Ophthalmologic Techniques That Evaluate the Posterior Segment for Glaucoma

Policy Number: 9.03.06  Last Review: 9/2017

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for ophthalmologic techniques for evaluating glaucoma when it is determined to be medically necessary because the criteria shown below are met.

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

When Policy Topic 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.

Considerations
Optic nerve/retinal nerve fiber analysis may be performed by both ophthalmologists and optometrists.

Description of Procedure or Service

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<th>Populations</th>
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<th>Outcomes</th>
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<td>Interventions of interest are:</td>
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<td>Relevant outcomes include:</td>
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<td>• Imaging of the optic nerve and retinal nerve</td>
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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 open-angle glaucoma or glaucoma suspect who receive digital imaging of the optic nerve and retinal nerve fiber layer, the evidence includes studies on diagnostic accuracy. Relevant outcomes include test accuracy, other test performance measures, symptoms, morbid events, 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 glaucoma suspect. Numerous articles describe findings from patients with known and suspected glaucoma using CSLO, SLP, and OCT. These studies report that abnormalities may be detected on these examinations before functional changes are noted. The literature and specialty society guidelines indicate that optic nerve analysis using CSLO, SLP, and OCT has become an additional test that may be used in the diagnosis and management of patients with glaucoma and those who are glaucoma suspects. These results are often considered along with other findings to make diagnostic and therapeutic decisions about glaucoma care. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have open-angle glaucoma or glaucoma suspect who receive evaluation of ocular blood flow, the evidence includes association studies. Relevant outcomes include test accuracy, other test performance measures, symptoms, morbid events, and medication use. Techniques to measure ocular blood flow or ocular blood velocity are used in evaluating various glaucoma treatments. The data for these techniques remain limited. Literature reviews have not identified studies that demonstrate the clinical utility for use of pulsatile ocular blood flow or blood flow velocity in patients with glaucoma. Some publications have described their use in studies comparing medication regimens in glaucoma. Others have suggested that these parameters may be helpful in understanding the variability in visual field changes in patients with glaucoma, ie, this may help explain why patients with similar levels of intraocular pressure may 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, and their relationship to clinical outcomes is unclear. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Background**

**Glaucoma**

Glaucoma is characterized by degeneration of the optic nerve (optic disc). Elevated intraocular pressure (IOP) has long been thought to be the primary etiology, but the relation between IOP and optic nerve damage varies among patients, suggesting a multifactorial origin. For example, some patients with clearly elevated
IOP will show no optic nerve damage, while others with marginal or no pressure elevation will show optic nerve damage. The association between glaucoma and other vascular disorders (eg, diabetes, 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. Diagnosis of angle-closure glaucoma is detailed in a separate policy.

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 and RNFL**

**Confocal Scanning Laser Ophthalmoscopy**

Confocal scanning laser ophthalmoscopy (CSLO) is an image acquisition technique intended to improve the quality of the eye examination compared with 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 RNFL thickness. In addition, this technique does not require maximal mydriasis, which may be problematic in patients with glaucoma. The Heidelberg Retinal Tomograph is probably the most common example of this technology.

**Scanning Laser Polarimetry**
The RNFL is birefringent (or biorefractive), meaning that it causes 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 SLP device. GDx contains a normative database and statistical software package that compare scan results with 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 completed in 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 analysis software is being developed to include optic nerve head parameters with spectral domain OCT, 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 relation between ocular pressure and ocular volume. Pulsatile blood flow is primarily determined by the choroidal vessels, particularly relevant to patients with glaucoma, because 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.¹

**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 clinical diagnosis
and management of retinal diseases. The RTVue XR OCT Avanti™ with Normative
Database is a quantitative tool for comparing retina, retinal nerve fiber layer, and
optic disk measurements in the human eye to a database of known normal
subjects. It is intended 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) was cleared for marketing by FDA through the 510(k) process. The iExaminer™ consists of a hardware adapter and associated software (iPhone® App) to capture, store, send, and retrieve images from the PanOptic™ Ophthalmoscope (Welch Allyn) using an iPhone®.

**Rationale**

This evidence review was originally created in April 1998 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through January 25, 2017.

Assessment of a diagnostic technology typically focuses on 3 categories of evidence: (1) its technical performance (test-retest reliability or interrater reliability); (2) diagnostic accuracy (sensitivity, specificity, and positive and negative predictive value) in relevant populations of patients; and (3) demonstration that the diagnostic information can be used to improve patient outcomes. In addition, subsequent use of a technology outside of the investigational setting may also be evaluated. These categories of evidence, although not always evaluated in sequence, can be considered similar to the 4 phases of therapeutic studies.

The use of various techniques of retinal nerve fiber layer (RNFL) analysis (confocal scanning laser ophthalmoscopy [CSLO], scanning laser polarimetry [SLP], optical coherence tomography [OCT]) for the diagnosis and management of glaucoma was addressed by 2 TEC Assessments (2001, 2003). Literature searches focusing on longitudinal results have been performed since the 2003 TEC Assessment.

Following is a summary of the key literature to date.

**Imaging of the Optic Nerve and RNFL**

**Clinical Context and Test Purpose**

The diagnosis and monitoring of optic nerve damage are essential for evaluating the progression of glaucoma and determining appropriate treatment.

The question addressed in this evidence review is: Do imaging techniques for the optic nerve and RNFL improve diagnosis and monitoring?

The following PICOTS were used to select literature to inform this review.

**Patients**

The relevant population is patients with glaucoma or who are suspected to have glaucoma being evaluated for diagnosis and monitoring of glaucoma progression.
**Interventions**
The technologies of interest for assessment of the optic nerve and RNFL include CLSO, SLP, and OCT. They are considered add-on tests to the standard clinical evaluation.

**Comparators**
There is no single criterion standard for the diagnosis of glaucoma. This diagnosis is made from a combination of visual field testing, intraocular pressure (IOP) measurement, and optic nerve and RNFL assessment by an ophthalmologist.

**Outcomes**
Relevant outcomes include the clarity of the images and how reliable the test is at evaluating the optic nerve and nerve fiber layer changes. Demonstration that the information can be used to improve patient outcomes is essential for determining the utility of an imaging technology. Although direct evidence on the impact of the imaging technology from controlled trials would be preferred, in most cases, a chain of evidence needs to be constructed to determine whether there is a tight linkage between the technology and improved health outcomes. The outcomes relevant to this evidence review are IOP, loss of vision, and changes in IOP-lowering medications used to treat glaucoma.

**Timing**
For patients with manifest glaucoma, the relevant period of follow-up is the immediate diagnosis of glaucoma. For patients with suspected glaucoma, longer term follow-up would be needed to detect changes in visual field or RNFL. Clinical utility might be demonstrated by a change in the management and reduction in glaucoma progression across follow-up.

**Setting**
Patients may be self-referred, referred by optometrists, or referred by a general ophthalmologist to a glaucoma specialist. These procedures can be performed in an ophthalmologist’s office.

**Technical Performance**
We did not identify studies reporting on the technical performance of imaging techniques for the optic nerve and RNFL.

**Diagnostic Accuracy**
In 2012, the Agency for Healthcare Research and Quality published a comparative effectiveness review of screening for glaucoma. Included were randomized controlled trials (RCTs), quasi-RCTs, observational cohort and case-control studies, and case series with more than 100 participants. The interventions evaluated included ophthalmoscopy, fundus photography or computerized imaging (OCT, retinal tomography, SLP), pachymetry (corneal thickness measurement), perimetry, and tonometry. No evidence was identified that addressed whether an open-angle glaucoma screening program led to a reduction in IOP, less visual impairment, reduction in visual field loss or optic nerve damage, or improvement in patient-reported outcomes. No evidence was identified on harms of a screening program.
program. Over 100 studies were identified on the diagnostic accuracy of screening tests. However, due to the lack of a definitive diagnostic reference standard and heterogeneity in study designs, synthesis of results could not be completed.

A 2015 Cochrane review assessed the diagnostic accuracy of optic nerve head and nerve fiber layer imaging for glaucoma. Included were 103 case-control studies and 3 cohort studies (total N=16,260 eyes) that evaluated the accuracy of recent commercial versions of OCT (spectral domain), Heidelberg Retinal Tomograph (HRT) III, or SLP (GDx VCC or ECC) for diagnosing glaucoma. The population was patients who had been referred for suspected glaucoma, typically due to an elevated IOP, abnormal optic disc appearance, and/or an abnormal visual field identified in primary eye care. Population-based screening studies were excluded. Most comparisons examined different parameters within the 3 tests, and the parameters with the highest diagnostic odds ratio were compared. The 3 tests (OCT, HRT, SLP) had similar diagnostic accuracy. Specificity was close to 95%, while sensitivity was 70%. Because a case-control design with healthy participants and glaucoma patients was used in nearly all studies, concerns were raised about the potential for bias, overestimation of accuracy, and applicability of the findings to clinical practice.

**Effect on Health Outcomes**
A technology assessment issued by American Academy of Ophthalmology in 2007 reviewed 159 studies, published between January 2003 and February 2006, evaluating optic nerve head and RNFL devices used to diagnose or detect glaucoma progression. The assessment concluded: “The information obtained from imaging devices is useful in clinical practice when analyzed in conjunction with other relevant parameters that define glaucoma diagnosis and progression.” Management changes for patients diagnosed with glaucoma may include the use of IOP-lowering medications, monitoring for glaucoma progression, and potentially surgery to slow the progression of glaucoma.

**Section Summary: Imaging of the Optic Nerve and RNFL**
Numerous studies and systematic reviews have described findings from patients with glaucoma using CSLO, SLP, and OCT. Although the specificity in these studies was high, it is likely that accuracy was overestimated due to the case-control designs used in the studies. The literature and specialty society guidelines have indicated that optic nerve analysis using CSLO, SLP, and OCT are established add-on tests that can be used with other established tests to improve the diagnosis and direct management of patients with glaucoma and those who are glaucoma suspects. Management changes for patients diagnosed with glaucoma may include the use of IOP-lowering medications, monitoring for glaucoma progression, and potentially surgery.

**Evaluation of Ocular Blood Flow**

**Clinical Context and Test Purpose**
The diagnosis and monitoring of optic nerve damage are essential for evaluating the progression of glaucoma and determining appropriate treatment. Measurement
of ocular blood flow has been studied as a technique to evaluate patients with glaucoma or suspected glaucoma.

The question addressed in this evidence review is: Do the techniques described below for assessing ocular blood flow improve diagnosis and monitoring? One potential application is the early detection of normal tension glaucoma.\(^7\)

The following PICOTS were used to select literature to inform this review.

**Patients**
The relevant patient population is patients with glaucoma or suspected glaucoma who are being evaluated for diagnosis and monitoring of glaucoma progression. These tests may have particular utility for normal tension glaucoma (NTG).

**Interventions**
The technologies of interest for assessment of the optic nerve and optic nerve layer include color Doppler imaging (CDI), Doppler Fourier domain OCT, laser Doppler velocimetry, confocal scanning laser Doppler flowmetry, and retinal functional imager.

**Comparators**
There is no other criterion standard for the diagnosis of glaucoma. The diagnosis of glaucoma is made from a combination of visual field testing, IOP measurements, and optic nerve and RNFL assessment.

**Outcomes**
Relevant outcomes include the reliability of the test for evaluating ocular blood flow and the association between ocular blood flow parameters and glaucoma progression. Demonstration that the information can be used to improve patient outcomes is essential to determining the utility of a diagnostic technology. Although direct evidence on the impact of the imaging technology from controlled trials would be preferred, in most cases, a chain of evidence is needed to determine whether there is a tight linkage between the technology and improved health outcomes. The outcomes relevant to this evidence review are IOP, loss of vision, and changes in IOP-lowering medications used to treat glaucoma.

**Timing**
Longitudinal studies are needed to evaluate whether changes in blood flow are predictive of future visual loss.

**Setting**
Many of these procedures are performed with specialized equipment. While reports of use are longstanding (eg, Bafa et al [2001]\(^8\)), investigators have commented on the complexity of these parameters\(^9\) and have noted that many of these technologies are not commonly used in clinical settings.\(^10\)
Technical Performance
We did not identify studies reporting on the technical performance of ocular blood flow evaluation techniques.

Diagnostic Accuracy
In 2016, Abegao Pinto et al reported the results from the prospective, cross-sectional, case-control, Leuven Eye Study, which included 614 individuals who had primary open-angle glaucoma (POAG; n=214), NTG (n=192), ocular hypertension (n=27), suspected glaucoma (n=41), or healthy controls (n=140). The objective of this study was to identify the blood flow parameters most highly associated with glaucoma using technology commonly available in an ophthalmologist’s office or hospital radiology department. Assessment of ocular blood flow included CDI, retinal oximetry, dynamic contour tonometry, and OCT enhanced-depth imaging of the choroid. The glaucoma groups had higher perfusion pressure compared to controls (p<0.001), with lower velocities in both central retinal vessels (p<0.05), and choroidal thickness asymmetries. The NTG group, but not the POAG group, had higher retinal venous saturation compared to healthy controls (p=0.005). There were no significant differences in macular scans. The diagnostic accuracy or effects on health outcomes were not addressed.

A 2011 study reported on CDI in normal and glaucomatous eyes. Using data from other studies, a weighted mean was derived for the peak systolic velocity, end-diastolic velocity, and Pourcelot Resistive Index in the ophthalmic, central retinal, and posterior ciliary arteries. Data from 3061 glaucoma patients and 1072 controls were included. Mean values for glaucomatous eyes were within 1 SD of the values for controls for most CDI parameters. Methodologic differences created interstudy 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 had overlapping ranges, caution should be used when classifying glaucoma status based on a single CDI measurement.

Effect on Health Outcomes
The clinical utility of techniques to evaluate ocular blood flow is similar to the other imaging techniques. The objective is to improve the diagnosis and direct management of patients with glaucoma or suspected glaucoma. Measures of ocular blood flow may have particular utility for the diagnosis and monitoring of NTG.

The only longitudinal study identified was a 2012 study by Calvo et al on the predictive value of retrobulbar blood flow velocities in a prospective series of 262 who were glaucoma suspect. At baseline, all participants had normal visual field, increased IOP (mean, 23.56 mm Hg), and glaucomatous optic disc appearance. Blood flow velocities were measured by CDI during the baseline examination, and conversion to glaucoma was assessed at least yearly according to changes observed with CLSO. During the 48-month follow-up, 36 (13.7%) patients developed glaucoma and 226 did not. Twenty (55.5%) of those who developed glaucoma also showed visual field worsening (moderate agreement, κ=0.38). Mean end-diastolic and mean velocity in the ophthalmic artery were significantly
reduced at baseline in subjects who developed glaucoma compared with subjects who did not.

**Section Summary: Evaluation of Ocular Blood Flow**

Techniques to measure ocular blood flow or ocular blood velocity are being evaluated for the diagnosis of glaucoma. Data for these techniques remain limited. Current literature focuses on which technologies are most reliably associated with glaucoma. Literature reviews have not identified studies whether these technologies improve the diagnosis of glaucoma or whether measuring ocular blood flow in patients with glaucoma or suspected glaucoma improves health outcomes.

**Summary of Evidence**

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.
Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 1 physician specialty society and 3 academic medical centers while this policy was under review in 2009. Most reviewers supported use of these techniques (confocal scanning laser ophthalmoscopy, scanning laser polarimetry, optical coherence tomography) in the care of patients with glaucoma and those with suspected glaucoma suspect. Reviewers provided data to demonstrate that this testing is equivalent to expert assessment of optic disc photography for both detecting glaucoma and showing disease progression. Reviewers also commented on favorable aspects of this testing. For example, unlike other glaucoma testing, these tests can be done more easily (eg, testing does not always need to be done with dilated pupils) and ambient light level may be (is) less critical. In addition, while serial stereophotographs of the optic nerves are considered by many as the criterion standard, they are not always practical, especially for general ophthalmologists. This testing also requires less cooperation from the patient, which can help when evaluating some older patients.

Practice Guidelines and Position Statements

American Academy of Ophthalmology
The American Academy of Ophthalmology’s (AAO) 2015 preferred practice patterns on primary open-angle glaucoma (POAG) suspect and POAG both recommended evaluating the optic nerve and retinal nerve fiber layer.14,15

The documents stated that “Although they are distinctly different methodologies, stereoscopic disc photographs and computerized images of the nerve are complementary with regard to the information they provide the clinician who must manage the patient.” The guidelines described 3 types of computer-based imaging devices (confocal scanning laser ophthalmoscopy, scanning laser polarimetry, optical coherence tomography) currently available for glaucoma, which are similar in their ability to distinguish glaucoma from controls and noted that “computer-based digital imaging of the ONH [optic nerve head] and RNFL [retinal nerve fiber layer] is routinely used to provide quantitative information to supplement the clinical examination of the optic nerve.... One rationale for using computerized imaging is to distinguish glaucomatous damage from eyes without glaucoma when thinning of the RNFL is measured, thereby facilitating earlier diagnosis and detection of optic nerve damage”. In addition, AAO concluded that, as device
technology evolves, the performance of diagnostic imaging devices is expected to improve.

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

**Medicare National Coverage**
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**Ongoing and Unpublished Clinical Trials**
Some currently unpublished trials that might influence this review are listed in Table 1.

### Table 1. Summary of Key Trials

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<td>Ongoing</td>
<td>Longitudinal Observational Study Using Functional and Structural Optical Coherence Tomography to Diagnose and Guide Treatment of Glaucoma</td>
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NCT: national clinical trial.

References


**Billing Coding/Physician Documentation Information**

**0198T** Measurement of ocular blood flow by repetitive intraocular pressure sampling, with interpretation and report

**0329T** Monitoring of intraocular pressure for 24 hours or longer, unilateral or bilateral, with interpretation and report

**92133** Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral; optic nerve.

**ICD-10 Codes**

**H40.001-H42** Glaucoma, code range

**Z01.00-Z01.01** Encounter for examination of eyes and vision

**Policy Implementation/Update Information**

9/1/09 New policy; considered investigational

9/1/10 Policy statement updated to include testing using scanning laser ophthalmoscopy, scanning laser polarimetry, and optical coherence tomography as considered medically necessary in patients with glaucoma and glaucoma suspects. Title changed from Measurement of Pulsatile Ocular Blood Flow to Ophthalmologic Techniques for Evaluating Glaucoma.

9/1/11 Policy statement revised, ocular blood flow added as investigational, no other changes in policy statements.

9/1/12 No policy statement changes.

9/1/13 Updated coding. No policy statement changes.

9/1/14 No policy statement changes.

9/1/15 No policy statement changes.

9/1/16 No policy statement changes.

9/1/17 Doppler ultrasonography removed from the second policy statement. The intent of the policy statement is unchanged. Title changed to “Ophthalmologic Techniques That Evaluate the Posterior Eye Segment for Glaucoma.”

State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational...
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