

Policy Name:	Keratoprosthesis for Corneal Opacity
Effective Date:	10/15/2018

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy

Keratoprosthesis procedures for treatment of corneal blindness are **COVERED** when there is severe corneal opacity and there is either failure of two prior corneal transplants or corneal transplant is not a viable option.

Keratoprosthesis procedures using all non-FDA approved devices and for all other indications are investigative and therefore **NOT COVERED**.

Note: This policy is no longer scheduled for routine review of the scientific literature.

Description

A keratoprosthesis, also known as an artificial cornea, is a device intended to restore vision to patients with severe corneal disease where corneal transplantation has repeatedly failed or is not an option, such as in cases involving chemical or traumatic injuries and certain immunological conditions, including pemphigoid and Stevens-Johnson syndrome. Permanent devices are implanted in the eye to replace opacified corneal tissue, thus providing a clear window, which allows the transmission of light. Keratoprosthetic devices do not become opaque (i.e., opacify) and cannot vascularize like human donor corneas.

Various models exist. The most researched and widely used device is the Boston KPro (formerly Dohlman-Doane KPro, Massachusetts Eye & Ear Infirmary, Boston, MA). While the different models vary, the Boston KPro is a collar button design. It is composed of a front plate with a stem housing the cylindrical optical portion of the device, a back plate, and a titanium locking c-ring. The optical part is inserted into a central circular opening of the opaque cornea and acts as a periscope, focusing the images on a functioning retina. Keratoprosthesis procedures are performed in the outpatient or same day surgery setting.

FDA Approval

The U.S. Food and Drug Administration (FDA) clears keratoprosthesis devices for marketing as Class II devices under the 510(k) clearance process. Devices currently approved for marketing in the U.S. include:

1. Boston Keratoprosthesis (KPro), Type I or Type II (formerly known as Dohlman-Doane Keratoprosthesis) (Massachusetts Eye and Ear Infirmary)
2. AlphaCor™ (previously known as the Chirila keratoprosthesis) (Argus Biomedical).

Prior Authorization

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

65770 - Keratoprosthesis
C1818 - Integrated keratoprosthesis
L8609 - Artificial cornea

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Re-Review Date(s): 3/17/2009
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