

MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	Keratoprosthesis
Policy Number	9.01.15
Category	Technology Assessment
Original Effective Date	04/22/10
Committee Approval Date	04/21/11, 04/19/12, 04/18/13, 04/17/14, 04/16/15, 04/21/16, 4/20/17, 04/19/18, 04/18/19, 04/16/20, 04/15/21
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Product Disclaimer	<ul style="list-style-type: none"> If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit. If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, 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 the peer-reviewed literature, use of the Boston keratoprosthesis (type I or II) is considered **medically appropriate** for the treatment of corneal blindness with the following indications:
 - A. severely opaque and vascularized cornea;

AND ONE of the following:

 1. One or more prior failed corneal transplants (not required for an infant age one year or less); **or**
 2. 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 the peer-reviewed literature, all other types of keratoprostheses (e.g., AlphaCor, osteo-odonto-keratoprosthesis) have not been proven to be medically effective and, therefore, are considered **investigational**.

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services.

DESCRIPTION

The cornea, which is 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

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conditions, such as Stevens-Johnson syndrome, cicatricial pemphigoid, chemical injury, or a 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. KPros are made of clear plastic with excellent tissue tolerance and optical properties. They vary in design and size, and implantation techniques may differ across different treatment centers. In general, KPros 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 designs of KPros differ primarily in the haptical portion of the devices. During implantation of the Boston KPro, the device is assembled with a donor corneal graft positioned between the front and back plate, that is then sutured into place in a similar fashion to traditional penetrating keratoplasty (PK). Although many KPros 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).

Implantation of a KPro 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 severe bilateral corneal disease and staffed by surgeons adequately trained in techniques addressing implantation of a KPro.

RATIONALE

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

The KPro 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.

As the implantation of a KPro 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 medically appropriate,

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

CODES

- *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.*

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Code	Description
65770	Keratoprosthesis

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Code	Description
C1818	Integrated keratoprosthesis
L8609	Artificial cornea

ICD10 Codes

Code	Description
H17.10-H17.13	Central corneal opacity (code range)
H54.0X-H54.8	Blindness and low vision (code range)
L51.1	Stevens-Johnson syndrome
T26.10-T26.12	Burn of cornea and conjunctival sac (code range)
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
T85.398A	Other mechanical complication of other ocular prosthetic devices, implants and grafts, initial encounter
T86.840-T86.8419	Corneal transplant rejection or failure (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.