9.03.01 Keratoprosthesis

Summary

A keratoprosthesis, consisting of a central optic held in a cylindrical frame, is an artificial cornea that is intended to restore vision to patients with severe bilateral corneal disease for whom a corneal transplant is not an option. The keratoprosthesis replaces the cornea that has been removed and is held in place by the surrounding tissue. Various biologic materials are being investigated to improve integration of the prosthetic into the eye.

The evidence for Boston Keratoprosthesis in individuals who have corneal blindness and failed or are not candidates for corneal transplantation includes case series and systematic reviews. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. Systematic reviews and case series with longer follow-up (ie, at least 2 years) have shown improvement in visual outcomes in a substantial percentage of patients with Boston KPro. This procedure is high risk and is associated with numerous complications (eg, growth of retro prosthetic membranes) and a probable need for additional surgery, thus careful patient selection is important. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for a keratoprosthesis other than the Boston KPro in individuals who have corneal blindness and failed or are not candidates for corneal transplantation includes case series and systematic reviews. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. The data are more limited for devices other than the Boston KPro. Available evidence suggests that complications with other keratoprosthesis designs are worse than those associated with the Boston KPro. The evidence is insufficient to determine the effects of the technology on health outcome.

FDA REGULATORY STATUS

A keratoprosthesis is a Class II U.S. Food and Drug Administration (FDA) device intended to provide a transparent optical pathway through an opacified cornea, in an eye that is not a reasonable candidate for a corneal transplant. Two permanent keratoprosthesis have received 510(k) marketing clearance by the FDA. The Dohlman-Doane Keratoprosthesis, also referred to as the Boston Keratoprosthesis (KPro), is manufactured under the auspices of the Harvard Medical School-affiliated Massachusetts Eye and Ear Infirmary. The Boston type I KPro uses an optic between a central stem and a back plate. The Boston type II prostheses is a modification of the type I prosthesis and is designed with an anterior extension to allow implantation through surgically closed eyelids. The AlphaCor, previously known as the Chirila keratoprosthesis (Chirila KPro) marketed by Argus Biomedical was cleared for marketing by the FDA in 2016.
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2002. The AlphaCor prosthesis consists of a PMMA device with a central optic region fused with a surrounding sponge skirt; the device is inserted in a 2-stage surgical procedure. According to the 510(k) summary, the AlphaCor keratoprosthesis was shown to be substantially equivalent to the Dohlman Doane Type I keratoprosthesis. Both devices are indicated as permanent implantable keratoprosthesis for eyes that are not corneal transplant candidates and are made of materials that have been proven to be biocompatible. FDA product code: HQM.

POLICY STATEMENT

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims

The Boston (Dohlman-Doane) Keratoprosthesis (Boston KPro) may be considered medically necessary for the surgical treatment of severe corneal opacification in situations where cadaveric corneal transplants have failed or have a very low likelihood of success (see Policy Guidelines).

All other types of permanent keratoprosthesis are considered investigational.

POLICY GUIDELINES

Implantation of a keratoprosthesis is considered 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 this condition and staffed by surgeons adequately trained in techniques addressing implantation of this device.

Conditions under which cadaveric corneal transplants have a likelihood of failure include but are not limited to the following:

- The cornea is severely opaque and vascularized AND
- Best-corrected visual acuity is 20/400 or less in the affected eye and 20/40 or less in the contralateral eye AND
- No end-stage glaucoma or retinal detachment is present AND
- The patient has one of the following indications:
  - History of 1 or more corneal transplant graft failures
  - Stevens-Johnson syndrome
  - Ocular cicatricial pemphigoid
  - Autoimmune conditions with rare ocular involvement
  - Ocular chemical burns
  - An ocular condition unlikely to respond favorably to primary corneal transplant surgery (eg, libel stem cell compromise, aniridic keratopathy or post herpetic anesthesia)

Note that patients should be able and expected to comply with postoperative care.

RATIONALE

Assessment of efficacy for therapeutic interventions involves a determination of whether the intervention improves health outcomes. The optimal study design for a therapeutic intervention is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established
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link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as noncomparability of treatment groups, the placebo effect, and variable natural history of the condition.

The keratoprosthesis is intended for the relatively small number of patients with severe corneal damage who have lost vision and for whom a corneal transplant is not expected to result in satisfactory outcomes. This generally refers to the population of patients who have failed one or more corneal transplants and who therefore have very limited options to prevent blindness. Since this is considered a salvage procedure with no acceptable alternative treatment, comparative studies are limited/lacking. The available literature primarily consists of retrospective case series. This literature review examines the types of devices currently being tested in humans, focusing on reports that allow assessment of integration within the eye, durability, visual outcomes, and adverse events following implantation.

Boston (Dohlman-Doane) Keratoprosthesis (KPro)

A 2015 systematic review from the American Academy of Ophthalmology identified 22 studies on the efficacy and safety of the Boston (Dohlman-Doane) Keratoprosthesis (Boston KPro). (1) Studies were published in English and retrospective series needed to include at least 25 eyes. No RCTs were identified. The proportion of patients with visual acuity of 20/200 after surgery ranged from 54% to 84% in the 10 studies reporting this outcome. Five articles reported that 11% to 39% of treated eyes attained visual acuities of 20/40 or better. The review authors noted that published data were skewed toward visual improvement. Fourteen articles reported retention rates (eyes retaining the KPro device without loss, extrusion or dehiscence of the device), and these rates ranged from 65% to 100% (mean, 88%). The most common reasons for KPro loss were corneal melts with device exposure or extrusion, endophthalmitis, infectious keratitis, or corneal ulceration. The most common complication was retroprosthetic membrane formation, which ranged from 1% to 65% (mean, 30%) in the 13 studies reporting complications.

Representative larger series are described below.

A 2013 report from the Boston Type 1 Keratoprosthesis Study Group assessed retention of the device in 300 eyes of 300 patients. (2) At a mean follow-up duration of 17.1 months (range, 1 week to 6 years), 93% of the keratoprostheses were retained. The probability of retention was 94% at 1 year and 89% at 2 years. Mean device durability was 3.8 years. Risk factors for keratoprosthesis loss were autoimmune disease, ocular surface exposure, and number of prior failed penetrating keratoplasties (PKs). Additional data on this cohort were published in 2016. (3) Preoperative visual acuity, available for 47% of eyes was 20/1205. During a mean follow-up of 17 months (range, 1 week to 6 years), visual acuity improved significantly for 85% of eyes to a final mean of 20/150. Median time to achieve visual acuity of 20/200 was 1 month, and this level of acuity lasted for a mean of 48 months among patients with sufficient follow-up.

In 2014, Srikumaran et al reported mean follow-up of 46.7 months (range, 6 weeks to 8.7 years) on 139 eyes of 133 patients who had received a Boston KPro at 1 of 5 tertiary referral centers in the United States. (4) Twenty-seven percent of eyes underwent a primary KPro procedure while 73% had a prior donor graft failure. Postoperatively, visual acuity improved to at least 20/200 in 70% of eyes. The probability of maintaining visual acuity of at least 20/200 was 50%, and device retention was estimated at 67% at 7 years. The 7-year cumulative incidence of complications was 49.7% for retroprosthetic membrane formation, 21.6% for glaucoma surgery, 18.6% for retinal detachment, and 15.5% for endophthalmitis.

In 2010, Dunlap et al reported a retrospective analysis of 122 patients (126 eyes) at 2 centers who received a Boston type 1 keratoprosthesis between 2004 and 2007. (5) For most patients, the affected eye had a visual acuity of less than 20/400, and the contralateral eye did not have better vision. Of the
126 eyes, 112 had a history of multiple failed corneal grafts, and 14 had received the keratoprosthesis as a primary procedure due to the presence of limbal stem cell deficiency or significant ocular surface diseases. Following implantation, 96 (76%) eyes had improved vision, 22 (17.4%) eyes did not improve, and 8 (6.3%) eyes lost vision. At 3-month follow-up, 54% of eyes had 20/200 vision or better, with 18% achieving 20/40 or better. In approximately 45% of the eyes, visual acuity remained less than 20/400. The percentage of patients with improved visual outcomes was lower than in other published studies, due in part to the presence of comorbid conditions (eg, glaucoma, retinal detachment).

Indications

A 2009 study reported expanding indications and outcomes from a consecutive series of 50 eyes of 49 patients implanted with the Boston type 1 keratoprosthesis and a donor cornea. (6) Thirty-one percent of patients had good preoperative vision (visual acuity of 20/40 or better) in the contralateral eye. Study inclusion criteria for keratoprosthesis implantation were: visually significant corneal opacification (best-corrected visual acuity [BCVA] ≤20/200); poor candidacy for repeat corneal transplantation because of a history of 2 or more failed transplantations, extensive corneal limbal stem cell failure with or without corneal vascularization and scarring, or both; and adequate visual potential for meaningful visual restoration. Exclusion criteria were: adequate potential for a successful outcome after PK; the presence of a comorbid ocular condition associated with a minimal chance of recovering meaningful vision (eg, chronic retinal detachment, near end-stage glaucoma); the presence of comorbid ocular conditions associated with an unacceptably high risk of postoperative complications (eg, inadequate eyelid function, severe ocular surface desiccation, ocular surface keratinization, recalcitrant intraocular inflammation, patient inability or unwillingness to comply with the routine postoperative regimen, combination thereof). Of the 50 eyes implanted with the Boston KPro, 42 had a history of prior corneal transplantation, varying between 1 and 5 prior transplantations (mean, 2.3). Preoperative visual acuity was 20/200 or worse in all eyes, with vision of counting fingers, hand movements, or light perception in 42 (88%) eyes. Glaucoma was present in 38 (76%) eyes, and tube shunt implantation was performed simultaneously with keratoprosthesis implantation in 45% of the eyes with glaucoma. A total of 57 Boston type 1 KPro devices were implanted in 50 eyes. Two eyes were excluded (1 patient died, 1 replacement of a type 1 KPro with a type 2 KPro). Nine of the 57 keratoprostheses implanted were removed, resulting in a retention rate of 84% during an average follow-up of 17 months (range, 3-49 months). Three of the 9 were removed in the first 6 months after surgery, and 5 were removed between 1 and 2 years after surgery. Final postoperative vision was improved over preoperative vision in 38 (79%) eyes, was unchanged in 9 (9%) eyes, and decreased in 1 (2%) eye (from counting fingers preoperatively to light perception postoperatively). The percentage of eyes with postoperative visual acuity of 20/100 or better was 75% of 28 eyes followed up to 1 year, 69% of 13 eyes at 2 years, and all of the 7 eyes followed up for at least 3 years. In 38 (76%) eyes, 1 or more postoperative complications developed. The most common postoperative complications were retroprosthetic membrane formation (44% of eyes) and persistent epithelial defects (38% of eyes). This detailed report provides information on visual outcomes and complications in a well-described patient population. The major limitation of this study is the small number of subjects who were followed beyond 6 months.

Use of the Boston KPro has been reported in patients with herpetic keratitis, autoimmune disease, aniridia, atopic keratoconjunctivitis, medication toxicity, and other corneal dystrophies. (7) Use has also been reported in children. The device has a lower retention rate (ie, eyes retaining the device without loss, extrusion or dehiscence) when used to treat highly inflammatory, cicatricial, and autoimmune ocular disorders. Other studies have also reported success in patients with severe ocular trauma (eg, mechanical trauma, chemical burns, thermal burns). (8)

Also reported is use of the KPro as a primary treatment in eyes with little or no chance of success with PK. (9-11) For example, in a study by Kang et al, the most common preoperative diagnosis was primary or secondary limbal stem cell disease (71.4%), including chemical/thermal injury (28.6%), aniridia (23.8%), and Stevens-Johnson syndrome (4.8%). (9) Retention rate of the keratoprosthesis was 90.5% at...
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a mean follow-up of 14.6 months (range, 6-36.3 months). In another series reporting on KPro as primary treatment in patients at high risk of failing PK, 37 (86%) of 43 eyes had corneal scarring with vascularization, and the most common underlying etiology was aniridic keratopathy (11/37 [27%] eyes).

A 2016 systematic review by Ahmad et al examined 26 studies on repeat PK versus Boston KPro implantation after failed PK. (12) Studies included focused on patients with corneal opacity who had failed 1 or more PKs. Studies were excluded if only selected patients with ocular surface disease. The primary outcome of interest was the proportion of patients with visual acuity of 20/200 or better at 2 or more years post-surgery. In a meta-analysis of 9 studies, the likelihood of 20/200 vision or better at least 2 years after repeat PK surgery was 42% (95% confidence interval [CI], 30% to 56%). A total of 104 eyes from 98 patients underwent KPro after failed PK surgery; 31 patients had only 1 previous PK. In a meta-analysis of data on KPro implantation after failed PK surgery, the probability of maintaining visual acuity of 20/200 or better at 2 years was 80% (95% CI, 68% to 88%). Among patients with a history of 1 failed PK, the probability of maintaining a visual acuity of 20/200 or better at 2 years was 74% (95% CI, 45% to 89%). (The authors did not specify the number of patients receiving KPro who were included in the analysis of 20/200 vision at 2 years.) In terms of complications after KPro following failed PK, at 2 years 29% of patients had elevated intraocular pressure (IOP) and 8% needed surgery for glaucoma. In an analysis limited to patients undergoing KPro after 1 failed KP, complication rates were 29% and 10%, respectively (which did not differ significantly from patients with KPro after >1 failed KPs). The authors did not report the number of patients included in the complication analyses.

Complications

In 2015, Odorcic et al published a literature review on fungal infections after Boston type 1 KPro. (13) The authors identified 15 relevant publications, primarily retrospective case series. Rates of fungal infections reported in these studies ranged from 0.009 to 0.02 per patient-year of follow-up. The largest case series assessed 291 eyes, and the incidence of fungal endophthalmitis was 2.4% over 10 years.

Longer-term vision outcomes and complications with the Boston type 1 KPro were reported by Greiner et al in 2011. (14) Included in the series were 40 eyes of 35 patients who received a Boston KPro between 2004 and 2010 at the authors' institution. Preoperative diagnoses included failed corneal transplants (47.5%), chemical injury (25%), and aniridia (12.5%). Preoperative visual acuity ranged from 20/150 to light perception and was 20/400 or less in 38 eyes (95%). Follow-up evaluations were performed at 1, 3, 6, 9, and 12 months and then annually, with a mean follow-up duration of 33.6 months (range, 5-72 months). Of 36 eyes followed for at least 1 year, 32 (89%) achieved postoperative BCVA of 20/200 or more. The percentage of eyes that retained BCVA of 20/200 or more was 59% (19/32) at 1 year, 59% (16/27) at 2 years, 50% (7/14) at 3 years, and 29% (2/7) at 4 years or longer. The most common reason for vision loss (54% [7/13] eyes when BCVA ≥20/200 was not retained) was end-stage glaucoma. Other complications included glaucoma drainage device erosion (22.5%), retroprosthetic membrane formation (55%), endophthalmitis (12.5%), and corneal melt (15%).

In a separate publication, this group of investigators reported that in 25 eyes implanted with both the Boston type 1 KPro and glaucoma drainage devices, conjunctival breakdown occurred in 10 implants in 9 eyes. (15) The authors noted that glaucoma is one of the most difficult postoperative management challenges in patients with a Boston type 1 keratoprosthesis.

A prospective series of 265 eyes (265 patients) from 18 medical centers, published by the Boston Type 1 Keratoprosthesis Study Group in 2012, focused on the time to development of retroprosthetic membranes. (16) Most eyes (85.4%) had undergone an average of 2.2 (range, 1-8) PKs before keratoprosthesis implantation. The remaining eyes (14.6%) were considered at high risk for PK failure and had received a primary keratoprosthesis. At a mean follow-up of 17.8 months, retroprosthetic membranes had formed in 31.7% of eyes. The time mean to development of retroprosthetic membranes
was 216.7 days (range, 7 days to 4 years). Risk factors were the indication for the keratoprosthesis; specifically, infectious keratitis had a hazard ratio of 3.20 and aniridia had a hazard ratio of 3.13.

Posterior segment complications were reported by Goldman et al in 2013. (17) Of 83 eyes (93 procedures) with follow-up of at least 6 months (range, 6-84 months), 38 (40.9%) eyes had at least 1 postoperative posterior segment complication, which included retinal detachment (16.9%), choroidal detachment (16.9%), and sterile vitritis (14.5%). Visual acuity was worse in eyes that experienced posterior segment complications than in eyes that did not. Pujari et al reported outcomes from 29 eyes of 26 patients who received the Boston type 2 keratoprosthesis between 2000 and 2009 at the Massachusetts Eye and Ear Infirmary. (18) Preoperative diagnoses were mucous membrane pemphigoid (51.7%), Stevens-Johnson syndrome and toxic epidermal necrolysis (41.4%), and other ocular surface disease (6.9%). In patients who had more than 1 year of follow-up (mean, 3.7 years), loss of visual acuity occurred due to retinal detachment (17.4%), end-stage glaucoma (8.7%), choroidal detachment (8.7%), endophthalmitis (4.3%), and unknown cause (21.7%). Fourteen (48.3%) eyes required treatment for retroprosthetic membranes. Of the 29 eyes, 12 (41.4%) either underwent reimplantation of the device or experienced partial or total extrusion of the keratoprosthesis during follow-up (hazard ratio, 0.11 per person-year).

Keratoprosthesis Other Than the Boston KPro

Osteo-Odonto-Keratoprosthesis (OOKP)

A 2012 systematic review by Tan et al included 8 case series describing surgical outcomes and complication rates of the osteo-odonto-keratoprosthesis (OOKP). (19) Sample sizes ranged from 4 to 181 eyes. At 5 years, the pooled anatomic survival rate was 87.8% (range, 67%-100%) and, at 20 years, based on pooled data from 3 series, the anatomic survival rate was 81.0% (range, 65%-98%). About half of the patients obtained visual acuity better than 6/18. Visual acuity in the other patients was not described.

The largest case series (included in Tan) is by Falcinelli et al who reported on OOKP in 181 patients. (20) At a median follow-up of 12 years, survival analysis estimated that the probability of retaining an anatomically intact OOKP 18 years after surgery with reasonable visual acuity was 85%.

In 2008, investigators from Spain published a retrospective review (also in Tan) of 227 patients who underwent OOKP (n=145), or osteokeratoprosthesis (OKP; n=82) using tibial bone in patients who lacked canine teeth to assemble the prosthesis. (21) A second publication in 2011 from the same study examined the impact of clinical factors on long-term functional and anatomic outcomes. (22) The primary diagnosis was chemical or thermal burn (48%), Steven-Johnson syndrome and Lyell syndrome (13%), cicatricial pemphigoid (11%), trachoma (11%), and 17% other or not assignable. Mean preoperative decimal BCVA was 0.00062 (range, light perception to 0.10). (On the decimal visual acuity scale, 0 = no light perception, 0.00001 = light perception, 0.0001 = light projection, and 0.001 = counting fingers.) Functional survival was defined as BCVA of 0.05 or more, and anatomic survival as retention of the keratoprosthesis lamina. Mean follow-up was 8.4 years for OOKP and 3.5 years for OKP. Anatomic success at 10 years was estimated to be 66% for OOKP and 47% for OKP. Functional success at 10 years was estimated to be 38% for OOKP and 17% for OKP. The best functional survival was in the Stevens-Johnson group, followed by chemical burn and trachoma. The least favorable prognosis was thermal burn. Complications included extrusion of the keratoprosthesis (28%), retinal detachment (16%), uncontrolled glaucoma (11%), infection (9%), retroprosthetic membrane (5%), and vitreous hemorrhage (3%). In cases without complications, functional survival was 57% at 5 years and 42% at 10 years.

Hughes et al reported vitreoretinal complications of the OOKP in a retrospective review of 35 patients performed at 1 hospital in England between 1996 and 2005. (23) Diagnoses were Stevens-Johnson...
syndrome in 15 patients, chemical injury in 5, mucous membrane pemphigoid in 3, and topical medication toxicity in 3. Follow-up at a mean 57 months (range, 13-105 months) revealed 9 vitreoretinal complications in 8 (23%) patients, which included vitreous hemorrhage, retinal detachment, and intraoperative choroidal hemorrhage. A 2008 publication of 36 patients treated at the same hospital between 1996 and 2006 (likely to have reported patients assessed by Hughes23) estimated that the probability of retaining visual acuity was 53% at 5 years and 44% at 9 years.(24) In addition to the vitreoretinal complications causing loss of vision, resorption of the bony lamina led to visual or anatomic compromise in 7 (19%) cases.

AlphaCor Device

Studies have suggested that, with the AlphaCor device, thinning or “melting” of the anterior corneal surface can lead to loss of biointegration. (25, 26) This complication appears most prevalent in patients with ocular herpes, hence, the AlphaCor device is contraindicated in these patients. In a 2003 case series, 42% of eyes had a visual acuity better than 20/200 at an average 30-month follow-up.25 An additional case series, evaluating the AlphaCor device implanted in 12 patients was published in 2015. (27) At a mean follow-up of 25 months, 8 (67%) of devices were retained and patients had a mean gain in BCVA of 2.5 lines. The most common complication was corneal necrosis, observed in 7 (59%) patients, 2 of whom had a history of ocular herpes.

BIOKOP Device

The BIOKOP device is similar to the AlphaCor device in that it uses a microporous polymer to promote host tissue integration. However, follow-up results for this device have been disappointing. In 1 case series of 11 patients with 5-year follow-up, the authors concluded that the BIOKOP keratoprosthesis was only able to restore vision for a short postoperative period. (28) Limited success was due to device instability and postoperative complications.

Summary of Evidence

The evidence for Boston Keratoprosthesis in individuals who have corneal blindness and failed or are not candidates for corneal transplantation includes case series and systematic reviews. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. Systematic reviews and case series with longer follow-up (ie, at least 2 years) have shown improvement in visual outcomes in a substantial percentage of patients with Boston KPro. This procedure is high risk and is associated with numerous complications (eg, growth of retro prosthetic membranes) and a probable need for additional surgery, thus careful patient selection is important. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for a keratoprosthesis other than the Boston KPro in individuals who have corneal blindness and failed or are not candidates for corneal transplantation includes case series and systematic reviews. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. The data are more limited for devices other than the Boston KPro. Available evidence suggests that complications with other keratoprosthesis designs are worse than those associated with the Boston KPro. The evidence is insufficient to determine the effects of the technology on health outcome.
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SUPPLEMENTAL INFORMATION

Ongoing and Unpublished Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
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<th>NCT No.</th>
<th>Trial Name</th>
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<td>NCT02084745</td>
<td>Timing of Glaucoma Drainage Device With Boston KPro Surgery (GDD-KPro)</td>
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<td>Mar 2017</td>
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NCT: national clinical trial.

Practice Guidelines and Position Statements
The United Kingdom’s National Institute for Clinical Excellence (NICE) concluded in 2004 that, “Current evidence on the safety and efficacy of insertion of hydrogel keratoprosthesis does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.” (29)

U.S. Preventive Services Task Force Recommendations
Not applicable

Medicare National Coverage
There is no Medicare national coverage policy. In 2006, Medicare has established an Ambulatory Payment Classification 0293 for level V anterior segment eye procedures that includes keratoprosthesis and for the prosthesis, integrated keratoprosthesis OR artificial cornea. (30)

REFERENCES
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14. Greiner MA, Li JY, Mannis MJ. Longer-term vision outcomes and complications with the Boston type 1 keratoprosthesis at the University of California, Davis. Ophthalmology. Aug 2011;118(8):1543-1550. PMID 21397948


### POLICY HISTORY

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<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tr>
<td>September 2012</td>
<td>New Policy</td>
<td>Policy updated with literature review; references 1, 7, and 15 added; policy statement unchanged.</td>
</tr>
<tr>
<td>June 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review; references 8 and 19 added; policy statement unchanged.</td>
</tr>
<tr>
<td>June 2014</td>
<td>Update Policy</td>
<td>Policy updated with literature review, adding references 10 and 11. Policy statement updated to indicate ocular conditions that are unlikely to respond favorably to primary corneal transplant surgery are medically necessary.</td>
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