

MEDICAL POLICY



SUBJECT: KERATOPROSTHESIS	EFFECTIVE DATE: 04/22/10
POLICY NUMBER: 9.01.15	REVISED DATE: 04/21/11, 04/19/12, 04/18/13, 04/17/14,
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- *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.*
- *If a commercial product, including and Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.*
- *If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.*

POLICY STATEMENT:

- I. Based upon our criteria and assessment of peer-reviewed literature, use of the Boston keratoprosthesis (type I or II) is considered **medically appropriate** for the treatment of corneal blindness for the following indications:
 - A. Severely opaque and vascularized cornea; AND either
 - B. One or more prior failed corneal transplants; however, a request for a Boston keratoprosthesis in an infant one year of age or less does not require a prior failed corneal transplant; OR
 - C. An ocular condition with a known low success rate for a primary corneal transplant (e.g., Stevens-Johnson syndrome, ocular cicatricial pemphigoid, autoimmune conditions with rare ocular involvement, ocular chemical burns).
- II. Based upon our criteria and assessment of peer-reviewed literature, all other types of keratoprostheses (e.g. AlphaCor, osteo-odonto-keratoprosthesis) have not been proven to be medically effective and are considered **investigational**.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

The cornea, a clear, dome-shaped membrane that covers the front of the eye, is a key refractive element of the eye. Corneal tissue is arranged in a number of layers: the epithelium (outermost layer); Bowman's layer; the stroma, which comprises approximately 90% of the cornea; Descemet's membrane; and the endothelium. For optimal vision, all layers of the cornea must be of normal shape and curvature and free of any cloudy or opaque areas. While many corneal disorders can be managed medically, there are certain conditions such as severe corneal dystrophies and degenerations that require surgical intervention. Scarring from infection or trauma may also cause corneal changes that may require surgery. The established surgical treatment for severe 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.

A keratoprosthesis (KPro) 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. Keratoprostheses are made of clear plastic with excellent tissue tolerance and optical properties. They vary in design, size and even the implantation techniques may differ across different treatment centers. In general, keratoprostheses consist of a transparent cylinder-shaped optical portion and a haptical portion. The optical cylinder is inserted into a central circular opening of the opacified cornea, focusing images on a functioning retina. The haptical section is fixed to and buried under neighboring tissue. The different designs of keratoprostheses vary primarily in the haptical portion of the devices. Although many keratoprostheses have been developed, the most commonly used include the Boston keratoprosthesis (Dohlman Doane Keratoprosthesis), Osteo-Odonto-Keratoprosthesis (OOKP) and AlphaCor, previously known as the Chirila keratoprosthesis.

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This is considered to be 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.

RATIONALE:

Permanent keratoprostheses that have received 510(k) marketing approval by the U.S. Food and Drug Administration (FDA) include the Boston Keratoprosthesis (Boston Kpro)/Dohlman-Doane keratoprosthesis that was approved in 1992; the AlphaCOR™ (formerly Chirila KPro) that was approved in 2002 and the Oculaid® by Ophtec B.V. USA, Inc. that was approved in 2004. The Oculaid KPro is supplied by special request only.

The keratoprosthesis is intended for the relatively small number of patients who have lost vision and for whom a corneal transplant is not expected to result in satisfactory outcomes. Complications such as implant extrusion, formation of a retroprosthesis membrane requiring additional surgery, worsening of glaucoma, chronic inflammation and bacterial endophthalmitis can occur. However, patients with severe corneal damage have few treatment options to prevent blindness.

Since the implantation of a keratoprosthesis is considered to be a salvage procedure with no acceptable alternative treatment, comparative studies are lacking. The literature mainly consists of case series with small patient sample populations with short to mid-term follow-up. The Boston KPro is the most widely studied and utilized in the United States. With the Boston KPro short to mid-term visual outcomes demonstrate an improvement in a substantial percentage of patients. Longer follow-up is still needed to further evaluate the effect of this technology on health outcomes. Given the available evidence and the absence of alternative treatment options, use of the Boston KPro is considered appropriate.

While studies on the use of a keratoprosthesis in the pediatric population are extremely limited, corneal transplantation in this aged population has an even higher rate of corneal graft rejection. Coupled with an infant's need to have a clear visual pathway to enable the brain to learn and process images, use of a keratoprosthesis as a primary procedure is reasonable.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT: 65770 Keratoprosthesis

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HCPCS: C1818 Integrated keratoprosthesis

L8609 Artificial cornea

ICD10: H17.10-H17.13 Central corneal opacity (code range)

H54.0-H54.8 Blindness and low vision (code range)

L51.1 Stevens-Johnson syndrome

T26.60XA-T26.62xA Corrosion of cornea and conjunctival sac, eye, initial encounter (code range)

T85.318A Breakdown (mechanical) of other ocular prosthetic devices, implants and grafts, initial encounter

T85.328A Displacement of other ocular prosthetic devices, implants and grafts, initial encounter

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T85.398A	Other mechanical complication of other ocular prosthetic devices, implants and grafts, initial encounter
T86.840-T86.841	Corneal transplant rejection or rejection code range

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* key article

KEY WORDS:

AlphaCor, BIOKOP, Boston type I, Boston type II, Dolhman-Doane, keratoprosthesis, KPro, osteo-odonto, OOKP

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based upon our review, the implantation of a keratoprosthesis is not addressed in National or Regional CMS coverage determinations or policies.