MEDICAL COVERAGE GUIDELINES
SECTION: VISION

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OPHTHALMOLOGIC TECHNIQUES THAT EVALUATE THE POSTERIOR SEGMENT FOR GLAUCOMA

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.

Description:

Glaucoma is a disease characterized by degeneration of the optic nerve (optic disc). A comprehensive ophthalmologic exam is required for the diagnosis of glaucoma but no single test is adequate for establishing the diagnosis. A comprehensive ophthalmologic examination includes an examination of the optic nerve by fundoscopy, evaluation of the visual fields and measurement of intraocular pressure. Additional evaluation tools may be utilized as adjuncts for diagnosis and evaluation of glaucoma.

OPHTHALMOLOGIC TECHNIQUES THAT EVALUATE THE POSTERIOR SEGMENT FOR GLAUCOMA (cont.)

Description: (cont.)

Retinal Nerve Fiber Layer Analysis (RNFLA):
Measurement of the thickness of the retinal nerve fiber layer using one of the following techniques:

- Confocal Scanning Laser Ophthalmoscopy (CSLO):
  A laser is scanned across the retina illuminating a single spot at a time resulting in a high-contrast reproducible image used to estimate RNFL thickness. May also be called scanning laser ophthalmoscopy (SLO). Devices include TopSS™ (Topographic Scanning System) and Heidelberg Retinal Tomography (HRT).

- Scanning Laser Polarimetry (SLP):
  A laser is used to directly illuminate the optic nerve and the polarization state of light coming from the eye is evaluated and correlated with RNFL thickness. Devices include the GDx®.

- Optical Coherence Tomography (OCT) of the Posterior Eye Segment:
  Near-infrared light is used to provide direct cross-sectional measurement of the RNFL. Devices include Humphrey OCT® Scanner and the RTVue®XR OCT Avanti™. The RTVue XR OCT Avanti with Normative Database is a quantitative tool for comparison of retina, retinal nerve fiber layer and optic disk measurements in the human eye to a database of known normal subjects. OCT has been investigated in the imaging and measurement of the anterior segment of the eye, such as corneal and LASIK flap thickness.

Techniques to Measure Ocular Blood Flow:

Pulsatile Ocular Blood Flow:
Pulsatile variations in ocular pressure are detected by continuous monitoring of intraocular pressure. The detected pressure pulse can then be converted into a volume measurement using the known relationship between ocular pressure and ocular volume to assess blood flow supplied by the choroidal vessels to the optic nerve.

Doppler Ultrasonography:
Color Doppler imaging measures the blood velocity in the retinal and choroidal arteries.

Other Techniques:

Corneal Hysteresis:
Measurement of the cornea's biomechanical response and lag time to rapid indentation by an air jet, to analyze corneal elasticity/rigidity for the purpose of aiding in the diagnosis and monitoring of glaucoma.

OPHTHALMOLOGIC TECHNIQUES THAT EVALUATE THE POSTERIOR SEGMENT FOR GLAUCOMA (cont.)

Description: (cont.)

Other Techniques: (cont.)

Continuous Intraocular Pressure (IOP) Monitoring:
Continuous IOP monitoring has been investigated as a method for evaluation of IOP fluctuations in glaucoma. The Triggerfish® Sensor is a soft hydrophilic contact lens (single use for use up to 24 hours) with embedded gauges to monitor variations in the corneoscleral junction diameter. An output signal directly correlated to IOP fluctuations is transmitted wirelessly to the Triggerfish antenna. The adhesive antenna, worn around the eye is connected to a portable recorder through a thin flexible data cable. Data collected by the recorder may be transmitted wirelessly for computer analysis.

Criteria:

For optical coherence tomography (OCT) of the anterior eye segment criteria, see BCBSAZ Medical Coverage Guideline #O707, *"Optical Coherence Tomography (OCT) of the Anterior Eye Segment".*

Retinal Nerve Fiber Layer Analysis (RNFLA):

- Analysis of the optic nerve (retinal nerve fiber layer) is considered ***medically necessary*** using scanning laser ophthalmoscopy, scanning laser polarimetry and optical coherence tomography for the diagnosis and evaluation of **ANY** of the following:
  - Glaucoma
  - Glaucoma suspect
  - Retinopathy
- Analysis of the optic nerve (retinal nerve fiber layer) for the diagnosis and evaluation of refractive errors is a ***benefit plan exclusion*** and ***not eligible for coverage***.
- Analysis of the optic nerve (retinal nerve fiber layer) for all other indications not previously listed is considered ***screening***, ***not medically necessary*** and ***not eligible for coverage***.

OPHTHALMOLOGIC TECHNIQUES THAT EVALUATE THE POSTERIOR SEGMENT FOR GLAUCOMA (cont.)

Criteria: (cont.)

Pulsatile Ocular Blood Flow, Doppler Ultrasonography:

- Pulsatile ocular blood flow and/or Doppler ultrasonography for the diagnosis and evaluation of retinopathy are considered ***medically necessary***.

- Ocular blood flow, pulsatile ocular blood flow and/or blood flow velocity for the diagnosis and evaluation of glaucoma or any glaucoma related condition or consequence (e.g. glaucomatous atrophy, cupping, flecks) 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, and
    4. Insufficient evidence to support improvement outside the investigational setting.

- Ocular blood flow, pulsatile ocular blood flow and/or blood flow velocity with Doppler ultrasonography for the diagnosis and evaluation of refractive errors are a ***benefit plan exclusion*** and ***not eligible for coverage***.

- Ocular blood flow, pulsatile ocular blood flow and/or blood flow velocity with Doppler ultrasonography for all other indications not previously listed is considered ***screening, not medically necessary*** and ***not eligible for coverage***.

Corneal Hysteresis:

- Corneal hysteresis 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.

OPHTHALMOLOGIC TECHNIQUES THAT EVALUATE THE POSTERIOR SEGMENT FOR GLAUCOMA (cont.)

Criteria: (cont.)

Continuous Intraocular Pressure (IOP) Monitoring:

- Continuous IOP monitoring 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, and
  4. Insufficient evidence to support improvement outside the investigational setting.

  Devices include, *but are not limited to:*

  - Triggerfish Sensor

Resources:

Literature reviewed 04/03/18. 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.

Resources prior to 09/27/16 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 9.03.06 BCBS Association Medical Policy Reference Manual. Ophthalmologic Techniques That Evaluate the Posterior Segment for Glaucoma. Re-issue date 03/08/2018, issue date 04/01/1998.

2. American Academy of Ophthalmology. Indications for Optical Coherence Tomography. Accessed 03/27/2015.

3. Aptel F, Musson C, Zhou T, Lesoin A, Chiquet C. 24-Hour Intraocular Pressure Rhythm in Patients With Untreated Primary Open Angle Glaucoma and Effects of Selective Laser Trabeculoplasty. *J Glaucoma.* Mar 2017;26(3):272-277.

4. Beltran-Agullo L, Buys YM, Jahan F, et al. Twenty-four hour intraocular pressure monitoring with the SENSIMED Triggerfish contact lens: effect of body posture during sleep. *Br J Ophthalmol.* Mar 07 2017.

OPHTHALMOLOGIC TECHNIQUES THAT EVALUATE THE POSTERIOR SEGMENT FOR GLAUCOMA (cont.)

Resources: (cont.)

5. Dunbar GE, Shen BY, Aref AA. The Sensimed Triggerfish contact lens sensor: efficacy, safety, and patient perspectives. *Clin Ophthalmol.* 2017;11:875-882.

6. Gaspar R, Pinto LA, Sousa DC. Corneal properties and glaucoma: a review of the literature and meta-analysis. *Arquivos brasileiros de oftalmologia.* Jun 2017;80(3):202-206.

7. He LY, Liang L, Zhu MN. [Application value of corneal hysteresis in diagnosis and treatment of glaucoma]. *[Zhonghua yan ke za zhi] Chinese journal of ophthalmology.* Feb 11 2017;53(2):140-143.

8. Ittoop SM, SooHoo JR, Seibold LK, Mansouri K, Kahook MY. Systematic Review of Current Devices for 24-h Intraocular Pressure Monitoring. *Advances in therapy.* Aug 16 2016.

9. Meier-Gibbons F, Berlin MS, Toteberg-Harms M. Twenty-four hour intraocular pressure measurements and home tonometry. *Curr Opin Ophthalmol.* Mar 2018;29(2):111-115.

10. Murphy ML, Pokrovskaya O, Galligan M, O'Brien C. Corneal hysteresis in patients with glaucoma-like optic discs, ocular hypertension and glaucoma. *BMC Ophthalmol.* Jan 10 2017;17(1):1.

11. Perucho-Gonzalez L, Saenz-Frances F, Morales-Fernandez L, et al. Structural and biomechanical corneal differences between patients suffering from primary congenital glaucoma and healthy volunteers. *Acta ophthalmologica.* Aug 29 2016.

12. Pillunat KR, Hermann C, Spoerl E, Pillunat LE. Analyzing biomechanical parameters of the cornea with glaucoma severity in open-angle glaucoma. *Graefe's archive for clinical and experimental ophthalmology = Albrecht von Graefes Archiv fur klinische und experimentelle Ophthalmologie.* Jul 2016;254(7):1345-1351.

13. Pniakowska Z, Klysik A, Gos R, Jurowski P. Corneal biomechanical changes and intraocular pressure in patients with thyroid orbitopathy. *International journal of ophthalmology.* 2016;9(3):439-443.

14. Rekas M, Danielewska ME, Byszewska A, et al. Assessing Efficacy of Canaloplasty Using Continuous 24-Hour Monitoring of Ocular Dimensional Changes. *Invest Ophthalmol Vis Sci.* May 1 2016;57(6):2533-2542.

15. Susanna CN, Diniz-Filho A, Daga FB, et al. A Prospective Longitudinal Study to Investigate Corneal Hysteresis as a Risk Factor for Predicting Development of Glaucoma. *Am J Ophthalmol.* Mar 2018;187:148-152.

OPHTHALMOLOGIC TECHNIQUES THAT EVALUATE THE POSTERIOR SEGMENT FOR GLAUCOMA (cont.)

Resources: (cont.)

16. Tojo N, Abe S, Ishida M, Yagou T, Hayashi A. The Fluctuation of Intraocular Pressure Measured by a Contact Lens Sensor in Normal-Tension Glaucoma Patients and Nonglaucoma Subjects. *J Glaucoma.* Aug 22 2016.

17. Tojo N, Hayashi A, Otsuka M, Miyakoshi A. Fluctuations of the Intraocular Pressure in Pseudoexfoliation Syndrome and Normal Eyes Measured by a Contact Lens Sensor. *J Glaucoma.* May 2016;25(5):e463-468.

18. Zhang C, Tatham AJ, Abe RY, et al. Corneal Hysteresis and Progressive Retinal Nerve Fiber Layer Loss in Glaucoma. *Am J Ophthalmol.* Jun 2016;166:29-36.

OPHTHALMOLOGIC TECHNIQUES THAT EVALUATE THE POSTERIOR SEGMENT FOR GLAUCOMA (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.

OPHTHALMOLOGIC TECHNIQUES THAT EVALUATE THE POSTERIOR SEGMENT FOR GLAUCOMA (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