Title: Scanning Computerized Ophthalmic Diagnostic Imaging Devices

Related Policy: • Optical Coherence Tomography of the Anterior Eye Segment

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

### OBJECTIVE
The objective of this evidence review is to assess whether methods that evaluate the optic nerve and nerve fiber layer or that evaluate retinal blood flow improve the net health outcome in individuals with glaucoma or who are suspected to have 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 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 intraocular pressure (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 are considered to be a type of primary open-angle glaucoma. Angle-closure glaucoma is another type of glaucoma associated with an increase in IOP. The increased IOP in angle-closure glaucoma arises from a reduction in aqueous outflow from the eye due to a closed angle in the anterior chamber.

Conventional management of patients with glaucoma principally involves drug therapy to control elevated IOPs, and serial evaluation of the optic nerve, to follow disease progression. Standard methods of evaluation include careful direct examination of the optic nerve using ophthalmoscopy or 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 retinal nerve fiber layer 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 normal-tension glaucoma, there is never an increase in IOP. It has been proposed that vascular dysregulation is a significant cause of damage to the retinal
nerve fiber layer, 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 normal-tension glaucoma. 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, retinal nerve fiber layer, 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 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 retinal nerve fiber layer thickness. In addition, this technique does not require maximal mydriasis, which may be problematic in patients with glaucoma. The Heidelberg Retinal Tomograph is a commonly used technology.

Scanning Laser Polarimetry
The retinal nerve fiber layer is birefringent (i.e., 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 retinal nerve fiber layer thickness. Unlike confocal scanning laser ophthalmoscopy, scanning laser polarimetry can directly measure the thickness of the retinal nerve fiber layer. GDx is a common scanning laser polarimetry device. GDx contains a normative database and statistical software package that compares 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 uses near-infrared light to provide direct cross-sectional measurement of the retinal nerve fiber layer. 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. Optical coherence tomography analysis software is being developed to include optic nerve head parameters with spectral domain optical coherence tomography, analysis of macular parameters, and hemodynamic parameters with Doppler optical coherence tomography and optical coherence tomography 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 IOP. 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 optical coherence tomography, 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 optical coherence tomography 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 with 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 optical coherence tomography Avanti™ (Optovue) is an optical coherence tomography 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 optical coherence tomography 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 optical coherence tomography and 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 the 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. Ocular Imaging Devices Cleared by the U.S. Food and Drug Administration

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<tr>
<th>Device</th>
<th>Manufacturer</th>
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<td>RESCAN 700 CALLISTO eye</td>
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POLICY

A. **Scanning Laser Ophthalmoscopy (SLO)** test is allowable for the diagnosis and the monitoring of the optic nerve, retinal conditions and glaucoma. Testing may be allowed every year. If the testing is done more frequently than every year, consultant review will be required.

B. **Optical Coherence Tomography (OCT)** test is allowed for the diagnoses, listed below, monitoring for retinal conditions, and ocular toxicity secondary to high-risk medications (i.e., chloroquine [Aralen], hydroxychloroquine [Plaquenil], Interferon alpha-2b, Amiodarone, tamoxifen citrate [Nolvadex], fingolimod [Gilenya], Seroquel).

Repeat testing:
1. If Exudative Age-Related Macular Degeneration (AMD): Repeat OCT will significantly help guide the need for retreatment (with photodynamic therapy [PDT] or intravitreal injection treatments) in conjunction with intravenous fluorescein angiography (IVF) / indocyanine green (ICG). Maximum of 8 per year linked to intravitreal injections.

2. If Macular Drusen: Repeat annually, only if subjective visual changes or suspicion of choroidal neovascularization: if more than 2 studies per year, then documentation is required.

3. If Diabetic Macular Edema (DME): Maximum of 8 per year linked to intravitreal injections or laser treatment.

4. If Retinal Detachment (RD): Repeat pre-treatment and post-surgical at 2 months (maximum of 2).

5. If Epiretinal Membrane (ERM): Repeat pre-treatment and post-surgical (maximum of 4 per year) if with macular edema.

6. If Macular Hole: Repeat pre-treatment and post-treatment (maximum of 4 per year) in cases of partially closed hole.

7. If Cystoid Macular Edema: Repeat every 2 months during acute treatment.

8. If Branch Retinal Vein Occlusion (BRVO): Maximum of 8 per year linked to intravitreal injections.

9. If Central Retinal Vein Occlusion (CRVO): Maximum of 8 per year linked to intravitreal injections.

10. If Vitreomacular Traction / Adhesion: Maximum of 4 per year.

C. OCT is also allowed for diagnosing and monitoring glaucoma, nerve fiber layer, and optic nerve conditions. Testing may be allowed every year. If the testing is done more frequently than every year, consultant review will be required.
RATIONALE
This evidence review has been updated regularly with searches of the PubMed database. The most recent literature update was performed through January 22, 2021.

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

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 (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 retinal nerve fiber layer improve the net health outcome in individuals with glaucoma or suspected glaucoma?

The following PICO was used to select literature to inform this review.

Populations
The relevant population is patients with glaucoma or who are suspected to have glaucoma and are being evaluated for diagnosis and monitoring of glaucoma progression.

Interventions
The tests being considered for assessment of the optic nerve and retinal nerve fiber layer include confocal scanning laser ophthalmoscopy, scanning laser polarimetry, and optical coherence tomography. These tests are considered add-ons to the standard clinical evaluation.

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.
Comparators
There is no single criterion standard for the diagnosis of glaucoma. This diagnosis is made from a combination of visual field testing, IOP measurement, and optic nerve and retinal nerve fiber layer assessment by an ophthalmologist.

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.

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 retinal nerve fiber layer. Clinical utility might be demonstrated by a change in the management and reduction in glaucoma progression across follow-up.

Study Selection Criteria
For the evaluation of clinical validity of optic nerve and retinal nerve fiber layer imaging, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores)
- Included a suitable reference standard
- Patient/sample clinical characteristics were described
- Patient/sample selection criteria were described.

Review of Evidence

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).

Systematic Review
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 (i.e., optical coherence tomography, retinal tomography, scanning laser polarimetry), pachymetry (i.e., 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. 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 Cochrane review (2015) assessed the diagnostic accuracy of optic nerve head and retinal nerve fiber layer imaging for glaucoma. Included were 103 case-control studies and 3 cohort studies (N=16,260 eyes) that evaluated the accuracy of recent commercial versions of optical coherence tomography (spectral domain), Heidelberg Retinal Tomograph III, or scanning laser polarimetry (with the variable corneal compensator or enhanced corneal compensation) for diagnosing glaucoma. The population was 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 (optical coherence tomography, Heidelberg Retinal Tomograph III, scanning laser polarimetry) 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.

**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, 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 RCTs.

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. 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, scanning laser polarimetry, and optical coherence tomography. 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 confocal scanning laser ophthalmoscopy, scanning laser polarimetry, and optical coherence tomography 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.5

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 PICO was used to select literature to inform this review.

Populations
The relevant 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.

Interventions
The tests being considered for assessment of the ocular blood flow include color doppler imaging, Doppler Fourier domain optical coherence tomography, 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]6), investigators have commented on the complexity of these parameters7 and have noted that many of these technologies are not commonly used in clinical settings8.

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.

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.
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
For the evaluation of clinical validity of optic nerve and retinal nerve fiber layer imaging, studies that meet the following eligibility criteria were considered:

• Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores)
• Included a suitable reference standard
• Patient/sample clinical characteristics were described
• Patient/sample selection criteria were described.

Review of Evidence
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).

Nonrandomized Studies
Abegao Pinto et al (2016) reported on the results from the prospective, cross-sectional, case-control, Leuven Eye Study, which included 614 individuals who had primary open-angle glaucoma (n=214), normal tension glaucoma (n=192), ocular hypertension (n=27), suspected glaucoma (n=41), or healthy controls (n=140). 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 color doppler imaging, retinal oximetry, dynamic contour tonometry, and optical coherence tomography 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.

Kury sheva et al (2017) compared ocular blood flow with choroidal thickness to determine which had a higher diagnostic value for detecting early glaucoma. Thirty-two patients with pre-perimetric glaucoma were matched with 30 control patients. Using optical coherence
tomography, retinal nerve fiber layer 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 receiver operating characteristic curve (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 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. 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%) (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 color doppler imaging 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 1,072 controls were included. Mean values for glaucomatous eyes were within 1 standard deviation of the values for controls for most color doppler imaging parameters. Methodologic differences created interstudy variance in color doppler imaging 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.

Table 2. Summary of Key Nonrandomized Study Characteristics

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Type</th>
<th>Country</th>
<th>Date(s)</th>
<th>Participants</th>
<th>Treatment 1</th>
<th>Treatment 2</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kurysheva et al (2017)</td>
<td>Prospective</td>
<td>Russia</td>
<td>NR</td>
<td>Patients with pre-perimetric glaucoma (n=32) and age-matched controls (n=30)</td>
<td>Optical coherence tomography</td>
<td>N/A</td>
<td>NR</td>
</tr>
<tr>
<td>Witkowska et al (2017)</td>
<td>Prospective</td>
<td>Austria</td>
<td>2015-2016</td>
<td>Healthy subjects (N=27)</td>
<td>Laser speckle flowgraphy</td>
<td>N/A</td>
<td>6 minutes</td>
</tr>
</tbody>
</table>

N/A: not applicable; NR: not reported.
### Table 3. Summary of Key Nonrandomized Study Results

<table>
<thead>
<tr>
<th>Study</th>
<th>AUC and Diagnostic Value AUC p-value</th>
<th>Increase in OPP from Baseline</th>
<th>Increase in MTONH from Baseline</th>
<th>Increase in MTPPR from Baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kuryshova et al (2017)</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>MBFV in VV</td>
<td>1.0; &lt;0.0001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MBFV in CRV</td>
<td>0.85; 0.0001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DBFV in CRA</td>
<td>0.73; 0.006</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DBFV in LSPCAs</td>
<td>0.71; 0.011</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Witkowska et al (2017)</td>
<td>NR</td>
<td>78.5+/-19.8%</td>
<td>18.1+/-7.7%</td>
<td>21.1+/-8.3%</td>
</tr>
</tbody>
</table>

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.

### Table 4. Study Relevance Limitations

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcomes</th>
<th>Duration of Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kuryshova et al (2017)</td>
<td>4. Study population included healthy controls</td>
<td>3. Intervention applied to all patients; No test utilized as comparator</td>
<td>5. Adverse events of test not described</td>
<td>1. Follow-up not reported</td>
<td></td>
</tr>
<tr>
<td>Witkowska et al (2017)</td>
<td>4. Study population was healthy individuals</td>
<td>3. No test utilized as comparator</td>
<td>5. Adverse events of test not described</td>
<td>1. Follow-up evaluated short-term changes only</td>
<td></td>
</tr>
</tbody>
</table>

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

- Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
- Intervention key: 1. Classification thresholds not defined; 2. Version used unclear; 3. Not intervention of interest.
- 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.
- 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).
- 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 5. Study Design and Conduct Limitations

<table>
<thead>
<tr>
<th>Study</th>
<th>Selectiona</th>
<th>Blindingb</th>
<th>Delivery of Testc</th>
<th>Selective Reportingd</th>
<th>Data Completeness e</th>
<th>Statisticalf</th>
</tr>
</thead>
</table>
| Kuryshева et al (2017)10    | 1. Selection of patients not described  
2. Selection of control subjects was not randomized, but based on person accompanyin g patients | 1. Examiner not blinded to patient group | 4. Evaluator description not provided |                      |                     |              |
| Witkowski et al (2017)11    | 1. Selection of patients not described | 1. All patients were healthy and underwen t same treatment, therefore no blinding was utilized | |                      |                     | 2. Comparison 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.

- **Selection key:** 1. Selection not described; 2. Selection not random or consecutive (i.e., convenience).
- **Blinding key:** 1. Not blinded to results of reference or other comparator tests.
- **Delivery of Test 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.
- **Selective Reporting key:** 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
- **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.
- **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, 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 RCTs.
The clinical utility of techniques to evaluate ocular blood flow is similar to that for 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 patients 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 color doppler imaging during the baseline examination, and conversion to glaucoma was assessed at least yearly according to changes observed with confocal scanning laser ophthalmoscopy. 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, \( \kappa = 0.38 \)). 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 of the variability in visual field changes in patients with glaucoma (i.e., 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 that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION
The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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, clinical input was sought 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, clinical input was received 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 that this use provides a clinically meaningful improvement in net health outcome and indicates that this use is consistent with generally accepted medical practice. Most reviewers supported the 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**
Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

**American Academy of Ophthalmology**
In 2020, the American Academy of Ophthalmology issued 2 preferred practice patterns on primary open-angle glaucoma suspect and primary open-angle glaucoma, both recommending evaluation of the optic nerve and retinal nerve fiber layer.\(^{14,15}\) 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**
Not applicable.

**Ongoing and Unpublished Clinical Trials**
Some currently ongoing and unpublished trials that might influence this review are listed in Table 4.

**Table 6. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT04646122</td>
<td>Predicting Glaucoma Progression with Optical Coherence Tomography Structural and Angiographic Parameters</td>
<td>100</td>
<td>Mar 2022</td>
</tr>
<tr>
<td>NCT01957267</td>
<td>Longitudinal Observational Study Using Functional and Structural Optical Coherence Tomography to Diagnose and Guide Treatment of Glaucoma</td>
<td>160</td>
<td>Dec 2023</td>
</tr>
<tr>
<td>Unpublished</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02178085</td>
<td>Ocular Blood Flow Assessment in Glaucoma (OBAMAg)</td>
<td>62</td>
<td>Sep 2019</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

92133  Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral; optic nerve
92134  Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral; retina
0198T  Measurement of ocular blood flow by repetitive intraocular pressure sampling, with interpretation and report

ICD-10 Diagnoses

A18.53  Tuberculous chorioretinitis
B39.4   Histoplasmosis capsulati, unspecified
B39.9   Histoplasmosis, unspecified
C69.31  Malignant neoplasm of right choroid
C69.32  Malignant neoplasm of left choroid
D31.31  Benign neoplasm of right choroid
D31.32  Benign neoplasm of left choroid
E08.311 Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy with macular edema
E08.3211 Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, right eye
E08.3212 Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, left eye
E08.3213 Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E08.3291 Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema, right eye
E08.3292 Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema, left eye
E08.3293 Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema, bilateral
E08.3311 Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, right eye
E08.3312 Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, left eye
E08.3313 Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
E08.3391 Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy without macular edema, right eye
E08.3392 Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy without macular edema, left eye
E08.3393 Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy without macular edema, bilateral
E08.3411 Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, right eye
E08.3412 Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, left eye
E08.3413 Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, bilateral
E08.3491 Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy without macular edema, right eye
E08.3492 Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy without macular edema, left eye
E08.3493 Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy without macular edema, bilateral
E08.3511 Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, right eye
E08.3512 Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, left eye
E08.3513 Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, bilateral
E08.3514 Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye
E08.3515 Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye
E08.3516 Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral
E08.3521 Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye
E08.3522 Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye
E08.3523 Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral
E08.3531 Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye
E08.3532 Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye
E08.3533 Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral
E08.3541 Diabetes mellitus due to underlying condition with stable proliferative diabetic retinopathy, right eye
E08.3542 Diabetes mellitus due to underlying condition with stable proliferative diabetic retinopathy, left eye
E08.3543 Diabetes mellitus due to underlying condition with stable proliferative diabetic retinopathy, bilateral
E08.3544 Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema, right eye
E08.3592  Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema, left eye

E08.3593  Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema, bilateral

E08.37X1  Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment, right eye

E08.37X2  Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment, left eye

E08.37X3  Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment, bilateral

E09.311  Drug or chemical induced diabetes mellitus with unspecified diabetic retinopathy with macular edema

E09.3211 Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye

E09.3212 Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye

E09.3213 Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral

E09.3291 Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye

E09.3292 Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye

E09.3293 Drug or chemical induced diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral

E09.3311 Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye

E09.3312 Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye

E09.3313 Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral

E09.3391 Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye

E09.3392 Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye

E09.3393 Drug or chemical induced diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral

E09.3411 Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye

E09.3412 Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye

E09.3413 Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral

E09.3491 Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye

E09.3492 Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye

E09.3493 Drug or chemical induced diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral
E09.3511  Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye
E09.3512  Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye
E09.3513  Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral
E09.3521  Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye
E09.3522  Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye
E09.3523  Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral
E09.3531  Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye
E09.3532  Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye
E09.3533  Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral
E09.3551  Drug or chemical induced diabetes mellitus with stable proliferative diabetic retinopathy, right eye
E09.3552  Drug or chemical induced diabetes mellitus with stable proliferative diabetic retinopathy, left eye
E09.3591  Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye
E09.3592  Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye
E09.3593  Drug or chemical induced diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral
E09.37X1  Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment, right eye
E09.37X2  Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment, left eye
E09.37X3  Drug or chemical induced diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral
E10.311  Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E10.3211 Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E10.3212 Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
E10.3213 Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral
E10.3291 Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye
E10.3292 Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye
E10.3293 Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral
E10.3211 Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
E10.3212 Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye
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E10.3541  Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye
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E10.3543  Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral
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E10.3552  Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, left eye
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E10.3591  Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye
E10.3592  Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye
E10.3593  Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral
E10.37X1  Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye
E10.37X2  Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye
E10.37X3  Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral
E11.311  Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E11.3211  Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye
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E11.3313  Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral
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<td>Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral</td>
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<td>Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye</td>
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<td>Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye</td>
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<td>Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral</td>
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<td>Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye</td>
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<td>Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral</td>
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<td>Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye</td>
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<td>Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye</td>
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<td>Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, left eye</td>
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<td>E11.3553</td>
<td>Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral</td>
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<tr>
<td>E11.3591</td>
<td>Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye</td>
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E11.3592 Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye
E11.3593 Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral
E11.37X1 Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye
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E13.37X2  Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, left eye
E13.37X3  Other specified diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral
H21.551  Recession of chamber angle, right eye
H21.552  Recession of chamber angle, left eye
H21.553  Recession of chamber angle, bilateral
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<td>Focal chorioretinal inflammation, juxtapapillary, bilateral</td>
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<td>Focal chorioretinal inflammation of posterior pole, bilateral</td>
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<td>Focal chorioretinal inflammation, peripheral, bilateral</td>
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<td>H30.041</td>
<td>Focal chorioretinal inflammation, macular or paramacular, left eye</td>
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<td>H30.103</td>
<td>Unspecified disseminated chorioretinal inflammation, bilateral</td>
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<td>H30.111</td>
<td>Disseminated chorioretinal inflammation of posterior pole, right eye</td>
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<td>H30.112</td>
<td>Disseminated chorioretinal inflammation of posterior pole, left eye</td>
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<td>Disseminated chorioretinal inflammation of posterior pole, bilateral</td>
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<td>H30.121</td>
<td>Disseminated chorioretinal inflammation, peripheral right eye</td>
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<td>Disseminated chorioretinal inflammation, peripheral, bilateral</td>
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<td>H30.131</td>
<td>Disseminated chorioretinal inflammation, generalized, right eye</td>
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<td>H30.141</td>
<td>Acute posterior multifocal placoid pigment epitheliopathy, right eye</td>
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<td>H30.811</td>
<td>Harada's disease, right eye</td>
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<td>Harada's disease, bilateral</td>
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<td>H31.101</td>
<td>Choroidal degeneration, unspecified, right eye</td>
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<td>Choroidal degeneration, unspecified, left eye</td>
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<td>H31.103</td>
<td>Choroidal degeneration, unspecified, bilateral</td>
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<td>H31.111</td>
<td>Age-related choroidal atrophy, right eye</td>
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H31.122  Diffuse secondary atrophy of choroid, left eye
H31.123  Diffuse secondary atrophy of choroid, bilateral
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H31.322  Choroidal rupture, left eye
H31.323  Choroidal rupture, bilateral
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H31.402  Unspecified choroidal detachment, left eye
H31.403  Unspecified choroidal detachment, bilateral
H31.411  Hemorrhagic choroidal detachment, right eye
H31.412  Hemorrhagic choroidal detachment, left eye
H31.413  Hemorrhagic choroidal detachment, bilateral
H31.421  Serous choroidal detachment, right eye
H31.422  Serous choroidal detachment, left eye
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H32  Chorioretinal disorders in diseases classified elsewhere
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H33.011  Retinal detachment with single break, right eye
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H33.013  Retinal detachment with single break, bilateral
H33.021  Retinal detachment with multiple breaks, right eye
H33.022  Retinal detachment with multiple breaks, left eye
H33.023  Retinal detachment with multiple breaks, bilateral
H33.031  Retinal detachment with giant retinal tear, right eye
H33.032  Retinal detachment with giant retinal tear, left eye
H33.033  Retinal detachment with giant retinal tear, bilateral
H33.041  Retinal detachment with retinal dialysis, right eye
H33.042  Retinal detachment with retinal dialysis, left eye
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H33.051  Total retinal detachment, right eye
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H33.053  Total retinal detachment, bilateral
H33.21  Serous retinal detachment, right eye
H33.22  Serous retinal detachment, left eye
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H33.41  Traction detachment of retina, right eye
H33.42  Traction detachment of retina, left eye
H33.43  Traction detachment of retina, bilateral
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H34.8111 Central retinal vein occlusion, right eye, with retinal neovascularization
H34.8112 Central retinal vein occlusion, right eye, stable
H34.8120 Central retinal vein occlusion, left eye, with macular edema
H34.8121 Central retinal vein occlusion, left eye, with retinal neovascularization
H34.8122 Central retinal vein occlusion, left eye, stable
H34.8130 Central retinal vein occlusion, bilateral, with macular edema
H34.8131 Central retinal vein occlusion, bilateral, with retinal neovascularization
H34.8132 Central retinal vein occlusion, bilateral, stable
H34.8310 Tributary (branch) retinal vein occlusion, right eye, with macular edema
H34.8311 Tributary (branch) retinal vein occlusion, right eye, with retinal neovascularization
H34.8312 Tributary (branch) retinal vein occlusion, right eye, stable
H34.8320 Tributary (branch) retinal vein occlusion, left eye, with macular edema
H34.8321 Tributary (branch) retinal vein occlusion, left eye, with retinal neovascularization
H34.8322 Tributary (branch) retinal vein occlusion, left eye, stable
H34.8330 Tributary (branch) retinal vein occlusion, bilateral, with macular edema
H34.8331 Tributary (branch) retinal vein occlusion, bilateral, with retinal neovascularization
H34.8332 Tributary (branch) retinal vein occlusion, bilateral, stable
H35.051 Retinal neovascularization, unspecified, right eye
H35.052 Retinal neovascularization, unspecified, left eye
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H35.31 Nonexudative age-related macular degeneration
H35.3110 Nonexudative age-related macular degeneration, right eye, stage unspecified
H35.3111 Nonexudative age-related macular degeneration, right eye, early dry stage
H35.3112 Nonexudative age-related macular degeneration, right eye, intermediate dry stage
H35.3113 Nonexudative age-related macular degeneration, right eye, advanced atrophic without subfoveal involvement
H35.3114 Nonexudative age-related macular degeneration, right eye, advanced atrophic with subfoveal involvement
H35.3120 Nonexudative age-related macular degeneration, left eye, stage unspecified
H35.3121 Nonexudative age-related macular degeneration, left eye, early dry stage
H35.3122 Nonexudative age-related macular degeneration, left eye, intermediate dry stage
H35.3123 Nonexudative age-related macular degeneration, left eye, advanced atrophic without subfoveal involvement
H35.3124 Nonexudative age-related macular degeneration, left eye, advanced atrophic with subfoveal involvement
H35.3130 Nonexudative age-related macular degeneration, bilateral, stage unspecified
H35.3131 Nonexudative age-related macular degeneration, bilateral, early dry stage
H35.3132 Nonexudative age-related macular degeneration, bilateral, intermediate dry stage
H35.3133 Nonexudative age-related macular degeneration, bilateral, advanced atrophic without subfoveal involvement
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H35.3210 Exudative age-related macular degeneration, right eye, stage unspecified
H35.3211 Exudative age-related macular degeneration, right eye, with active choroidal neovascularization
H35.3212 Exudative age-related macular degeneration, right eye, with inactive choroidal neovascularization
H35.3213 Exudative age-related macular degeneration, right eye, with inactive scar
H35.3220 Exudative age-related macular degeneration, left eye, stage unspecified
H35.3221 Exudative age-related macular degeneration, left eye, with active choroidal neovascularization
H35.3222 Exudative age-related macular degeneration, left eye, with inactive choroidal neovascularization
H35.3223 Exudative age-related macular degeneration, left eye, with inactive scar
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<td>H35.3233</td>
<td>Exudative age-related macular degeneration, bilateral, with inactive scar</td>
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<td>Macular cyst, hole, or pseudohole, right eye</td>
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<td>Macular cyst, hole, or pseudohole, left eye</td>
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<td>H35.343</td>
<td>Macular cyst, hole, or pseudohole, bilateral</td>
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<td>Cystoid macular degeneration, right eye</td>
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<td>H35.352</td>
<td>Cystoid macular degeneration, left eye</td>
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<tr>
<td>H35.353</td>
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<tr>
<td>H35.361</td>
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<td>Drusen (degenerative) of macula, left eye</td>
</tr>
<tr>
<td>H35.363</td>
<td>Drusen (degenerative) of macula, bilateral</td>
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<td>H35.371</td>
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<td>H35.373</td>
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<td>H35.53</td>
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<tr>
<td>H35.54</td>
<td>Dystrophies primarily involving the retinal pigment epithelium</td>
</tr>
<tr>
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<td>H35.89</td>
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<td>H40.002</td>
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<td>Open angle with borderline findings, high risk, right eye</td>
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<td>H40.022</td>
<td>Open angle with borderline findings, high risk, left eye</td>
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<td>H40.023</td>
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<td>H40.043</td>
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<td>H40.051</td>
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<td>H40.053</td>
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H40.1411  Capsular glaucoma with pseudoexfoliation of lens, right eye, mild stage
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H40.1421  Capsular glaucoma with pseudoexfoliation of lens, left eye, mild stage
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<td>H40.1424</td>
<td>Capsular glaucoma with pseudoexfoliation of lens, left eye, indeterminate stage</td>
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<td>Capsular glaucoma with pseudoexfoliation of lens, bilateral, mild stage</td>
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<td>Capsular glaucoma with pseudoexfoliation of lens, bilateral, moderate stage</td>
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<td>Capsular glaucoma with pseudoexfoliation of lens, bilateral, severe stage</td>
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<td>H40.1434</td>
<td>Capsular glaucoma with pseudoexfoliation of lens, bilateral, indeterminate stage</td>
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<td>Residual stage of open-angle glaucoma, bilateral</td>
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<td>Chronic angle-closure glaucoma, left eye, indeterminate stage</td>
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<td>Chronic angle-closure glaucoma, bilateral, moderate stage</td>
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<td>H40.231</td>
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<td>Intermittent angle-closure glaucoma, left eye</td>
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<td>Intermittent angle-closure glaucoma, bilateral</td>
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<td>H40.241</td>
<td>Residual stage of angle-closure glaucoma, right eye</td>
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<td>H40.243</td>
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<td>Glaucoma secondary to eye trauma, right eye, mild stage</td>
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<td>Glaucoma secondary to eye trauma, right eye, moderate stage</td>
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<td>Glaucoma secondary to eye trauma, right eye, severe stage</td>
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<td>Glaucoma secondary to eye trauma, right eye, indeterminate stage</td>
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<td>Glaucoma secondary to eye trauma, bilateral, mild stage</td>
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<td>H40.41X1</td>
<td>Glaucoma secondary to eye inflammation, right eye, mild stage</td>
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H40.42X2  Glaucoma secondary to eye inflammation, left eye, moderate stage  
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H40.42X4  Glaucoma secondary to eye inflammation, left eye, indeterminate stage  
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H40.53X1  Glaucoma secondary to other eye disorders, bilateral, mild stage  
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Contains Public Information*
REVISIONS

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<tr>
<td>04-19-2007</td>
<td>Added the indications for OCT use for diagnosing and monitoring glaucoma, nerve fiber, and optic nerve conditions.</td>
</tr>
<tr>
<td>05-09-2007</td>
<td>The policy section was updated to split the first bullet under B. to create two bullets, one for age-related macular degeneration and one for diabetic macular edema and to set a maximum number of OCT services per year for each.</td>
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<tr>
<td>04-30-2010</td>
<td>In Policy Section:</td>
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<tr>
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<td>• Revised repeat testing For Diabetic Macular Edema (DME), from &quot;Repeat every 2 or 3 months&quot; to &quot;Repeat every 3 or 4 months&quot;</td>
</tr>
<tr>
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<td>• Revised repeat testing For Epiretinal Membrane (ERM) from &quot;pre-treatment and post-surgical at 3 months, 6 months&quot; to &quot;pre-treatment and post-surgical after 6 weeks, 6 months&quot;.</td>
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<tr>
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<td>• Added &quot;If Cystoid Macular Edema: Repeat every 2 months during acute treatment.&quot;</td>
</tr>
<tr>
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<td>• Added &quot;If Branch Retinal Vein Occlusion: Repeat every 3 or 4 months indefinitely.&quot;</td>
</tr>
<tr>
<td></td>
<td>• Added &quot;If Central Retinal Vein Occlusion: Repeat every 3 or 4 months for approximately 2 years&quot;</td>
</tr>
<tr>
<td></td>
<td>• Added &quot;If Macular Drusen: Repeat annually, allowing one study by treating MD / DO per year.&quot;</td>
</tr>
<tr>
<td></td>
<td>• Corrected wording of &quot;treating MD / OD&quot; to &quot;treating MD / DO&quot;</td>
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<tr>
<td>10-26-2010</td>
<td>In Policy Section:</td>
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<td></td>
<td>• Item A, inserted &quot;, retinal conditions&quot; to read &quot;Scanning Laser Ophthalmoscopy (SLO) test is allowable for the diagnoses and the monitoring of the optic nerve, retinal conditions, and glaucoma.&quot;</td>
</tr>
<tr>
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<td>• Item B, #1 through #3, removed &quot;by treating MD/DO&quot; to read:</td>
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<td></td>
<td>1. If Exudative Age-related Macular Degeneration (AMD): Repeat OCT will significantly help guide the need for retreatment (with photodynamic therapy [PDT] or intravitreal injections) in conjunction with intravenous fluorescein angiography (IVF) / indocyanine green (ICG). Maximum of 8 per year linked to intravitreal injections.</td>
</tr>
<tr>
<td></td>
<td>2. If Diabetic Macular Edema (DME): Repeat 3 or 4 months (maximum of 4 per year linked to intravitreal injections / or laser treatment.</td>
</tr>
<tr>
<td></td>
<td>3. If Retinal Detachment (RD): Repeat pre-treatment and post-surgical at 2 months (maximum of 2).</td>
</tr>
<tr>
<td></td>
<td>4. If Epiretinal Membrane (ERM): Repeat pre-treatment and post-surgical after 6 weeks, 6 months (maximum of 3) if with macular edema.</td>
</tr>
<tr>
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<td>• Item B, #7, replaced &quot;indefinitely,&quot; with &quot;for approximately two years.&quot; To read &quot;Repeat every 3 or 4 months for approximately two years.&quot;</td>
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</table>
|            | • Item B, #9, replaced "allowing one study by treating MD/DO per year" with "if subjective visual changes or suspicion of choroidal neovascularization: if more than
two studies per year, then documentation is required" to read "Repeat annually, if subjective visual changes or suspicion of choroidal neovascularization: if more than two studies per year, then documentation is required."

<table>
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<tr>
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<td>02-16-2011</td>
<td>In Coding section:</td>
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<tr>
<td></td>
<td>• Added CPT codes: 92133, 92134, 92227, 92228.</td>
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<tr>
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<td>• Removed CPT code: 92135.</td>
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<tr>
<td>01-01-2012</td>
<td>In the Coding section:</td>
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<td>• Removed HCPCS code: S0625</td>
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<td>01-15-2013</td>
<td>In the Policy section:</td>
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<td>• In Item B, revised the following statement, &quot;Optical Coherence (OCT) test is allowed for the diagnoses and the monitoring for retinal conditions.&quot; to &quot;Optical Coherence (OCT) test is allowed for the diagnoses, listed below, monitoring for retinal conditions, and ocular toxicity secondary to high-risk medications (i.e., chloroquine [Aralen], hydroxychloroquine [Plaquenil], Interferon alpha-2b, Amiodarone, tamoxifen citrate [Nolvadex], fingolimod [Gilenya], Seroquel).&quot;</td>
</tr>
<tr>
<td></td>
<td>• In Coding section:</td>
</tr>
<tr>
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<td>• Added Diagnosis codes: 362.57, 379.21, V58.69.</td>
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<tr>
<td>01-22-2013</td>
<td>Corrections were made to the Current Effective Date and the Revision Date section.</td>
</tr>
<tr>
<td>07-30-2013</td>
<td>In Policy section:</td>
</tr>
<tr>
<td></td>
<td>• Item B, 9 moved to become new #2.</td>
</tr>
<tr>
<td></td>
<td>• In new Item B, 2, inserted &quot;only&quot; to read &quot;Repeat annually, only if subjective visual changes...&quot;</td>
</tr>
<tr>
<td></td>
<td>In Coding section:</td>
</tr>
<tr>
<td></td>
<td>• Added ICD-10 Diagnosis codes (Effective October 1, 2014)</td>
</tr>
<tr>
<td>04-28-2015</td>
<td>Updated Description section.</td>
</tr>
<tr>
<td></td>
<td>Added Rationale section.</td>
</tr>
<tr>
<td></td>
<td>In Coding section:</td>
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<tr>
<td></td>
<td>• Added 377.14 to ICD-9 Diagnosis codes</td>
</tr>
<tr>
<td></td>
<td>• Added H47.231-H47.233 to ICD-10 Diagnosis codes.</td>
</tr>
<tr>
<td>08-19-2015</td>
<td>Updated References section.</td>
</tr>
<tr>
<td></td>
<td>In Coding section:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>Policy details</th>
</tr>
</thead>
</table>

In Coding section:
- Added ICD-10 diagnosis codes: H40.021, H40.022, H40.023, H40.31X1, H40.31X2, H40.31X3, H40.31X4, H40.32X1, H40.32X2, H40.32X3, H40.32X4, H40.33X1, H40.33X2, H40.33X3, H40.33X4, H40.41X1, H40.41X2, H40.41X3, H40.41X4, H40.42X1, H40.42X2, H40.42X3, H40.42X4, H40.43X1, H40.43X2, H40.43X3, H40.43X4.

In Coding section:

Updated References section.

10-12-2016
- Updated Description section.
- Updated Rationale section.
- Updated References section.

05-12-2017
- Updated Description section.
- In Policy section:
  - In Item B, removed "diagnosis" and "and the" and added "diagnoses, listed below" and ", and ocular toxicity secondary to high-risk medications (i.e., chloroquine [Aralen], hydroxychloroquine [Plaquenil], Interferon alpha-2b, Amiodarone, tamoxifen citrate [Nolvadex], fingolimod [Gilenya], Seroquel)" to read, "Optical Coherence Tomography (OCT) test is allowed for the diagnoses, listed below, and the monitoring for retinal conditions, and ocular toxicity secondary to high-risk medications (i.e., chloroquine [Aralen], hydroxychloroquine [Plaquenil], Interferon alpha-2b, Amiodarone, tamoxifen citrate [Nolvadex], fingolimod [Gilenya], Seroquel)." (These revisions to policy language were inadvertently removed in the revision of 07-30-2013.)
- Updated Rationale section.
- In Coding section:
  - Added CPT code: 0198T.
  - Removed CPT codes: 92227, 92228.
  - Added ICD-10 codes: H33.001, H33.002, H33.003, H33.011, H33.012, H33.013, H33.021, H33.022, H33.023, H33.031, H33.032, H33.033, H33.041, H33.042, H33.043, H33.051, H33.052, H33.053, H35.50, H35.51, H35.53, H35.54, H43.811, H43.812, H43.813, H47.031, H47.032, H47.033, H47.20, H47.211, H47.212, H47.213, H47.22, H47.291, H47.292, H47.293, H47.321, H47.322, H47.323, H47.331, H47.332, H47.333, H47.391, H47.392, H47.393.
- In Revision section, revision date was changed from "01-15-2012" to "01-15-2013."
- Updated References section.

10-01-2017
- In Coding section:
  - Added ICD-10 codes: H44.2A1, H44.2A2, H44.2A3, H44.2B1, H44.2B2, H44.2B3, H44.2C1, H44.2C2, H44.2C3, H44.2D1, H44.2D2, H44.2D3, H44.2E1, H44.2E2, H44.2E3.

04-11-2018
- Updated Description section.
- Updated Rationale section.
- In Coding section:
  - Removed ICD-9 codes.
- Updated References section.

08-01-2018
- In Policy section:
  - Added new Item B 10, "If Vitreomacular Traction / Adhesion: Maximum of 4 per year."
- In Coding section:
  - Added ICD-10 codes: H43.821, H43.822, H43.823.
- Updated References section.

04-15-2019
- In Coding section:
• Added ICD-10 code: H35.051.

09-27-2019
Policy published to the bcbksks.com website on 08-28-2019 with an effective date of 09-29-2019.

In Coding section:
• Added ICD-10 codes: H59.031, H59.032, H59.033.

05-05-2021
Updated Description section.
Updated Rationale section.
Updated References section.

REFERENCES


Other References
2. Blue Cross and Blue Shield of Kansas Ophthalmology Liaison Committee minutes, May 9, 2007.
6. Blue Cross and Blue Shield of Kansas Optometry Liaison Committee, June 2010; May 2013; August 2016.
7. Blue Cross and Blue Shield of Kansas Ophthalmology/Optometry Liaison Committee, February 2017; May 2018; August 2019.