

Corporate Medical Policy

Keratoprosthesis

File Name:	keratoprosthesis
Origination:	11/1989
Last CAP Review:	6/2011
Next CAP Review:	6/2012
Last Review:	6/2011

Description of Procedure or Service

A keratoprosthesis 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.

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. 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, 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. 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 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

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 keratoprostheses 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

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Infirmity. The Boston KPro uses a PMMA (rigid plastic) optic stabilized between a front and back plate. The AlphaCor, previously known as the Chirila keratoprosthesis (Chirila KPro) marketed by Argus Biomedical was cleared for marketing by the FDA in 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 two-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.

See also 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 treatment of 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 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.

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 able to be complaint with postoperative care.

Successful development of a keratoprosthesis requires durable clarity, retention, and bioincorporation. The published literature reveals ongoing modifications of the design of the keratoprosthesis, both in terms of the optics and the techniques used for anchoring the optic in place, the surgical technique, and the postoperative management. Randomized trials are unlikely. Although patients can serve as their own controls, with comparison of pre- and postoperative visual acuity, case series are likely to remain small due to the low volume of the procedure. The largest case series focuses on the use of the OOKP prosthesis, which is not widely used in this country. Anatomical retention with the OOKP appears good, but restoration of vision is not well reported, and may not be much better than light perception or hand motion.

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Based on the literature and clinical input, the Boston KPro is the most widely used and accepted keratoprosthesis in the United States at this time. Anatomical retention and visual success of this device at mid- to long-term outcomes are unknown, but short-term visual outcomes with the Boston KPro are promising. It should be noted that this remains a high-risk procedure that is associated with numerous complications (such as growth of retroprosthetic membranes) and a probable need for additional surgery. Complications with other designs of keratoprostheses appear to be worse than those associated with the Boston KPro. Therefore, given the absence of alternative treatment options, the Boston KPro may be considered medically necessary for patients with corneal opacification who have failed corneal transplantation.

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, 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

Specialty Matched Consultant Advisory Panels - 4/2001

BCBSA Medical Policy Reference Manual - Policy 9.03.01 - Review date: 12/18/2002

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

Specialty Matched Consultant Advisory Panel - 3/2003

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>

ECRI Hotline Response - Synthetic Cornea (AlphaCor Keratoprosthesis), (09/30/2004) retrieved on 11/3/04 from

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

Specialty Matched Consultant Advisory Panel - 1/2005

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BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.01, 4/25/06.

Specialty Matched Consultant Advisory Panel review - 1/25/07

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.01, 9/18/07.

National Institute for Clinical Excellence (NICE). Insertion of hydrogel keratoprosthesis. Interventional Procedure Guidance 69. London, UK: NICE; June 2004. Retrieved on December 15, 2008 from <http://nice.org.uk/page.aspx?o=208469>.

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

Policy Implementation/Update Information

8/88	Evaluated: Investigative
7/96	Reaffirmed: National Association reviewed 3/96. No changes.
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

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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)

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.