



Louisiana

Ophthalmologic Techniques That Evaluate the Posterior Segment for Glaucoma

Policy # 00089

Original Effective Date: 06/05/2002

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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**.*

Background/Overview

GLAUCOMA

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.

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 IOP, is sufficient for a definitive diagnosis. However, some patients will show ophthalmologic evidence of glaucoma with normal

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IOPs. These cases of normal tension glaucoma (NTG) are considered to be a type of primary open-angle glaucoma (POAG). 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 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 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 NTG, 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 NTG. 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 RNFL

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 (HRT) is probably the most common example of this technology.

Scanning Laser Polarimetry

The RNFL is birefringent (or 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 RNFL thickness. Unlike CSLO, 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.

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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 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 (CDI), 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

CDI 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 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.

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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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

A number of CSLO, SLP, and OCT devices have been cleared by the U.S. 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 disk measurements in the human eye to 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 with 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.

Centers for Medicare and Medicaid Services (CMS)

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

Rationale/Source

Assessment of a diagnostic technology typically focuses on 3 categories of evidence: (1) its technical performance (test-retest reliability or interrater reliability); (2) diagnostic accuracy (sensitivity, specificity, and positive and negative predictive value) in relevant populations of patients; and (3) demonstration that the diagnostic information can be used to improve patient outcomes. In addition, subsequent use of a technology outside of the investigational setting may also be evaluated. These categories of evidence, although not always evaluated in sequence, can be considered similar to the 4 phases of therapeutic studies.

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The use of various techniques of RNFL analysis CSLO, SLP, OCT for the diagnosis and management of glaucoma was addressed by 2 TEC Assessments (2001, 2003). Literature searches focusing on longitudinal results have been performed since the 2003 TEC Assessment.

Following is a summary of the key literature to date.

IMAGING OF THE OPTIC NERVE AND RNFL

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.

The question addressed in this evidence review Do imaging techniques for the optic nerve and RNFL improve diagnosis and monitoring?

The following PICOTS were used to select literature to inform this review.

Patients

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

Interventions

The technologies of interest for assessment of the optic nerve and RNFL include CLSO, SLP, and OCT. They are considered add-on tests to the standard clinical evaluation.

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 RNFL assessment by an ophthalmologist.

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.

Timing

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

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in visual field or RNFL. Clinical utility might be demonstrated by a change in the management and reduction in glaucoma progression across follow-up.

Setting

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.

Technical Performance

We did not identify studies reporting on the technical performance of imaging techniques for the optic nerve and RNFL.

Diagnostic Accuracy

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 (OCT, retinal tomography, SLP), pachymetry (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 2015 Cochrane review assessed the diagnostic accuracy of optic nerve head and nerve fiber layer imaging for glaucoma. Included were 103 case-control studies and 3 cohort studies (total N=16,260 eyes) that evaluated the accuracy of recent commercial versions of OCT (spectral domain), HRT III, or SLP (GDx VCC or ECC) for diagnosing glaucoma. The population was patients who had been 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 (OCT, HRT, SLP) 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.

Effect on Health Outcomes

A technology assessment issued by American Academy of Ophthalmology in 2007 reviewed 159 studies, published between January 2003 and February 2006, evaluating optic nerve head and RNFL 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

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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 RNFL

Numerous studies and systematic reviews have described findings from patients with glaucoma using CSLO, SLP, and OCT. 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 CSLO, SLP, and OCT 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.

The question addressed in this evidence review is: Do the techniques described below for assessing ocular blood flow improve diagnosis and monitoring? One potential application is the early detection of NTG.

The following PICOTS were used to select literature to inform this review.

Patients

The relevant patient 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 NTG.

Interventions

The technologies of interest for assessment of the optic nerve and optic nerve layer include CDI, Doppler Fourier domain OCT, laser Doppler velocimetry, confocal scanning laser Doppler flowmetry, and retinal functional imager.

Comparators

There is no other criterion standard for the diagnosis of glaucoma. The diagnosis of glaucoma is made from a combination of visual field testing, IOP measurements, and optic nerve and RNFL assessment.

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.

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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.

Timing

Longitudinal studies are needed to evaluate whether changes in blood flow are predictive of future visual loss.

Setting

Many of these procedures are performed with specialized equipment. While reports of use are longstanding (e.g., Bafa et al [2001]), investigators have commented on the complexity of these parameters and have noted that many of these technologies are not commonly used in clinical settings.

Technical Performance

We did not identify studies reporting on the technical performance of ocular blood flow evaluation techniques.

Diagnostic Accuracy

In 2016, Abegao Pinto et al reported the results from the prospective, cross-sectional, case-control, Leuven Eye Study, which included 614 individuals who had POAG; n=214, NTG (n=192), ocular hypertension (n=27), suspected glaucoma (n=41), or healthy controls (n=140). The objective of this study 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 CDI, retinal oximetry, dynamic contour tonometry, and OCT enhanced-depth imaging of the choroid. The glaucoma groups had higher perfusion pressure compared to controls ($p<0.001$), with lower velocities in both central retinal vessels ($p<0.05$), and choroidal thickness asymmetries. The NTG group, but not the POAG group, had higher retinal venous saturation compared to healthy controls ($p=0.005$). There were no significant differences in macular scans. The diagnostic accuracy or effects on health outcomes were not addressed.

A 2011 study reported on CDI 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 1072 controls were included. Mean values for glaucomatous eyes were within 1 SD of the values for controls for most CDI parameters. Methodologic differences created interstudy variance in CDI 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 CDI measurement.

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Effect on Health Outcomes

The clinical utility of techniques to evaluate ocular blood flow is similar to the 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 NTG.

The only longitudinal study identified was a 2012 study by Calvo et al on the predictive value of retrobulbar blood flow velocities in a prospective series of 262 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 CDI during the baseline examination, and conversion to glaucoma was assessed at least yearly according to changes observed with CLSO. 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.

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 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 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 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 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 on the technical performance of these tests (e.g., test-

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retest reliability), 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 the effects of the technology on health outcomes.

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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.

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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
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.

Next Scheduled Review Date: 01/2019

Coding

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Louisiana

Ophthalmologic Techniques That Evaluate the Posterior Segment for Glaucoma

Policy # 00089
Original Effective Date: 06/05/2002
Current Effective Date: 01/17/2018

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

Code Type	Code
CPT	0198T
HCPCS	No codes
ICD-10 Diagnosis	H40.001-H40.069, H40.10X0-H40.10X4, H40.111-H40.1194, H40.1210-H40.1294 H40.1310-H40.1394, H40.1410-H40.1494, H40.151-H40.159, H40.20X0-H40.20X4 H40.211-H40.219, H40.2210-H40.2294, H40.231-H40.249, H40.30X0-H40.33X4, H40.40X0-H40.40X4, H40.41X0-H40.41X4, H40.42X0-H40.42X4, H40.43X0-H40.43X4, H40.50X0-H40.50X4, H40.51X0-H40.51X4, H40.52X0-H40.52X4, H40.53X0-H40.53X4, H40.60.X0-H40.60.X4, H40.61X0-H40.61X4, H40.62X0-H40.62X4, H40.63X0-H40.63X4, H40.811-H40.839, H40.89, H40.9, H42, Q15.0, Z13.5

*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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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.

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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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