



Louisiana

Keratoprosthesis

Policy # 00450

Original Effective Date: 05/20/2015

Current Effective Date: 06/08/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Intrastromal Corneal Ring Segments is addressed separately in medical policy 00164.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the Boston (Dohlman-Doane) Keratoprosthesis (Boston KPro) for the surgical treatment of severe corneal opacification in situations where cadaveric corneal transplants have failed or have a very low likelihood of success under the following conditions to be **eligible for coverage.****

- The cornea is severely opaque and vascularized; AND
- Best-corrected vision 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 one or more corneal transplant graft failures; or
 - Stevens-Johnson syndrome; or
 - Ocular cicatricial pemphigoid; or
 - Autoimmune conditions with rare ocular involvement; or
 - Ocular chemical burns; or
 - An ocular condition unlikely to respond favorably to primary corneal transplant surgery (eg, limbal stem cell compromise or postherpetic anesthesia)

Note: Patients should be able and expected to comply with postoperative care.

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers a permanent keratoprosthesis for all other conditions to be **investigational**.*

Based on review of available data, the Company considers all other types of permanent keratoprosthesis to be **investigational**.*

Background/Overview

Cornea

The cornea, a clear, dome-shaped membrane that covers the front of the eye, is a key refractive element of sight. Layers of the cornea consist of the epithelium (outermost layer); Bowman layer; the stroma, which comprises approximately 90% of the cornea; Descemet membrane; and the endothelium.

Treatment

The established surgical treatment for corneal disease is penetrating keratoplasty, which involves making a large central opening through the cornea and then filling the opening with a full-thickness donor cornea. In certain conditions, such as Stevens-Johnson syndrome, ocular cicatricial pemphigoid, chemical injury, or prior failed corneal transplant, survival of transplanted cornea is poor. The keratoprosthesis was developed to restore vision in patients for whom a corneal transplant is not an option.

Keratoprosthetic devices consist of a central optic held in a cylindrical frame. The keratoprosthesis replaces the section of the cornea that has been removed, and, along with being held in place by the surrounding tissue, may be covered by a membrane to further anchor the prosthesis. A variety of biologic materials are being investigated to improve the integration of prosthetic corneal implants into the stroma and other corneal layers.

The Dohlman-Doane keratoprosthesis, most commonly referred to as the Boston Keratoprosthesis (KPro), is manufactured under the auspices of the Harvard Medical School-affiliated Massachusetts

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Eye and Ear Infirmary. The Boston type 1 KPro uses a donor cornea between a central stem and a back plate. The Boston type 2 prosthesis is a modification of the type 1 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), consists of a polymethylmethacrylate (PMMA) device with a central optic region fused to a surrounding sponge skirt; the device is inserted in a 2-stage surgical procedure.

Autologous keratoprotheses use a central PMMA optic supported by a skirt of either tibia bone or the root of a tooth with its surrounding alveolar bone. The most common is the osteo-odonto-keratoprosthesis, which uses osteodental lamina derived from an extracted tooth root and attached alveolar bone that has been removed from the patient's jaw. Insertion of the osteo-odonto-keratoprosthesis device requires a complex staged procedure, in which the cornea is first covered with buccal mucosa. The prosthesis itself consists of a PMMA optical cylinder, which replaces the cornea, and is held in place by biologic support made from a canine tooth extracted from the recipient. A hole is drilled through the dental root and alveolar bone, and the PMMA prosthesis is placed within. This entire unit is placed into a subcutaneous ocular pocket and is then retrieved 6 to 12 months later for final insertion.

Hydroxyapatite, with a similar mineral composition to both bone and teeth (phosphate and calcium), may also be used as a bone substitute and as a bioactive prosthesis with the orbit. Collagen coating and scaffolds have also been investigated to improve growth and biocompatibility with the corneal epithelial cells, which form the protective layer of the eye. Many of these materials and devices are currently being tested in vitro or animal models.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 1992, the Boston KPro (Dohlman-Doane keratoprosthesis; Massachusetts Eye and Ear Infirmary) was approved by the U.S. Food and Drug Administration through the premarket approval process for use in patients with severe corneal opacity. The device is used when standard corneal transplant has failed or would be unlikely to succeed. There are 2 types of Boston KPro. Type 1 is used in eyes when eyelids, blink mechanism, and tear film are intact. Type 2 is used with severe dry eye and in eyes with mucosal keratinization and obliteration of normal conjunctival fornices.

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In August 2002, the AlphaCor^{®†} (Chirila Keratoprosthesis) was cleared for marketing by the Food and Drug Administration through the 510(k) process. The Food and Drug Administration determined that this device was substantially equivalent to the Dolman-Doane keratoprosthesis. The AlphaCor^{®†} device is indicated as a keratoprosthesis in adults with corneal opacity when standard penetrating keratoplasty with donor tissue is not suitable, when patients have declined standard penetrating keratoplasty, or when adjunctive procedures to prevent graft rejection are contraindicated.

Rationale/Source

A keratoprosthesis, consisting of a central optic held in a cylindrical frame, is an artificial cornea 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.

For individuals who have corneal blindness and have failed or are not candidates for corneal transplantation who receive a Boston Keratoprosthesis (Boston KPro), the evidence includes case series and systematic reviews. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. Numerous case series have been published. Together, studies have assessed thousands of eyes. A 2015 systematic review of Boston KPro efficacy included 22 series with a total of 2176 eyes. 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 associated with numerous complications (eg, the growth of retro prosthetic membranes) and a probable need for additional surgery, thus careful patient selection is important. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have corneal blindness and have failed or are not candidates for corneal transplantation who receive a keratoprosthesis using the AlphaCor device, the evidence includes case series. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. Only a few published case series have evaluated the AlphaCor device. There are insufficient data on improvement in vision outcomes using the AlphaCor device. Moreover, the device has been associated with complications, including thinning or melting of the

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anterior corneal surface and corneal necrosis. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have corneal blindness and have failed, or are not candidates for corneal transplantation who receive an osteo-odonto-keratoprosthesis, the evidence includes case series and a systematic review. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. A 2012 systematic review of case series, all conducted outside of the United States, found high anatomic survival rates at 5 and 20 years, but vision outcomes were not well-described. Osteo-odonto-keratoprosthesis is a complex surgical procedure and has been associated with a number of complications, including extrusion of the keratoprosthesis, retinal detachment, and vitreoretinal complications. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 1 specialty society and 4 academic medical centers while this policy was under review in 2009. Reviewers generally supported a limited role for the Boston Keratoprosthesis in select patients. Some reviewers recommended use without first attempting a transplant under specific conditions that have a poor prognosis for corneal transplant; however, others found this controversial. Some reviewers recommended use only in patients with limited visual acuity in the contralateral eye. Overall, input indicated that the Boston Keratoprosthesis should be reserved for cases in which no other alternative (ie, corneal transplantation) is available for treatment of corneal opacification.

Practice Guidelines and Position Statements

A 2013 Preferred Practice Parameter on ocular edema and opacification by the American Academy of Ophthalmology did not provide specific recommendations on the keratoprosthesis, but included this discussion of the technology:

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“...Significant improvements in the design and postoperative management of the Boston type 1 keratoprosthesis has resulted in a steady rise in the number of these procedures performed both in the United States and abroad. Reduced incidence of postoperative stromal necrosis and bacterial endophthalmitis due to the chronic use of protective soft contact lenses and topical antibiotics has resulted in improved retention and visual outcomes and has had a positive impact on surgeons’ perceptions of when to recommend keratoprosthesis. Once considered a procedure of last resort in patients with severe bilateral visual impairment, it is now being used for a variety of unilateral and bilateral indications, such as ocular trauma, herpetic keratitis, aniridia, Stevens-Johnson syndrome, and congenital corneal opacification. More recently, as corneal surgeons have gained a greater appreciation of the failure rate of repeat corneal transplantation, a role for a keratoprosthesis in cases of multiple graft failure has become clearer.”

“Patients with severe dry eye and autoimmune ocular surface diseases (particularly Stevens-Johnson syndrome and OMMP [ocular mucous membrane pemphigoid]) remain a difficult management group despite the other successes of the Boston type 1 keratoprosthesis. Epithelial defects, scleral necrosis, extrusion, and endophthalmitis are the principal concerns. This group of patients has had some success with a Boston type 2 keratoprosthesis designed to be used through the lid and the osteo-odonto-keratoprosthesis.”

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no Medicare national coverage policy.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02084745	Timing of Glaucoma Drainage Device With Boston KPro Surgery (GDD-KPro)	40	Mar 2020

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NCT: national clinical trial.

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05/07/2015 Medical Policy Committee review

05/20/2015 Medical Policy Implementation Committee approval. New policy.

05/05/2016 Medical Policy Committee review

05/18/2016 Medical Policy Implementation Committee approval. A bullet stating “an ocular condition unlikely to respond favorably to primary corneal transplant surgery” was

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added to the medically necessary policy statement. In medically necessary policy statement, “multiple graft failures changed” to “history of 1 or more” graft failures.

01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes

05/04/2017 Medical Policy Committee review

05/17/2017 Medical Policy Implementation Committee approval. No change to coverage.

05/03/2018 Medical Policy Committee review

05/16/2018 Medical Policy Implementation Committee approval. No change to coverage.

05/02/2019 Medical Policy Committee review

05/15/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

05/07/2020 Medical Policy Committee review

05/13/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

09/16/2020 Coding update

Next Scheduled Review Date: 05/2021

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	65770
HCPCS	C1818, L8609
ICD-10 Diagnosis	H17.10-H17.13, H54.0, H54.40-H54.42, L51.1, T26.60XA-T26.62XA, T85.318A, T85.328A, T85.398A, T85.72XA, T85.79XA Codes deleted eff 10/1/2020: T86.840-T86.842 Codes added eff 10/1/2020: T86.8401-T86.8409, T86.8411-T86.8419, T86.8421-T86.8429, T86.8481-T86.8489, T86.8491-T86.8499

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or

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3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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