



MEDICAL COVERAGE GUIDELINES
SECTION: VISION

ORIGINAL EFFECTIVE DATE: 10/06/11
LAST REVIEW DATE: 09/04/18
LAST CRITERIA REVISION DATE: 09/13/16
ARCHIVE DATE:

CONTACT LENS, THERAPEUTIC

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 Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline 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.

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.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.



MEDICAL COVERAGE GUIDELINES
SECTION: VISION

ORIGINAL EFFECTIVE DATE: 10/06/11
LAST REVIEW DATE: 09/04/18
LAST CRITERIA REVISION DATE: 09/13/16
ARCHIVE DATE:

CONTACT LENS, THERAPEUTIC (cont.)

Description:

Contact lens may be used for the therapeutic *medical* treatment of acute or chronic eye conditions.

Gas Permeable Scleral Contact Lens:

Hard contact lens with an elevated chamber over the cornea that can be filled with artificial tears and a haptic base fit over the sclera. Also referred to as ocular surface prostheses or prosthetic replacement of the ocular surface ecosystem (PROSE). Scleral contact lens may function as a liquid bandage for corneal surface disease.

Hydrophilic Contact Lens:

A soft contact lens. A non-refractive hydrophilic contact lens may be used therapeutically as a moist bandage for protection or to speed healing.

Hard Contact Lens:

Hard contact lens is also known as gas permeable, rigid gas permeable or oxygen permeable lens. May be used therapeutically for treatment of keratoconus.

Criteria:

CONTACT LENSES FOR CORRECTION OF REFRACTIVE DISORDERS ARE NOT A COVERED MEDICAL BENEFIT FOR MANY PLANS. REFER TO THE MEMBER'S SPECIFIC BENEFIT PLAN BOOK.

Hydrophilic Contact Lens:

- Hydrophilic contact lenses are considered *medically necessary* for the treatment of the following conditions and post-operative care, to include, *but not limited to*:
 - Bullous keratopathy
 - Corneal abrasions, erosions and ulcerations
 - Corneal dystrophy (Anterior)
 - Corneal ectasis
 - Corneal edema
 - Descemetocoele
 - Dry eye syndrome (sicca syndrome)
 - Ectatic dystrophia
 - Eye lid pathology (entropion, trichiasis)
 - Keratitis, chemical
 - Keratitis, filamentosa
 - Keratoconus
 - Mooren's ulcer
 - Neurotrophic keratoconjunctivitis



MEDICAL COVERAGE GUIDELINES
SECTION: VISION

ORIGINAL EFFECTIVE DATE: 10/06/11
LAST REVIEW DATE: 09/04/18
LAST CRITERIA REVISION DATE: 09/13/16
ARCHIVE DATE:

CONTACT LENS, THERAPEUTIC (cont.)

Criteria: (cont.)

Hydrophilic Contact Lens: (cont.)

- Hydrophilic contact lenses for services, procedures, medical devices and drugs related to the diagnosis and/or correction of refractive errors or for cosmetic use are a **medical benefit plan exclusion** and **not eligible for coverage**.
- Drug coated or drug loaded hydrophilic contact lenses for all indications are considered **experimental or investigational** based upon:
 1. Lack of final approval from the Food and Drug Administration, and
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 3. Insufficient evidence to support improvement of the net health outcome, and
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 5. Insufficient evidence to support improvement outside the investigational setting.

Hard Contact Lens:

- Hard contact lenses are considered **medically necessary** for the treatment of keratoconus.
- Hard contact lenses for services, procedures, medical devices and drugs related to the diagnosis and/or correction of refractive errors or for cosmetic use are a **medical benefit plan exclusion** and **not eligible for coverage**.

MEDICAL COVERAGE GUIDELINES
SECTION: VISION

ORIGINAL EFFECTIVE DATE: 10/06/11
LAST REVIEW DATE: 09/04/18
LAST CRITERIA REVISION DATE: 09/13/16
ARCHIVE DATE:

CONTACT LENS, THERAPEUTIC (cont.)

Criteria: (cont.)

Scleral Contact Lens:

- Rigid gas permeable scleral contact lenses for the treatment of individuals who have not responded to topical medications or standard spectacle or contact lens are considered **medically necessary** with documentation of **ANY** of the following:
 1. Corneal ectatic disorders, including *but not limited to*:
 - Ectasia, post-surgery
 - Fuchs' superficial marginal keratitis
 - Keratoconus
 - Keratoglobus
 - Pellucid marginal degeneration
 - Terrien's marginal degeneration
 2. Corneal scarring and/or vascularization
 3. Irregular corneal astigmatism after keratoplasty or other corneal surgery
 4. Ocular surface disease with pain and/or decreased visual acuity, including *but not limited to*:
 - Dry eye, severe
 - Epithelial defects, persistent
 - Exposure keratopathy
 - Graft vs. host disease
 - Mucus membrane pemphigoid
 - Neurotrophic keratopathy
 - Post-ocular surface tumor excision
 - Post-glaucoma filtering surgery
 - Stevens Johnson syndrome sequelae
- Rigid gas permeable scleral lens for services, procedures, medical devices and drugs related to the diagnosis and/or correction of refractive errors or for cosmetic use are a **medical benefit plan exclusion** and **not eligible for coverage**.



MEDICAL COVERAGE GUIDELINES
SECTION: VISION

ORIGINAL EFFECTIVE DATE: 10/06/11
LAST REVIEW DATE: 09/04/18
LAST CRITERIA REVISION DATE: 09/13/16
ARCHIVE DATE:

CONTACT LENS, THERAPEUTIC (cont.)

Criteria: (cont.)

Contact Lens for Aphakia:

- Contact lenses/eyeglasses for the treatment of aphakia (absence of lens) are considered a refractive error correction and therefore, a **medical benefit plan exclusion** and **not eligible for coverage**.
- Contact lenses/eyeglasses for the treatment of aphakia following surgery to remove cataracts may be **eligible for coverage** under the medical benefit plan when prescribed and purchased within six (6) months of post-surgery, up to a benefit plan maximum. Refer to member's benefit plan booklet.
- Contact lenses/eyeglasses for the treatment of aphakia following surgery to remove cataracts are considered a refractive error correction and therefore, a **medical benefit plan exclusion** and **not eligible for coverage** when prescribed and purchased after six (6) months post-surgery. Refer to member's benefit plan booklet.

Resources:

Literature reviewed 09/04/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

1. 9.03.25 BCBS Association Medical Policy Reference Manual. Gas Permeable Scleral Contact Lens. Re-issue date 09/11/2014, issue date 09/01/2011.
2. Blue Cross Blue Shield of Arizona. Benefit Plan Booklet.
3. Braga ME, Costa VP, Pereira MJ, et al. Effects of operational conditions on the supercritical solvent impregnation of acetazolamide in Balafilcon A commercial contact lenses. *Int J Pharm.* Nov 28 2011;420(2):231-243.
4. Ciolino JB, Hoare TR, Iwata NG, et al. A drug-eluting contact lens. *Invest Ophthalmol Vis Sci.* 2009 Jul 2009;50(7):3346-3352.
5. Dixon P, Chauhan A. Effect of the surface layer on drug release from delefilcon-A (Dailies Total1(R)) contact lenses. *Int J Pharm.* Aug 30 2017;529(1-2):89-101.
6. Farley D. Keeping an eye on contact lenses. Safety, options shape contact lens decisions. *FDA Consum.* 1998 Mar-Apr 1998;32(2):17-21.

**MEDICAL COVERAGE GUIDELINES
SECTION: VISION**

**ORIGINAL EFFECTIVE DATE: 10/06/11
LAST REVIEW DATE: 09/04/18
LAST CRITERIA REVISION DATE: 09/13/16
ARCHIVE DATE:**

CONTACT LENS, THERAPEUTIC (cont.)

Resources: (cont.)

7. Garhwal R, Shady SF, Ellis EJ, et al. Sustained ocular delivery of ciprofloxacin using nanospheres and conventional contact lens materials. *Invest Ophthalmol Vis Sci*. Mar 2012;53(3):1341-1352.
8. Gause S, Hsu KH, Shafor C, Dixon P, Powell KC, Chauhan A. Mechanistic modeling of ophthalmic drug delivery to the anterior chamber by eye drops and contact lenses. *Advances in colloid and interface science*. Jul 2016;233:139-154.
9. Gonzalez-Chomon C, Silva M, Concheiro A, Alvarez-Lorenzo C. Biomimetic contact lenses eluting olopatadine for allergic conjunctivitis. *Acta biomaterialia*. Sep 1 2016;41:302-311.
10. Gulsen D, Chauhan A. Ophthalmic drug delivery through contact lenses. *Invest Ophthalmol Vis Sci*. 2004 Jul 2004;45(7):2342-2347.
11. Hori K, Sotozono C, Hamuro J, et al. Controlled-release of epidermal growth factor from cationized gelatin hydrogel enhances corneal epithelial wound healing. *J Control Release*. 2007 Apr 2 2007;118(2):169-176.
12. Hsu KH, Carbia BE, Plummer C, Chauhan A. Dual drug delivery from vitamin E loaded contact lenses for glaucoma therapy. *Eur J Pharm Biopharm*. Aug 2015;94:312-321.
13. Hui A, Willcox M. In Vivo Studies Evaluating the Use of Contact Lenses for Drug Delivery. *Optometry and vision science : official publication of the American Academy of Optometry*. Apr 2016;93(4):367-376.
14. Janoria KG, Hariharan S, Dasari CR, Mitra AK. Recent patents and advances in ophthalmic drug delivery. *Recent Pat Drug Deliv Formul*. 2007 2007;1(2):161-170.
15. Kim J, Conway A, Chauhan A. Extended delivery of ophthalmic drugs by silicone hydrogel contact lenses. *Biomaterials*. 2008 May 2008;29(14):2259-2269.
16. Lasowski F, Sheardown H. Atropine and Roscovitine Release from Model Silicone Hydrogels. *Optometry and vision science : official publication of the American Academy of Optometry*. Apr 2016;93(4):404-411.
17. Lee D, Cho S, Park HS, Kwon I. Ocular Drug Delivery through pHEMA-Hydrogel Contact Lenses Co-Loaded with Lipophilic Vitamins. *Sci Rep*. Sep 28 2016;6:34194.
18. Malakooti N, Alexander C, Alvarez-Lorenzo C. Imprinted Contact Lenses for Sustained Release of Polymyxin B and Related Antimicrobial Peptides. *Journal of pharmaceutical sciences*. Oct 2015;104(10):3386-3394.

**MEDICAL COVERAGE GUIDELINES
SECTION: VISION**

**ORIGINAL EFFECTIVE DATE: 10/06/11
LAST REVIEW DATE: 09/04/18
LAST CRITERIA REVISION DATE: 09/13/16
ARCHIVE DATE:**

CONTACT LENS, THERAPEUTIC (cont.)

Resources: (cont.)

19. Maulvi FA, Soni TG, Shah DO. A review on therapeutic contact lenses for ocular drug delivery. *Drug delivery*. Jan 29 2016;1-10.
20. Mohammadi S, Jones L, Gorbet M. Extended latanoprost release from commercial contact lenses: in vitro studies using corneal models. *PLoS One*. 2014;9(9):e106653.
21. Paradiso P, Serro AP, Saramago B, Colaco R, Chauhan A. Controlled Release of Antibiotics From Vitamin E-Loaded Silicone-Hydrogel Contact Lenses. *Journal of pharmaceutical sciences*. Mar 2016;105(3):1164-1172.
22. Phan CM, Bajgrowicz M, McCanna DJ, Subbaraman LN, Jones L. Effects of Antifungal Soaked Silicone Hydrogel Contact Lenses on *Candida albicans* in an Agar Eye Model. *Eye Contact Lens*. Sep 2016;42(5):313-317.
23. Rad MS, Mohajeri SA. Simultaneously Load and Extended Release of Betamethasone and Ciprofloxacin from Vitamin E-Loaded Silicone-Based Soft Contact Lenses. *Current eye research*. Feb 2 2016;1-7.
24. Rad MS, Sajadi Tabassi SA, Moghadam MH, Mohajeri SA. Controlled release of betamethasone from vitamin E-loaded silicone-based soft contact lenses. *Pharm Dev Technol*. Nov 2016;21(7):894-899.
25. Schrader S, Wedel T, Moll R, Geerling G. Combination of serum eye drops with hydrogel bandage contact lenses in the treatment of persistent epithelial defects. *Graefes Arch Clin Exp Ophthalmol*. 2006 Oct 2006;244(10):1345-1349.
26. Schultz CL, Poling TR, Mint JO. A medical device/drug delivery system for treatment of glaucoma. *Clin Exp Optom*. 2009 Jul 2009;92(4):343-348.
27. Shayani Rad M, Mohajeri SA. Extended Ciprofloxacin Release Using Vitamin E Diffusion Barrier From Commercial Silicone-Based Soft Contact Lenses. *Eye Contact Lens*. Mar 2017;43(2):103-109.
28. UpToDate. Overview of contact lenses. 10/04/2016.
29. Venkatesh S, Sizemore SP, Byrne ME. Biomimetic hydrogels for enhanced loading and extended release of ocular therapeutics. *Biomaterials*. 2007 Feb 2007;28(4):717-724.
30. Yang M, Yang Y, Lei M, et al. Experimental studies on soft contact lenses for controlled ocular delivery of pifnedone: in vitro and in vivo. *Drug delivery*. Nov 2016;23(9):3538-3543.



MEDICAL COVERAGE GUIDELINES
SECTION: VISION

ORIGINAL EFFECTIVE DATE: 10/06/11
LAST REVIEW DATE: 09/04/18
LAST CRITERIA REVISION DATE: 09/13/16
ARCHIVE DATE:

CONTACT LENS, THERAPEUTIC (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 nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idííkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idííkidgo beehaz'áanii hólg díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' 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 تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

