Vestibular Function Testing

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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 May Be 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 vestibular function testing using an electronystagmography (ENG) and videonystagmography (VNG) testing batteries, caloric testing, or rotational chair testing to be eligible for coverage when the following conditions have been met:

Patient Selection Criteria
Coverage eligibility will be considered when all of the following criteria have been met:

- The patient has symptoms of a vestibular disorder (eg, dizziness, vertigo, imbalance); AND
- A clinical evaluation, including maneuvers such as the Dix-Hallpike test if indicated, has failed to identify the cause of the symptoms.

When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of vestibular function testing for the assessment of typical benign paroxysmal positional vertigo that can be diagnosed clinically to be not medically necessary.**

Based on review of available data, the Company considers repeat vestibular function testing when treatment resolves symptoms to be not medically necessary.**

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 vestibular function testing in all other situations to be investigational.*

Based on review of available data, the Company considers vestibular evoked myogenic potential (VEMP) tests to be investigational.*

Based on review of available data, the Company considers all other laboratory-based vestibular function tests not described above to be investigational.*

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Vertigo
The vestibular system controls balance. It includes 5 end organs, 3 semicircular canals sensitive to head rotations, and 2 otolith organs (saccule, utricle) that sense gravity and straight-line (forward, backward, left, right, downward or upward) accelerations. Vertigo is the primary symptom of vestibular dysfunction. It can be experienced as illusory movement such as spinning, swaying, or tilting. Vertigo may be associated with a feeling of being pushed or pulled to the ground, blurred vision, nausea and vomiting, or postural and gait instability. Vertigo may arise from damage or dysfunction of the vestibular labyrinth, vestibular nerve, or central vestibular structures in the brainstem.

Vertigo may be caused by loose particles (otoconia) from the otolith organs that pass into one of the semicircular canals, most frequently the posterior canal. Specific head movements cause the particle to stimulate the canal, causing brief benign paroxysmal positional vertigo.

Diagnosis
Brief benign paroxysmal positional vertigo can usually be diagnosed clinically based on history of positional vertigo, response to the Dix-Hallpike maneuver or lateral roll tests, and resolution of symptoms with canal repositioning maneuvers.

If vertigo cannot be attributed to benign paroxysmal positional vertigo based on history, symptoms, or response to the standard maneuvers, a number of laboratory-based tests can be used to determine whether the vertigo is due to loss of vestibular function. These tests are based on the vestibulo-ocular reflex, which is an involuntary beating movement of the eyes (nystagmus) in response to vestibular stimulation. Nystagmus induced by these tests can help to distinguish between central and peripheral etiologies, in addition to determining whether the deficit is unilateral or bilateral. The typical tests include the ENG or VNG test batteries, caloric testing, and rotational chair testing.

ENG/VNG Test Batteries
The ENG/VNG test batteries include oculomotor evaluation and positional testing. ENG uses electrodes at the canthus of the eyes to detect nystagmus while VNG uses infrared video monitoring with goggles to measure nystagmus.

Caloric Testing
Caloric testing evaluates unilateral vestibular function. In the caloric test, warm or cold water or warm or cold air is introduced into each of the external ear canals. In some descriptions, caloric testing is conducted as part of ENG/VNG test batteries.

Rotational Chair Testing
Rotational chair testing evaluates bilateral vestibular function. Rotational chair devices include a lightproof booth, computer-driven chair with a head restraint that rotates around a vertical axis, ENG recording, an infrared camera, and a 2-way communication system. Typically, the chair is rotated in 4 different patterns,
constant acceleration followed by deceleration, rotating followed by a rapid stop, rotating at progressively increasing velocities, and alternating directions.

Passive rotational testing without a rotational chair may be performed when the rotational chair is not available. For the head impulse test, the patient is instructed to keep his or her eyes on a target. The examiner then turns the head rapidly by about 15°. With passive whole body testing, the examiner rotates the whole body to the rhythm of a metronome.

**Vestibular Evoked Myogenic Potential Testing**

VEMP tests are newer techniques that use loud sound (eg, click, tone burst) or bone vibration (eg, tendon hammer tap to the forehead or mastoid) to assess otolith function. Both the saccule and utricle are sensitive to sound as well as vibration and movement.

Cervical VEMPs (cVEMPs) are measured by surface electrodes on the ipsilateral sternocleidomastoid muscle in the neck and are thought to originate primarily in the saccule. Abnormality in any part of the auditory cVEMP pathway (saccule, inferior vestibular nerve, vestibular nucleus, medial vestibulospinal tract, the accessory nucleus, the eleventh nerve, sternocleidomastoid) can affect the response.

Ocular VEMPs (oVEMPs) detect subtle activity of an extraocular muscle using surface electrodes under the contralateral eye during an upward gaze, and are thought to be due primarily to stimulation of the utricle. The vestibulo-ocular reflex stimulated by sound or vibration is very small, but synchronous bursts of activity of the extraocular muscles can be detected by electromyography. Lesions that affect the oVEMP may occur in the utricle, superior vestibular nerve, vestibular nucleus, and the crossed vestibulo-ocular reflex pathways.

**Dynamic Posturography**

Dynamic posturography may also be used to evaluate balance.

**Treatment**

The central vestibular system is able to compensate for loss of peripheral vestibular function. Thus, the primary therapy for peripheral vestibular dysfunction is exercise-based and includes exercises to promote gaze stability, habituate symptoms, and improve balance and gait. Medications such as vestibular suppressants or antiemetics may be used in the acute stage but are not recommended for chronic use. For patients who have recurrent symptoms uncontrolled by other methods, a surgical or ablative approach may be used. The objective of ablation is to stabilize the deficit to allow central compensation.

**FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration (FDA)

Vestibular analysis devices are currently regulated by the U.S. FDA through the 510(k) pathway, under FDA product code LXV. The term “vestibular analysis devices” includes both diagnostic devices (eg, rotary
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chairs, multiaxial chairs) and therapeutic devices (eg, balance training and balance rehabilitation devices). Some devices indicated for diagnostic testing are included in Table 1.

Table 1. Vestibular Analysis Devices Approved by the Food and Drug Administration

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer (510k applicant)</th>
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<th>Date</th>
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<tr>
<td>ICS Impulse®</td>
<td>Otometrics</td>
<td>K122550</td>
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</tr>
<tr>
<td>Sway Balance™</td>
<td>Sway Medical (Capacity Sports)</td>
<td>K121590</td>
<td>2012</td>
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<td>Nydiag 200 Rotary Chair</td>
<td>Interacoustics A/S</td>
<td>K102364</td>
<td>2010</td>
</tr>
<tr>
<td>Epley Omniañx®</td>
<td>Vesticon</td>
<td>K071973</td>
<td>2008</td>
</tr>
<tr>
<td>VMT System</td>
<td>Target Health</td>
<td>K971549</td>
<td>1998</td>
</tr>
<tr>
<td>VOIETQ™ (Vestibular Ocular Reflex Test</td>
<td>Micromedical Technologies</td>
<td>K891008</td>
<td>1989</td>
</tr>
<tr>
<td>Equipment)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chair, Vestibular, Rotary, Computerized</td>
<td>Contraves</td>
<td>K781268</td>
<td>1987</td>
</tr>
<tr>
<td>RVT-50 Rotary Chair for Vestibular Testing</td>
<td>ICS Medical</td>
<td>K872093</td>
<td>1987</td>
</tr>
<tr>
<td>EquiTest®</td>
<td>Natus Medical (NeuroCom International)</td>
<td>K851744</td>
<td>1985</td>
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An example of equipment used for vestibular evoked myogenic potentials is the Bio-Logic Nav-Pro (Bio-logic Systems Corp), which in 2003 was cleared for marketing by the Food and Drug Administration through the 510(k) process (K994149) for use in the recording and displaying human physiologic data, and for auditory screening and assisting in evaluation of auditory and hearing-related disorders using auditory brainstem responses recorded from electroencephalography electrodes placed on the scalp.

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
Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be
adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice. The following is a summary of the key literature to date.

Laboratory-based vestibular function testing is well-established and has a large evidence base. In a 2000 technology assessment, the American Academy of Neurology (AAN) evaluated tests that stimulate the vestibular system (see Table 2). AAN included caloric irrigation and rotational chair testing as established as effective, with passive examiner-generated head rotation testing and active head rotation as probably effective but not yet fully accepted by expert consensus. AAN noted that quantitative vestibular testing is not always necessary, and a number of bedside methods can be used to evaluate nystagmus.

SUSPECTED BENIGN PAROXYSMAL POSITIONAL VERTIGO
Electronystagmography and Videonystagmography Test Batteries
The basic ENG and VNG test batteries include a spontaneous nystagmus test that measures the ability of the eyes to maintain a fixed position, a positional nystagmus test that measures the ability of the eyes to maintain a static position when the head is in different positions, an optokinetic nystagmus test that measures nystagmus caused by viewing a series of targets moving to the right and then to the left, and an oscillating tracking test that evaluates patient ability to track a moving target. The basic ENG/VNG test batteries with these 4 tests are well-established for evaluating vestibular function in patients who have a suspected vestibular disorder. A 2000 technology assessment by AAN concluded there was strong evidence (level A) of the usefulness of ENG and VNG testing, based on results from prospective and retrospective studies, as well as from expert consensus (see Table 2). Gofrit et al (2017) assessed 135 patients with vestibular symptoms using physical exam, a specialized questionnaire (Dizziness Handicap Inventory), and ENG testing, which included caloric testing. The physical exam included spontaneous and gaze-evoked nystagmus, tandem and standard walk tests, head shake test, and Romberg maneuver, but excluded the Dix-Hallpike test. Among those with a normal physical exam, testing identified 40 (48.8%) patients who had abnormal ENG results (p=0.46); conversely, among patients who had a normal ENG result, 17 (32.2%) had an abnormal physical exam. When severely disabled patients were selected by the Dizziness Handicap Inventory, these patients were equally as likely to have a normal (42.9%) ENG result as to have an abnormal (46.4%) ENG result. Physical examination excluded Dix-Hallpike test by necessity, and the authors noted this and the heterogeneous sample were study limitations.

Section Summary: Electronystagmography and Videonystagmography Test Batteries
Available evidence from controlled studies and expert consensus indicates that ENG/VNG is an appropriate test of vestibular function.

Caloric Testing
Caloric testing is the most widely used vestibular function test and is considered the criterion standard for detecting unilateral vestibular loss. When warm or cold water or air is introduced into one of the external ear canals, the temperature change is transmitted through the middle ear and bone, causing a thermal gradient...
in the semicircular canal and resulting in nystagmus. Cold water will cause a movement response of the eye opposite to the stimulation, while warm water will induce nystagmus in the direction of the ear being stimulated. These eye movements can be measured by electrodes at the canthus or by video monitoring. An asymmetrical response after stimulating both ears indicates unilateral vestibular dysfunction. The 2000 AAN technology assessment concluded there was level A evidence supporting the usefulness of caloric testing. This decision was based on controlled studies, as well as from expert consensus (see Table 2).

Section Summary: Caloric Testing
Available evidence from controlled studies and expert consensus indicates that caloric testing is an appropriate test of vestibular function.

Rotational Chair Testing
Rotational chair testing is considered the criterion standard for detecting bilateral vestibular loss. Rotational chair devices include a lightproof booth, computer-driven chair with a head restraint that rotates around a vertical axis, ENG recording, an infrared camera, and a 2-way communication system. Typically, the chair is rotated in 4 different patterns, constant acceleration followed by deceleration, rotation followed by a rapid stop, rotation at progressively increasing velocities, and alternating directions. Each pattern is repeated in both directions several times, and the accompanying post-rotation nystagmus, including parameters of gain, phase, and symmetry, is measured and averaged. Although traditionally used to detect bilateral vestibular loss, this battery can identify a unilateral vestibular deficit and identify the site of the lesion. The 2000 AAN technology assessment concluded there was level A evidence supporting the usefulness of rotational chair testing. This decision was based on the results of prospective and retrospective studies, as well as from expert consensus (see Table 2).

Section Summary: Rotational Chair Testing
Available evidence from prospective studies, retrospective studies, and expert consensus indicates that caloric testing is an appropriate test of vestibular function.

Vestibular Evoked Myogenic Potential Testing
VEMP tests use sound or vibration to stimulate the otolith organs. cVEMP measures evoked electrical potentials in the ipsilateral sternocleidomastoid muscle following stimulation of the saccule, while oVEMP measures electrical potentials in the extraocular muscles contralateral to the utricle. There is a large and rapidly growing literature on VEMPs for the assessment of otolith function, although most studies assess how cVEMP and oVEMP change with various disease states. VEMPs have been evaluated in superior canal dehiscence, vestibular neuritis, benign paradoxical positional vertigo (BPPV), vestibular schwannoma, Meniere disease, vestibular migraine, and central vestibular disorders.

There are a number of concerns about using VEMPs to assess the otolith organs. One issue is that sound and bone conduction stimuli are likely to influence senses other than the saccule and utricle, and stimulation of structures other than the utricle can affect the VEMP. In addition, VEMP responses have been shown to decrease with age, with a high rate of absent responses in normal older adults. Another is
that latency and amplitude measures are very sensitive to variables that can be introduced by the examiner, as observed in a 2016 study that included 1038 patients whose ailments included vestibular migraine or neuritis, BPPV, somatoform, phobic postural vertigo, unilateral or bilateral vestibulopathy, Menière disease, downbeat nystagmus syndrome, and other diagnoses. The authors observed significant differences between examiners for measures of oVEMP and cVEMP latencies, concluding that the field should "work on a better standard for VEMP recordings.

A cohort study (Hunter et al [2017]) compared cVEMP and oVEMP testing in 39 individuals who had known superior semicircular canal dehiscence, with a control cohort of 84 age-matched symptom-free individuals. Primary end points included peak-to-peak amplitudes of the 2 treatments and sensitivity and specificity. The authors observed that between cVEMP and oVEMP, cVEMP peak amplitudes (>214.3 μV) were less effective overall for diagnosis of semicircular canal dehiscence (area under the curve, 0.731). At the 2 treatment centers from which patients were drawn, oVEMP amplitudes and cVEMP thresholds proved to be the superior tests (overall area under the curve scores, 0.856 and 0.912, respectively). For patients between 50 and 60 years of age, testing cVEMP threshold (<75 decibels) provided sensitivity of 100%, as well as good specificity (92.9%). Overall, findings suggested superiority of cVEMP thresholds or oVEMP amplitudes over measurement of cVEMP amplitudes.

**Section Summary: Vestibular Evoked Myogenic Potential Testing**

The available evidence has indicated that the use of VEMP tests to evaluate suspected vestibular disorders is at a very early stage of development. Standardization of procedures and studies on the diagnostic accuracy of these procedures are needed.

**DIAGNOSED BENIGN PAROXYSMAL POSITIONAL VERTIGO**

**Laboratory-Based Vestibular Function Testing**

BPPV with a typical presentation is usually diagnosed clinically with a combination of a history of periods of brief positional vertigo, recurrence of symptoms with the Dix-Hallpike maneuver or lateral roll procedures, and/or alleviation of symptoms after canal repositioning maneuver. The Dix-Hallpike maneuver is the criterion standard for the diagnosis of posterior canal BPPV, limiting evaluation of its performance characteristics. The 2008 practice guidelines from the American Academy of Otolaryngology – Head and Neck Surgery gave a strong recommendation for the diagnosis of BPPV of the posterior canal when vertigo associated with nystagmus has been provoked by the Dix-Hallpike maneuver. If the Dix-Hallpike maneuver is negative, but the history is consistent with BPPV, a lateral roll test can be used to assess BPPV of the horizontal canal. In the event that both the Dix-Hallpike maneuver and lateral roll tests are negative, alleviation of symptoms with the canal repositioning maneuver supports a diagnosis of BPPV. The Academy has recommended against vestibular testing in patients who meet clinical criteria for the diagnosis of BPPV. The cited the weak nature of the evidence, which included expert opinion, case reports, and reason from first principles, as the basis for its recommendation. The AAN came to a similar conclusion in its 2017 practice guidelines, citing insufficient (level C) evidence to recommend vestibular testing for BPPV patients. If the clinical presentation is atypical, if Dix-Hallpike testing elicits equivocal or unusual nystagmus findings,
if symptoms do not resolve following treatment, or if there are additional symptoms or signs, vestibular function testing may be indicated.

Section Summary: Laboratory-Based Vestibular Function Testing
There is sufficient evidence to suggest that laboratory-based vestibular function testing is not indicated in patients who are diagnosed with benign paroxysmal positional vertigo.

SUMMARY OF EVIDENCE
Undiagnosed Benign Paroxysmal Positional Vertigo
For individuals who have a suspected vestibular disorder not clinically diagnosed as BPPV who receive electronystagmography/videonystagmography test batteries, caloric testing, or rotational chair testing, the evidence includes technology assessments of a large body of literature. Relevant outcomes are test accuracy, symptoms, functional outcomes, and quality of life. Based on review of controlled studies, caloric testing was given a level A recommendation that this test is predictive of loss of vestibular function. Based on a prospective study assessing a narrow spectrum of patients with the suspected vestibular dysfunction and a well-designed retrospective study, which included a criterion standard test, rotational chair testing was also given a level A recommendation. These tests are both considered criterion standard tests of vestibular function. electronystagmography/videonystagmography test batteries, which may include caloric testing, are also established methods of assessing loss of vestibular function. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have a suspected vestibular disorder not clinically diagnosed as BPPV who receive VEMP testing, the evidence includes mainly association studies. Relevant outcomes are test accuracy, symptoms, functional outcomes, and quality of life. There is a large and rapidly growing literature on VEMP tests for the assessment of otolith function, although most studies have assessed how the cVEMP and oVEMP change with various disease states. Studies on diagnostic accuracy and clinical utility of this technique for evaluating otolith organs and central pathways are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

Diagnosed BPPV
For individuals who have clinically diagnosed BPPV with typical presentation who receive laboratory-based vestibular function testing, the evidence includes technology assessments and practice guidelines. Relevant outcomes are test accuracy, symptoms, functional outcomes, and quality of life. BPPV with a typical presentation can be diagnosed clinically based on history, the Dix-Hallpike maneuver, lateral roll test, and canalith repositioning procedures; thus, laboratory-based vestibular function testing does not add diagnostic information in such routine cases. The evidence is sufficient to determine that the technology is unlikely to improve the net health outcome.

References
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04/06/2017 Medical Policy Committee review
04/19/2017 Medical Policy Implementation Committee approval. New policy.
04/05/2018 Medical Policy Committee review
04/18/2018 Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date: 04/2019

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<tr>
<td>ICD-10 Diagnosis</td>
<td>A88.1, H81.01-H82.9, R42</td>
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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. 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.

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A. In accordance with nationally accepted standards of medical practice;
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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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