Ophthalmologic Techniques for Evaluating Glaucoma

Policy #  00089
Original Effective Date:  06/05/2002
Current Effective Date:  01/18/2017

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) 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 with Doppler ultrasonography in the diagnosis and follow-up of patients with glaucoma to be investigational.*

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

Glaucoma is a disease characterized by degeneration of the optic nerve (optic disc). Elevated intraocular pressure (IOP) has long been thought to be the primary etiology, but the relationship 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 other patients with marginal or no pressure elevation will, nonetheless, show optic nerve damage. The association between glaucoma and other vascular disorders such as diabetes or 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.

A comprehensive ophthalmologic exam is required for the diagnosis of glaucoma, but no single test is adequate for establishing the diagnosis. A comprehensive ophthalmologic examination includes an examination of the optic nerve by fundoscopy, 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, is sufficient for a definitive diagnosis. However, some patients will show...
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Ophthalmologic evidence of glaucoma with normal intraocular pressures, therefore an elevated IOP is not essential for diagnosis.

Conventional management of patients with glaucoma principally involves drug therapy, to control elevated IOPs, and serial evaluation of the optic nerve, to follow disease progression. Standard methods of evaluation include careful direct examination of the optic nerve using ophthalmoscopy or stereophotography, or evaluation of visual fields. There is interest in developing more objective, reproducible techniques both to document optic nerve damage and to detect early changes in the optic nerve and retinal nerve fiber layer (RNFL) before the development of permanent visual field deficits. Specifically, evaluating changes in the thickness of the RNFL has been investigated as a technique to diagnose and monitor glaucoma. In addition, there is interest in measuring ocular blood flow as a diagnostic and management tool for glaucoma. Various new techniques have been developed, as described below.

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 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 a problem in patients with glaucoma. The Heidelberg Retinal Tomograph is probably the most common example of this technology.

Scanning Laser Polarimetry
The RNFL is birefringent, causing 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 to allow comparison 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 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 is an example of this technology. 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.
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Techniques to Measure Ocular Blood Flow

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.

Doppler Ultrasonography
Color Doppler imaging has also been investigated as a technique to measure the blood velocity in the retinal and choroidal arteries.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
A number of confocal scanning laser ophthalmoscopy, scanning laser polarimetry, and OCT devices have been cleared by the FDA through the 510(k) process for imaging the posterior eye segment. For example, the RTVue XR OCT Avanti™ (Optovue) is an OCT system indicated for the in vivo imaging and measurement of the retina, retinal nerve fiber layer, and optic disc as a tool and aid in the diagnosis and management of retinal diseases by a clinician. The RTVue XR OCT Avanti with Normative Database is a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disk measurements in the human eye to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases. In 2016, the RTVue XR OCT with Avanti with AngioVue™ Software was cleared by 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) received marketing clearance from the FDA. The iExaminer consists of a hardware adapter and associated software (iPhone® App) to capture, store, send and retrieve images from the Welch Allyn PanOptic™ Ophthalmoscope using an iPhone.

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
The use of various techniques of RNFL analysis CSLO, SLP, and OCT for the diagnosis and management of glaucoma was addressed by Technology Evaluation Center (TEC) Assessments in 2001 and 2003. The 2003 Assessment offered the following observations:

- A variety of techniques to evaluate the RNFL were considered, including CSLO, SLP, and OCT. All 3 devices use different principles to directly evaluate the RNFL. All 3 devices give multiple specific measurement of the RNFL that can be followed up over time to evaluate a rate of change in the RNFL. In theory, they are highly sensitive and can detect subtle changes to the RNFL earlier than
standard qualitative evaluations. The major potential benefit of these technologies is that they can provide a quantitative objective evaluation in contrast with the subjective evaluation provided by other methods of diagnosing and monitoring primary open angle glaucoma (POAG).

- The Assessment evaluated whether adding RNFL analysis to other tests improves health outcomes. It is assumed that RNFL analysis would not influence decisions to begin treatment for suspected POAG when IOP is elevated or results of 2 of 3 conventional tests are positive. Conventional tests include ophthalmoscopic detection of atrophy of the optic nerve, visual field defect on perimetric testing, and increased IOP on tonometry. In patients without clear indications for topical medication, signs of optic nerve atrophy on RNFL analysis seen in advance of meeting other current diagnostic criteria for POAG may be used to begin early treatment. Using RNFL analysis to initiate early topical medication requires knowing how well RNFL results predict the development of visual loss. If the RNFL analysis is a poor predictor of future visual loss, its use could lead to errors in management, leading, for example, to overtreatment.

- The best evidence would be direct evidence comparing outcomes of management guided by conventional tests with and without RNFL analysis. No randomized trials were identified that compare the health outcomes of management guided by conventional tests alone with outcomes of management guided by conventional tests plus RNFL analysis in the detection or monitoring of POAG.

Regarding pulsatile ocular blood flow or blood flow velocity (techniques not addressed by the TEC Assessment), there are similar deficiencies reported in the published literature. Specifically, no data from published clinical trials document how these devices should be incorporated into clinical practice and whether treatment decisions based on the use of these devices result in improved patient outcomes compared with the conventional methods of evaluation. Additional information is also needed to 1) document the association between blood flow and glaucoma; 2) determine the relevant vessels for study considering the complex blood supply to the optic nerve; and 3) establish the range of normal values, particularly in relation to other factors such as blood pressure, heart rate, and compliance of the blood vessels.

Evidence Subsequent to the 2003 TEC Assessment

Periodic literature updates focusing on longitudinal results, have been performed since the 2003 TEC Assessment. The most recent literature search was performed through July 11, 2016. Following is a summary of the key literature to date.

In 2012, the Agency for Healthcare Research and Quality (AHRQ) published a comparative effectiveness review of screening for glaucoma. Included in the review were randomized controlled trials (RCTs), quasi-randomized controlled trials, observational study designs including cohort and case control studies, and case series with more than 100 participants. The interventions evaluated included ophthalmoscopy, fundus photography/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 regarding harms of a screening program. Over 100 studies were identified on the diagnostic accuracy of
Techniques to Evaluate the Optic Nerve and RNFL
A 2015 Cochrane review assessed the diagnostic accuracy of optic nerve head and 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), Heidelberg Retinal Tomograph (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 were for 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. With specificity close to 95%, sensitivity was 70%. Thus, if 200 out of 1000 people were referred by primary eye care, the tests would miss about 60 cases of the 200, and incorrectly refer 50 of 800 patients without glaucoma. Because a case-control design 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.

The CSLO Ancillary Study, a subset of the Ocular Hypertension Treatment Study (OHTS), was designed to determine whether annual optic disc topographic measurements can accurately predict visual field loss. The OHTS randomly assigned patients with elevated IOP to either topical hypotensive medication or observation. Baseline data reported from the CSLO Ancillary Study did not allow reaching conclusions about how well RNFL analysis measurements predict visual loss over time.

Follow-up of the CSLO Ancillary Study was reported in 2005. Of 438 participants, 34% had abnormal CSLO values according to HRT criteria. The average interval between CSLO exams to POAG was 48.4 months (standard deviation [SD]: 25.2). Eyes not developing POAG were followed up a mean of 79.5 months (SD: 20.8). Sensitivity of CSLO for development of POAG using HRT criteria was 55.6% (95% confidence interval [CI]: 39.6 to 70.5%), specificity 68.2% (95% CI: 63.5 to 72.5%), and PPV 13.5% (95% CI: 8.9 to 20.0%). The investigators concluded that “[t]he current analysis did not directly determine whether the prediction model that includes baseline CSLO measurements is improved over the OHTS prediction model that includes baseline stereophotographic cup-disc ratio measurements…. Longer follow-up is required to evaluate the true predictive accuracy of CSLO measures.”

At Manchester Royal Eye Hospital (UK), HRT and GDx systems were evaluated in cross-sectional (98 normal controls and 152 patients with POAG) and longitudinal studies (240 at risk of developing glaucoma due to high IOP or fellow eye with POAG and 75 with POAG). With specificity set at 95%, sensitivities of the HRT and GDx in detecting POAG were 59% and 45%, respectively, in the cross-sectional study. In the longitudinal study, patients were evaluated biannually over an average 3.5-year follow-up. Evidence of visual field defects developed in 72 of the at-risk group. Poor agreement was found between the HRT and GDx for development of visual field abnormalities. Although sensitivities might vary according to definitions for conversion to a visual field defect, among patients with baseline HRT and GDx abnormalities, sensitivities could be as low as 13% to 39%. The authors concluded that “on account of the fact that the
HRT and GDx fail to detect a significant number of cases of conversion, they cannot provide a replacement for visual field examination."

Longitudinal results have also been reported from the University of California, San Diego (UCSD) Diagnostic Innovations in Glaucoma Study (DIGS). In the first publication, eyes from 160 glaucoma suspects evaluated with SLP were followed up for 1.7 to 4.1 years. Visual field damage developed in 16 (10%) participants. Only relative risks (RRs) for visual field damage were reported as opposed to sensitivities, specificities, and predictive values. From 12 SLP parameters and a 13th calculated from those parameters, 3 were significantly associated with the visual field outcome in multivariable analyses (models were incorrectly specified owing to the small number of outcomes). In a subsequent report, 114 glaucoma suspects were examined with OCT (one eye per patient). Over a 4.2-year average follow-up, 23 (20%) developed changes consistent with glaucoma. While the RR of developing glaucomatous changes was increased with thinner RNFL results (1.5-fold per 10 micrometers), sensitivities and specificities demonstrating clinical utility were not reported.

A technology assessment issued by the American Association of Ophthalmology (AAO) 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."

Studies continue to report on use of these techniques in patients with glaucoma/glaucoma suspects. In addition, studies report correlation of changes in RNFL analysis and changes in visual fields.

**Section Summary: Techniques to Evaluate the Optic Nerve and RNFL**

Numerous articles have described findings from patients with glaucoma and who are glaucoma suspect using CSLO, SLP, and OCT. The literature and specialty society guidelines have shown that optic nerve analysis using CSLO, SLP, and OCT has become an additional test that may be used in the diagnosis and management of patients with glaucoma and those who are glaucoma suspect.

**Techniques to Evaluate Ocular Blood Flow**

Measurement of ocular blood flow has been studied as a technique for evaluating patients with glaucoma. One potential application is the early detection of normal tension glaucoma. While reports of use have been longstanding (eg, Bafa et al), the clinical impact of this technique is unknown. Reports have commented on the complexity of these parameters and have noted that these technologies are not commonly used in clinical settings.

In 2012, Calvo et al. reported the predictive value of retrobulbar blood flow velocities in a prospective series of 262 glaucoma suspects. At baseline, all participants had normal visual field, increased IOP (mean of 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 confocal laser scanning. During the 48-month follow-up period, there were 36 converters (13.7%) and 226 non-converters. Twenty of the converters (55.5%) 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 converted to glaucoma compared to subjects who did not convert. Post-hoc subgroup analysis comparing patients with resistivity lower than 0.75 to those with resistivity greater than 0.75 revealed statistically significant differences in those not converting to glaucoma (survival of 93.9% vs. 81.7%, respectively). The clinical significant of this difference is unclear.

A 2011 publication reported on CDI in normal and glaucomatous eyes. Using data from reported studies, a weighted mean was derived for the peak systolic velocity, end diastolic velocity and Pourcelot's resistive index in the ophthalmic, central retinal and posterior ciliary arteries. Data from 3,061 glaucoma patients and 1,072 controls were included. The mean values for glaucomatous eyes were within 1 SD of the values for controls for most CDI parameters. Methodologic differences created inter-study 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 have overlapping ranges, caution should be used when classifying glaucoma status based on a single CDI measurement.

Resch and colleagues reported a cross-sectional study of optic disc morphology and ocular perfusion parameters in 103 patients with POAG in 2011. Choroidal and optic nerve head blood flow was assessed using laser Doppler flowmetry, retinal blood velocity was measured with laser Doppler velocimetry, and retinal vessel diameters were measured with a Retinal Vessel Analyzer. Choroidal blood flow was not significantly associated with measures of glaucomatous damage or with morphologic parameters of the optic nerve head. Reduced retinal vessel diameters were slightly correlated with the degree of glaucomatous damage. Multiregression analysis showed optic nerve head blood flow to be most strongly associated with most measures of structural nerve head damage (e.g., r=0.28 for RNFL) and visual field loss. As indicated in the TEC Assessment, cross-sectional studies cannot determine whether changes in blood flow precede or are secondary to changes in the optic nerve head. Longitudinal studies are needed to evaluate if changes in blood flow are predictive of future visual loss.

Section Summary: Techniques to Evaluate Ocular Blood Flow
Techniques to measure ocular blood flow or ocular blood velocity are used to evaluate various glaucoma treatments. Data for these techniques remain limited. Literature reviews have not identified studies that demonstrate the clinical utility of pulsatile ocular blood flow or blood flow velocity in treating patients with glaucoma.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

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<th>Trial Name</th>
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<td>Ongoing</td>
<td>Longitudinal Observational Study Using Functional and Structural Optical Coherence Tomography to Diagnose and Guide Treatment of Glaucoma</td>
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NCT: national clinical trial.
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Summary
For individuals who have open-angle glaucoma or who are glaucoma suspect who receive digital imaging of the optic nerve and retinal nerve fiber layer, the evidence includes studies on diagnostic accuracy. Relevant outcomes include test accuracy, other test performance measures, symptoms, morbid events, and medication use. Confocal scanning laser ophthalmoscopy, SLP, and OCT can be used to evaluate the optic nerve and retinal nerve fiber layer in patients with glaucoma and who are glaucoma suspect. 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 has become an additional test that may be used to diagnose and manage patients with glaucoma and those who are glaucoma suspect. These results are often considered along with other findings to make diagnostic and therapeutic decisions about glaucoma care. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have open-angle glaucoma or who are glaucoma suspect who receive ocular blood flow evaluation, the evidence includes association studies. Relevant outcomes include test accuracy, other test performance measures, symptoms, morbid events, and medication use. Techniques to measure ocular blood flow or ocular blood velocity are used to evaluate various glaucoma treatments. The data for these techniques remain limited. Literature reviews have not identified studies that demonstrate the clinical utility of pulsatile ocular blood flow or blood flow velocity in the treatment of patients with glaucoma. Some publications have compared their use to medication regimens in glaucoma. Others 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, and their relation to clinical outcomes is unclear. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical Input Received through 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 in 2009. A majority of reviewers providing input supported use of these techniques (CSLO, SLP, OCT) in the care of patients with glaucoma and those who are glaucoma suspects. 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, in contrast to other glaucoma testing, these tests can be done more easily, e.g., this testing does not always need to be done with dilated pupils, and ambient light level may be (is) less critical. In addition, while serial stereophotographs of the optic nerves are considered by many as the gold
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standard, these are not always practical, especially for general ophthalmologists. This testing also requires less cooperation from the patient, which can be helpful in some older patients.

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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
07/26/2004 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
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.

Next Scheduled Review Date: 01/2018
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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 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 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
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**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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