# Protocol

# Keratoprosthesis

(90301)

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| **Medical Benefit** | | **Effective Date**: 10/01/16 | **Next Review Date**: 07/21 |
| **Preauthorization** | No | **Review Dates**: 05/07, 07/08, 05/09, 01/10, 01/11, 01/12, 01/13, 09/13, 07/14, 07/15, 07/16, 07/17, 07/18, 07/19, 07/20 | |

***Preauthorization is not required.***

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

## RELATED PROTOCOLS

Endothelial Keratoplasty

Implantation of Intrastromal Corneal Ring Segments

| Populations | Interventions | Comparators | Outcomes |
|---|---|---|---|
| Individuals:<br>• With corneal blindness who have failed or are not candidates for corneal transplantation | Interventions of interest are:<br>• Boston Keratoprosthesis | Comparators of interest are:<br>• Penetrating keratoplasty | Relevant outcomes include:<br>• Change in disease status<br>• Morbid events<br>• Quality of life<br>• Treatment-related morbidity |
| Individuals:<br>• With corneal blindness who have failed or are not candidates for corneal transplantation | Interventions of interest are:<br>• Keratoprosthesis using the AlphaCor device | Comparators of interest are:<br>• Penetrating keratoplasty | Relevant outcomes include:<br>• Change in disease status<br>• Morbid events<br>• Quality of life<br>• Treatment-related morbidity |
| Individuals:<br>• With corneal blindness who have failed or are not candidates for corneal transplantation | Interventions of interest are:<br>• Osteo-odonto-keratoprosthesis | Comparators of interest are:<br>• Penetrating keratoplasty | Relevant outcomes include:<br>• Change in disease status<br>• Morbid events<br>• Quality of life<br>• Treatment-related morbidity |

## DESCRIPTION

A keratoprosthesis, consisting of a central optic held in a cylindrical frame, is an artificial cornea intended to restore vision to patients with severe bilateral corneal disease for whom a corneal transplant is not an option. The keratoprosthesis replaces the cornea that has been removed and is held in place by the surrounding tissue. Various biologic materials are being investigated to improve integration of the prosthetic into the eye.

## SUMMARY OF EVIDENCE

For individuals who have corneal blindness and have failed or are not candidates for corneal transplantation who receive a Boston Keratoprosthesis (Boston KPro), the evidence includes case series and systematic reviews. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. Numerous case series have been published. Together, studies have assessed thousands of eyes. A 2015 systematic review of Boston KPro efficacy included 22 series with a total of 2,176 eyes. Systematic reviews and case series with longer follow-up (i.e., at least two years) have shown improvement in visual outcomes in a substantial percentage of patients with Boston KPro. This procedure is high-risk and associated with numerous complications (e.g., the growth of retro prosthetic membranes) and a probable need for additional surgery, thus careful patient selection is important. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have corneal blindness and have failed or are not candidates for corneal transplantation who receive a keratoprosthesis using the AlphaCor device, the evidence includes case series. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. Only a few published case series have evaluated the AlphaCor device. There are insufficient data on improvement in vision outcomes using the AlphaCor device. Moreover, the device has been associated with complications, including thinning or melting of the anterior corneal surface and corneal necrosis. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have corneal blindness and have failed, or are not candidates for corneal transplantation who receive an osteo-odonto-keratoprosthesis, the evidence includes case series and a systematic review. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. A 2012 systematic review of case series, all conducted outside of the United States, found high anatomic survival rates at five and 20 years, but vision outcomes were not well-described. Osteo-odonto-keratoprosthesis is a complex surgical procedure and has been associated with a number of complications, including extrusion of the keratoprosthesis, retinal detachment, and vitreoretinal complications. The evidence is insufficient to determine the effects of the technology on health outcomes.

## POLICY

The Boston (Dohlman-Doane) Keratoprosthesis (Boston KPro) may be considered **medically necessary** for the surgical treatment of severe corneal opacification in situations where cadaveric corneal transplants have failed or have a very low likelihood of success (see Policy Guidelines).

All other types of permanent keratoprostheses are considered **investigational**.

## POLICY GUIDELINES

Implantation of a keratoprosthesis is considered 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.

Conditions under which cadaveric corneal transplants have a likelihood of failure include but are not limited to the following:

- The cornea is severely opaque and vascularized AND

- Best-corrected visual acuity is 20/400 or less in the affected eye and 20/40 or less in the contralateral eye AND
- No end-stage glaucoma or retinal detachment is present AND
- The patient has one of the following indications:
  - History of one or more corneal transplant graft failures
  - Stevens-Johnson syndrome
  - Ocular cicatricial pemphigoid
  - Autoimmune conditions with rare ocular involvement
  - Ocular chemical burns
  - An ocular condition unlikely to respond favorably to primary corneal transplant surgery (e.g., libel stem cell compromise or postherpetic anesthesia)

Note that patients should be able and expected to comply with postoperative care.

**BACKGROUND**

CORNEA

The cornea, a clear, dome-shaped membrane that covers the front of the eye, is a key refractive element of sight. Layers of the cornea consist of the epithelium (outermost layer); Bowman layer; the stroma, which comprises approximately 90% of the cornea; Descemet membrane; and the endothelium.

Treatment

The established surgical treatment for corneal disease is penetrating keratoplasty, which involves making a large central opening through the cornea and then filling the opening with a full-thickness donor cornea. In certain conditions, such as Stevens-Johnson syndrome, ocular cicatricial pemphigoid, chemical injury, or prior failed corneal transplant, survival of transplanted cornea is poor. The keratoprosthesis was 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 the 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.

The Dohlman-Doane keratoprosthesis, most commonly referred to as the Boston Keratoprosthesis (KPro), is manufactured under the auspices of the Harvard Medical School affiliated Massachusetts Eye and Ear Infirmary. The Boston type 1 KPro uses a donor cornea between a central stem and a back plate. The Boston type 2 prosthesis is a modification of the type 1 prosthesis and is designed with an anterior extension to allow implantation through surgically closed eyelids. The AlphaCor, previously known as the Chirila keratoprosthesis (Chirila KPro), consists of a polymethylmethacrylate device with a central optic region fused to a surrounding sponge skirt; the device is inserted in a two-stage surgical procedure.

Autologous keratoprostheses use a central polymethylmethacrylate 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, 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 osteo-odonto-keratoprosthesis device requires a complex staged procedure, in which the cornea is first covered with buccal mucosa. The prosthesis itself

consists of a polymethylmethacrylate optical cylinder, which replaces the cornea, and is held in place by biologic support made from a canine tooth extracted from the recipient. A hole is drilled through the dental root and alveolar bone, and the polymethylmethacrylate prosthesis is placed within. This entire unit is placed into a subcutaneous ocular pocket and is then retrieved six 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 corneal epithelial cells, which form the protective layer of the eye. Many of these materials and devices are currently being tested in vitro or animal models.

**REGULATORY STATUS**

In 1992, the Boston KPro (Dohlman-Doane keratoprosthesis; Massachusetts Eye and Ear Infirmary) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process for use in patients with severe corneal opacity. The device is used when standard corneal transplant has failed or would be unlikely to succeed. There are two types of Boston KPro. Type one is used in eyes when eyelids, blink mechanism, and tear film is intact. Type two is used with severe dry eye and in eyes with mucosal keratinization and obliteration of normal conjunctival fornices.

In August 2002, the AlphaCor® (Chirila Keratoprosthesis) was cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to the Dolman-Doane keratoprosthesis. The AlphaCor® device is indicated as a keratoprosthesis in adults with corneal opacity when standard penetrating keratoplasty with donor tissue is not suitable, when patients have declined standard penetrating keratoplasty, or when adjunctive procedures to prevent graft rejection are contraindicated.

FDA product code: HQM

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Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

**REFERENCES**

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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