

## FEP 9.03.06 Ophthalmologic Techniques That Evaluate the Posterior Segment for Glaucoma

**Effective Date:** July 15, 2018

**Related Policies:**

9.03.18 Optical Coherence Tomography of the Anterior Eye Segment

### Ophthalmologic Techniques That Evaluate the Posterior Segment for Glaucoma

#### 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.

#### FDA REGULATORY STATUS

A number of CSLO, SLP, and OCT devices have been cleared by the U.S. Food and Drug Administration (FDA) through the 510(k) process for imaging the posterior eye segment. For example, the RTVue XR OCT Avanti™ (Optovue) is an OCT system indicated for the in vivo imaging and measurement of the retina, RNFL, 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, RNFL, and optic disc 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 and Avanti™ with AngioVue™ Software was cleared by FDA through the 510(k) process (K153080) as an aid in the visualization of vascular structures of the retina and choroid. FDA product code: HLI, OBO.

In 2012, the iExaminer™ (Welch Allyn) was cleared for marketing by FDA through the 510(k) process. The iExaminer™ consists of a hardware adapter and associated software (iPhone® App) to capture, store, send, and retrieve images from the PanOptic™ Ophthalmoscope (Welch Allyn) using an iPhone. FDA product code: HKI.

#### POLICY STATEMENT

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

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

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### POLICY GUIDELINES

This policy addresses techniques used to evaluate for glaucoma and does not address other ophthalmic conditions.

### BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

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

### RATIONALE

#### Summary of Evidence

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

For individuals who have glaucoma or suspected glaucoma who receive evaluation of ocular blood flow, the evidence includes association studies. Relevant outcomes are test accuracy, symptoms, morbid events, functional outcomes, and medication use. Techniques to measure ocular blood flow or ocular blood velocity are used to determine appropriate glaucoma treatment options. The data for these techniques remain limited. Literature reviews have not identified studies 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, ie, they may help explain why patients with similar levels of IOP develop markedly different visual impairments. However, data on use of ocular blood flow, pulsatile ocular blood flow, and/or blood flow velocity are currently lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

### SUPPLEMENTAL INFORMATION

#### Practice Guidelines and Position Statements

##### American Academy of Ophthalmology

The American Academy of Ophthalmology issued 2 preferred practice patterns (2015) on primary open-angle glaucoma suspect and primary open-angle glaucoma, both recommending evaluation of the optic nerve and retinal nerve fiber layer (RNFL).<sup>16,17</sup> The documents stated that “Although they are distinctly different methodologies, stereoscopic disc photographs and computerized images of the nerve are complementary with regard to the information they provide the clinician who must manage the patient.” The guidelines described 3 types of computer-based imaging devices (confocal scanning laser ophthalmoscopy, scanning laser polarimetry, optical coherence tomography) currently available for

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glaucoma, which are similar in their ability to distinguish glaucoma from controls and noted that “computer-based digital imaging of the ONH [optic nerve head] and RNFL is routinely used to provide quantitative information to supplement the clinical examination of the optic nerve.... One rationale for using computerized imaging is to distinguish glaucomatous damage from eyes without glaucoma when thinning of the RNFL is measured, thereby facilitating earlier diagnosis and detection of optic nerve damage”. In addition, 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.

### Medicare National Coverage

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

### REFERENCES

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### POLICY HISTORY

Date	Action	Description
June 2012	New Policy	
June 2013	Update Policy	Policy updated with literature review with references 9 and 21 added. Policies statements unchanged.
June 2014	Update Policy	Policy updated with literature review reference 21 added; policy statements unchanged.
June 2015	Update Policy	Policy updated with literature review, adding reference 26. Policy statements are unchanged.
September 2016	Update Policy	Policy updated with literature review; reference 9 added; references 24-25 updated. Policy statements unchanged.
June 2018	Update Policy	Policy updated with literature review through January 8, 2018; references 1, 11 and 12-13 added; some references removed. Doppler ultrasonography removed from the second policy statement. The intent of the policy statement is unchanged. Title changed to "Ophthalmologic Techniques That Evaluate the Posterior Eye Segment for Glaucoma."

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