BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Ophthalmologic Techniques That Evaluate the Posterior Segment for Glaucoma

Policy: #465
Category: Medical

Latest Review Date: March 2020
Policy Grade: C

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service March, 24, 2020, and after:

Blue Advantage will treat **analysis of the optic nerve (retinal nerve fiber layer) in the diagnosis and evaluation of patients with glaucoma or glaucoma suspects** as a **covered benefit** when using scanning laser ophthalmoscopy, scanning laser polarimetry, and optical coherence tomography. (This test is usually not considered non-covered more than one per 12 months.)

Blue Advantage will treat **measurement of ocular blood flow, pulsatile ocular blood flow or blood flow velocity with Doppler ultrasonography** as a **non-covered benefit** and **investigational** in the diagnosis and follow-up of patients with glaucoma.

Effective for dates of service February 26, 2018, through March 23, 2020, refer to LCD L34555.

Effective for dates of service prior to February 26, 2018:

Blue Advantage will treat **analysis of the optic nerve (retinal nerve fiber layer) in the diagnosis and evaluation of patients with glaucoma or glaucoma suspects** as a **covered benefit** when using scanning laser ophthalmoscopy, scanning laser polarimetry, and optical coherence tomography. (This test is usually not considered medically necessary more than one per 12 months.)

Blue Advantage will treat the **measurement of ocular blood flow, pulsatile ocular blood flow or blood flow velocity with Doppler ultrasonography** as a **non-covered benefit** and as **investigational** in the diagnosis and follow-up of patients with glaucoma.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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

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. Diagnosis of angle-closure glaucoma is detailed in *MP 311 Optical Coherence Tomography of the Anterior Eye Segment.*

Conventional management of patients with glaucoma principally involves drug therapy to control elevated IOPs, and serial evaluation of the optic nerve, to follow disease progression. Standard methods of evaluation include careful direct examination of the optic nerve using ophthalmoscopy or stereophotography, or evaluation of visual fields. There is interest in developing more objective, reproducible techniques both to document optic nerve damage and to detect early changes in the optic nerve and retinal nerve fiber layer (RNFL) before the development of permanent visual field deficits. Specifically, evaluating changes in RNFL thickness has been investigated as a technique to diagnose and monitor glaucoma. However, IOP reduction is not effective in decreasing disease progression in a significant number of patients, and in patients with 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 RNFL, and there is interest in measuring ocular blood flow as both a diagnostic and a management tool for glaucoma. Changes in blood flow to the retina and choroid may be particularly relevant for diagnosis and treatment of 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, RNFL, or blood flow to the retina and choroid in patients with glaucoma.)

Techniques to Evaluate the Optic Nerve and Retinal Nerve Fiber Layer

Confocal Scanning Laser Ophthalmoscopy

Confocal scanning laser ophthalmoscopy (CSLO) is an image acquisition technique intended to improve the quality of the eye examination compared with standard ophthalmologic examination. A laser is scanned across the retina along with a detector system. Only a single spot on the retina is illuminated at any time, resulting in a high-contrast image of great reproducibility that can be used to estimate RNFL thickness. In addition, this technique does not require maximal mydriasis, which may be problematic in patients with glaucoma. The Heidelberg Retinal Tomograph is a commonly used technology.

Scanning Laser Polarimetry

The RNFL is birefringent (or biorefractive), meaning that it causes a change in the state of polarization of a laser beam as it passes. A 780-nm diode laser is used to illuminate the optic nerve. The polarization state of the light emerging from the eye is then evaluated and correlated with RNFL thickness. Unlike CSLO, scanning laser polarimetry (SLP) can directly measure the

thickness of the RNFL. GDx is a common SLP device. GDx contains a normative database and statistical software package that compare scan results with age-matched normal subjects of the same ethnic origin. The advantages of this system are that images can be obtained without pupil dilation and evaluation can be completed in 10 minutes. Current instruments have added enhanced and variable corneal compensation technology to account for corneal polarization.

Optical Coherence Tomography
Optical coherence tomography (OCT) uses near-infrared light to provide direct cross-sectional measurement of the RNFL. The principles employed are similar to those used in B-mode ultrasound except light, not sound, is used to produce the 2-dimensional images. The light source can be directed into the eye through a conventional slit-lamp biomicroscope and focused onto the retina through a typical 78-diopter lens. This system requires dilation of the patient's pupil. OCT analysis software is being developed to include optic nerve head parameters with spectral domain OCT, analysis of macular parameters, and hemodynamic parameters with Doppler OCT and OCT angiography.

Pulsatile Ocular Blood Flow
The pulsatile variation in ocular pressure results from the flow of blood into the eye during cardiac systole. Pulsatile ocular blood flow can thus be detected by the continuous monitoring of intraocular pressure. The detected pressure pulse can then be converted into a volume measurement using the known relationship between ocular pressure and ocular volume. Pulsatile blood flow is primarily determined by the choroidal vessels, particularly relevant to patients with glaucoma, since the optic nerve is supplied in large part by the choroidal circulation.

Techniques to Measure Ocular Blood Flow
A number of techniques have been developed to assess ocular blood flow. They include laser speckle flowgraphy, color Doppler imaging, Doppler Fourier domain OCT, laser Doppler velocimetry, confocal scanning laser Doppler flowmetry, and retinal functional imaging.

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 velocity in the retinal and choroidal arteries. This technique delivers ultrasound in pulsed Doppler mode with a transducer set on closed eyelids. The examination takes 30 to 40 minutes, and is most effective for the mean velocity of large ophthalmic vessels such as the ophthalmic artery, the central retinal artery, and the short posterior ciliary arteries. However, total blood flow cannot be determined with this technique, and imaging is highly dependent on probe placement.

Doppler Fourier Domain OCT
Doppler Fourier domain OCT is a noncontact imaging technique that detects the intensity of the light scattered back from erythrocytes as they move in the vessels of the ocular tissue. This induces a frequency shift that represents the velocity of the blood in the ocular tissue.

Laser Doppler Velocimetry
Laser Doppler velocimetry compares the frequency of reflected laser light from a moving particle to stationary tissue.

Confocal Scanning Laser Doppler Flowmetry
Confocal scanning laser Doppler flowmetry combines laser Doppler flowmetry with confocal scanning laser tomography. Infrared laser light is used to scan the retina, and the frequency and amplitude of Doppler shifts are determined from the reflected light. Determinations of blood velocity and blood volume are used to compute the total blood flow and create a physical map of retinal flow values.

KEY POINTS:
The most recent literature search was performed through January 9, 2020.

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, i.e., 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.

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). The documents stated that "Although they are distinctly different methodologies, stereoscopic disc photographs and computerized images of the nerve are complementary with regard to the information they provide the clinician who must manage the patient." The guidelines described 3 types of computer-based imaging devices (confocal scanning laser ophthalmoscopy, scanning laser polarimetry, optical coherence tomography) currently available for glaucoma, which are similar in their ability to distinguish glaucoma from controls and noted that "computer-based digital imaging of the ONH [optic nerve head] and RNFL 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.

KEY WORDS:
Doppler ultrasonography, glaucoma, GDx, Glaucoma scope, Heidelberg Retinal Tomograph, Nerve Fiber Analyzer, Ophthalmologic Evaluation, Glaucoma, Optic Nerve Head Analyzer, Optical Coherence Tomography, Pulsatile Ocular Blood Flow, Retinal Nerve Fiber Layer Analysis, Scanning Laser Ophthalmoscope, Scanning Laser Polarimetry, TopSS Device, RTVue® XR OCT Avanti™, The iExaminer™

APPROVED BY GOVERNING BODIES:
A number of CSLO, SLP, and OCT devices have been cleared by the FDA through the 510(k) process for imaging the posterior eye segment. For example, the RTVue® XR OCT Avanti™ is an OCT system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disc as a tool and aid in the diagnosis and management of retinal diseases by a clinician. The RTVue XR OCT Avanti with Normative Database is a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disk measurements in the human eye to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases. In 2016, the RTVue XR OCT with Avanti with AngioVue™ Software was cleared by the FDA through the 510(k) process (K153080) as an aid in the visualization of vascular structures of the retina and choroid.

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.

Table 3. Ocular Imaging Devices Cleared by the US Food and Drug Administration

Device	Manufacturer	Date Cleared	510.k No.	Indication
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	Topcon Corporation	11/1/2017	K171370	Imaging of optic

Ophthalmic Data System				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	Heidelberg Engineering GmbH	5/6/2016	K152205	Imaging of optic nerve and retinal nerve

FA+OCT Spectralis ICGA+OCT Spectralis OCT Blue Peak Spectralis OCT with Multicolor				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

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

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

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POLICY HISTORY:

Adopted for Blue Advantage, February 2011
Available for comment February 9 – March 25, 2011
Medical Policy Group, February 2012
Medical Policy Group, February 2013
Medical Policy Group, February 2014
Medical Policy Group, February 2015
Medical Policy Group, September 2016
Medical Policy Group, April 2017
Medical Policy Group, December 2017
Medical Policy Group, April 2020: Reinstated policy effective March 24, 2020.

common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.