Anthem

Clinical UM Guideline

Subject: Keratoprosthesis
Guideline #: CG-SURG-94
Status: Revised

Publish Date: 01/03/2024
Last Review Date: 11/09/2023

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 *either* of the following criteria are met (A *or* B):

A. For individuals with prior corneal transplant:
   1. The cornea is severely opaque and vascularized; **and**
   2. There is documentation of at least one prior failed corneal transplant procedure;
   or
B. There is documentation of the presence of a condition predisposing the individual to a high likelihood of corneal transplant failure, including but not limited to *any* of the following:
   1. Autoimmune conditions with ocular involvement; **or**
   2. Heavily vascularized corneal scars; **or**
   3. Limbal stem cell compromise; **or**
   4. Mucus membrane pemphigoid; **or**
   5. Neuropathic keratopathy; **or**
   6. Ocular chemical burns; **or**
   7. Ocular cicatricial pemphigoid; **or**
   8. Postherpetic anesthesia; **or**
   9. Severe dry eye; **or**
   10. Stevens-Johnson Syndrome.

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

B02.23	Postherpetic polyneuropathy

B02.29	Other postherpetic nervous system involvement
H04.121-H04.129	Dry eye syndrome
H16.441-H16.449	Deep vascularization of cornea
H17.10-H17.13	Central corneal opacity
H18.40-H18.49	Corneal degeneration
H18.811-H18.819	Anesthesia and hypoesthesia of cornea
H18.891-H18.9	Other specified and unspecified disorders of cornea
H54.0X33-H54.8	Blindness and low vision
L12.1	Cicatricial pemphigoid
L51.1	Stevens-Johnson syndrome
M30.0-M36.8	Systemic connective tissue disorders
Q13.1	Absence of iris
T26.00XA-T26.92XS	Burn and corrosion confined to eye and adnexa
T86.8401-T86.8499	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 one device is currently available in the U.S. and has clearance from the U.S. Food and Drug Administration (FDA), the Dohlman-Doane Boston KPro (Massachusetts Eye & Ear Infirmary, Boston, MA). A second device the AlphaCor™ (CooperVision Surgical Inc., Lake Forest, CA) had been cleared by the FDA, but is no longer available in the U.S. The Boston KPro utilizes a rigid plastic optic positioned between a front and back plate in the shape of a “collar button.”

Boston KPro device

The Boston KPro device was originally cleared by the FDA in 1992 as a Class II device and is indicated to “provide a transparent optical pathway through an opacified cornea in an eye that is not a reasonable candidate for any form of corneal transplant, including penetrating keratoplasty.”

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 participants 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 participants 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 participants 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 participants (44 eyes) who received a Boston KPro device. The primary indication for a Boston Kpro was failed corneal transplantation in 70% of participants with the remaining 30% being a primary procedure. The mean follow-up time was 21 ± 12 months (range 12-57 months) with 95% of participants 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 participants 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 participants who received a Boston KPro device reported follow-up times ranging from 2 to 12 months with 20 of the 25 participants retaining a VA of 20/400 or better, and 12 participants 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 participants (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).

In 2023, El-Khoury published the results of a retrospective comparative study involving 48 participants (48 eyes) who had failed a single penetrating keratoplasty procedure and underwent either a second penetrating keratoplasty (n=23) or keratoprosthesis implantation with the Boston type 1 device (n=25). The mean follow-up was 6.4 years in the penetrating keratoplasty group and 9.6 years for keratoprosthesis group (p<0.001). The logMAR BCVA was similar in both groups, with visual gains of 1.02 in the penetrating keratoplasty group and 1.32 in the keratoprosthesis group (p=0.24), which corresponds to 5.2 lines and 5.3 lines of improvement on the Snellen chart, respectively (p=0.94). The postoperative BCVA was maintained for an average of 4.8 years and 6.7 years respectively, with no significant difference between groups (p=0.28). A total of 6 (26.1%) penetrating keratoplasty participants and 10 (40.0%) keratoprosthesis group participants had irreversible visual loss (p=0.31, non-significant). Terminal glaucoma was responsible for 3 and 9 cases, respectively. Maintenance of 20/200 BCVA throughout follow-up duration was not significantly different between groups (p=0.83). No significant differences were reported with regard to development of new glaucoma (n=3 vs. n=6, respectively; p=0.06). The most frequent complication was worsening glaucoma, with 17 (73.9%) penetrating keratoplasty participants and 23 (92.0%) keratoprosthesis group participants having at least one complication in the postoperative period (p=0.09). Three keratoprosthesis group participants underwent a pars plana vitrectomy after developing retinal detachment. Subsequent procedures, including glaucoma surgeries and corneal replacement procedures, were reported for 13 (56.5%) penetrating keratoplasty participants and 17 (68.0%) keratoprosthesis group participants (p=0.41). The keratoprosthesis group participants experienced 5 instances of corneal melt, extrusion, or both. Failure rates of the second intervention were significantly higher in the penetrating keratoplasty group (n=16 vs. n=5; p<0.006). Significantly more penetrating keratoplasty participants underwent additional corneal grafts (p=0.001). The authors concluded, “Both interventions showed similar visual outcomes. Complication profiles were different, with more posterior segment complications in the KPro group, and more corneal complications in the PKP group, often necessitating regraft.”

Lázaro-Rodríguez (2023) reported a retrospective case series involving 22 participants (23 eyes) with a heterogenous collection of indications treated with the Boston type I keratoprosthesis as a primary corneal procedure. Participants were from two separate cohorts, one at high risk of complications (n=13) and one not at high risk of complications (n=10). The mean follow-up times were 42.0 ± 35.9 months in the high-risk group and 44.8 ± 38.8 months in the non-high-risk group (p=0.862). Anatomical failure, defined as keratoprosthesis extrusion during the follow-up period, was reported in 3 (23%) high-risk group eyes and none in the non-high-risk group. No significant differences in survival were reported between groups (p=0.230). Improvement in BV_CDVA was reported in 11 (84%) of high risk eyes and 8 (80%) in the non-high risk group. The mean postoperative BV_CDVA was significantly better in the high risk group (0.9±0.6 LogMAR) than in the NHR group (1.7±0.6 LogMAR) (p<0.01). Functional failure was reported in 5 (38%) eyes in the high risk group, with 2 related to endophthalmitis, 2 due to previous age-related macular degeneration and glaucoma, and 1due to secondary glaucoma. The non-high-risk group had functional failure in 8 (80%) eyes, with 5 related to previous pathologies such as glaucoma and retinal detachment. The 3 remaining cases failed due to secondary glaucoma. Postoperative complications were reported in 9 cases in the high-risk group and 8 cases in non-high-risk group. The most common complication was development of a retroprosthetic membrane, which appeared in 5 (38%) cases in the high-risk group and 6 (60%) cases in the non-high-risk group. Other complications in the high-risk group included secondary glaucoma (n=4), retinal detachment (n=2), endophthalmitis (n=2), persistent epithelial defect (n=2), graft infection (n=1), 5 B1-KPro exchanges (n=1), and choroidal detachment (n=1). In the non-high-risk group, other complications were secondary glaucoma (n=2), endophthalmitis (n=2), stromal lysis with amniotic membrane graft (n=1), stromal necrosis that required tectonic graft (n=1), choroidal detachment (n=1), and vitreous hemorrhage (n=1). The authors reported that use of keratoprosthesis was a valid option as a primary procedure in high risk cases.

Two 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 (2018) reported results of 67 implanted KPros and Kang (2018) reported results of 28 eyes implanted with KPros. The authors concluded that the study’s results were promising, with no differences observed in KPro retention when compared to matched controls who had previously failed keratoplasty. While the evidence for use of keratoprosthesis as a primary therapy is limited, such use has become standard clinical practice for the treatment of individuals with significant systemic or local disease that predispose an individual to a high likelihood of corneal transplant failure.

Specialty Society Documents

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 2019 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).

The AAO also 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.

Conclusion

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 or have a high likelihood of failure.

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Dohlman Doane
KeraKlear
KPRO, Boston
Keratoprosthesis

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	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Reformatted MN section. Revised MN criteria regarding number of previous failed corneal transplants. Added new MN criteria for when corneal transplant is likely to fail. Updated Discussion and References sections. Updated Coding section with additional ICD-10-CM diagnosis codes.
Reviewed	11/10/2022	MPTAC review. Updated Coding section to correct ICD-10-CM diagnosis codes to T86.8401-T86.8499.
Reviewed	11/11/2021	MPTAC review. Updated References and Websites sections.
Revised	11/05/2020	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.

Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.