

Corporate Medical Policy

Keratoprosthesis

File Name:	keratoprosthesis
Origination:	11/1989
Last CAP Review:	6/2019
Next CAP Review:	6/2020
Last Review:	6/2019

Description of Procedure or Service

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 (such as prior failed corneal transplants, chemical injuries, or certain immunological conditions) 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.

Background

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

Treatment

The established surgical treatment for 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, ocular cicatricial pemphigoid, chemical injury, or prior failed corneal transplant, survival of transplanted cornea is poor. The keratoprosthesis has been 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 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 Eye and Ear Infirmary. The Boston type I KPro uses a donor cornea between a central stem and a back plate. The Boston type II prosthesis 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) consists of a polymethylmethacrylate (PMMA) device with a central optic region fused with a surrounding sponge skirt; the device is inserted in a 2-stage surgical procedure.

Autologous keratoprostheses use a central polymethylmethacrylate (PMMA) optic supported by a skirt of either tibia bone or the root of a tooth with its surrounding alveolar bone. The most common

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is the osteo-odonto keratoprosthesis (OOKP), 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 OOKP 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, held in place by a biological 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 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 cornea epithelial cells, which form the protective layer of the eye. Many of these materials and devices are currently being tested in vitro or in animal models.

Regulatory Status

In January 1992, the Boston KPro (Dohlman-Doane keratoprosthesis; Massachusetts Eye and Ear Infirmary) was approved by the U.S. Food and Drug Administration (FDA) 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.

In August 2002, the AlphaCor (Chirila keratoprosthesis) was cleared for marketing by FDA through the 510(k) process. FDA determined that this device was substantially equivalent to the Dolman-Doane keratoprosthesis. The 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.

Related policies:

Implantation of Intrastromal Corneal Ring Segments
Endothelial Keratoplasty

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for The Boston Keratoprosthesis (Boston KPro) for the surgical treatment of severe corneal blindness when it is determined to be medically necessary and when medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Keratoprosthesis is covered

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).

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When Keratoprosthesis is not covered

- A permanent keratoprosthesis for all other conditions is considered **investigational**.
- All other types of permanent keratoprostheses are considered **investigational**.

Policy Guidelines

Patients should be expected to be compliant with postoperative care.

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 vision is <20/400 in the affected eye and <20/40 in the opposite eye; **AND**;
- No end-stage glaucoma or retinal detachment is present; **AND**;
- The patient has one of the following indications:
 1. History of 1 or more corneal transplant graft failures
 2. Stevens-Johnson syndrome
 3. Ocular cicatricial pemphigoid
 4. Autoimmune conditions with rare ocular involvement
 5. Ocular chemical burns
 6. An ocular condition unlikely to respond favorably to primary corneal transplant surgery (eg; limbal stem cell compromise or post-herpetic anesthesia).

For individuals who have corneal blindness and failed or are not candidates for corneal transplantation who receive a Boston Keratoprosthesis, 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 studies have been published. Together, studies have included thousands of eyes. A 2015 systematic review of 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 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.

For individuals who have corneal blindness and 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. There are only a few published case series evaluating the AlphaCor device. There are insufficient data on improvement in vision outcomes using the AlphCor device. Moreover, the device has been associated with complications including thinning or melting of the anterior corneal surface and corneal necrosis. The evidence is insufficient to determine the effects of the technology on health outcome.

For individuals who have corneal blindness and failed or are not candidates for corneal transplantation who receive an osteo-odonto-keratoprosthesis (OOKP), the evidence includes case series and a systematic review. Relevant outcomes are change in disease status, morbid events,

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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. OOKP 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 outcome.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable code: 65770, C1818, L8609

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual 3/96

MEDLINE search January 1996 through July 1997.

Garcia-Valenzuela, E. Outcome of vitreoretinal surgery and penetrating keratoplasty using temporary keratoprosthesis. *Retina*. 1999;19(5):424-9

Netland, PA. Glaucoma associated with keratoprosthesis. *Ophthalmology*. 1998 Apr;105(4):751-7

Medical Policy Advisory Group (MPAG) - 9/14/00

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ECRI Hotline Response: Synthetic Cornea (AlphaCor Keratoprosthesis); Accessed 3/20/2003

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BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.01, 7/15/04.

Technote #27. Keratoprosthesis for the treatment of severe bilateral cornea disease. Alberta Heritage Foundation for Medical Research. [April 2001]. Retrieved on 11/3/04 from <http://www.ahfmr.ab.ca/publications.html>

Interventional procedures overview of insertion of a hydrogel synthetic keratoplasty. IP overview: Synthetic penetrating keratoplasty using a hydrogel cornea. National Institute for Clinical Excellence (NICE). [3/2004]. Retrieved on 11/3/04 from <http://www.nice.org.uk/pdf/ip/225overview.pdf>

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http://www.ta.ecri.org/Hotline/Prod/summary/detail.aspx?doc_id=7525&q=keratoprosthesis&anm

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Specialty Matched Consultant Advisory Panel review - 4/6/09

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.01, 12/10/09

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

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.01, 2/10/11

Specialty Matched Consultant Advisory Panel review -6/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.01, 2/9/12

Specialty Matched Consultant Advisory Panel Review-10/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.01, 2/14/13

Specialty Matched Consultant Advisory Panel review- 6/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.01, 2/13/14

Specialty Matched Consultant Advisory Panel review- 6/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.01, 3/12/15

Specialty Matched Consultant Advisory Panel review- 6/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.01, 3/10/16

Specialty Matched Consultant Advisory Panel review- 6/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.01, 3/9/17

Specialty Matched Consultant Advisory Panel review- 6/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.01, 3/8/18

Specialty Matched Consultant Advisory Panel review- 6/2018

Medical Director review 8/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.01, 3/14/19

Specialty Matched Consultant Advisory Panel review- 6/2019

Policy Implementation/Update Information

8/88 Evaluated: Investigative

7/96 Reaffirmed: National Association reviewed 3/96. No changes.

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- 7/97 Reaffirmed: PCP and MedPoint added to Product Indicators. MEDLINE search indicated no change in policy.
- 7/99 Reformatted, Medical Term Definition added.
- 11/99 Archived. No activity
- 6/00 Review by BCBSNC Medical Policy Group of current literature. Reactivated policy due to investigational status.
- 7/00 System coding changes
- 9/00 Medical Policy Advisory Group reviewed. Approved. No change in criteria.
- 4/01 Specialty Matched Consultant Advisory Panel review. No change to policy.
- 4/03 Specialty Matched Consultant Advisory Panel review 3/24/03. No change in criteria. Revised Description section. Removed statements under Policy Guidelines. Statement added to Billing/ Coding section indicating that medical records may be ordered. System coding changes.
- 4/04 Benefits Application and Billing/Coding sections updated for consistency.
- 1/20/05 Specialty Matched Consultant Advisory Panel review 1/5/2005. No change in criteria. Rationale added to "Policy Guidelines" section. Reference sources added.
- 1/19/06 Added 2006 HCPCS code L8609 to Billing/Coding section.
- 2/26/07 Specialty Matched Consultant Advisory Panel review. No changes to criteria. Reference sources added. (pmo)
- 4/27/09 Description section and Policy Guidelines updated. Reference Sources added. (pmo)
- 3/30/10 Description section extensively revised. Policy statement changed to read: BCBSNC will provide coverage for The Boston Keratoprosthesis (Boston KPro) for the treatment of corneal blindness when it is determined to be medically necessary and when medical criteria and guidelines shown below are met. When Covered section changed to read: "The Boston Keratoprosthesis (Boston KPro) may be considered **medically necessary** for the treatment of corneal blindness under the following conditions: The cornea is severely opaque and vascularized; AND The patient has had two or more prior failed corneal transplants." The When Not Covered section changed to read : "A permanent keratoprosthesis for all other conditions is considered investigational. All other types of permanent keratoprostheses are considered investigational." Rationale updated in policy guidelines section. References updated. (lr)
- 6/22/10 Policy Number(s) removed (amw)
- 4/26/11 References updated. No changes to policy statements. (mco)
- 7/19/11 Specialty Matched Consultant Advisory Panel review 6/29/2011. No changes to policy statement. (lpr)
- 10/30/12 Description section updated. Reference added. Specialty Matched Consultant Advisory Panel review 10/17/2012. No change to policy statement. (lpr)
- 4/1/13 References updated. No changes to policy statements. (lpr)
- 7/16/13 Specialty matched consultant advisory panel review 6/19/2013. No change to policy statement. (lpr)
- 4/1/14 Reference updated. No change to policy statement. (lpr)
- 7/15/14 Specialty matched consultant advisory panel review meeting 6/24/2014. No change to policy statement. (lpr)
- 4/28/15 Updated "Description and Policy Guidelines" sections. Under "When Covered" section: added medically necessary indications: "Best-corrected vision is <20/400 in the affected eye and <20/40 in the opposite eye; No end-stage glaucoma or retinal detachment is

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- present; Multiple 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”. Reference added. Sr. Medical Director review 3/2015. (lpr)
- 7/28/15 Specialty Matched Consultant Advisory Panel review 6/24/2015. No change to policy statement. (lpr)
- 4/29/16 Updated Policy Guidelines. Under “When Covered” section: changed #1. to “History of 1 or more” from “multiple.” Reference added. Senior medical director review. (lpr)
- 7/26/16 Specialty Matched Consultant Advisory Panel review 6/29/2016. No change to policy statement. (lpr)
- 4/28/17 Updated Description and Policy Guidelines sections as well as Regulatory Status. Reference added. No change in policy statement. (lpr)
- 7/28/17 Specialty Matched Consultant Advisory Panel review 6/28/2017. Added HCPCS code C1818 to the Billing/Coding section. No change to policy statement. (lpr)
- 8/10/18 Specialty Matched Consultant Advisory Panel review 6/2018. Reference added. No change to policy statement. (lpr)
- 10/12/18 Updated coverage statement in “When Covered” section and moved medical conditions to the Policy Guidelines section. Medical Director review 8/2018. (lpr)
- 7/16/19 Specialty Matched Consultant Advisory Panel review 6/19/2019. Reference added. No change to policy statement. (lpr)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.