BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE: 09/19/22**
SECTION: MEDICINE	**LAST REVIEW DATE: 08/16/22**
	CURRENT EFFECTIVE DATE: 09/19/22
	LAST CRITERIA REVISION DATE:
NEXT ANNUAL REVIEW DATE: 3RD QTR 2023	**ARCHIVE DATE:**

KERATOPROSTHESIS

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

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

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

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.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

KERATOPROSTHESIS (cont.)

Description:

A keratoprosthesis, consisting of a central optic held in a cylindrical frame, is an artificial cornea intended to restore vision to individuals 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.

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 individual'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.

The Boston KPro (Dohlman-Doane keratoprosthesis; Massachusetts Eye and Ear Infirmary) was approved by the U.S. Food and Drug Administration (FDA) for use in individuals with severe corneal opacity. The device is used when standard corneal transplant has failed or would be unlikely to succeed. There are 2 types of Boston KPro. Type 1 is used in eyes when eyelids, blink mechanism, and tear film are intact. Type 2 is used with severe dry eye and in eyes with mucosal keratinization and obliteration of normal conjunctival fornices.

The AlphaCor® (Chirila Keratoprosthesis) was approve by the FDA who 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 individuals have declined standard penetrating keratoplasty, or when adjunctive procedures to prevent graft rejection are contraindicated.

Criteria:

- The Boston (Dohlman-Doane) Keratoprosthesis (Boston KPro) for the surgical treatment of severe corneal opacification in situations where cadaveric corneal transplants have failed or have a very low likelihood of success is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. The cornea is severely opaque and vascularized.

  2. Best-corrected visual acuity is 20/400 or less in the affected eye and 20/40 or less in the contralateral eye

  3. No end-stage glaucoma or retinal detachment is present

  4. Individual should be able and expected to comply with postoperative care

KERATOPROSTHESIS (cont.)

Criteria: (cont.)

5. The individual 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, libel stem cell compromise or postherpetic anesthesia).

- All other types of permanent keratoprostheses are considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:

1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
3. Insufficient evidence to support improvement outside the investigational setting.

Resources:

Literature reviewed 08/16/22. We do not include marketing materials, poster boards and non-published literature in our review.

1. Ahmad S, Mathews PM, Lindsley K, et al. Boston Type 1 Keratoprosthesis versus Repeat Donor Keratoplasty for Corneal Graft Failure: A Systematic Review and Meta-analysis. *Ophthalmology*. Jan 2016;123(1):165-77. doi:10.1016/j.ophtha.2015.09.028

2. Chan CC, LoVerde L, Qiang J, Nordlund ML, Holland EJ. Incidence, Risk Factors, and Surgical Management of Boston Type 1 Keratoprothesis Corneal Melts, Leaks, and Extrusions. *Cornea*. Aug 2016;35(8):1049-56. doi:10.1097/ICO.0000000000000911

3. Ciolino JB, Belin MW, Todani A, Al-Arfaj K, Rudnisky CJ, Boston Keratoprosthesis Type 1 Study G. Retention of the Boston keratoprosthesis type 1: multicenter study results. *Ophthalmology*. Jun 2013;120(6):1195-200. doi:10.1016/j.ophtha.2012.11.025

4. Crawford GJ, Hicks CR, Lou X, et al. The Chirila Keratoprosthesis: phase I human clinical trial. *Ophthalmology*. May 2002;109(5):883-9. doi:10.1016/s0161-6420(02)00958-2

KERATOPROSTHESIS (cont.)

Resources: (cont.)

5. De La Paz MF, De Toledo JA, Charoenrook V, et al. Impact of clinical factors on the long-term functional and anatomic outcomes of osteo-odonto-keratoprosthesis and tibial bone keratoprosthesis. *Am J Ophthalmol*. May 2011;151(5):829-839 e1. doi:10.1016/j.ajo.2010.11.011

6. Dunlap K, Chak G, Aquavella JV, Myrowitz E, Utine CA, Akpek E. Short-term visual outcomes of Boston type 1 keratoprosthesis implantation. *Ophthalmology*. Apr 2010;117(4):687-92. doi:10.1016/j.ophtha.2009.09.024

7. Falcinelli G, Falsini B, Taloni M, Colliardo P, Falcinelli G. Modified osteo-odonto-keratoprosthesis for treatment of corneal blindness: long-term anatomical and functional outcomes in 181 cases. *Arch Ophthalmol*. Oct 2005;123(10):1319-29. doi:10.1001/archopht.123.10.1319

8. Farid M, Rhee MK, Akpek EK, et al. Corneal Edema and Opacification Preferred Practice Pattern(R). *Ophthalmology*. Jan 2019;126(1):P216-P285. doi:10.1016/j.ophtha.2018.10.022

9. Goldman DR, Hubschman JP, Aldave AJ, et al. Postoperative posterior segment complications in eyes treated with the Boston type I keratoprosthesis. *Retina*. Mar 2013;33(3):532-41. doi:10.1097/IAE.0b013e3182641848

10. Hicks CR, Crawford GJ, Lou X, et al. Corneal replacement using a synthetic hydrogel cornea, AlphaCor: device, preliminary outcomes and complications. *Eye (Lond)*. Apr 2003;17(3):385-92. doi:10.1038/sj.eye.6700333

11. Hoffart L, Carles G, Matonti F. Lamellar corneal lenticule graft to treat keratolysis after AlphaCor keratoprosthesis implantation. *Eur J Ophthalmol*. Jan-Feb 2015;25(1):1-7. doi:10.5301/ejo.5000497

12. Hughes EH, Mokete B, Ainsworth G, et al. Vitreoretinal complications of osteoodontokeratoprosthesis surgery. *Retina*. Oct 2008;28(8):1138-45. doi:10.1097/IAE.0b013e318174e10e

13. Lee WB, Shtein RM, Kaufman SC, Deng SX, Rosenblatt MI. Boston Keratoprosthesis: Outcomes and Complications: A Report by the American Academy of Ophthalmology. *Ophthalmology*. Jul 2015;122(7):1504-11. doi:10.1016/j.ophtha.2015.03.025

14. Liu C, Okera S, Tandon R, Herold J, Hull C, Thorp S. Visual rehabilitation in end-stage inflammatory ocular surface disease with the osteo-odonto-keratoprosthesis: results from the UK. *Br J Ophthalmol*. Sep 2008;92(9):1211-7. doi:10.1136/bjo.2007.130567

KERATOPROSTHESIS (cont.)

Resources: (cont.)

15. Michael R, Charoenrook V, de la Paz MF, Hitzl W, Temprano J, Barraquer RI. Long-term functional and anatomical results of osteo- and osteoodonto-keratoprosthesis. *Graefes Arch Clin Exp Ophthalmol*. Aug 2008;246(8):1133-7. doi:10.1007/s00417-008-0850-3

16. Odorcic S, Haas W, Gilmore MS, Dohlman CH. Fungal Infections After Boston Type 1 Keratoprosthesis Implantation: Literature Review and In Vitro Antifungal Activity of Hypochlorous Acid. *Cornea*. Dec 2015;34(12):1599-605. doi:10.1097/ICO.0000000000000639

17. Rudnisky CJ, Belin MW, Guo R, Ciolino JB, Boston Type 1 Keratoprosthesis Study G. Visual Acuity Outcomes of the Boston Keratoprosthesis Type 1: Multicenter Study Results. *Am J Ophthalmol*. Feb 2016;162:89-98 e1. doi:10.1016/j.ajo.2015.10.023

18. Rudnisky CJ, Belin MW, Todani A, et al. Risk factors for the development of retroprosthetic membranes with Boston keratoprosthesis type 1: multicenter study results. *Ophthalmology*. May 2012;119(5):951-5. doi:10.1016/j.ophtha.2011.11.030

19. Srikumaran D, Munoz B, Aldave AJ, et al. Long-term outcomes of boston type 1 keratoprosthesis implantation: a retrospective multicenter cohort. *Ophthalmology*. Nov 2014;121(11):2159-64. doi:10.1016/j.ophtha.2014.05.030

20. Tan A, Tan DT, Tan XW, Mehta JS. Osteo-odonto keratoprosthesis: systematic review of surgical outcomes and complication rates. *Ocul Surf*. Jan 2012;10(1):15-25. doi:10.1016/j.jtos.2012.01.003

Coding:

CPT: 65770
HCPCS: L8609, C1818

History:	**Date:**	**Activity:**
Medical Policy Panel	08/16/22	Approved guideline (Effective 09/19/22)

Policy Revisions:

KERATOPROSTHESIS (cont.)

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nílínigíí Blue Cross Blue Shield of Arizona haada yit'éego bína'ídíłkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yína'ídíłkidgo beehaz'áanii hóló díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo bąąh íłínígóó. Ata' halne'ígíí kojį' bich'į' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:
إن كان لديك أو لدى شخص تساعده أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون اية تكلفة. للتحدث مع مترجم اتصل ب 877-475-4799.

KERATOPROSTHESIS (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulangan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:
اگر شما، یا کسی که شما به او کمک میکنید ، سوال در مورد Blue Cross Blue Shield of Arizona ، داشته باشید حق این را دارید که کمک و
اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799
تماس حاصل نمایید.]

Assyrian:
[illegible] Blue Cross Blue Shield of Arizona [illegible]
[illegible] 877-475-4799.

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคณ หรอคนทคณกาลงชวยเหลอมคาถามเกยวกบ Blue Cross Blue Shield of Arizona
คณมสทธทจะไดรบความชวยเหลอและขอมลในภาษา ของคณไดโดยไมมคาใชจาย พดคยกบลาม โทร 877-475-4799