Medical Policy

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Title: Ophthalmologic Techniques that Evaluate the Posterior Segment for Glaucoma

Description/Background

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.

BACKGROUND

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 an examination of the optic nerve by fundoscopy, 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 intraocular pressure (IOP), is sufficient for a definitive diagnosis. However, some patients will show ophthalmologic evidence of glaucoma with normal intraocular pressures. 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 intraocular pressure (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 intraocular pressures, 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 stereo photography, 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 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 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 new 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 Retinal Nerve Fiber Layer

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 Tomography is probably the most common example of this technology.

Scanning Laser Polarimetry

The RNFL is birefringent (or bio refractive), 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 scanning laser polarimeter. 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 two-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 relationship 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 Optical Coherence Tomography
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 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 with 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 the 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®. FDA product code: HKI

Table 1 lists selected devices cleared by the U.S. FDA for imaging the posterior eye segment.

Table 1. Selected Ocular Imaging Devices Cleared by the US Food and Drug Administration

Device	Manufacturer	Date Cleared	510k No.	Indication
SOLIX	Optovue Inc.	11/9/2022	K222166	Imaging of optic nerve and retinal nerve fiber layer
RESCAN 700 CALLISTO eye	Carl Zeiss Meditec AG	1/11/2019	K180229	Imaging of optic nerve and retinal nerve fiber layer
Retina Workplace	Carl Zeiss Meditec Inc	10/24/2018	K182318	Imaging of optic nerve and retinal nerve fiber layer
Spectralis HRA+OCT and variants with High Magnification Module	Heidelberg Engineering GmbH	10/18/2018	K182569	Imaging of optic nerve and retinal nerve fiber layer
Spectralis HRA+OCT and variants with OCT Angiography Module	Heidelberg Engineering GmbH	9/13/2018	K181594	Imaging of optic nerve and retinal nerve fiber layer
Spectralis HRA + OCT and variants	Heidelberg Engineering GmbH	8/30/2018	K173648	Imaging of optic nerve and retinal nerve fiber layer
Image Filing Software NAVIS-EX	Nidek Co. Ltd	7/19/2018	K181345	Imaging of optic nerve and retinal nerve fiber layer
Avanti	Optovue Inc.	6/8/2018	K180660	Imaging of optic nerve and retinal nerve fiber layer
P200TE	Optos plc	2/28/2018	K173707	Imaging of optic nerve and retinal nerve fiber layer
DRI OCT Triton	Topcon Corporation	1/19/2018	K173119	Imaging of optic nerve and retinal nerve fiber layer
IMAGEnet 6 Ophthalmic Data System	Topcon Corporation	11/1/2017	K171370	Imaging of optic nerve and retinal nerve fiber layer
Spectralis HRA + OCT and variants Spectralis FA+OCT Spectralis ICGA+OCT	Heidelberg Engineering GmbH	11/1/2017	K172649	Imaging of optic nerve and retinal nerve fiber layer

Spectralis OCT Blue Peak Spectralis OCT with Multicolor				
PRIMUS	Carl Zeiss Suzhou Co. Ltd.	6/21/2017	K163195	Imaging of optic nerve and retinal nerve fiber layer
Retina Workplace	Carl Zeiss Meditec AG	6/21/2017	K170638	Imaging of optic nerve and retinal nerve fiber layer
iVue	Optovue Inc.	6/9/2017	K163475	Imaging of optic nerve and retinal nerve fiber layer
3D OCT-1 Maestro	Topcon Corporation	3/3/2017	K170164	Imaging of optic nerve and retinal nerve fiber layer
EnFocus 2300 EnFocus 4400	Bioptigen Inc.	12/9/2016	K162783	Imaging of optic nerve and retinal nerve fiber layer
PLEX Elite 9000 SS-OCT	CARL ZEISS MEDITEC INC.	10/26/2016	K161194	Imaging of optic nerve and retinal nerve fiber layer
3D OCT-1 Maestro	Topcon Corporation	7/28/2016	K161509	Imaging of optic nerve and retinal nerve fiber layer
LSFG-NAVI	Softcare Co. Ltd	5/12/2016	K153239	Imaging of optic nerve and retinal nerve fiber layer
Spectralis HRA + OCT and variants Spectralis FA+OCT Spectralis ICGA+OCT Spectralis OCT Blue Peak Spectralis OCT with Multicolor	Heidelberg Engineering GmbH	5/6/2016	K152205	Imaging of optic nerve and retinal nerve fiber layer
RTVue XR OCT Avanti with AngioVue Software	OPTOVUE INC.	2/11/2016	K153080	Imaging of optic nerve and retinal nerve fiber layer
EnFocus 2300 EnFocus 4400	BIOPTIGEN INC.	12/2/2015	K150722	Imaging of optic nerve and retinal nerve fiber layer
Optical Coherence Tomography	CARL ZEISS MEDITEC INC	9/1/2015	K150977	Imaging of optic nerve and retinal nerve fiber layer
OCT-Camera	OptoMedical Technologies GmbH	3/4/2015	K142953	Imaging of optic nerve and retinal nerve fiber layer
Rescan 700 Callisto Eye	CARL ZEISS MEDITEC AG	11/18/2014	K141844	Imaging of optic nerve and retinal nerve fiber layer
Propper Insight Binocular Indirect Ophthalmoscope	PROPPER MANUFACTURING CO.INC.	9/17/2014	K141638	Imaging of optic nerve and retinal nerve fiber layer
Centervue Macular Integrity Assessment	CENTERVUE SPA	4/23/2014	K133758	Imaging of optic nerve and retinal nerve fiber layer
AMICO DH-W35 Ophthalmoscope Series	AMICO DIAGNOSTIC INCORPORATED	3/26/2014	K131939	Imaging of optic nerve and retinal nerve fiber layer
IVUE 500	OPTOVUE INC.	3/19/2014	K133892	Imaging of optic nerve and retinal nerve fiber layer

RS-3000 Advance	NIDEK CO. LTD.	2/19/2014	K132323	Imaging of optic nerve and retinal nerve fiber layer

Medical Policy Statement

Scanning computerized ophthalmic diagnostic imaging, using confocal scanning laser ophthalmoscopy, scanning laser polarimetry and optical coherence tomography, has been established as a safe and effective procedure for those members who meet specific criteria.

The measurement of ocular blood flow, pulsatile ocular blood flow or blood flow velocity is considered experimental/investigational in the diagnosis and/or follow-up of members with glaucoma. It has not been scientifically demonstrated to be as effective as standard testing.

Inclusionary and Exclusionary Guidelines

Inclusions:
Scanning computerized ophthalmic diagnostic imaging (SCODI), including confocal scanning laser ophthalmoscopy, scanning laser polarimetry and optical coherence tomography when used for:

- analysis of the optic nerve as well as the retinal nerve fiber layer to diagnosis and/or evaluation of patients with glaucoma or suspected glaucoma.

Exclusions:
Scanning computerized ophthalmic diagnostic imaging used for diagnosis and/or follow-up of members with glaucoma when used for indications other than those listed above, including but not limited to the measurement of:

- Ocular blood flow
- Pulsatile ocular blood flow
- Blood flow velocity

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

92133 92134

Other codes (investigational, not medically necessary, etc.):

0198T 0464T 93880

Note: Code(s) may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.

Rationale

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 intraocular pressure (IOP) and optic nerve damage varies among patients, suggesting a multifactorial origin. For example, some patients with clearly elevated intraocular pressure (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 (e.g., 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.

IMAGING OF THE OPTIC NERVE AND RETINAL NERVE FIBER LAYER

Clinical Context and Test Purpose

The purpose of optic nerve and retinal nerve fiber layer imaging in patients with or suspected to have glaucoma is to inform a decision about appropriate treatment.

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

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

Populations

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 tests being considered for assessment of the optic nerve and RNFL include CLSO, SLP, and OCT. These test are considered add-on 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.

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.

Study Selection Criteria
Below are selection criteria for studies to assess whether a test is clinically valid.

- The study population represents the population of interest. Eligibility and selection are described.
- The test is compared with a credible reference standard.
- If the test is intended to replace or be an adjunct to an existing test; it should also be compared with that test.
- Studies should report sensitivity, specificity, and predictive values. Studies that completely report true- and false positive results are ideal. Studies reporting other measures (e.g., receiver operating characteristic, area under receiver operating characteristic, c-statistic, likelihood ratios) may be included but are less informative.
- Studies should also report reclassification of diagnostic or risk category.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Systemic Reviews
The Agency for Healthcare Research and Quality (2012) published a comparative effectiveness review of screening for glaucoma.(2) Included were randomized controlled trials (RCTs), quasi-randomized controlled trials, observational cohort and case control studies, and case series with more than 100 participants. The interventions evaluated included ophthalmoscopy, fundus photography/computerized imaging (OCT, retinal tomography, scanning laser polarimetry), 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 regarding harms of a screening 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, synthesis of results could not be completed.

A Cochrane review (2015) assessed diagnostic accuracy of optic nerve head and RNFL imaging for glaucoma.(3) Included were 103 case-control studies and 3 cohort studies (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 were patients 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 the sensitivity was 70%. Because a case-control design with healthy participants and glaucoma patients was used in nearly all of the studies, concerns were raised about the potential for bias, overestimating accuracy, and applicability of the findings to clinical practice.

A systematic review, conducted by Chou et al (2022), was commissioned by the US Preventive Services Task Force (USPSTF) to update its recommendations on screening for glaucoma in adults.(4) A total of 83 studies were included, of which 53 evaluated the diagnostic accuracy of screening tests (optical coherence tomography, optic disc photography, ophthalmoscopy and biomicroscopy, pachymetry, tonometry, and visual fields). Most studies evaluated spectral-domain optical coherence tomography (29 studies; n=11,434). Retinal nerve fiber layer thickness on spectral-domain optical coherence tomography was associated with a pooled sensitivity of 0.79 (95% confidence interval [CI], 0.75 to 0.83) and specificity of 0.92 (95% CI, 0.87 to 0.96) for distinguishing between glaucomatous eyes and controls, based on 15 studies; the pooled area under the receiver operating characteristic curve was 0.90 (95% CI, 0.86 to 0.93), based on 16 studies. Evidence on diagnostic accuracy was also robust for tonometry and the Humphrey Visual Field Analyzer but limited for other screening tests.

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

A technology assessment conducted by Lin et al (2007) for the American Academy of Ophthalmology, reviewed 159 studies, published between 2003 and 2006, evaluating optic nerve head and retinal nerve fiber layer devices used to diagnose or detect glaucoma progression.(5) 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 Retinal Nerve Fiber Layer
Numerous studies and systematic reviews have described findings from patients with glaucoma using confocal scanning laser ophthalmoscopy (CSLO), scanning laser polarimetry (SLP), and optical coherence tomography (OCT). A recent systematic review found that retinal nerve fiber layer thickness on spectral-domain optical coherence tomography was associated with a pooled sensitivity of 0.79 and specificity of 0.92 for glaucoma diagnosis. Although the specificity in several 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. One potential application is the early detection of normal tension glaucoma.(6)

The purpose of evaluating ocular blood flow in patients who have glaucoma or suspected glaucoma is to inform a decision about appropriate treatment.

The question addressed in this evidence review is: Does evaluation of ocular blood flow using various techniques (e.g., color Doppler imaging , Doppler Fourier domain optical coherence tomography, laser Doppler velocimetry, confocal scanning laser Doppler flowmetry, retinal functional imager) in patients with glaucoma or suspected glaucoma improve diagnosis and monitoring of glaucoma?

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

Populations

The relevant population are patients with glaucoma or suspected glaucoma who are being evaluated for diagnosis and monitoring of glaucoma progression. Tests for assessment of the ocular blood flow may have particular utility for normal tension glaucoma.

Interventions

The test being considered 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.

Many of these procedures are performed with specialized equipment. While reports of use are longstanding (e.g., Bafa et al [2001] [7]), investigators have commented on the complexity of these parameters,(8) and have noted that many of these technologies are not commonly used in clinical settings.(9)

Comparators

There is no criterion standard for the diagnosis of glaucoma. The diagnosis of glaucoma is made using a combination of visual field testing, IOP measurements, and optic nerve and retinal nerve fiber layer 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.

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 IOP and loss of vision. Clinical utility might be demonstrated by a change in the management and reduction in glaucoma progression across follow-up.

Study Selection Criteria
Selection criteria for studies to assess whether a test is clinically valid are discussed in the first indication.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Review of Evidence
A technology assessment, conducted by WuDunn et al (2021) for the AAO, reviewed 75 articles published through June 2020, evaluating the utility of optical coherence tomography angiography of the peripapillary or macular regions to help detect glaucomatous damage associated with the diagnosis of primary open-angle glaucoma.(10) Per the AAO, the majority of data demonstrates that peripapillary microcirculation measured by vessel density on optical coherence tomography angiography is decreased in glaucomatous versus healthy eyes. Therefore, this technology can be helpful in detecting vessel density loss associated with glaucoma. Furthermore, peripapillary, macular, and choroidal vessel density parameters may complement visual field and structural optical coherence tomography measurements in the diagnosis of glaucoma.

Systematic Review
Gu et al (2021) published a systematic review with meta-analysis evaluating the diagnostic value of laser speckle flow graphy in glaucoma by investigating the mean blur rate in the optic nerve head.(11) A total of 15 studies, including 692 glaucomatous and 386 healthy eyes, were included; only 1 study was based in the US (Tables 2 and 3). Results are summarized in Table 4. Briefly, the mean blur rate was significantly reduced in glaucomatous versus healthy eyes in the entire area, indicating that blood flow velocity in all areas of the optic nerve head was lower in glaucomatous eyes. Furthermore, the mean blur rate was significantly reduced in glaucomatous versus healthy eyes in the tissue area, indicating that there is insufficient blood supply in the deep fundus tissues and optic nerve head ischemia in glaucomatous eyes. Lastly, the mean blur rate was significantly reduced in glaucomatous versus healthy eyes in the vascular area, indicating that patients with glaucoma have an insufficient retinal blood supply. The authors concluded that while laser speckle flow graphy is a feasible diagnostic tool for glaucoma, more prospective studies are needed to fully evaluate this technology.

Table 2. Comparison of Trials/Studies Included in Systematic Review & Meta-Analysis

Study	Gu et al (2021)
Aizawa (2011)	●
Gardiner (2019)	●
Iida (2017)	●
Inoue Yanagimachi (2018)	●
Kiyota (2017)	●
Kiyota (2017)	●
Kiyota (2018)	●
Kobayashi (2014)	●
Kohmoto (2019)	●

Kuroda (2020)	●
Mursch-Edlmayr (2018)	●
Mursch-Edlmayr (2019)	●
Mursch-Edlmayr (2020)	●
Shiga (2016)	●
Takeyama (2018)	●

Table 3. Systematic Review & Meta-Analysis Characteristics

Study	Dates	Trials	Participants	N	Design	Duration
Gu et al (2021)	Through Dec 2020	15	Patients with glaucomatous or healthy eyes undergoing laser speckle flowgraphy to examine the ocular blood flow. The majority of participants in the included studies were Japanese (N=11 studies).	692 glaucomatous eyes; 386 healthy eyes.	Observational studies or randomized controlled trials.	N/A.

N/A: not applicable.

Table 4. Systematic Review & Meta-Analysis Results

Study	MBR – entire area	MBR – tissue area	MBR – vascular area
Gu et al (2021)			
Total N			
Glaucomatous eyes	541	660	573
Healthy eyes	254	372	268
MD (95% CI)	-5.59 (-6.19 to -4.99)	-2.2 (-2.49 to -1.91)	-5.92 (-7.77 to -4.07)
p-value	.1	.07	.0003

CI: confidence interval; MBR: mean blur rate; MD: mean difference.

Nonrandomized Studies

Abegao Pinto et al (2016) reported the results from the prospective, cross-sectional, case-control, Leuven Eye Study, which included 614 individuals who had primary open-angle glaucoma (n=214), NTG (n=192), ocular hypertension (n=27), suspected glaucoma (n=41), or healthy controls (n=140).(27) The study objective 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 than controls ($p<0.001$), with lower velocities in both central retinal vessels ($p<0.05$), and choroidal thickness asymmetries. The normal tension glaucoma group, but not the primary open-angle glaucoma group, had higher retinal venous saturation than healthy controls ($p=0.005$). There were no significant differences in macular scans. The diagnostic accuracy and clinical utility were not addressed.

Kurysheva et al (2017) compared ocular blood flow with choroidal thickness to determine which had a higher diagnostic value for detecting early glaucoma.(28) Thirty-two patients with pre-perimetric glaucoma were matched with 30 control patients. Using OCT, RNFL thickness between groups was found to be comparable; the ganglion cell complex was thicker in the control patients, and there was no significant difference between groups for choroid foveal loss volume. Mean blood flow velocity in the vortex veins had the highest area under the receiver

operating characteristic curve ROC (1.0) and *z*-value (5.35). Diastolic blood flow velocity in the central retinal artery had a diagnostic value of 2.74 and area under the receiver operating characteristic curve of 0.73. The authors concluded that this study suggested a diagnostic benefit in measuring blood flow velocities.

Witkowska et al (2017) investigated blood flow regulation using laser speckle flowgraphy in 27 individuals.(29) In this prospective study, the authors specifically looked at mean blur rate blood flow in the optic nerve head and a peripapillary region. First, participants' blood flow was measured when they were in a sitting position; then, participants were asked to perform an isometric "squatting" exercise for 6 minutes. Compared with baseline (sitting), exercise significantly increased ocular perfusion blood pressure (78.5%), mean blur rate in the tissue of the optic nerve head (18.1%), and mean blur rate in the peripapillary region (21 +/-18.3%) ($p<0.001$). Few studies have used laser speckle flowgraphy to study autoregulation of ocular blood flow during a change in blood pressure, and this study is limited to Japanese populations. Despite the lack of literature and limited population, the authors noted laser speckle flowgraphy could be a valuable tool to study the regulation of blood flow in the optic nerve head, particularly in patients suspected of having glaucoma or patients who have glaucoma.

Rusia et al (2011) reported on use of CDI in normal and glaucomatous eyes.(30) Using data from other 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. Mean values for glaucomatous eyes were within 1 standard deviation 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 had overlapping ranges, caution should be used when classifying glaucoma status based on a single color doppler imaging measurement.

Tables 5 and 6 summarize characteristics and results of key nonrandomized studies, respectively. Tables 7 and 8 summarize study limitations.

Table 5. Summary of Key Nonrandomized Study Characteristics

Study	Study Type	Country	Dates	Participants	Treatment[1]	Treatment[2]	Follow-up
Kurysheva (2017)	Prospective	Russia	NR	Patients with pre-perimetric glaucoma (n=32) and age-matched controls (n=30) All patients were White.	Optical coherence tomography	N/A	NR
Witkowska (2017)	Prospective	Austria	2015-2016	Healthy participants (n=27) All participants were White.	Laser speckle flowgraphy	N/A	6 minutes

N/A: not applicable; NR: not reported.

Table 6. Summary of Key Nonrandomized Study Results

Study	AUC and Diagnostic Value AUC p-value	Increase in OPP from Baseline	Increase in MTONH from Baseline	Increase in MTPPR from Baseline
Kurysheva (2017)		NR	NR	NR
MBFV in VV	1.0; <0.0001			

MBFV in CRV	0.85; 0.0001				
DBFV in CRA	0.73; 0.006				
DBFV in LSPCAs	0.71; 0.011				
Witkowska (2017)	NR	78.5+/-19.8%	18.1+/-7.7%	21.1+/-8.3%	

AUC: area under the receiver operating characteristic curve; CRA: central retinal artery; CRV: central retinal vein; DBFV: diastolic blood flow velocity; LSPCA: lateral short posterior ciliary artery; MBFV: mean blood flow velocity; MTPPR: mean blur rate in the peripapillary region; MTONH: mean blur rate in the tissue of the optic nerve head; NR: not reported; OPP: ocular perfusion pressure; VV: vortex veins; LSPCA: lateral short posterior ciliary artery.

Table 7. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Kurysheva et al (2017)	3. Study population included healthy controls; 4. Enrolled populations do not reflect relevant diversity		3. Intervention applied to all patients; No test utilized as comparator	5. Adverse events of test not described	1. Follow-up not reported
Witkowska et al (2017)	3. Study population was healthy individuals 4. Enrolled populations do not reflect relevant diversity		3. No test utilized as comparator	5. Adverse events of test not described	1. Follow-up evaluated short-term changes only

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Classification thresholds not defined; 2. Version used unclear; 3. Not intervention of interest.
[c] Comparator key: 1. Classification thresholds not defined; 2. Not compared to credible reference standard; 3. Not compared to other tests in use for same purpose.
[d] Outcomes key: 1. Study does not directly assess a key health outcome; 2. Evidence chain or decision model not explicated; 3. Key clinical validity outcomes not reported (sensitivity, specificity and predictive values); 4. Reclassification of diagnostic or risk categories not reported; 5. Adverse events of the test not described (excluding minor discomforts and inconvenience of venipuncture or noninvasive tests).
[e] Follow-Up key: 1. Follow-up duration not sufficient with respect to natural history of disease (true positives, true negatives, false positives, false negatives cannot be determined).

Table 8. Study Design and Conduct Limitations

Study	Selection[a]	Blinding[b]	Delivery of Test[c]	Selective Reporting[d]	Data Completeness[e]	Statistical[f]
Kuryshev a et al (2017)	1. Selection of patients not described. 2. Selection of control subjects was not randomized, but based on person accompanying patients	1. Examiner not blinded to patient group	4. Evaluator description not provided			
Witkowsk a et al (2017)	1. Selection of patients not described	1. All patients were healthy and underwent same treatment, therefore no blinding was utilized				2. Compariso n to other tests not included in study, since no comparator utilized

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Selection key: 1. Selection not described; 2. Selection not random or consecutive (i.e., convenience).

[b] Blinding key: 1. Not blinded to results of reference or other comparator tests.
[c] Test Delivery key: 1. Timing of delivery of index or reference test not described; 2. Timing of index and comparator tests not same; 3. Procedure for interpreting tests not described; 4. Expertise of evaluators not described.
[d] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[e] Data Completeness key: 1. Inadequate description of indeterminate and missing samples; 2. High number of samples excluded; 3. High loss to follow-up or missing data.
[f] Statistical key: 1. Confidence intervals and/or p values not reported; 2. Comparison to other tests not reported.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

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 normal-tension glaucoma.

The only longitudinal study identified is a study by Calvo et al (2012) on the predictive value of retrobulbar blood flow velocities in a prospective series of 262 who were glaucoma suspects.(31) 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.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

The evidence does not permit any inferences about the utility of ocular blood flow evaluation in the evaluation of glaucoma.

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 that suggest 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, scanning laser polarimetry, and optical coherence tomography 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 confocal scanning laser ophthalmoscopy, scanning laser polarimetry, and optical coherence tomography. 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 confocal scanning laser ophthalmoscopy, scanning laser polarimetry, and optical coherence tomography 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 an 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 addressing 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 the variability in visual field changes in patients with glaucoma, i.e., this 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 that the technology results in an improvement in the net health outcomes.

ONGOING AN UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this review are listed in Table 9.

Table 9. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05344274	Direct Measures of Retinal Blood Flow and Autoregulation as Robust Biomarkers for Early Glaucoma	90	Sep 2026 (recruiting)
NCT04646122	Predicting Glaucoma Progression with Optical Coherence Tomography Structural and Angiographic Parameters	100	Mar 2022 (recruitment status unknown)
NCT01957267	Longitudinal Observational Study Using Functional and Structural Optical Coherence Tomography to Diagnose and Guide Treatment of Glaucoma	160	Dec 2025 (recruiting)

NCT02178085	Ocular Blood Flow Assessment in Glaucoma (OBAMAg)	62	Sep 2019 (recruitment status unknown)

NCT: national clinical trial.

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 2009, the Blue Cross Blue Shield Association (BCBSA) sought clinical input to help determine whether the use of optic nerve or retinal nerve fiber layer imaging or ocular blood flow evaluation for individuals with glaucoma or suspected glaucoma would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, BCBSA received clinical input from 4 respondents, including 1 physician specialty society and 3 academic medical centers.

For individuals who have glaucoma or suspected glaucoma who receive imaging of the nerve and retinal nerve fiber layer, clinical input supports this use provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice. Most reviewers supported use of confocal scanning laser ophthalmoscopy, scanning laser polarimetry, and optical coherence tomography in the care of patients with glaucoma and those with suspected glaucoma. 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 (e.g., testing does not always need to be done with dilated pupils) and ambient light level may be (is) less critical. In addition, while serial stereo photographs 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 (2020) issued two preferred practice patterns on primary open-angle glaucoma suspect and primary open-angle glaucoma, both recommending evaluation the optic nerve and retinal nerve fiber layer.(32,33) The documents stated that stereoscopic visualization and computer based imaging of the optic nerve head and retinal nerve fiber layer provide different information about the optic nerve and are complementary. Both imaging methods are useful adjuncts as part of a comprehensive clinical examination. 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 optic nerve head and retinal nerve fiber

layer is routinely used to provide quantitative information to supplement the clinical examination of the optic nerve…. computerized imaging may be useful to distinguish between glaucomatous and nonglaucomatous retinal nerve fiber layer thinning. In addition, the Academy concluded that, as device technology evolves, the performance of diagnostic imaging devices is expected to improve.

U.S. Preventive Services Task Force Recommendations
The U.S. Preventative Task Force (USPSTF) published recommendations on screening for primary open-angle glaucoma in adults (40 years or older) in 2022.(34) Based on findings from the systematic review by Chou et al (discussed in Rationale section), the USPSTF concluded that the evidence is insufficient to assess the balance of benefits and harms of screening in these patients. This recommendation is consistent with the previous 2013 statement. With regard to screening tests, the USPSTF states: "Diagnosis of open-angle glaucoma is based on a combination of tests showing degenerative changes in the optic disc, increased IOP [intraocular pressure], and defects in visual fields... Imaging tests such as optical coherence tomography (OCT) or spectral-domain OCT (which analyzes the spectrum of reflected light on the retina) and optic disc photography (to view the optic nerve head, retina, or both) can supplement the clinical examination."

Government Regulations
National:
No national coverage decisions were identified.

Local:
Wisconsin Physicians Services Local Coverage Determination (LCD): Scanning Computerized Ophthalmic Diagnostic Imaging (SCODI) (L34760), Original Effective Date: For services performed on or after 10/01/15, Revision Effective Date: For services performed on or after 6/29/23

COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY
Medicare will consider scanning computerized ophthalmic diagnostic imaging (SCODI) medically reasonable and necessary in evaluating retinal disorders, glaucoma and anterior segment disorders as documented in this local coverage determination (LCD).

SCODI includes the following tests:
- **Confocal Laser Scanning Ophthalmoscopy (topography)** uses stereoscopic videographic digitized images to make quantitative topographic measurements of the optic nerve head and surrounding retina.
- **Scanning Laser Polarimetry (nerve fiber analyzer)** measures change in the linear polarization of light (retardation). It uses both a polarimeter (an optical device to measure linear polarization change) and a scanning laser ophthalmoscope, to measure the thickness of the nerve fiber layer of the retina.
- **Optical Coherence Tomography (OCT)** a non-invasive, non-contact imaging technique.

OCT, especially SCODI, produces high resolution, cross-sectional tomographic images of ocular structures and is used for the evaluation of the optic nerve head, nerve fiber layer, and retina.

Scanning computerized ophthalmic diagnostic imaging allows earlier detection of glaucoma and more sophisticated analysis for ongoing management. These tests also provide more precise methods of observation of the optic nerve head and can more accurately reveal subtle glaucomatous changes over the course of time than visual fields and/or disc photos. This allows earlier and more efficient efforts of treatment toward the disease process.

INDICATIONS

Glaucoma

Glaucoma is a leading cause of blindness, and a disease for which treatment methods clearly are available and in common use. Glaucoma also is diagnostically challenging. Almost 50% of glaucoma cases remain undetected. Elevated intraocular pressure is a clear risk factor for glaucoma, but over 30% of those suffering from the disease have pressures in the normal range.

Glaucoma commonly causes a spectrum of related eye and vision changes, including erosion of the optic nerve and the associated retinal nerve fibers, and also loss of peripheral vision. A diagnosis of glaucoma seldom is made on the basis of a single clinical observation, but instead relies upon analysis of an assemblage of clinical data, including: optic nerve, retinal nerve fiber, and anterior chamber structures, as well as looking for hemorrhages of the optic nerve, pigment in the anterior chamber, and especially visual field loss. Each of these methods has its own strengths and limitations, thus the dependence upon multiple observations. Careful reliance upon all available clinical data can allow early treatment and can prevent unnecessary end-stage therapies.

Scanning Computer Ophthalmic Diagnostic Imaging (SCODI) allows earlier detection of those patients with normal tension glaucoma and more sophisticated analysis for ongoing management. Because SCODI detects glaucomatous damage to the nerve fiber layer or optic nerve of the eye, it can distinguish patients with glaucomatous damage irrespective of the status of intraocular pressure (IOP). It may separate patients with elevated IOP and early glaucoma damage from those without glaucoma.

Technological improvements have rendered SCODI as a valuable diagnostic tool in the diagnosis and treatment of glaucoma. These improvements enable discernment of changes of the optic nerve and nerve fiber layer, even in advanced cases of glaucoma.

It is expected that only two (SCODI) exams/eye/year would be required to manage the patient who has glaucoma or is suspected of having glaucoma.

Retinal Disorders

Retinal disorders are the most common causes of severe and permanent vision loss. Scanning computerized ophthalmic diagnostic imaging (SCODI) is a valuable tool for the evaluation and treatment of patients with retinal disease, especially macular abnormalities. SCODI is able to detail the microscopic anatomy of the retina and the vitreo-retinal interface. SCODI is useful to measure the effectiveness of therapy, and in determining the need for ongoing therapy, or the safety of cessation of that therapy

Retinal thickness analysis is a non-invasive and non-contact imaging technique that takes

direct cross-sectional images of the retina. These high-resolution images capture ocular structures and provide data to create thickness maps of the retina. Retinal thickness is directly correlated to ocular disease, including retinal disorders and glaucoma. In contrast, Scanning Laser Polarimetry is not an appropriate diagnostic technique for the management of retinal disorders.

Long Term Use of Chloroquine (CQ) and or Hydroxychloroquine (HCQ)
Clinical evidence has shown that long-term use of chloroquine (CQ) and/or hydroxychloroquine (HCQ) can lead to irreversible retinal toxicity. Therefore, these two medications are deemed high risk, and scanning optical coherence tomography may be indicated to provide a baseline prior to starting the medication and as an annual follow-up. Clinical evidence shows that the resolution of time domain OCT instruments is not sufficient to detect early toxic retinal changes. Because of that, spectral domain-optical coherence tomography (SD-OCT) is expected to be used to detect retinal changes that are due to the use of CQ or HCQ.

Anterior Segment Disorders
SCODI may be used to examine the structures in the anterior segment structures of the eye. However, it is still seen as experimental/investigational except in the following:

- Narrow angle, suspected narrow angle, and mixed narrow and open angle glaucoma
- Determining the proper intraocular lens for a patient who has had prior refractive surgery and now requires cataract extraction
- Iris tumor
- Presence of corneal edema or opacity that precludes visualization or study of the anterior chamber
- Calculation of lens power for cataract patients who have undergone prior refractive surgery. Payment will only be made for the cataract codes as long as additional documentation is available in the patient record of their prior refractive procedure. Payment will not be made in addition to A-scan or IOL master.

Limitations
The following codes/ procedures would generally not be necessary with SCODI. When medically needed the same day, documentation must justify the procedures.

- 92250 - Fundus photography with interpretation and report
- 92225 - Ophthalmoscopy extended with retinal drawing (e.g. For retinal detachment, melanoma) with interpretation and report initial
- 92226 - Subsequent ophthalmoscopy
- 76512 - B-scan (with or without superimposed non-quantitative A-scan)

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Electroretinography (ERG), Multifocal Electroretinography (mfERG) and Pattern Electroretinography (pERG)
- Optical Coherence Tomography Imaging, Anterior Eye

- Home Monitoring Device for Age-Related Macular Degeneration
- Retinal Telescreening for Diabetic Retinopathy

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 7/25/23, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
6/4/02	6/4/02	6/4/02	Joint policy established
11/18/03	11/18/03	11/18/03	Policy retired
7/1/08	5/17/08	5/1/08	CPT code description for this policy updated; policy re-retired.
1/1/10	10/13/09	10/13/09	Policy unretired. Updated description, inclusions and exclusions.
5/1/11	2/15/11	3/3/11	Deleted CPT code 92135; added new procedure codes 92133 and 92134; references updated; rationale section expanded
9/1/12	6/12/12	6/19/12	Policy revised to incorporate Pulsatile Ocular Blood Flow and Doppler Ultrasonography; title changed from “Scanning Computerized Ophthalmic Diagnostic Imaging” to “Ophthalmologic Techniques for Evaluating Glaucoma”; description, rationale and references sections revised; codes 0198T and 93880 added to policy as experimental and investigational; added exclusion “As a method of monitoring disease progression in patients with glaucoma”.
3/1/14	12/10/13	1/6/14	Routine maintenance
7/1/15	4/24/15	5/8/15	Routine maintenance
7/15/16	4/19/16	4/19/16	Routine approval
1/1/17	10/11/16	10/11/16	Routine maintenance
1/1/18	10/19/17	10/19/17	• Routine maintenance • 0464T Added to E/I • Updated MPS, inclusions/exclusion to realign with BCBSA • Updated rationale and references
1/1/19	10/16/18	10/16/18	Routine maintenance

1/1/20	10/15/19		Routine maintenance
1/1/21	10/20/20		Routine maintenance
1/1/22	10/19/21		Routine maintenance
1/1/23	10/18/22		Routine maintenance Title changed from: Ophthalmologic techniques for evaluating glaucoma (slp)
1/1/24	10/17/23		Routine maintenance (slp) Vendor managed: N/A

Next Review Date: 4th Qtr, 2024

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: OPHTHALMOLOGIC TECHNIQUES THAT EVALUATE THE POSTERIOR SEGMENT FOR GLAUCOMA

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.