



MASSACHUSETTS

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Medical Policy Keratoprosthesis

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Policy Number: 221

BCBSA Reference Number: 9.03.01

NCD/LCD: N/A

Related Policies

- Endothelial Keratoplasty, #180
- Implantation of Intrastromal Corneal Ring Segments, #235

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

The Boston (Dohlman-Doane) Keratoprosthesis (Boston KPro) may be considered **MEDICALLY NECESSARY** for the treatment of severe corneal opacification under the following conditions:

- The cornea is severely opaque and vascularized AND
- Best-corrected visual acuity is $\leq 20/400$ 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 1 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 (eg, limbal stem cell compromise or postherpetic anesthesia).

Note: 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**.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is not required .
Commercial PPO and Indemnity	Prior authorization is not required .
Medicare HMO Blue SM	Prior authorization is not required .
Medicare PPO Blue SM	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above **medical necessity criteria** **MUST** be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
65770	Keratoprosthesis

HCPCS Codes

HCPCS codes:	Code Description
C1818	Integrated keratoprosthesis
L8609	Artificial cornea

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT and HCPCS codes above if **medical necessity criteria** are met:

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
B02.33	Zoster keratitis
H16.401	Unspecified corneal neovascularization, right eye
H16.402	Unspecified corneal neovascularization, left eye
H16.403	Unspecified corneal neovascularization, bilateral
H16.409	Unspecified corneal neovascularization, unspecified eye
H16.411	Ghost vessels (corneal), right eye
H16.412	Ghost vessels (corneal), left eye

H16.413	Ghost vessels (corneal), bilateral
H16.419	Ghost vessels (corneal), unspecified eye
H16.421	Pannus (corneal), right eye
H16.422	Pannus (corneal), left eye
H16.423	Pannus (corneal), bilateral
H16.429	Pannus (corneal), unspecified eye
H16.431	Localized vascularization of cornea, right eye
H16.432	Localized vascularization of cornea, left eye
H16.433	Localized vascularization of cornea, bilateral
H16.439	Localized vascularization of cornea, unspecified eye
H16.441	Deep vascularization of cornea, right eye
H16.442	Deep vascularization of cornea, left eye
H16.443	Deep vascularization of cornea, bilateral
H16.449	Deep vascularization of cornea, unspecified eye
H17.00	Adherent leukoma, unspecified eye
H17.01	Adherent leukoma, right eye
H17.02	Adherent leukoma, left eye
H17.03	Adherent leukoma, bilateral
H17.10	Central corneal opacity, unspecified eye
H17.11	Central corneal opacity, right eye
H17.12	Central corneal opacity, left eye
H17.13	Central corneal opacity, bilateral
H17.811	Minor opacity of cornea, right eye
H17.812	Minor opacity of cornea, left eye
H17.813	Minor opacity of cornea, bilateral
H17.819	Minor opacity of cornea, unspecified eye
H17.821	Peripheral opacity of cornea, right eye
H17.822	Peripheral opacity of cornea, left eye
H17.823	Peripheral opacity of cornea, bilateral
H17.829	Peripheral opacity of cornea, unspecified eye
H17.89	Other corneal scars and opacities
H17.9	Unspecified corneal scar and opacity
H18.891	Other specified disorders of cornea, right eye
H18.892	Other specified disorders of cornea, left eye
H18.893	Other specified disorders of cornea, bilateral
H18.899	Other specified disorders of cornea, unspecified eye
H54.0X33	Blindness right eye category 3, blindness left eye category 3
H54.0X34	Blindness right eye category 3, blindness left eye category 4
H54.0X35	Blindness right eye category 3, blindness left eye category 5
H54.0X43	Blindness right eye category 4, blindness left eye category 3
H54.0X44	Blindness right eye category 4, blindness left eye category 4
H54.0X45	Blindness right eye category 4, blindness left eye category 5
H54.0X53	Blindness right eye category 5, blindness left eye category 3
H54.0X54	Blindness right eye category 5, blindness left eye category 4
H54.0X55	Blindness right eye category 5, blindness left eye category 5
H54.10	Blindness, one eye, low vision other eye, unspecified eyes
H54.1131	Blindness right eye category 3, low vision left eye category 1
H54.1132	Blindness right eye category 3, low vision left eye category 2
H54.1141	Blindness right eye category 4, low vision left eye category 1
H54.1142	Blindness right eye category 4, low vision left eye category 2
H54.1151	Blindness right eye category 5, low vision left eye category 1

H54.1152	Blindness right eye category 5, low vision left eye category 2
H54.1213	Low vision right eye category 1, blindness left eye category 3
H54.1214	Low vision right eye category 1, blindness left eye category 4
H54.1215	Low vision right eye category 1, blindness left eye category 5
H54.1223	Low vision right eye category 2, blindness left eye category 3
H54.1224	Low vision right eye category 2, blindness left eye category 4
H54.1225	Low vision right eye category 2, blindness left eye category 5
H54.2X11	Low vision right eye category 1, low vision left eye category 1
H54.2X12	Low vision right eye category 1, low vision left eye category 2
H54.2X21	Low vision right eye category 2, low vision left eye category 1
H54.2X22	Low vision right eye category 2, low vision left eye category 2
H54.40	Blindness, one eye, unspecified eye
H54.413A	Blindness right eye category 3, normal vision left eye
H54.414A	Blindness right eye category 4, normal vision left eye
H54.415A	Blindness right eye category 5, normal vision left eye
H54.42A3	Blindness left eye category 3, normal vision right eye
H54.42A4	Blindness left eye category 4, normal vision right eye
H54.42A5	Blindness left eye category 5, normal vision right eye
H54.50	Low vision, one eye, unspecified eye
H54.511A	Low vision right eye category 1, normal vision left eye
H54.512A	Low vision right eye category 2, normal vision left eye
H54.52A1	Low vision left eye category 1, normal vision right eye
H54.52A2	Low vision left eye category 2, normal vision right eye
H54.8	Legal blindness, as defined in USA
T26.60xA	Corrosion of cornea and conjunctival sac, unspecified eye, initial encounter
T26.60xD	Corrosion of cornea and conjunctival sac, unspecified eye, subsequent encounter
T26.60xS	Corrosion of cornea and conjunctival sac, unspecified eye, sequela
T26.61xA	Corrosion of cornea and conjunctival sac, right eye, initial encounter
T26.61xD	Corrosion of cornea and conjunctival sac, right eye, subsequent encounter
T26.61xS	Corrosion of cornea and conjunctival sac, right eye, sequela
T26.62xA	Corrosion of cornea and conjunctival sac, left eye, initial encounter
T26.62xD	Corrosion of cornea and conjunctival sac, left eye, subsequent encounter
T26.62xS	Corrosion of cornea and conjunctival sac, left eye, sequela

Description

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 (PMMA) device with a central optic region fused to a surrounding sponge skirt; the device is inserted in a 2-stage surgical procedure.

Autologous keratoprotheses use a central 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, 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 PMMA 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 PMMA prosthesis is placed within. This entire unit is placed into a subcutaneous ocular pocket and is then retrieved 6 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.

Summary

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.

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 2176 eyes. Systematic reviews and case series with longer follow-up (ie, at least 2 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 (eg, 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 5 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 History

Date	Action
4/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
10/2017	Clarified coding information.
4/2017	New references added from BCBSA National medical policy.
5/2016	BCBSA National medical policy. In medically necessary policy statement, “multiple graft failures” clarified to “history of 1 or more” graft failures.
7/2015	BCBSA National medical policy review. New medically necessary indications described. Added coding language. Effective 7/1/2015.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
5/2014	New references from BCBSA National medical policy.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
2/2011	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
8/1/2010	Medical Policy 221 effective 8/1/2010 describing covered and non-covered indications. Policy information previously addressed on medical policy #241, Surgical Vision Services.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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