BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

**MEDICAL COVERAGE GUIDELINES**
**SECTION: VISION**

**ORIGINAL EFFECTIVE DATE: 03/20/13**
**LAST REVIEW DATE: 03/18/14**
**LAST CRITERIA REVISION DATE: 07/23/13**
**ARCHIVE DATE:**

# OPHTHALMOLOGIC TECHNIQUES FOR EVALUATING GLAUCOMA

**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:

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 FOR EVALUATING 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. OCT has been investigated in the imaging and measurement of the anterior segment of the eye, such as corneal and LASIK flap thickness.

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.

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.

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. The Triggerfish has not been approved by the FDA.

## OPHTHALMOLOGIC TECHNIQUES FOR EVALUATING GLAUCOMA (cont.)

**Criteria:** (cont.)

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

**Retinal Nerve Fiber Layer Analysis (RNFLA):**

- Retinal nerve fiber layer analysis 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
- Retinal nerve fiber layer analysis for the diagnosis and evaluation of refractive errors is a ***benefit plan exclusion*** and ***not eligible for coverage***.
- Retinal nerve fiber layer analysis for all other indications not previously listed is considered ***screening***, ***not medically necessary*** and ***not eligible for coverage***.

**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 with Doppler ultrasonography 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.

## OPHTHALMOLOGIC TECHNIQUES FOR EVALUATING GLAUCOMA (cont.)

**Criteria:** (cont.)

- 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.

**Continuous Intraocular Pressure (IOP) Monitoring:**

- Continuous IOP monitoring is 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.

  Devices include, *but are not limited to:*

  - Triggerfish Sensor

## OPHTHALMOLOGIC TECHNIQUES FOR EVALUATING GLAUCOMA (cont.)

**Resources:**

**Resources prior to 03/20/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.**

1. 9.03.06 BCBS Association Medical Policy Reference Manual. Ophthalmologic Techniques for Evaluating Glaucoma. Re-issue date 02/14/2013, issue date 04/01/1998.

2. Aref AA. What happens to glaucoma patients during sleep? *Curr Opin Ophthalmol.* Dec 19 2012.

3. De Smedt S, Mermoud A, Schnyder C. 24-hour intraocular pressure fluctuation monitoring using an ocular telemetry Sensor: tolerability and functionality in healthy subjects. *J Glaucoma.* Oct-Nov 2012;21(8):539-544.

4. Mansouri K, Medeiros FA, Tafreshi A, Weinreb RN. Continuous 24-Hour Monitoring of Intraocular Pressure Patterns With a Contact Lens Sensor: Safety, Tolerability, and Reproducibility in Patients With Glaucoma. *Arch Ophthalmol.* Aug 13 2012:1-6.

5. Mansouri K, Weinreb R. Continuous 24-hour intraocular pressure monitoring for glaucoma--time for a paradigm change. *Swiss Med Wkly.* 2012;142:w13545.

6. Mansouri K, Weinreb RN. Meeting an unmet need in glaucoma: continuous 24-h monitoring of intraocular pressure. *Expert Rev Med Devices.* May 2012;9(3):225-231.

7. Pajic B, Pajic-Eggspuchler B, Haefliger I. Continuous IOP fluctuation recording in normal tension glaucoma patients. *Curr Eye Res.* Dec 2011;36(12):1129-1138.

## OPHTHALMOLOGIC TECHNIQUES FOR EVALUATING GLAUCOMA (cont.)

**Resources:** (cont.)

FDA Summary Statements for Ac-powered ophthalmoscope. Device names include, *but are not limited to*:

TopSS
Heidelberg Retina Angiograph
Humphrey OCT® Scanner
GDx

- FDA-approved indication: For viewing the retinal and/or choroidal circulation patterns that are illuminated using fluorescein or indocyanine green dye, and for aiding in the:

  1. Management of age-related macular degeneration (AMD)
  2. Detection of choroidal neovascularization
  3. Assessment of diabetic retinopathy
  4. Assessment of diabetic maculopathy
  5. Treatment control of diabetic maculopathy, AMD, CNV
  6. Detection of retinal vascular disturbances
  7. Assessment of choroidal circulation
  8. Diagnosis of choroiditis or choroidal

FDA 510(k) Summary for Reichert, Inc. Ocular Response Analyzer® (ORA):

- FDA-approved indication: To measure intra-ocular pressure of the eye and the biomechanical response of the cornea for the purpose of aiding in the diagnosis and monitoring of glaucoma.