Protocol

Keratoprosthesis

(90301)

Medical Benefit		**Effective Date**: 04/01/10	**Next Review Date**: 07/15
Preauthorization	No	**Review Dates**: 05/07, 07/08, 05/09, 01/10, 01/11, 01/12, 01/13, 09/13, 07/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is not required.*** *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.*

Description

A keratoprosthesis 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 immunologic conditions) for whom a corneal transplant is not an option.

Background

The cornea, a clear, dome-shaped membrane that covers the front of the eye, is a key refractive element of the eye. Layers of the cornea consist of the epithelium (outermost layer); Bowman's layer; the stroma, which comprises approximately 90% of the cornea; Descemet's membrane; and the endothelium. The established surgical treatment for 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. The keratoprosthesis has been 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 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.

Autologous keratoprostheses use a central polymethylmethacrylate (PMMA) 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 (OOKP), 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 OOKP device requires a complex staged procedure, in which the cornea is first covered with buccal mucosa. The prosthesis itself consists of a PMMA optical cylinder, which replaces the cornea, held in place by a biological support made from a canine tooth extracted from the recipient. A hole is drilled through the dental root and alveolar bone, and the PMMA 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 cornea epithelial cells, which form the protective layer of the eye. Many of these materials and devices are currently being tested in vitro or in animal models.

Regulatory Status

A keratoprosthesis is a Class II U.S. Food and Drug Administration (FDA) device intended to provide a transparent optical pathway through an opacified cornea, in an eye that is not a reasonable candidate for a corneal transplant. Two permanent keratoprostheses have received 510(k) marketing clearance by FDA. The Dohlman-Doane Keratoprosthesis, also 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 I KPro uses an optic between a central stem and a back plate. The Boston type II prosthesis is a modification of the type I 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) marketed by Argus Biomedical was cleared for marketing by FDA in 2002. The AlphaCor prosthesis consists of a PMMA device with a central optic region fused with a surrounding sponge skirt; the device is inserted in a two-stage surgical procedure. According to the 510(k) summary, the AlphaCor keratoprosthesis was shown to be substantially equivalent to the Dohlman-Doane Type I Keratoprosthesis. Both devices are indicated as permanent implantable keratoprostheses for eyes that are not corneal transplant candidates and are made of materials that have been proven to be biocompatible.

Related Protocols

Implantation of Intrastromal Corneal Ring Segments

Endothelial Keratoplasty

Policy (Formerly Corporate Medical Guideline)

The Boston Keratoprosthesis (Boston KPro) may be considered **medically necessary** for the treatment of corneal blindness under the following conditions:

- The cornea is severely opaque and vascularized; AND
- The patient has had two or more prior failed corneal transplants.

Patients should be expected to be able to be compliant with postoperative care.

A permanent keratoprosthesis for all other conditions is considered **investigational**.

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

Policy Guideline

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.

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