MEDICAL COVERAGE GUIDELINES
SECTION: VISION

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KERATOPROSTHESIS

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

A keratoprosthesis is an artificial cornea of acrylic plastic which replaces the central area of an opacified cornea. It has been investigated to restore vision to individuals with severe bilateral corneal disease when a corneal transplant is not an option. Keratoprostheses devices may be permanent or temporary. Devices include:

- AlphaCor Keratoprosthesis, an acrylic central optic which is fused with a surrounding sponge skirt
- BIOKOP device, an acrylic central optic with a surrounding microporous polymer
- Dohlman Doane Keratoprosthesis (also known as Boston Keratoprosthesis or K-Pro), a rigid acrylic optic stabilized between a front and back plate, which is anchored in place using a corneal graft
- Osteo-odonto-keratoprosthesis (OOKP), in which the cornea is first covered with buccal mucosa and the prosthesis is held in place by a biological support made from a tooth extracted from the recipient. A hole is drilled through the dental root and alveolar bone and the prosthesis is placed inside. This entire unit is placed into a subcutaneous pocket, and then retrieved after 6-12 months for final insertion.

KERATOPROSTHESIS (cont.)

Criteria:

- Boston Keratoprosthesis (Boston KPro, Dohlman Doane) for the treatment of corneal blindness is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Cornea is severely opaque and vascularized
  2. Two or more prior failed corneal transplants

- Boston Keratoprosthesis (Boston KPro, Dohlman Doane) for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

- All other keratoprosthesis devices for all indications are considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

  Keratoprosthesis devices include, *but are not limited to*:

  - AlphaCor Keratoprosthesis
  - BIOKOP device
  - Osteo-odonto-keratoprosthesis (OOKP)

KERATOPROSTHESIS (cont.)

Resources:

Resources prior to 03/12/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 9.03.01 BCBS Association Medical Policy Reference Manual. Keratoprosthesis. Re-issue date 02/13/2014, issue date 03/31/1996.

FDA Summary Statements for Keratoprosthesis. Device names include, *but are not limited to*:

AlphaCor™, AlphaCor-P™, AlphaCor-A™
Dohlman-Doane Keratoprosthesis

- FDA-approved indication: Adult patients with corneal opacity not suitable for standard penetrating keratoplasty with donor tissue or donor tissue has been declined or adjunctive measures required to prevent graft rejection are medically contraindicated.