



Louisiana

Ophthalmologic Techniques That Evaluate the Posterior Eye Segment for Glaucoma

Policy # 00089

Original Effective Date: 06/05/2002

Current Effective Date: 02/12/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider analysis of the optic nerve (retinal nerve fiber layer [RNFL]) in the diagnosis and evaluation of patients with glaucoma or glaucoma suspects when using scanning laser ophthalmoscopy, scanning laser polarimetry (SLP), and optical coherence tomography (OCT) to be **eligible for coverage**.**

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the measurement of ocular blood flow, pulsatile ocular blood flow or blood flow velocity in the diagnosis and follow-up of patients with glaucoma to be **investigational**.*

Policy Guidelines

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

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Background/Overview

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: medical policy 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.)

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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 (ie, birefractive), 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.

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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.

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.

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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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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^{TM†} (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^{TM†} 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^{TM†} with AngioVue^{TM†} 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^{TM†} (Welch Allyn) was cleared for marketing by the FDA through the 510(k) process. The iExaminer^{TM†} consists of a hardware adapter and associated software (iPhone^{®†} App) to capture, store, send, and retrieve images from the PanOpticTM Ophthalmoscope (Welch Allyn) using an iPhone.

FDA product code: HKI.

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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

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Device	Manufacturer	Date Cleared	510.k No.	Indication
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

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Device	Manufacturer	Date Cleared	510.k No.	Indication
				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

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Device	Manufacturer	Date Cleared	510.k No.	Indication
				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

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Device	Manufacturer	Date Cleared	510.k No.	Indication
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

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Device	Manufacturer	Date Cleared	510.k No.	Indication
				nerve fiber layer
Optical Coherence Tomography	CARL ZEISS MEDITEC INC	9/1/2015	K150977	Imaging of optic nerve and retinal nerve fiber layer
OCT-Camera	OptoMedical Technologies GmbH	3/4/2015	K142953	Imaging of optic nerve and retinal nerve fiber layer
RESCAN 700 CALLISTO EYE	CARL ZEISS MEDITEC AG	11/18/2014	K141844	Imaging of optic nerve and retinal nerve fiber layer
PROPPER INSIGHT BINOCULAR INDIRECT OPHTHALMOSCOPE	PROPPER MANUFACTURING CO.INC.	9/17/2014	K141638	Imaging of optic nerve and retinal nerve fiber layer
CENTERVUE MACULAR INTEGRITY ASSESSMENT	CENTERVUE SPA	4/23/2014	K133758	Imaging of optic

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Device	Manufacturer	Date Cleared	510.k No.	Indication
				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/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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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.

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

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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

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 (eg, 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.

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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. 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. 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."

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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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT05344274	Direct Measures of Retinal Blood Flow and Autoregulation as Robust Biomarkers for Early Glaucoma	90	Sep 2026 (recruiting)
NCT04646122	Predicting Glaucoma Progression with Optical Coherence Tomography Structural and Angiographic Parameters	100	Mar 2022 (recruitment status unknown)
NCT01957267	Longitudinal Observational Study Using Functional and Structural Optical Coherence Tomography to Diagnose and Guide Treatment of Glaucoma	160	Dec 2025 (recruiting)
NCT02178085	Ocular Blood Flow Assessment in Glaucoma (OBAMAg)	62	Sep 2019 (recruitment status unknown)

NCT: national clinical trial.



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05/16/2002	Medical Policy Committee review
06/05/2002	Managed Care Advisory Council approval
06/24/2002	Format revision. No substance change to policy.
06/01/2004	Medical Director review
07/20/2004	Medical Policy Committee review. Format revision. Clinical criteria revision.
07/26/2004	Managed Care Advisory Council approval
07/14/2005	Medical Director review
07/19/2005	Medical Policy Committee review
07/25/2005	Managed Care Advisory Council approval
02/07/2007	Medical Director review
02/21/2007	Medical Policy Committee approval
02/13/2008	Medical Director review
02/20/2008	Medical Policy Committee approval
02/04/2009	Medical Director review
02/19/2009	Medical Policy Committee approval. No change to coverage.
02/04/2010	Medical Policy Committee approval
02/17/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/31/2010	Coding updated.
02/03/2011	Medical Policy Committee review
02/16/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/02/2012	Medical Policy Committee review
02/15/2012	Medical Policy Implementation Committee approval. Ocular blood flow added as investigational.
01/03/2013	Medical Policy Committee review
01/09/2013	Medical Policy Implementation Committee approval. Patient selection criteria deleted.
03/04/2013	Coding updated
01/09/2014	Medical Policy Committee review

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01/15/2014	Medical Policy Implementation Committee approval. No change to coverage.
01/08/2015	Medical Policy Committee review
01/21/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
01/07/2016	Medical Policy Committee review
01/22/2016	Medical Policy Implementation Committee approval. No change to coverage.
10/01/2016	Coding update
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
01/05/2017	Medical Policy Committee review
01/18/2017	Medical Policy Implementation Committee approval. No change to coverage.
01/04/2018	Medical Policy Committee review
01/17/2018	Medical Policy Implementation Committee approval. Title changed from "Ophthalmologic Techniques for Evaluating Glaucoma" to "Ophthalmologic Techniques That Evaluate the Posterior Segment for Glaucoma". Doppler ultrasonography removed from the investigational statement. Coverage eligibility unchanged.
01/10/2019	Medical Policy Committee review
01/23/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/03/2020	Medical Policy Committee review
01/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/07/2021	Medical Policy Committee review
01/13/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/06/2022	Medical Policy Committee review
01/12/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/05/2023	Medical Policy Committee review
01/11/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/04/2024	Medical Policy Committee review

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01/10/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 01/2025

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)®, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0198T, 0604T, 0605T, 0606T
HCPCS	No codes
ICD-10 Diagnosis	H40.001-H40.9, H42, Q15.0, Z13.5, All related Diagnoses



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***Investigational** – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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