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FEP Medical Policy Manual

FEP 9.03.06 Ophthalmologic Techniques That Evaluate the Posterior Segment for Glaucoma

Effective Policy Date: July 1, 2023

Original Policy Date: June 2012

Related Policies:

9.03.18 - Optical Coherence Tomography of the Anterior Eye Segment

Ophthalmologic Techniques That Evaluate the Posterior Segment for Glaucoma

Description

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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 retinal nerve fiber layer or that evaluate ocular blood flow improve the net health outcome in individuals with glaucoma or who are suspected to have glaucoma.

POLICY STATEMENT

Analysis of the optic nerve and retinal nerve fiber layer in the diagnosis and evaluation of individuals 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 individuals with glaucoma.

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.

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

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

Device	Manufacturer	Date Cleared	510.k No.	Indication
SOLIX	Optovue Inc.	11/9/2022	K222166	Imaging of optic nerve and retinal nerve fiber layer
RESCAN 700 CALLISTO eye	Carl Zeiss Meditec AG	1/11/2019	K180229	Imaging of optic nerve and retinal nerve fiber layer
Retina Workplace	Carl Zeiss Meditec Inc	10/24/2018	K182318	Imaging of optic nerve and retinal nerve fiber layer
Spectralis HRA+OCT and variants with High Magnification Module	Heidelberg Engineering GmbH	10/18/2018	K182569	Imaging of optic nerve and retinal nerve fiber layer
Spectralis HRA+OCT and variants with OCT Angiography Module	Heidelberg Engineering GmbH	9/13/2018	K181594	Imaging of optic nerve and retinal nerve fiber layer

Spectralis HRA + OCT and variants	Heidelberg Engineering GmbH	8/30/2018	K173648	Imaging of optic nerve and retinal nerve fiber layer
Image Filing Software NAVIS-EX	Nidek Co. Ltd	7/19/2018	K181345	Imaging of optic nerve and retinal nerve fiber layer
Avanti	Optovue Inc.	6/8/2018	K180660	Imaging of optic nerve and retinal nerve fiber layer
P200TE	Optos plc	2/28/2018	K173707	Imaging of optic nerve and retinal nerve fiber layer
DRI OCT Triton	Topcon Corporation	1/19/2018	K173119	Imaging of optic nerve and retinal nerve fiber layer
IMAGEnet 6 Ophthalmic Data System	Topcon Corporation	11/1/2017	K171370	Imaging of optic nerve and retinal nerve fiber layer
Spectralis HRA + OCT and variants Spectralis FA+OCT Spectralis ICGA+OCT Spectralis OCT Blue Peak Spectralis OCT with Multicolor	Heidelberg Engineering GmbH	11/1/2017	K172649	Imaging of optic nerve and retinal nerve fiber layer
PRIMUS	Carl Zeiss Suzhou Co. Ltd.	6/21/2017	K163195	Imaging of optic nerve and retinal nerve fiber layer
Retina Workplace	Carl Zeiss Meditec AG	6/21/2017	K170638	Imaging of optic nerve and retinal nerve fiber layer
iVue	Optovue Inc.	6/9/2017	K163475	Imaging of optic nerve and retinal nerve fiber layer
3D OCT-1 Maestro	Topcon Corporation	3/3/2017	K170164	Imaging of optic nerve and retinal nerve fiber layer
EnFocus 2300 EnFocus 4400	Bioptigen Inc.	12/9/2016	K162783	Imaging of optic nerve and retinal nerve fiber layer
PLEX Elite 9000 SS-OCT	CARL ZEISS MEDITEC INC.	10/26/2016	K161194	Imaging of optic nerve and retinal nerve fiber layer
3D OCT-1 Maestro	Topcon Corporation	7/28/2016	K161509	Imaging of optic nerve and retinal nerve fiber layer
LSFG-NAVI	Softcare Co. Ltd	5/12/2016	K153239	Imaging of optic nerve and retinal nerve fiber layer

Spectralis HRA + OCT and variants (e.g.s below) Spectralis FA+OCT Spectralis ICGA+OCT Spectralis OCT Blue Peak Spectralis OCT with Multicolor	Heidelberg Engineering GmbH	5/6/2016	K152205	Imaging of optic nerve and retinal nerve fiber layer
RTVue XR OCT Avanti with AngioVue Software	OPTOVUE INC.	2/11/2016	K153080	Imaging of optic nerve and retinal nerve fiber layer
EnFocus 2300 EnFocus 4400	BIOPTIGEN INC.	12/2/2015	K150722	Imaging of optic nerve and retinal nerve fiber layer
Optical Coherence Tomography	CARL ZEISS MEDITEC INC	9/1/2015	K150977	Imaging of optic nerve and retinal nerve fiber layer
OCT-Camera	OptoMedical Technologies GmbH	3/4/2015	K142953	Imaging of optic nerve and retinal nerve fiber layer
RESCAN 700 CALLISTO EYE	CARL ZEISS MEDITEC AG	11/18/2014	K141844	Imaging of optic nerve and retinal nerve fiber layer
PROPPER INSIGHT BINOCULAR INDIRECT OPHTHALMOSOPE	PROPPER MANUFACTURING CO.INC.	9/17/2014	K141638	Imaging of optic nerve and retinal nerve fiber layer
CENTERVUE MACULAR INTEGRITY ASSESSMENT	CENTERVUE SPA	4/23/2014	K133758	Imaging of optic nerve and retinal nerve fiber layer
AMICO DH-W35 OPHTHALMOSCOPE SERIES	AMICO DIAGNOSTIC INCORPORATED	3/26/2014	K131939	Imaging of optic nerve and retinal nerve fiber layer
IVUE 500	OPTOVUE INC.	3/19/2014	K133892	Imaging of optic nerve and retinal nerve fiber layer
RS-3000 ADVANCE	NIDEK CO. LTD.	2/19/2014	K132323	Imaging of optic nerve and retinal nerve fiber layer

RATIONALE

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 the use of topical medication, monitoring, and surgery to lower intraocular pressure. Thus, an 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 an 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 intraocular pressure develop markedly different visual impairments). However, data on the 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

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.[32,33,] The documents stated that stereoscopic visualization and computer-based imaging of the optic nerve head and retinal nerve fiber layer provide different information about the optic nerve and are complementary. Both imaging methods are useful adjuncts as part of a comprehensive clinical examination. The guidelines described 3 types of computer-based imaging devices (confocal scanning laser ophthalmoscopy, scanning laser polarimetry, optical coherence tomography) currently available for glaucoma, which are similar in their ability to distinguish glaucoma from controls and noted that "computer-based digital imaging of the optic nerve head and retinal nerve fiber layer is routinely used to provide quantitative information to supplement the clinical examination of the optic nerve.... computerized imaging may be useful to distinguish between glaucomatous and nonglaucomatous retinal nerve fiber layer thinning." In addition, the Academy concluded that, as device technology evolves, the performance of diagnostic imaging devices is expected to improve.

U.S. Preventive Services Task Force Recommendations

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

Medicare National Coverage

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

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
June 2012	New policy	
June 2013	Replace policy	Policy updated with literature review with references 9 and 21 added. Policies statements unchanged.
June 2014	Replace policy	Policy updated with literature review reference 21 added; policy statements unchanged.
June 2015	Replace policy	Policy updated with literature review, adding reference 26. Policy statements are unchanged.
September 2016	Replace policy	Policy updated with literature review; reference 9 added; references 24- 25 updated. Policy statements unchanged.
June 2018	Replace 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.,
June 2019	Replace policy	Policy updated with literature review through January 6, 2019; no references added. Policy statements unchanged.
June 2020	Replace policy	Policy updated with literature review through January 9, 2020; no references added. Policy statements unchanged.
June 2021	Replace policy	Policy updated with literature review through January 22, 2021; no references added. Policy statements unchanged.
June 2022	Replace policy	Policy updated with literature review through January 26, 2022; references added. Policy statements unchanged.
June 2023	Replace policy	Policy updated with literature review through January 10, 2023; references added. Minor editorial refinements to policy statements; intent unchanged.