



Louisiana

Ophthalmologic Techniques That Evaluate the Posterior Eye Segment for Glaucoma

Policy # 00089

Original Effective Date: 06/05/2002

Current Effective Date: 02/08/2021

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 intraocular pressures (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 intraocular pressure (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: This evidence review 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 (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 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 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 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 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. Ocular Imaging Devices Cleared by the U.S. 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

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Device	Manufacturer	Date Cleared	510.k No.	Indication
				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	Heidelberg Engineering GmbH	11/1/2017	K172649	Imaging of optic nerve and retinal nerve fiber layer

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Device	Manufacturer	Date Cleared	510.k No.	Indication
Spectralis OCT with Multicolor				
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

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Device	Manufacturer	Date Cleared	510.k No.	Indication
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

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Device	Manufacturer	Date Cleared	510.k No.	Indication
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 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 nerve and retinal

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Device	Manufacturer	Date Cleared	510.k No.	Indication
				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

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.

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

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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 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 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 use of ocular blood flow, pulsatile ocular blood flow, and/or blood flow velocity are currently lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

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 response to requests, input was received from 1 physician specialty society and 3 academic medical centers while this policy was under review in 2009. Most reviewers supported use of

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confocal scanning laser ophthalmoscopy, scanning laser polarimetry, and optical coherence tomography in the care of patients with glaucoma and those with suspected glaucoma suspect. 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.

Practice Guidelines and Position Statements

American Academy of Ophthalmology

In 2015, 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 “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 optic nerve head and retinal nerve fiber layer 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 retinal nerve fiber layer 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.

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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 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>			
NCT02178085	Ocular Blood-flow Assessment by Magnetic Resonance Angiography in Glaucoma	62	Sep 2019
NCT01957267	Longitudinal Observational Study Using Functional and Structural Optical Coherence Tomography to Diagnose and Guide Treatment of Glaucoma	160	Dec 2022

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

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Louisiana

Ophthalmologic Techniques That Evaluate the Posterior Eye Segment for Glaucoma

Policy # 00089

Original Effective Date: 06/05/2002

Current Effective Date: 02/08/2021

- 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.
- 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.

Next Scheduled Review Date: 01/2022

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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 2020 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.

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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	
CPT	0198T Add codes eff 7/1/2020: 0604T, 0605T, 0606T
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-

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	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
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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 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

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- 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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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.

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