathy; **or**
    viii. Vernal keratoconjunctivitis

B. Limitations

PROSE is not recommended for individuals with any of the following as these conditions may lead to treatment failure:

1. Corneal edema secondary to endothelial dysfunction; **or**
2. Lower endothelial cell counts after penetrating keratoplasty; **or**
3. Fuch's dystrophy; **or**
4. Debris accumulation on the device, particularly those with ocular surface inflammation; **or**
5. Poor patient hygiene and compliance

VI. Retinal Prosthesis

Retinal prosthesis is an implantable electronic device, designed to stimulate sensation of vision in the eyes of individuals with significant retinal diseases, such as retinitis pigmentosa or age-related macular degeneration, where the optic nerve and visual cortex are unaffected. At this time, this technology is investigational and experimental as the effectiveness and clinical availability of this treatment have not been established.

Definitions:

Ocular prosthesis/Prosthetic eye (commonly called a "glass eye" or "fake eye") is a type of craniofacial prosthesis that replaces an absent natural eye following an enucleation, evisceration, or orbital exenteration. It is usually made from acrylic and can be custom-made to match the appearance of a natural eye.

Scleral shell is a thin, hard shell, to be worn over a damaged or eviscerated eye when a prosthetic eye is too large for a disfigured eye that is still present.

Flush shell is a special type of scleral shell for people with eyes that are almost full size.

Conformer shell is a clear acrylic shell, used as a temporary covering after eye surgery to help expand the socket and maintain its shape.

Prosthetic Replacement of the Ocular Surface Ecosystem (PROSE)
(PROSE) is an iterative and integrated medical treatment that promotes healing, reduces symptoms, and/or restores vision for patients with complex corneal disease.

Retinal Prostheses
Retinal prostheses are implantable electronic vision devices for people with profound vision loss secondary to severe stages of retinal degenerative disease such as retinitis pigmentosa and age-related macular

degeneration. The patient is required to have a relatively intact posterior visual pathway (optic nerve, lateral geniculate nucleus and visual cortex) when the implant is inserted in or near the retina in order for the retinal prosthetic device to stimulate the residual elements of the patient's visual pathway to have an improved ability to localize high-contrast objects, navigate, and perform basic orientation task.

References:

1. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) LCD - Eye Prostheses (L33737). Accessed: 07/17/2024. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33787&ver=29&keyword=lower%20extremity%20prostheses&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1
2. Asghari, B., Carrasquillo, K. G., Kwok, A., & Sippel, K. C. (2023). Use of PROSE for long-term ocular surface support in patients with a permanent keratoprosthesis. American journal of ophthalmology case reports, 32, 101919. https://doi.org/10.1016/j.ajoc.2023.101919
3. Fadel, D., & Kramer, E. (2019). Potential contraindications to scleral lens wear. Contact lens & anterior eye: the journal of the British Contact Lens Association, 42(1), 92–103. https://doi.org/10.1016/j.clae.2018.10.024
4. Cohen ED. Retinal Prostheses. 2018 Mar 19. In: Kolb H, Fernandez E, Nelson R, editors. Webvision: The Organization of the Retina and Visual System [Internet]. Salt Lake City (UT): University of Utah Health Sciences Center; 1995-. https://www.ncbi.nlm.nih.gov/books/NBK493746/
5. Bloch, E., Luo, Y., & da Cruz, L. (2019). Advances in retinal prosthesis systems. Therapeutic advances in ophthalmology, 11, 2515841418817501. https://doi.org/10.1177/2515841418817501
6. Geruschat, D. R., Richards, T. P., Arditi, A., da Cruz, L., Dagnelie, G., Dorn, J. D., Duncan, J. L., Ho, A. C., Olmos de Koo, L. C., Sahel, J. A., Stanga, P. E., Thumann, G., Wang, V., & Greenberg, R. J. (2016). An analysis of observer-rated functional vision in patients implanted with the Argus II Retinal Prosthesis System at three years. Clinical & experimental optometry, 99(3), 227–232. https://doi.org/10.1111/cxo.12359
7. Daschner R, Rothermel A, Rudorf R, Rudorf S, Stett A. Functionality and Performance of the Subretinal Implant Chip Alpha AMS. Sensors and Materials. 2018;30(2):179-192. https://www.researchgate.net/publication/322693141_Functionality_and_Performance_of_the_Subretinal_Implant_Chip_Alpha_AMS
8. Akihide Watanabe, Swati Singh, Dinesh Selva, Jessica Y. Tong, Teruyuki Ogura, Shinnosuke Kajiyama, Chie Sotozono. Socket expansion with conformers in congenital anophthalmia and microphthalmia. *Journal of American Association for Pediatric Ophthalmology and Strabismus,* Volume 26, Issue 6, 2022, Pages 318.e1-318.e6, ISSN 1091-8531. https://doi.org/10.1016/j.jaapos.2022.08.523.
9. Ayton, L. N., Barnes, N., Dagnelie, G., Fujikado, T., Goetz, G., Hornig, R., Jones, B. W., Muqit, M. M. K., Rathbun, D. L., Stingl, K., Weiland, J. D., & Petoe, M. A. (2020). An update on retinal prostheses. *Clinical neurophysiolog : official journal of the International Federation of Clinical*

Neurophysiology, *131*(6), 1383–1398.
10. Chow AY. Retinal prostheses development in retinitis pigmentosa patients-progress and comparison. *Asia Pac J Ophthalmol* 2013; 2:253–68. https://doi.org/10.1016/j.clinph.2019.11.029
11. Chow, A. Y., Chow, V. Y., Packo, K. H., Pollack, J. S., Peyman, G. A., & Schuchard, R. (2004). The artificial silicon retina microchip for the treatment of vision loss from retinitis pigmentosa. *Archives of ophthalmology (Chicago, Ill.: 1960)*, *122*(4), 460–469. https://doi.org/10.1001/archopht.122.4.460
12. Agranat JS, Kitos NR, Jacobs DS. Prosthetic replacement of the ocular surface ecosystem: impact at 5 years. Br J Ophthalmol. 2016 Sep;100(9):1171-5. doi: 10.1136/bjophthalmol-2015-307483. Epub 2015 Dec 7. PMID: 26644423; PMCID: PMC5013114. https://pmc.ncbi.nlm.nih.gov/articles/PMC5013114/
13. Bita Asghari, Karen G. Carrasquillo, Alan Kwok, Kimberly C. Sippel. Use of PROSE for long-term ocular surface support in patients with a permanent keratoprosthesis. *American Journal of Ophthalmology Case Reports,* Volume 32, 2023, 101919, ISSN 2451-9936. https://doi.org/10.1016/j.ajoc.2023.101919. https://www.sciencedirect.com/science/article/pii/S2451993623001275

Approval History

Effective June 01, 2016, state filing is no longer required per Maryland House Bill HB 798 – Health Insurance – Reporting

Date approved by RUMC	Date of Implementation
11/21/2024	11/212024

*The Regional Utilization Management Committee received delegated authority in 2011 to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any particular set of circumstances for an individual member.