Healthy Blue

Clinical UM Guideline

Subject:	Keratoprosthesis		
Guideline #:	CG-SURG-94	**Publish Date:**	12/16/2020
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Description

This document addresses the permanent keratoprosthesis. This ocular device functions as an implanted artificial cornea intended to restore useful vision to individuals with severe corneal disease not amenable to conventional corneal transplantation.

Note: For information concerning other ophthalmic topics, see:

- SURG.00061 Presbyopia and Astigmatism-Correcting Intraocular Lenses
- CG-SURG-72 Endothelial Keratoplasty
- CG-SURG-77 Refractive Surgery

Clinical Indications

Medically Necessary:

Keratoprosthesis using the Dohlman Doane Boston KPro ("Boston KPro") device is considered **medically necessary** for the treatment of corneal blindness when the following two (2) criteria are met:

- The cornea is severely opaque and vascularized; **and**
- There is documentation of two (2) or more prior failed corneal transplant procedures.

Not Medically Necessary:

Keratoprosthesis procedures using an artificial cornea device other than the Boston KPro are considered **not medically necessary.**

Keratoprosthesis procedures are considered **not medically necessary** for all other indications not listed above as medically necessary.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT

65770	Keratoprosthesis

HCPCS

C1818	Integrated keratoprosthesis
L8609	Artificial cornea

ICD-10 Procedure

08R83JZ	Replacement of right cornea with synthetic substitute, percutaneous approach
08R8XJZ	Replacement of right cornea with synthetic substitute, external approach
08R93JZ	Replacement of left cornea with synthetic substitute, percutaneous approach
08R9XJZ	Replacement of left cornea with synthetic substitute, external approach
08U80JZ	Supplement right cornea with synthetic substitute, open approach
08U83JZ	Supplement right cornea with synthetic substitute, percutaneous approach
08U8XJZ	Supplement right cornea with synthetic substitute, external approach
08U90JZ	Supplement left cornea with synthetic substitute, open approach
08U93JZ	Supplement left cornea with synthetic substitute, percutaneous approach
08U9XJZ	Supplement left cornea with synthetic substitute, external approach

ICD-10 Diagnosis

H16.441-H16.449	Deep vascularization of cornea
H17.10-H17.13	Central corneal opacity
H54.0X33-H54.8	Blindness and low vision
T86.840-T86.849	Complications of corneal transplant

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met or for all other diagnoses not listed; or when the code describes a procedure or situation designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

A keratoprosthetic device is intended to provide a transparent optical pathway through an opacified cornea, either intraoperatively or permanently, in an eye which is not a reasonable candidate for a corneal transplant. A temporary keratoprosthesis is used intraoperatively to aid in visualization of ocular structures. The temporary device is removed following surgery. A permanent keratoprosthesis has been proposed for individuals when attempts at corneal transplant have failed.

Keratoprosthetic devices differ in design but basically consist of a special tube that acts as a periscope that is anchored to the front surface of the cornea. Implantation techniques differ, and success rates are variable and highly dependent on the skill of the surgeon.

While several keratoprosthetic devices and techniques are under investigation, only two devices have current clearance from the U.S. Food and Drug Administration (FDA). They are the Dohlman-Doane Boston KPro (Massachusetts Eye & Ear Infirmary, Boston, MA) and the AlphaCor™ (CooperVision Surgical Inc., Lake Forest, CA). The Boston KPro utilizes a rigid plastic optic positioned between a front and back plate in the shape of a "collar button." The AlphaCor prosthesis consists of a poly (2-hydroxyethyl methacrylate) device with a central transparent optic fused to an outer sponge skirt which is inserted in a two-stage surgical procedure.

The Boston KPro device was originally cleared by the FDA in 1992 as a Class II device. Both the Boston KPro and AlphaCor devices are indicated as permanent implantable keratoprostheses for eyes that are not corneal transplant candidates and are made of materials that have been proven to be biocompatible. However, only the Boston KPro device is considered medically necessary in this document when criteria are met. Additional information appears below for the AlphaCor device.

In the first multicenter, mixed retrospective/prospective case series study of the Boston KPro, Zerbe reported on 136 eyes that received the device between 2003 and 2005. Each eye had an average of two prior failed corneal transplants. The main outcome measure was visual acuity (VA) and keratoprosthesis survival. The number of subjects with best corrected visual acuity (BCVA) of 20/200 or better went from 3.6% preoperatively to 57% postoperatively. Postoperative BCVA of 20/40 or better was achieved in 19% of the recipients. In the subgroup of 62 postoperative eyes that were followed for at least 1 year, 56.4% retained their BCVA of 20/200 or better and 22.6% retained a BCVA of 20/40 or better. In this subgroup at last follow-up, 11 eyes had improved VA (17.7%) and 8 eyes had decreased VA (12.9%). Decreased vision was most often due to end-stage glaucoma, followed by retinal detachment and age-related macular degeneration. Retroprosthetic membrane formation was the most common postoperative complication occurring in 25% of eyes with 18% of these subjects requiring further treatment (4 required surgical membranectomy; 9 cases required no further treatment). Vitritis was reported in 7 eyes with no incidence of bacterial endophthalmitis or other bacterial complication. The authors concluded that the Boston KPro is a viable option based on early follow-up (Zerbe, 2006).

The largest study published to date involved 300 subjects who received a Boston KPro device (Rudnisky, 2016). In this retrospective case series study, it was reported that visual acuity at an average of 17.1 months improved significantly ($p<0.0001$) to a mean final value of 0.89 ± 0.64 (20/150). There were also significantly fewer eyes with light perception (6.7%; n=19; $p<0.0001$), although 3.1% (n=9) progressed to no light perception. The authors reported no association between age ($p=0.08$), sex ($p=0.959$), operative side ($p=0.167$), or failure ($p=0.494$) and final visual acuity. The median time to achieve 20/200 visual acuity was 1 month and it was retained for an average of 47.8 months. In a multivariate analysis, controlling for preoperative visual acuity, it was demonstrated that two factors were associated with final visual outcome: chemical injury was associated with better final vision ($p=0.007$) and age-related macular degeneration was associated with poorer vision ($p<0.0001$).

In 2016, Noel and colleagues reported the results of a retrospective case series study of 43 subjects (44 eyes) who received a Boston KPro device. The primary indication for a Boston Kpro was failed corneal transplantation in 70% of subjects with the remaining 30% being a primary procedure. The mean follow-up time was 21 ± 12 months (range 12-57 months) with 95% of subjects completing the last follow-up visit. The authors reported a best-

achieved median visual acuity of 20/100 (range 20/20 to no light perception [NLP]), with 37% of subjects achieving a visual acuity of > 20/40 at some point during their postoperative course. At the last follow-up, median visual acuity was 20/400 (range 20/30 to NLP). The two most commonly reported complications included retroprosthetic membrane formation (23 eyes, 52%) and elevated intraocular pressure (10 eyes, 23%). There were 5 cases (11%) of stromal melt and 1 case (2%) of infective keratitis. The authors concluded that their study demonstrates that the Boston KPro improves visual acuity in a majority of cases, and is a viable option in situations in which there is a poor prognosis for traditional penetrating keratoplasty.

A retrospective case series of 25 subjects who received a Boston KPro device reported follow-up times ranging from 2 to 12 months with 20 of the 25 subjects retaining a VA of 20/400 or better, and 12 subjects achieved better than 20/40 vision. There were no dislocations or extrusions, and no reoperations were required within the 2-12 month follow-up (Aquavella, 2005). Additional studies with up to 35 months of outcomes data have reported similar results for anatomic retention of the device and improvements in VA (Chew, 2009; Harissa-Dagher, 2008). In 2009, Bradley reported a case series of 30 eyes (28 individuals) who had received a Boston KPro keratoprosthesis. Average follow-up was 19 months (range, 1-48 months), and retention of the device was 83% with 5 failures (4 corneal melt; 1 infectious keratitis). The number of trial participants with BCVA of 20/200 or better increased from 14% preoperatively to 77% postoperatively, and 23% of individuals had a BCVA of 20/40 or better. Keratoprosthesis replacement was required at least once in 5 eyes (17%).

In 2011, results were published for a retrospective chart review of 35 subjects (40 eyes) who underwent Boston type 1 keratoprosthesis surgery at the University of California, Davis between 2004 and 2010. The purpose of this cohort study was to evaluate retention of VA and development of complications after Boston type 1 keratoprosthesis implantation over a longer follow-up period than previously reported. Preoperative VA ranged from 20/150 to light perception and was ≤ 20/400 in 38 eyes (95%). Preoperative diagnoses included failed corneal transplants (19 eyes, 47.5%), chemical injury (10 eyes, 25%), and aniridia (5 eyes, 12.5%). The mean follow-up duration was 33.6 months (range, 5-72 months). Of 36 eyes followed for 1 year and beyond, 32 eyes (89%) achieved postoperative BCVA ≥ 20/200. Of eyes that achieved BCVA ≥ 20/200, at last follow-up, 19 of 32 eyes (59%) followed for greater than or equal to 1 year retained BCVA ≥ 20/200; 16 of 27 eyes (59%) followed for greater than or equal to 2 years retained BCVA ≥ 20/200; 7 of 14 eyes (50%) followed for greater than or equal to 3 years retained BCVA ≥ 20/200; and 2 of 7 eyes (29%) followed for greater than or equal to 4 years retained BCVA ≥ 20/200. End-stage glaucoma most commonly caused vision loss (7 of 13 eyes, 54%) when BCVA ≥ 20/200 was not retained (follow-up ≥ 1 year). Glaucoma was newly diagnosed in 11 eyes (27.5%); progression was noted in 9 eyes (22.5%). Glaucoma drainage device erosion occurred in 9 eyes (22.5%). Retroprosthetic membrane formed in 22 eyes (55%), 5 eyes (12.5%) developed endophthalmitis, 6 eyes (15%) developed corneal melt, 7 eyes (17.5%) underwent keratoprosthesis replacement, and 23 eyes (57.5%) required major surgery to treat postoperative complications. The initial keratoprosthesis was retained in 32 eyes (80%). The authors concluded that keratoprosthesis implantation remains a viable option for salvaging vision. It was noted that a significant number of participants lost vision over the postoperative course, glaucoma and complications related to glaucoma surgery being significant challenges to maintaining good vision after keratoprosthesis surgery. It was acknowledged that this study highlighted the need for long-term follow-up and a team approach to management, and points to a more guarded long-term visual prognosis after surgery (Greiner, 2011).

The AlphaCor artificial cornea is intended:

For use as a keratoprosthesis in adult patients with corneal opacity to include the following:

- Eyes that are not suitable for standard penetrating keratoplasty with donor tissue;
- Eyes in patients who have declined to have standard penetrating keratoplasty performed with donor tissue;
- Eyes in which the adjunctive measures required to prevent graft rejection are medically contraindicated (FDA, 2002).

There are few studies of the AlphaCor keratoprosthesis reported in the published literature. Hicks and colleagues (2006) reported the outcomes of AlphaCor implantations recorded in a registry. In this registry, 322 implants are recorded with a mean follow-up of 15.5 months. The probability of retention of the device at 6 months, 1 and 2 years was 92%, 80%, and 62% respectively. Holak and colleagues (2009) reported, in a retrospective review, the outcomes of 6 subjects treated with AlphaCor. The follow-up time was 23 months (range 13-36 months). In this series, 3 individuals developed melting of the anterior corneal lamella, and the prosthesis had to be removed (15-34 months after implantation) and replaced by donor cornea. At this time, AlphaCor keratoprosthesis is not in accordance with generally accepted standards of medical practice.

Although there is no official position statement currently available from the American Academy of Ophthalmology (AAO) that addresses keratoprosthesis procedures, the following comment is noted in the AAO updated 2018 Preferred Practice Pattern® Guidelines on Conjunctivitis: "In advanced disease with corneal blindness, keratoprosthesis surgery may improve vision, however, all ocular reconstructive surgery is considered high risk" (Varu, 2019).

Additionally, the AAO released a report addressing the outcomes and complications of the Boston Keratoprosthesis (Lee, 2015). This review included 22 studies determined to be relevant for the assessment objectives. Nine studies were rated as level II evidence and 13 were rated as level III evidence. Excluded studies included Level III evidence, case reports, review articles, letters, editorials, and case series with fewer than 25 eyes. Their review indicated that in 9 articles, a best-corrected Snellen visual acuity (BCSVA) of 20/200 or better occurred in 45% to 89% of eyes. Five articles described a BCSVA of 20/50 or better in 43% to 69% of eyes, and 4 articles found a BCSVA of 20/40 or better in 11% to 39% of eyes. Retention rates of the Boston KPro ranged from 65% to 100%. Reasons for loss of vision after Boston KPro implantation most commonly included corneal melts from exposure keratopathy, endophthalmitis, and infectious keratitis or corneal ulceration. The two most common complications after surgery were retroprosthetic membrane formation and elevated intraocular pressure. The two most common posterior segment complications were endophthalmitis and vitritis. Their conclusions were that the Boston KPro device improves vision in cases of severe corneal opacification that are not amenable to corneal transplantation using human cadaveric keratoplasty techniques. However, a number of severe anterior and posterior segment complications can develop, making ongoing close observation paramount for individuals undergoing this surgery.

Studies have shown that keratoprosthesis procedures are associated with a significant failure rate (Aravena, 2018). For this reason, they are intended for select individuals who have lost vision and for whom corneal transplants have not been successful. The keratoprosthesis is considered to be a salvage procedure where no acceptable alternatives

exist. For this reason, comparative studies are lacking. Two recently published studies included cases in which keratoprosthesis was the primary procedure used to treat a variety of indications (e.g., corneal scarring, chemical/thermal injury and Stevens-Johnson syndrome). Driver and colleagues (2018) reported results of 67 implanted KPros and Kang and colleagues (2018) reported results of 28 eyes implanted with KPros. Although the authors conclude that the studies results' were promising (no differences observed in KPro retention when compared to matched-controls who had previously failed keratoplasty), both trials were small, retrospective, have significant loss to follow-up, and lack long-term data.

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Government Agency, Medical Society, and Other Authoritative Publications:

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Revised	11/05/2020	Medical Policy & Technology Assessment Committee (MPTAC) review. Clarified the MN statement. Updated References and Websites sections. Reformatted Coding section.
Reviewed	11/07/2019	MPTAC review. Updated Background/Overview, References and Websites sections.
New	01/24/2018	MPTAC review. Initial document development. Moved content of SURG.00115 Keratoprosthesis to new clinical utilization management guideline document with the same title.