Corporate Medical Policy

Glaucoma, Evaluation by Ophthalmologic Techniques

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Description of Procedure or Service

Several techniques have been developed to measure the thickness of the optic nerve/retinal nerve fiber layer (RNFL) as a method to diagnose and monitor glaucoma. Measurement of ocular blood flow is also being evaluated as a diagnostic and management tool for glaucoma.

Glaucoma is a disease characterized by degeneration of the optic nerve (optic disc). Elevated intraocular pressure has long been thought to be the primary etiology, but the relationship between intraocular pressure and optic nerve damage varies among patients, suggesting a multifactorial origin. For example, some patients with clearly elevated intraocular pressure will show no optic nerve damage, while other patients with marginal or no pressure elevation will, nonetheless, show optic nerve damage. The association between glaucoma and other vascular disorders such as diabetes or hypertension suggests vascular factors may play a role in glaucoma. Specifically, it has been hypothesized that reductions in blood flow to the optic nerve may contribute to the visual field defects associated with glaucoma.

Diagnosis and Management

A comprehensive ophthalmologic exam is required for the diagnosis of glaucoma, but no single test is adequate to establish diagnosis. A comprehensive ophthalmologic examination includes assessment of the optic nerve, evaluation of visual fields, and measurement of ocular pressure. The presence of characteristic changes in the optic nerve or abnormalities in visual field, together with increased IOP, is sufficient for a definitive diagnosis. However, some patients will show ophthalmologic evidence of glaucoma with normal IOPs. These cases of normal tension glaucoma (NTG) are considered to be a type of primary open-angle glaucoma (POAG). Angle-closure glaucoma is another type of glaucoma associated with an increase in IOP. The increased IOP in angle-closure glaucoma arises from a reduction in aqueous outflow from the eye due to a closed angle in the anterior chamber.

Conventional management of patients with glaucoma principally involves drug therapy to control elevated IOPs, and serial evaluation of the optic nerve, to follow disease progression. Standard methods of evaluation include careful direct examination of the optic nerve using ophthalmoscopy or stereophotography, or evaluation of visual fields. There is interest in developing more objective, reproducible techniques both to document optic nerve damage and to detect early changes in the optic nerve and retinal nerve fiber layer (RNFL) before the development of permanent visual field deficits. Specifically, evaluating changes in RNFL thickness has been investigated as a technique to diagnose and monitor glaucoma. However, IOP reduction is not effective in decreasing disease progression in a significant number of patients, and in patients with NTG, there is never an increase in IOP. It has been proposed that vascular dysregulation is a significant cause of damage to the RNFL, and there is interest in measuring ocular blood flow as both a diagnostic and a management tool for glaucoma. Changes in blood flow to the retina and choroid may be particularly relevant for diagnosis and treatment of NTG. A variety of techniques have been developed, as described below. (Note: This evidence review only addresses techniques related to the evaluation of the optic nerve, RNFL, or blood flow to the retina and choroid in patients with glaucoma.)

Techniques to Evaluate the Optic Nerve/Retinal Nerve Fiber Layer (RNFL)
(Note: This policy only addresses uses of these techniques related to glaucoma.)

Confocal Scanning Laser Ophthalmoscopy
Confocal scanning laser ophthalmoscopy (CSLO) is a laser-based image acquisition technique, which is intended to improve the quality of the examination compared to standard ophthalmologic examination. A laser is scanned across the retina along with a detector system. Only a single spot on the retina is illuminated at any time, resulting in a high-contrast image of great reproducibility that can be used to estimate the thickness of the RNFL. In addition, this technique does not require maximal mydriasis, which may be a problem in patients with glaucoma. The Heidelberg Retinal Tomograph is probably the most common example of this technology.

Scanning Laser Polarimetry
The RNFL is birefringent, causing a change in the state of polarization of a laser beam as it passes. A 780-nm diode laser is used to illuminate the optic nerve. The polarization state of the light emerging from the eye is then evaluated and correlated with RNFL thickness. Unlike CSLO, scanning laser polarimetry (SLP) can directly measure the thickness of the RNFL. GDx® is a common example of a scanning laser polarimeter. GDx® contains a normative database and statistical software package to allow comparison to age-matched normal subjects of the same ethnic origin. The advantages of this system are that images can be obtained without pupil dilation, and evaluation can be done in approximately 10 minutes. Current instruments have added enhanced and variable corneal compensation technology to account for corneal polarization.

Optical Coherence Tomography
Optical coherence tomography (OCT) uses near-infrared light to provide direct cross-sectional measurement of the RNFL. The principles employed are similar to those used in B-mode ultrasound except light, not sound, is used to produce the 2-dimensional images. The light source can be directed into the eye through a conventional slit-lamp biomicroscope and focused onto the retina through a typical 78-diopter lens. This system requires dilation of the patient's pupil. OCT® is an example of this technology. OCT analysis software is being developed to include optic nerve head parameters with spectral domain OCT (SDOCT), analysis of macular parameters, and hemodynamic parameters with Doppler OCT and OCT angiography.

Pulsatile Ocular Blood Flow
The pulsatile variation in ocular pressure results from the flow of blood into the eye during cardiac systole. Pulsatile ocular blood flow can thus be detected by the 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. Pulsatile blood flow is primarily determined by the choroidal vessels, particularly relevant to patients with glaucoma, since the optic nerve is supplied in large part by choroidal circulation.

Techniques to Measure Ocular Blood Flow
A number of techniques have been developed to assess ocular blood flow. They include laser speckle flowgraphy, color Doppler imaging, Doppler Fourier domain OCT, laser Doppler velocimetry, confocal scanning laser Doppler flowmetry, and retinal functional imaging.

Laser Speckle Flowgraphy
Laser speckle is detected when a coherent light source such as laser light is dispersed from a diffusing surface such as retinal and choroidal vessels and the circulation of the optic nerve head. The varying patterns of light can be used to determine red blood cell velocity and retinal blood flow. However, due to differences in the tissue structure in different eyes, flux values cannot be used for comparisons between eyes. This limitation may be overcome by subtracting background choroidal blood flow results from the overall blood flow results in the region of interest.

Color Doppler Imaging
Color Doppler imaging has also been investigated as a technique to measure the blood flow velocity in the retinal and choroidal arteries. This technique delivers ultrasound in pulsed Doppler mode with a transducer set on closed eyelids. The examination takes 30 to 40 minutes, and is most effective for the mean velocity of large ophthalmic vessels such as the ophthalmic artery, the central retinal artery, and the short posterior ciliary arteries. However, total blood flow cannot be determined with this technique, and imaging is highly dependent on probe placement.

Doppler Fourier Domain OCT
Doppler Fourier domain OCT is a noncontact imaging technique that detects the intensity of the light scattered back from erythrocytes as they move in the vessels of the ocular tissue. This induces a frequency shift that represents the velocity of the blood in the ocular tissue.

Laser Doppler Velocimetry
Laser Doppler velocimetry compares the frequency of reflected laser light from a moving particle to stationary tissue.

Confocal Scanning Laser Doppler Flowmetry
Confocal scanning laser Doppler flowmetry combines laser Doppler flowmetry with confocal scanning laser tomography. Infrared laser light is used to scan the retina, and the frequency and amplitude of Doppler shifts are determined from the reflected light. Determinations of blood velocity and blood volume are used to compute the total blood flow and create a physical map of retinal flow values.

Regulatory Status
A number of confocal scanning laser ophthalmoscopy, scanning laser polarimetry, and optical coherence tomography (OCT) devices have been cleared by the U.S. Food and Drug Administration (FDA) through the 510(k) process for imaging the posterior eye segment. For example, the RTVue XR OCT Avanti™ (Optovue) is an OCT system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disc as a tool and aid in the diagnosis and management of retinal diseases by a clinician. The RTVue XR OCT Avanti™ with Normative Database is a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disk measurements in the human eye to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases. In 2016, the RTVue XR OCT with Avanti™ with AngioVue™ Software was cleared by FDA through the 510(k) process (K153080) as an aid in the visualization of vascular structures of the retina and choroid. FDA product code: HLI, OBO.

In 2012, The iExaminer™ (Welch Allyn) received marketing clearance from the U.S. Food and Drug Administration (FDA). The iExaminer consists of a hardware adapter and associated software (iPhone®App) to capture, store, send and retrieve images from the Welch Allyn PanOptic™ Ophthalmoscope using an iPhone®.

Related Policies:
Optical Coherence Tomography (OCT) Anterior Segment of the Eye

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Glaucoma, Evaluation by Ophthalmologic Techniques when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Glaucoma, Evaluation by Ophthalmologic Techniques is covered

Analysis of the optic nerve (retinal nerve fiber layer) using scanning laser ophthalmoscopy, scanning laser polarimetry, and optical coherence tomography may be considered medically necessary when performed for the diagnosis and evaluation of patients with glaucoma or glaucoma suspects.

Patients who are defined as a glaucoma suspect should have **at least one** of the following documented in their medical record:

- IOP $\geq$ 22 mm of mercury; **OR**
- Cup to disc ratio of $\geq$ 0.4 with a family history of glaucoma or risk of low tension glaucoma; **OR**
- Documented increase of cup to disc ratio $\geq$ 0.2; **OR**
- Cup to disc ratio $\geq$ 0.5; **OR**
- Focal notch with rim/disc $\geq$ 0.2; **OR**
- Disc hemorrhage**; OR**
- Optic disc abnormality; **OR**
- Visual field defect**.**

When Glaucoma, Evaluation by Ophthalmologic Techniques is not covered

The measurement of ocular blood flow, pulsatile ocular blood flow or blood flow velocity is considered **investigational** in the diagnosis and follow- up of patients with glaucoma.

Policy Guidelines

Several techniques have been developed to measure the thickness of the optic nerve/retinal nerve fiber layer (RNFL) as a method to diagnose and monitor glaucoma. Measurement of ocular blood flow is also being evaluated as a diagnostic and management tool for glaucoma.

For individuals who have glaucoma or suspected glaucoma who receive imaging of the optic nerve and retinal nerve fiber layer, the evidence includes studies on diagnostic accuracy. Relevant outcomes are test accuracy, symptoms, morbid events, functional outcomes, and medication use. Confocal scanning laser ophthalmoscopy (CSLO), scanning laser polarimetry (SLP), and optical coherence tomography (OCT) can be used to evaluate the optic nerve and retinal nerve fiber layer in patients with glaucoma and suspected glaucoma. Numerous articles have described findings from patients with known and suspected glaucoma using CSLO, SLP, and OCT. These studies have reported that abnormalities may be detected on these examinations before functional changes are noted. The literature and specialty society guidelines have indicated that optic nerve analysis using CSLO, SLP, and OCT are established add-on tests that may be used to diagnose and manage patients with glaucoma and suspected glaucoma. These results are often considered along with other findings to make diagnostic and therapeutic decisions about glaucoma care, including use of topical medication, monitoring, and surgery to lower intraocular pressure. Thus, accurate diagnosis of glaucoma would be expected to reduce the progression of glaucoma. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have glaucoma or suspected glaucoma who receive evaluation of ocular blood flow, the evidence includes association studies. Relevant outcomes are test accuracy, symptoms, morbid events, functional outcomes, and medication use. Techniques to measure ocular blood flow or ocular blood velocity are used to determine appropriate glaucoma treatment options. The data for these techniques remain limited. Literature reviews have not identified studies on the technical performance of these tests (eg, test-retest reliability), whether these technologies improve diagnostic accuracy, or whether they improve health outcomes in patients with glaucoma. Some have suggested that these parameters may inform understanding of the variability in visual field changes in patients with glaucoma, ie, they may help explain why patients with similar levels of intraocular pressure develop markedly different visual impairments. However, data on use of ocular blood flow, pulsatile ocular blood flow, and/or blood flow velocity are currently lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: *0198T, 0333T, 0464T, 92133, 92134*

Codes 92133 and 92134 cannot be reported for the same patient encounter. The use in glaucoma testing will now be reported with 92133. The most common use of 92134 will be for assessments of the efficacy of intraocular injection treatment of macular degeneneration.

92134 could be used to describe both scanning laser ophthalmoscopy and scanning laser polarimetry. There is no specific code describing optical coherence tomography.

93875 could be used to describe Doppler ultrasonography of the choroidal arteries.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual, 7/16/1999; 9.03.06

BCBSA Medical Policy Reference Manual, 11/20/01; 9.03.06

Specialty Matched Consultant Advisory Panel - 3/2003

BCBSA Medical Policy Reference Manual, 7/17/03; 9.03.06

Specialty Matched Consultant review - 2/19/2004

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.06, 7/15/04.

Specialty Matched Consultant Advisory Panel - 1/2005

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.06, 12/14/05

Specialty Matched Consultant Advisory Panel review - 1/25/07

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.06, 12/12/06.

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.06, 1/10/08.

Specialty Matched Consultant Advisory Panel review - 4/6/09.

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.06, 1/13/11.

Medical Director – 4/2011

Specialty Matched Consultant Advisory Panel Review- 6/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.06, 1/12/12.

Specialty Matched Consultant Advisory Panel Review- 10/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.06, 2/14/13.

Specialty Matched Consultant Advisory Panel review- 6/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.06, 2/13/14

Specialty Matched Consultant Advisory Panel review- 6/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.06, 2/12/15

Specialty Matched Consultant Advisory Panel review- 6/2015

Specialty Matched Consultant Advisory Panel review- 6/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.06, 8/11/16

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.06, 3/9/17

Specialty Matched Consultant Advisory Panel review- 6/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.06, 3/8/18

Specialty Matched Consultant Advisory Panel review- 6/2018

Medical Director review 6/2018

Medical Director review 8/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 9.03.06, 3/14/19

Specialty Matched Consultant Advisory Panel review- 6/2019

Medical Director review 6/2019

Medical Director review 7/2019

Policy Implementation/Update Information

3/01	Original policy issued.
3/02	Policy revised to include analysis of the retinal nerve fiber layer and optical coherence tomography as additional investigational indications. Policy statement revised for clarity.
4/22/04	Specialty Matched Consultant Advisory Panel review 3/24/2003. "Description of Procedure" section revised to clarify techniques to evaluate the retinal nerve fiber layer. Benefits Application and Billing/Coding sections revised. Specialty Matched Consultant review 2/19/04. "Policy, "When covered" and "When not covered" sections revised based on specialty matched consultant review. Policy name changed from "Glaucoma, Evaluation by Ophthalmic Techniques" to Glaucoma, Evaluation by Ophthalmologic Techniques". Notification given 4/22/04. Effective date 7/1/04.

1/20/05 Specialty Matched Consultant Advisory Panel review 1/5/05. No changes to criteria.

8/21/06 Medical Policy changed to Evidence Based Guideline. (pmo)

2/26/07 Specialty Matched Consultant Advisory Panel review. No changes to guidelines. Reference sources added. (pmo)

4/27/09 No changes to guidelines. Reference sources added. (pmo)

6/22/10 Policy Guideline Number(s) removed (amw)

2/15/11 Added new 2011 CPT codes 92133 and 92134 to Billing/Coding section. (lpr)

4/26/11 "Description" section revised and updated. The "Evidence Based Guideline" section revised, removed the following statements; "Techniques to evaluate the retinal nerve fiber layer (scanning laser ophthalmoscopy, scanning laser polarimetry and optical coherence tomography) will be referred to as scanning laser glaucoma tests (SLGT). SLGT may be appropriate when performed for the evaluation of individuals at high risk for developing glaucoma and for the monitoring of patients with a diagnosis of glaucoma." Added the following statement; "Analysis of the optic nerve (retinal nerve fiber layer) using scanning laser ophthalmoscopy, scanning laser polarimetry, and optical coherence tomography may be appropriate when performed for the diagnosis and evaluation of patients with glaucoma or glaucoma suspects." Revised the wording in the "When Not Recommended" section from; "When the above medical criteria are not met. The use of SLGT to screen for glaucoma. The use of optic nerve head analyzers (i.e. Glaucoma Scope), the measurement of pulsatile ocular blood flow or blood flow velocity with Doppler ultrasonography are not recommended for the diagnosis and follow up of patients with glaucoma." to "The measurement of ocular blood flow, pulsatile ocular blood flow or blood flow velocity with Doppler ultrasonograpy is not recommended for the diagnosis and follow up of patients with glaucoma." "A literature review did not identify any studies that demonstrate the clinical utility for use of pulsatile ocular blood flow or blood flow velocity in patients with glaucoma. These techniques are used in evaluating various glaucoma treatments. A recent publication reported on color Doppler imaging (CDI) in normal and glaucomatous eyes. Using data from reported studies, a weighted mean was derived for the peak systolic velocity, end diastolic velocity and Pourcelot's resistive index in the ophthalmic, central retinal and posterior ciliary arteries. Data from 3,061 glaucoma patients and 1,072 controls were included. The mean values for glaucomatous eyes were within 1 SD of the values for controls for most CDI parameters. Methodologic differences created inter-study variance in CDI values, complicating the construction of a normative database and limiting its utility. The authors noted that because the mean values for glaucomatous and normal eyes have overlapping ranges, caution should be used when classifying glaucoma status based on a single CDI measurement. Measurement of ocular blood flow has also been studied as a technique for evaluating patients with glaucoma. While reports of use have been longstanding, the clinical impact of this technique is not known. Reports have commented on the complexity of these parameters and have noted that these technologies are not commonly used in clinical settings. The impact on health outcomes is not known." Added 0198T to "Billing/Coding" section and removed deleted CPT code, 92135. References added. (btw)

7/19/11 Specialty Matched Advisory Consultant Panel Review 6/29/11. No changes to criteria. (lpr)

11/22/11 Deleted CPT codes 92120, 93875 from Billing/Coding section. (lpr)

10/30/12 Specialty Matched Consultant Advisory Panel review 10/17/2012. Reference updated. No change to guideline statement. (lpr)

1/13 References updated. Added Regulatory Status to description section. No change to guideline statement. (lpr)

7/16/13 Specialty matched consultant advisory panel review 6/19/2013. No change to guideline statement. (lpr)

4/1/14 References updated. No change to guideline statement. (lpr)

7/15/14 Specialty matched consultant advisory panel review meeting 6/24/2014. Under "Evidenced Based Guideline for OphthalmologicTechniques to Evaluate Glaucoma" section: Patients who are defined as a glaucoma suspect should have **at least one** of the following documented: 4th bullet: changed the value to 0.5 from 5 for cup disc ratio. No change to guideline statement. (lpr)

7/28/15 Evidence based guideline converted to corporate medical policy. Medical director review 3/2015. Reference added. Specialty Matched Consultant Advisory Panel review 6/24/2015. Notification given 7/28/15 for effective date 10/1/15. (lpr)

7/26/16 Specialty Matched Consultant Advisory Panel review 6/29/2016. No change to policy statement. (lpr)

9/30/16 Reference added. No change to policy statement. (lpr)

12/30/16 Added CPT codes 0333T and 0464T to Billing/Coding section for effective date 1/1/2017. (lpr)

4/28/17 Updated Description and Policy Guidelines sections. Doppler ultrasonography removed from Description section and "When Not Covered" section. No change to intent nor policy statement. Added CPT code 0469T to Billing/Coding section for effective date 7/1/17. Reference added. (lpr)

7/28/17 Deleted CPT code 0469T from Billing/Coding section. Specialty Matched Consultant Advisory Panel review 6/28/2017. No change to policy statement. (lpr)

9/28/18 Specialty Matched Consultant Advisory Panel review 6/2018. Reference added. No change to policy statement. Medical Director review 8/2018. (lpr)

7/16/19 Specialty Matched Consultant Advisory Panel review 6/19/2019. Reference added. Removed the following paragraph in "When Covered" section: Factors defining individuals at high risk for developing glaucoma include **any** of the following:African Americans over 40 years old; Caucasians over 65 years old; Family history of glaucoma; Diabetes. Medical Director review 7/2019. (lpr)