

## Medical Policy



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### **Title: Keratoprosthesis**

#### **Professional**

Original Effective Date: September 29, 2003

Revision Date(s): July 9, 2009

Current Effective Date: July 9, 2009

#### **Institutional**

Original Effective Date: August 10, 2009

Revision Date(s):

Current Effective Date: August 10, 2009

#### **DESCRIPTION**

A keratoprosthesis is a device intended to restore vision to patients with severe bilateral corneal disease for whom a corneal transplant is not an option, such as in cases involving chemical injuries or certain immunological conditions. Keratoprosthetic devices differ in design but, in general, consist of a central rigid polymethacrylate optic that perforates the cornea and is covered or surrounded by various tissues or surfaces to anchor the prosthesis. Implantation techniques differ, and success rates are variable and highly dependent on the skill of the surgeon.

There are 2 permanent keratoprostheses that received 510(k) marketing approval by the U.S. Food and Drug Administration (FDA). The AlphaCor, previously known as the Chirila keratoprosthesis (Chirila KPro), marketed by Argus Biomedical and the Dohlman Doane Keratoprosthesis. The Dohlman Doane Keratoprosthesis is also referred to as the Boston Keratoprosthesis and is manufactured under the auspices of the Harvard Medical School-affiliated Massachusetts Eye and Ear Infirmary. A temporary keratoprosthesis is a Class II FDA device.

#### **POLICY**

Temporary and permanent keratoprostheses are considered **experimental / investigational**.

#### **RATIONALE**

Successful development of a keratoprosthesis requires durable clarity, retention, and bioincorporation. These features remain elusive, and 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 likely not necessary, as patients can serve as their own controls, with comparison of pre- and postoperative visual acuity. However, case series will likely 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. It should be noted that patients with severe corneal damage have few treatment options to prevent blindness. The American Academy of Ophthalmology has not established guidelines for either a temporary or permanent keratoprosthesis, and considers this procedure to be a rare, last resort for treatment to prevent loss of the eye.

Effective July 1, 2003, Medicare established a HCPCS C code for integrated keratoprosthesis. The integrated keratoprosthesis became eligible for pass-through payment under the Outpatient Prospective Payment System and was scheduled to expire December 31, 2005.

Alio and colleagues (2004) reported that corneal keratoprosthesis (BIOKOP I, II) did not provide a stable anatomical relation with the surrounding ocular structures. Its ability to restore vision is limited to a short post-operative period in eyes implanted with severe ocular surface disease.

Zerbe and colleagues reported results from a mixed prospective/retrospective multicenter study of the Boston Type 1 keratoprosthesis. Thirty-nine surgeons were encouraged to mail standardized pre- and postoperative reports on their patients to a central collection site. Seventeen sites (44%) provided data on 133 patients (136 eyes). The number of patients with best-corrected visual acuity of 20/200 increased from 3.6% to 57%; 19% had postoperative vision of 20/40 or better. One hundred and nine postoperative complications were reported, with 35 occurrences of retroprosthetic membrane and 21 cases of high intraocular pressures. Pre-operatively, each eye had an average of 2 (range of 0 to 8) prior corneal transplants per eye; at an average follow-up of 8.5 months (range of 0.03 to 24), retention was reported to be 95%, with 7 failures. Limitations of this report include the short follow-up time and potential bias in the discretionary submission of data.

The United Kingdom's National Institute for Clinical Excellence (NICE) concludes that, "Current evidence on the safety and efficacy of insertion of hydrogel keratoprostheses does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research."

### **CODING**

**The following codes for treatment and procedures applicable to this policy 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. 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.**

#### CPT/HCPCS

65770	Keratoprosthesis
L8609	Artificial cornea
C1818	Integrated keratoprosthesis

**REVISIONS**

07-09-2009	Policy added to the bcbsks.com web site. No policy changes were made.
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