MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Keratoprosthesis**
Policy Number	**9.01.15**
Category	**Technology Assessment**
Original Effective Date	**04/22/10**
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Archive Review Date	**04/21/22, 03/23/23, 03/21/24**
Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, use of the Boston keratoprosthesis (type I or II) is considered **medically appropriate** for the treatment of corneal blindness with severely opaque and vascularized cornea and **ANY** of the following:
   A. One or more prior failed corneal transplants (not required for an infant age one (1) year or less);
   B. An ocular condition with a known low success rate for a primary corneal transplant (e.g., Stevens-Johnson syndrome, ocular cicatricial pemphigoid, autoimmune conditions with rare ocular involvement, ocular chemical burns).

II. Based upon our criteria and assessment of the peer-reviewed literature, all other types of keratoprostheses (e.g., AlphaCor, osteo-odonto-keratoprosthesis) have not been proven to be medically effective and, therefore, are considered **investigational.**

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

DESCRIPTION

The cornea, which is a clear, dome-shaped membrane that covers the front of the eye, is a key refractive element of the eye. Corneal tissue is arranged in a number of layers: the epithelium (outermost layer); Bowman's layer; the stroma, which comprises approximately 90% of the cornea; Descemet's membrane; and the endothelium. For optimal vision, all layers of the cornea must be of normal shape and curvature and free of any cloudy or opaque areas. While many corneal disorders can be managed medically, there are certain conditions, such as severe corneal dystrophies and degenerations, that require surgical intervention. Scarring from infection or trauma may also cause corneal changes that may require surgery. The established surgical treatment for severe corneal disease is penetrating keratoplasty (PK), which involves making a large central opening through the cornea and then filling the opening with full-thickness donor cornea. In certain conditions, such as Stevens-Johnson syndrome, cicatricial pemphigoid, chemical injury, or a prior failed corneal transplant, survival of transplanted cornea is poor.

A keratoprosthesis (KPro) is an artificial cornea that is intended to restore vision to patients with severe bilateral corneal disease (such as prior failed corneal transplants, chemical injuries, or certain immunological conditions) for whom a corneal transplant is not an option. KPros are made of clear plastic with excellent tissue tolerance and optical properties. They vary in design and size, and implantation techniques may differ across different treatment centers. In general, KPros consist of a transparent, cylinder-shaped optical portion and a haptical portion. The optical cylinder is inserted into a central circular opening of the opacified cornea, focusing images on a functioning retina. The haptical section is fixed to and buried under neighboring tissue**.** The designs of KPros differ primarily in the haptical portion of the devices. During implantation of the Boston KPro, the device is assembled with a donor corneal graft positioned between the front and back plate, which is then sutured into place in a similar fashion to traditional penetrating keratoplasty (PK). Although many KPros have been developed, the most commonly used include the Boston keratoprosthesis (Dohlman Doane Keratoprosthesis), Osteo-Odonto-Keratoprosthesis (OOKP), and AlphaCor (previously known as the Chirila keratoprosthesis).

Implantation of a KPro is considered to be a high-risk procedure, associated with numerous complications and probable need for additional surgery. Therefore, the likelihood of regaining vision and the patient's visual acuity in the contralateral eye should be taken into account when considering the appropriateness of this procedure. Treatment should be restricted to centers experienced in treating severe bilateral corneal disease and staffed by surgeons adequately trained in techniques addressing implantation of a KPro.

RATIONALE

Permanent KPros that have received 510(k) marketing approval by the FDA include the Boston Keratoprosthesis (Boston Kpro)/Dohlman-Doane keratoprosthesis, which was approved in 1992; the AlphaCOR (formerly Chirila KPro), which was approved in 2002, and the Oculaid by Ophtec B.V. USA, Inc., which was approved in 2004. The Oculaid KPro is supplied by special request only.

The KPro is intended for the relatively small number of patients who have lost vision and for whom a corneal transplant is not expected to result in satisfactory outcomes. Complications such as implant extrusion, formation of a retroprosthesis membrane requiring additional surgery, worsening of glaucoma, chronic inflammation, and bacterial endophthalmitis can occur. However, patients with severe corneal damage have few treatment options to prevent blindness.

As the implantation of a KPro is considered to be a salvage procedure with no acceptable alternative treatment, comparative studies are lacking. The literature mainly consists of case series with small patient sample populations, with short to mid-term follow-up. The Boston KPro is the most widely studied and utilized in the United States. With the Boston KPro, short- to mid-term visual outcomes demonstrate an improvement in a substantial percentage of patients. Longer follow-up is still needed to further evaluate the effect of this technology on health outcomes. Given the available evidence and the absence of alternative treatment options, use of the Boston KPro is considered medically appropriate,

While studies on the use of a KPro in the pediatric population are extremely limited, corneal transplantation in the pediatric population has an even higher rate of corneal graft rejection; however, given an infant's need to have a clear visual pathway to enable the brain to learn and process images, use of a KPro as a primary procedure is reasonable for infants.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
65770	Keratoprosthesis

HCPCS Codes

Code	Description
C1818	Integrated keratoprosthesis
L8609	Artificial cornea

ICD10 Codes

Code	Description
H17.10-H17.13	Central corneal opacity (code range)
H54.0X-H54.8	Blindness and low vision (code range)
L51.1	Stevens-Johnson syndrome
T26.10-T26.12	Burn of cornea and conjunctival sac (code range)
T26.60-T26.62xA	Corrosion of cornea and conjunctival sac, eye, initial encounter (code range)
T85.318A	Breakdown (mechanical) of other ocular prosthetic devices, implants and grafts, initial encounter
T85.328A	Displacement of other ocular prosthetic devices, implants and grafts, initial encounter
T85.398A	Other mechanical complication of other ocular prosthetic devices, implants and grafts, initial encounter
T86.840-T86.8419	Corneal transplant rejection or failure (code range)

REFERENCES

*Ahmad S, et al. Predictors of visual outcomes following Boston Type 1 keratoprosthesis implantation. Am J Ophthalmology 2014 Dec 30.

*Alio JL, et al. Five year follow-up of biocolonisable microporous fluorocarbon haptic (BIOKOP) keratoprosthesis implantation in patients with high risk of corneal graft failure. Br J Ophthalmol 2004;88:1585-9.

*American Academy of Ophthalmology. Boston Keratoprosthesis (KPro). 2023 Sep. [https://eyewiki.org/Boston_Keratoprosthesis_(KPro)] accessed 02/02/24.

*Akpek EK, et al. Outcomes of Boston Keratoprosthesis in aniridia: a retrospective multicenter study. Am J Ophthalmol 2007 Aug;144(2):227-31.

*Aldave AJ, et al. The Boston type I keratoprosthesis: improving outcomes and expanding indications. Ophthalmology 2009 Apr;116(4):640-51.

*Aquavella JV, et al. Pediatric keratoprosthesis. Ophthalmology 2007 May;114(5):989-94.

*Ament JD, et al. Cost effectiveness of the Boston Keratoprosthesis. Am J Ophthalmol 2010 Feb;149(2):221-8.

*Bleckmamn H, et al. preliminary results after implantation of four AlphaCor artificial corneas. Graefes Arch Clin Exp Ophthalmol 2006 Apr;244(4):502-6.

*Bradley JC, et al. Boston type 1 keratoprosthesis: the University of California Davis experience. Cornea 2009 Apr;28(3):321-7.

Bouhout S, et al. Mid-term prognosis of type I Boston keratoprosthesis reimplantation. Br J Ophthalmol 2020 Oct; 0: 1-5.

*Cade F, et al. Glaucoma in eyes with severe chemical burn, before and after keratoprosthesis. Cornea 2011 Dec;30(12):1322-7.

*Chew HF, et al. Boston keratoprosthesis outcomes and complications. Cornea 2009 Oct;28(9):989-96.

*Colby KA, et al. Expanding indications for the Boston keratoprosthesis. Curr Opin Ophthalmol 2011 Jul;22(4):267-73.

*Crawford GJ, et al. The Chirila keratoprosthesis: phase I human clinical trial. Ophthalmology 2002 May;109(5):883-9.

*De La Paz MF, et al. Impact of clinical factors on the long-term functional and anatomic outcomes of osteo-ondonto-keratoprosthesis and tibial bone keratoprosthesis. Am J Ophthalmol 2011 May;151(5):829-39.

*Dunlap K, et al. Short-term visual outcomes of Boston type 1 keratoprosthesis implantation. Ophthalmology 2010 Apr;117(4):687-92.

*Eguchi H, et al. Cataract surgery with the AlphaCor artificial cornea. J Cataract Refract Surg 2004 Jul;30(7):1486-91.

*Falcinelli G, et al. Modified osteo-odonto-keratoprosthesis for treatment of corneal blindness: long-term anatomical and functional outcomes in 181 cases. Arch Ophthalmol 2005 Oct;123(10):1319-29.

*Greiner MA, et al. Longer-term vision outcomes and complications with the Boston type I keratoprosthesis at the University of California, Davis. Ophthalmol 2011 Aug;118(8):1543-50.

*Harissi-Dagher M, et al. The Boston keratoprosthesis in severe ocular trauma. Can J Ophthalmol 2008 Apr;43(2):165-9.

*Iyer G, et al. Modified osteo-odonto keratoprosthesis- the Indian experience- results of the first 50 cases. Cornea 2010 Jul;29(7):771-6.

*Kamyar R, et al. Glaucoma associated with Boston type I keratoprosthesis. Cornea 2010 Feb;31(2):134-9.

*Li JY, et al. Long-term complications associated with glaucoma drainage devices and Boston keratoprosthesis. Am J Ophthalmol 2011 Aug;152(2):209-18.

Moshiri A, et al. Posterior segment complications and impact on long-term visual outcomes in eyes with a type 1 Boston keratoprosthesis. Cornea 2019 Sep;38(9):1111–1116.

*Pineles SL, et al. Binocular visual function in patients with Boston type 1 keratoprosthesis. Cornea 2010 Dec;29(12):1397-400.

*Robert MC, et al. Boston type I keratoprosthesis: the CHUM experience. Can J Ophthalmol 2011 Apr;46(2):164-8.

*Sayegh RR, et al. The Boston keratoprosthesis in Stevens-Johnson syndrome. Am J Ophthalmol 2008 Mar;145(3):438-44.

Shousha MA, et al. Clinical study: risk of endophthalmitis in Boston type 1 keratoprosthesis combined with vitrectomy and silicone oil insertion. Journal of Ophthalmology 2019;Article ID 9648614.

Silva RN, et al. Glaucoma management in patients with aniridia and Boston type 1 keratoprosthesis. Am J Ophthalmol 2019;207:258–267.

*Srikumaran D, et al. Long-term outcomes of Boston type 1 keratoprosthesis implantation: a retrospective multicenter cohort. Ophthalmology 2014 Nov;121(11):2159-64.

Szigiato AA, et al. Long-term visual outcomes of the Boston type I keratoprosthesis in Canada. Br J Ophthalmol 2020 Feb; 104: 1601-07.

*Tay AB, et al. Osteo-odonto-keratoprosthesis surgery: a combined ocular-oral procedure for ocular blindness. Int J Oral Maxillofac Surg 2007 Sep;36(9):807-13.

Tsou BC, et al. Ten-Year Outcome of Boston Type I Keratoprosthesis Surgery at a Tertiary Care Center. Cornea 2024 Feb. doi: 10.1097/ICO.0000000000003489. Epub ahead of print. PMID: 38305331.

Yazdanpanah G, et al. Management of Congenital Aniridia-associated Keratopathy: Long-term outcomes from a tertiary referral center. Am J Ophthalmol 2020 Feb; 210: 8-18.

*Key Article

KEY WORDS

AlphaCor, BIOKOP, Boston type I, Boston type II, Dolhman-Doane, keratoprosthesis, KPro, osteo-odonto, OOKP

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, the implantation of a keratoprosthesis is not addressed in National or Regional Medicare coverage determinations or policies.