Neurodiagnostics

Policy # 00186
Original Effective Date: 05/15/2006
Current Effective Date: 07/11/2018

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.*

Electromyography and Nerve Conduction Studies
Based on review of available data, the Company may consider electrodiagnostic assessment, consisting of electromyography, nerve conduction study, and related measures as an adjunct to history, physical exam, and imaging studies when the following criteria are met to be **eligible for coverage:**

- Signs and symptoms of peripheral neuropathy and/or myopathy are present; and
- Definitive diagnosis cannot be made by physical exam and imaging studies alone; and
- Work-up for one or more of the following categories of disease is indicated
    - Nerve root compression
    - Traumatic nerve injuries
    - Generalized and focal neuropathies/myopathies
    - Plexopathies
    - Motor neuron diseases
    - Neuromuscular junction disorders.

Based on review of available data, the Company may consider a repeat electrodiagnostic assessment when at least one of the following criteria has been met to be **eligible for coverage:**

- Development of new symptoms or signs suggesting a second diagnosis in a patient who has received an initial diagnosis; or
- Interim progression of disease following an initial test that was inconclusive, such that a repeat test is likely to elicit additional findings; or
- Unexpected change(s) in the course of disease or response to treatment, suggesting that the initial diagnosis may be incorrect and that reexamination is indicated.

When Services Are Considered Not Medically Necessary
Needle electromyography, which uses invasive needle electrodes, must be performed by a physician specifically trained in electrodiagnostic medicine, such as a doctor of medicine, doctor of osteopathy specializing in neurology or physical and rehabilitation medicine, or other provider specialties that have documented specific training in the use of NEMG. The Company considers NEMG to be **not medically necessary** if not directly performed and interpreted by the physician or another specifically trained provider.

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Nerve conduction studies should be either (a) performed directly by the physician or (b) performed by a trained individual under the direct supervision of the physician. The Company considers NCSs to be **not medically necessary** if not performed either by the physician or a trained individual under his direct supervision. Direct supervision is defined by the American Association of Electrodiagnostic Medicine (AAEM) to mean that the physician trained in electrodiagnostic (EDX) medicine is in close physical proximity to the EDX laboratory while testing is underway, is immediately available to provide the trained individual with assistance and direction, and is responsible for selecting the appropriate studies to be performed.

Generally, the interpreting physician for both NEMG and NCS procedures should be a neurologist or physiatrist or physician with comparable supervised training within a residency or fellowship training program.

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Electromyography and Nerve Conduction Studies
Based on review of available data, the Company considers electrodiagnostic assessment, consisting of electromyography, nerve conduction study, and related measures when the above criteria are not met, including but not limited to, the following situations to be **investigational:***

- Screening of asymptomatic individuals
- Serial assessments to evaluate progression of disease in a patient with a previously diagnosed neuropathy or myopathy
- Evaluation of treatment response in a patient with previously diagnosed neuropathy or myopathy
- Evaluation of severity of disease in a patient with previously diagnosed neuropathy or myopathy
- Macro electromyography (EMG)
- Current perception threshold (CPT)
- Pressure specified sensory testing

Automated Point-of-Care Nerve Conduction Tests
Based on review of available data, the Company considers automated point-of-care nerve conduction tests to be **investigational.***

Quantitative Sensory Testing
Based on review of available data, the Company considers quantitative sensory testing, including but not limited to current perception threshold testing, pressure-specified sensory device testing, vibration perception threshold testing, and thermal threshold testing to be **investigational.***

Paraspinal Surface Electromyography (SEMG) to Evaluate and Monitor Back Pain
Based on review of available data, the Company considers paraspinal surface electromyography as a technique to diagnose or monitor back pain to be **investigational.***

Policy Guidelines

Electromyography and Nerve Conduction Studies

The following list gives specific diagnoses, according to categories of testing listed in the policy statement, for which electromyography (EMG) and nerve conduction study (NCS) generally provide useful information in confirming or excluding the diagnosis, above that provided by clinical examination and imaging. The list includes the most common diagnoses for testing, but is not exhaustive. There may also be less common disorders for which EMG/NCS provide useful diagnostic information.

- Compressive neuropathies
  - Carpal tunnel syndrome
  - Ulnar nerve entrapment
  - Thoracic outlet syndrome
  - Tarsal tunnel syndrome
  - Other peripheral nerve entrapments
- Nerve root compression (when physical exam and magnetic resonance imaging are inconclusive):
  - Cervical nerve root compression
  - Thoracic nerve root compression
  - Lumbosacral nerve root compression
- Traumatic nerve injuries
- Generalized and focal polyneuropathies:
  - Diabetic neuropathy
  - Uremic neuropathy
  - Alcohol-related neuropathy
  - Hereditary neuropathies:
    - Charcot-Marie-Tooth
    - Other hereditary neuropathies
  - Demyelinating polyneuropathies:
    - Guillain-Barré syndrome (acute)
    - Chronic idiopathic demyelinating polyneuropathy
- Generalized myopathies:
  - Polymyositis
  - Dermatomyositis
  - Muscular dystrophies
- Plexopathies:
  - Cervical plexopathy

  - Brachial plexopathy
  - Lumbosacral plexopathy
- Motor neuron diseases:
  - Amyotrophic lateral sclerosis
  - Progressive muscular atrophy
  - Progressive bulbar palsy
  - Pseudobulbar palsy
  - Primary lateral sclerosis
- Neuromuscular junction disorders:
  - Myasthenia gravis
  - Myasthenic syndrome
  - Lambert-Eaton syndrome.

The following recommendations on the number of repeat services are reproduced from the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) position statement (1999). These estimates do not represent absolute maximums for all patients; they are defined by AANEM as being sufficient to make a diagnosis in at least 90% of patients with that particular diagnosis. Therefore, there may be a small percentage of cases that require a greater number of tests than specified in Table PG1.

Table PG1. Recommended Maximum Number of Electrodiagnostic Studies for Specific Diagnoses

Indication	Needle EMG	NCSs		Other Studies	
	No. of Tests	Motor NCS (± F Wave)	Sensory NCS	H-Reflex	RNS Testing
Carpal tunnel syndrome (unilateral)	1	3	4	0	0
Carpal tunnel syndrome (bilateral)	2	4	6	0	0
Radiculopathy	2	3	2	2	0
Mononeuropathy	1	3	3	2	0
Polyneuropathy or mononeuropathy multiplex	3	4	4	2	0
Myopathy	2	2	2	0	2
Motor neuropathy (eg, amyotrophic lateral sclerosis)	4	4	2	0	2
Plexopathy	2	4	6	2	0
Neuromuscular junction	2	2	2	0	3
Tarsal tunnel syndrome (unilateral)	1	4	4	0	0
Tarsal tunnel syndrome (bilateral)	2	5	6	0	0
Weakness, fatigue, cramps, or twitching (focal)	2	3	4	0	2
Weakness, fatigue, cramps, or twitching (general)	4	4	4	0	2
Pain, numbness, or tingling (focal)	1	3	4	2	0
Pain, numbness, or tingling (focal)	2	4	6	2	0

EMG: electromyography; NCS: nerve conduction study; RNS: repetitive nerve stimulation.

The AANEM position statement (1999) also included minimum standards for a lab performing electrodiagnostic evaluation. They are:

- The tests should be medically indicated.
- The tests should be performed using equipment that provides assessment of all parameters of the recorded signals. Equipment designed for screening purposes is not acceptable.
- The NCS should be performed by a physician or by a trained technician under the direct supervision of a physician.
- A trained physician must perform the needle EMG exam.
- One physician should perform and supervise all components of the electrodiagnostic testing.

Background/Overview

Electromyography and Nerve Conduction Studies
ELECTRODIAGNOSTIC ASSESSMENT

EMG and NCS are used as adjuncts to a clinical evaluation of myopathy and peripheral neuropathy. The intent of these tests is to evaluate the integrity and electrical function of muscles and peripheral nerves. They are performed when there is a clinical suspicion for a myopathic or neuropathic process and when clinical examination and standard laboratory testing cannot make a definitive diagnosis.

Test results do not generally provide a specific diagnosis. Rather, they provide additional information that assists the physician in characterizing a clinical syndrome. According to the American Association of Neuromuscular % Electrodiagnostic Medicine, electrodiagnostic assessment has the following goals:

- To identify normal and abnormal nerve, muscle, motor or sensory neuron, and neuromuscular junction (NMJ) functioning
- To localize region(s) of abnormal function
- To define the type of abnormal function
- To determine the distribution and severity of abnormalities
- To estimate the date of a specific nerve injury and the duration of the disease
- To determine the progression of abnormalities or of recovery from abnormal function
- To aid in diagnosis and prognosis of disease
- To aid in selecting treatment options
- To aid in following response to treatment by providing objective evidence of change in neuromuscular function
- To localize correct locations for injections of intramuscular agents.

Components of the electrodiagnostic exam may include needle EMG, NCS, repetitive nerve stimulation study, somatosensory evoked potentials, and blink reflexes.

Needle EMG

An EMG needle electrode is inserted into selected muscles, chosen by the examining physician depending on the differential diagnosis and other information available during the exam. The response of the muscle to

electrical stimulation is recorded. Three components are evaluated: observation at rest, action potential with minimal voluntary contraction, and action potential with maximum contraction.

Single Fiber EMG
In single fiber EMG, a needle electrode records the response of a single muscle fiber. This test can evaluate "jitter," which is defined as the variability in time between activation of the nerve and generation of the muscle action potential. Single fiber EMG can also measure fiber density, which is defined as the mean number of muscle fibers for 1 motor unit.

Nerve Conduction Study
In NCS, both motor and sensory nerve conduction are assessed. For motor conduction, electrical stimuli are delivered along various points on the nerve and the electrical response is recorded from the appropriate muscle. For sensory conduction, electrical stimuli are delivered to 1 point on the nerve and the response recorded at a distal point on the nerve. Parameters recorded include velocity, amplitude, latency, and configuration.

Late Wave Responses
Late waves are a complement to the basic NCS and evaluate the functioning of the proximal segment of peripheral nerves, such as the nerve root and the anterior horn cells. There are 2 types of late responses: the H-reflex and the F wave.

The H-reflex is elicited by stimulating the posterior tibial nerve and measuring the response in the gastrocnemius muscle. It is analogous to the ankle reflex and can be prolonged by a radiculopathy at S1 or by a peripheral neuropathy.

The F wave is assessed by supramaximal stimulation of the distal nerve and can help estimate the conduction velocity in the proximal portion of the nerve. This will provide information on the presence of proximal nerve abnormalities, such as radiculopathy or plexopathy.

Repetitive Nerve Stimulation
Repetitive nerve stimulation studies evaluate the integrity and function of the NMJ. The test involves stimulating a nerve repetitively at variable rates and recording the response of the corresponding muscle(s). Disorders of the NMJ will show a diminished muscular response to repetitive stimulation.

Somatosensory Evoked Potentials
Somatosensory evoked potentials evaluate nerve conduction in various sensory fibers of both the peripheral and central nervous system and test the integrity and function of these nerve pathways. They are typically used to assess nerve conduction in the spinal cord and other central pathways that cannot be assessed by standard NCS.

Blink Reflexes
The blink reflexes, which are analogues of the corneal reflex, are evaluated by stimulating the orbicularis orbis muscle at the lower eyelid. They are used to localize lesions in the fifth or seventh cranial nerves.

The specific components of an individual test are not standardized. Rather, a differential diagnosis is developed by the treating physician, and/or the clinician performing the test, and the specific components of the exam are determined by the disorders being considered in the differential. In addition, the differential diagnosis may be modified during the exam to reflect initial findings, and this may also influence the specific components included in the final analysis.

Automated Point-of-Care Nerve Conduction Tests

ELECTRODIAGNOSTIC TESTING
NCSs and needle EMG, when properly performed by a trained practitioner, are considered the criterion standard of electrodiagnostic testing for the evaluation of focal and generalized disorders of peripheral nerves.

CARPAL TUNNEL SYNDROME
However, the need for specialized equipment and personnel may limit the availability of electrodiagnostic testing for some patients. One proposed use of automated nerve conduction devices is to assist in the diagnosis of carpal tunnel syndrome. Carpal tunnel syndrome is a pressure-induced entrapment neuropathy of the median nerve as it passes through the carpal tunnel, resulting in sensorimotor disturbances. This syndrome is defined by its characteristic clinical symptoms, which may include pain, subjective feelings of swelling, and nocturnal paresthesia. A variety of simple diagnostic tools are available, and a positive response to conservative management (steroid injection, splints, modification of activity) can confirm the clinical diagnosis. Electrodiagnostic studies may also be used to confirm the presence or absence of a median neuropathy at the wrist, assess the severity of the neuropathy, and assess associated diagnoses. Nerve conduction is typically assessed before the surgical release of the carpal tunnel, but the use of EMG in the diagnosis of carpal tunnel syndrome is controversial.

LUMBOSACRAL RADICULOPATHY
Electrodiagnostic studies are useful in the evaluation of lumbosacral radiculopathy in the presence of disabling symptoms of radiculopathy or neuromuscular weakness. These tests are most commonly considered in patients with persistent disabling symptoms when neuroimaging findings are inconsistent with clinical presentation. Comparisons of automated point-of-care (POC) NCSs with EMGs and standardized NCSs have been evaluated as alternative electrodiagnostic tools.

PERIPHERAL NEUROPATHY
POC nerve conduction testing has been proposed as an alternative to standard electrodiagnostic methods for the diagnosis of peripheral neuropathy and, in particular, for detecting neuropathy in patients with diabetes. Peripheral neuropathy is relatively common in patients with diabetes, and the diagnosis is often

made clinically through the physical examination. Diabetic peripheral neuropathy can lead to morbidity including pain, foot deformity, and foot ulceration. Clinical practice guidelines have recommended using simple sensory tools such as the 10-g Semmes-Weinstein monofilament or the 128-Hz vibration tuning fork for diagnosis. These simple tests predict the presence of neuropathy defined by electrophysiologic criteria with a high level of accuracy. Electrophysiologic testing may be used in research studies and may be required in cases with an atypical presentation.

Quantitative Sensory Testing
QUANTITATIVE SENSORY TESTING
Quantitative sensory testing (QST) systems measure and quantify the amount of physical stimuli required for sensory perception to occur. As sensory deficits increase, the perception threshold of QST will increase, which may be informative in documenting progression of neurologic damage or disease. QST has not been established for use as a sole tool for diagnosis and management but has been used with standard evaluative and management procedures (eg, physical and neurologic examination, monofilament testing, pinprick, grip and pinch strength, Tinel sign, and Phalen and Roos test) to enhance the diagnosis and treatment-planning process, and to confirm physical findings with quantifiable data. Stimuli used in QST includes touch, pressure, pain, thermal (warm and cold), or vibratory stimuli.

The criterion standard for evaluation of myelinated large fibers is the electromyography nerve conduction study. However, the function of smaller myelinated and unmyelinated sensory nerves, which may show pathologic changes before the involvement of the motor nerves, cannot be detected by nerve conduction studies. Small fiber neuropathy has traditionally been a diagnosis of exclusion in patients who have symptoms of distal neuropathy and a negative nerve conduction study.

Depending on the type of stimuli used, QST can assess both small and large fiber dysfunction. Touch and vibration measure the function of large myelinated A-alpha and A-beta sensory fibers. Thermal stimulation devices are used to evaluate pathology of small myelinated and unmyelinated nerve fibers; they can be used to assess heat and cold sensation, as well as thermal pain thresholds. Pressure-specified sensory devices assess large myelinated sensory nerve function by quantifying the thresholds of pressure detected with light, static, and moving touch. Finally, current perception threshold testing involves the quantification of the sensory threshold to transcutaneous electrical stimulation. In current perception threshold testing, typically 3 frequencies are tested: 5 Hz, designed to assess C fibers; 250 Hz, designed to assess A delta fibers; and 2000 Hz, designed to assess A beta fibers. Results are compared with those of a reference population.

Because QST combines the objective physical sensory stimuli with the subject patient response, it is psychophysical in nature and requires patients who are alert, able to follow directions, and cooperative. In addition, to get reliable results, examinations need to include standardized instructions to the patients, and stimuli must be applied in a consistent manner by trained staff. Psychophysical tests have greater inherent variability, making their results more difficult to reproduce.

QST has primarily been applied in patients with conditions associated with nerve damage and neuropathic pain. There have also been preliminary investigations to identify sensory deficits associated with conditions such as autism spectrum disorder, Tourette syndrome, restless legs syndrome, musculoskeletal pain, and response to opioid treatment.

Paraspinal Surface Electromyography (SEMG) to Evaluate and Monitor Back Pain
BACK PAIN
Back pain is a common condition that affects most individuals at some point in their lives. Identifying the pathogenesis of back pain is a challenging task, in part due to the complex anatomy of the back, which includes vertebrae, intervertebral discs, facet joints, spinal nerve roots, and numerous muscles. Back pain may be related to osteoarthritis, disc disease, subluxation, or muscular pathology, such as muscle strain or spasm. Moreover, due to referred pain patterns, the location of the pain may not be anatomically related to the pathogenesis of the pain. For example, buttock or leg pain may be related to pathology in the spine. In addition to the diagnostic challenges of back pain is the natural history of acute back pain. Most cases of acute low back pain resolve with conservative therapy (eg, physical therapy) while continuing normal activities within limits permitted by the pain. Therefore, initial imaging or other diagnostic testing is generally not recommended unless “red flag” warning signs are present or the pain persists for more than 4 to 6 weeks. Red flag findings include significant trauma, history of cancer, unrelenting night pain, fevers or chills, and progressive motor or sensory deficits.

Diagnosis
Aside from physical examination, diagnostic testing includes imaging technologies, such as magnetic resonance imaging, designed to identify pathology (eg, bulging discs), or tests such as discography to localize the abnormality by reproducing the pain syndrome. However, these tests lack specificity and must be carefully interpreted in the context of the clinical picture. For example, magnetic resonance imaging identifies 5% of asymptomatic patients as having bulging discs. However, the presence of a bulging disc may only be clinically significant if correlated with other symptoms. Assessment of the musculature may focus on range of motion or strength exercises.

In contrast to anatomic imaging, SEMG, which records the summation of muscle activity from groups of muscles, has been investigated as a technique to evaluate the physiologic functioning of the back. A noninvasive procedure, SEMG differs from needle electromyography, an invasive procedure in which the electrical activity of individual muscles is recorded. Paraspinal SEMG has been explored to evaluate abnormal patterns of electrical activity in the paraspinal muscles in patients with back pain symptoms such as spasm, tenderness, limited range of motion, or postural disorders. The technique is performed using a single or an array of electrodes placed on the skin surface, with recordings made at rest, in various positions, or after a series of exercises. Recordings can also be made by using a handheld device, which is applied to the skin at different sites. Electrical activity is assessed by computer analysis of the frequency spectrum (ie, spectral analysis), amplitude, or root mean square of the electrical action potentials. In particular, a spectral analysis that focuses on the median frequency has been used to assess paraspinal muscle fatigue during isometric endurance exercises. Paraspinal SEMG has been researched as a

technique to establish the etiology of back pain and has been used to monitor the response to therapy and establish physical activity limits, such as assessing capacity to lift heavy objects or ability to return to work.

Paraspinal SEMG is an office-based procedure that may be most commonly used by physiatrists or chiropractors. The following clinical applications of the paraspinal SEMG have been proposed:

- Clarification of a diagnosis (ie, muscle, joint, or disc disease)
- Selection of a course of medical therapy
- Selection of a type of physical therapy
- Preoperative evaluation
- Postoperative rehabilitation
- Follow-up of acute low back pain
- Evaluation of exacerbation of chronic low back pain
- Evaluation of pain management treatment techniques.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Electromyography and Nerve Conduction Studies

EMG/NCS measure nerve and muscle function and may be indicated when evaluating limb pain, weakness related to possible spinal nerve compression, or other neurologic injury or disorder. A number of electromyographic devices have received marketing clearance by the U.S. FDA. Some are listed in Table 1.

Table 1. Electromyographic Devices Approved by FDA

Device	Manufacturer	FDA Clearance	510(k) No.	FDA Product Code
EPAD™	SafeOp Surgical	2014	K132616	GWF
CERSR® Electromyography System	SpineMatrix	2011	K110048	IKN
Physical Monitoring Registration Unit-S (PMRU-S)	Oktx	2013	K123902	IKN
MyoVision 3G Wirefree™ System	Precision Biometrics	2013	K123399	IKN
NuVasive® NVM5 System	NuVasive	2011	K112718	ETN
Neuro Omega™ System	Alpha Omega Engineering	2013	K123796	GZL
CareFusion Nicolet® EDX	CareFusion 209	2012	K120979	GWF

FDA: Food and Drug Administration.

Automated Point-of-Care Nerve Conduction Tests

Multiple devices have been cleared for POC neural conduction testing. For example, in 1986, Neurometer®‡ CPT/C (Neurotron®)‡ was cleared for marketing by the U.S. FDA through the 510(k) process (K853608). The device evaluates and documents sensory nerve impairments at cutaneous or mucosal sites. The evaluation detects and quantifies hyperesthesia in early stages of progressive neuropathy and hypoesthesia in more advanced conditions.

In 1998 NC-stat®‡ (NeuroMetrix) was cleared by FDA through the 510(k) process (K982359). NC-stat is intended "to measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies." This version is no longer commercially available. It is the predicate device for the NC-stat DPNCheck®‡ (K041320), cleared in 2004, and the NeuroMetrix Advance (K070109), cleared in 2008. The NC-stat DPNCheck device measures the sural nerve conduction velocity and sensory nerve action potential amplitude. It is a handheld device with an infrared thermometer, noninvasive electrical stimulation probes, and a single-use biosensor for each test. NC-stat DPNCheck is designed specifically for NCS of the sural nerve in the assessment of diabetic peripheral neuropathy. The NeuroMetrix ADVANCE is a POC test that can be used to perform needle EMG in addition to surface electrodes for the performance of NCSs. If the needle EMG module is used, then the device is also intended to measure signals useful in evaluating disorders of muscles.

On January 23, 2017, Cadwell Sierra Summit, Cadwell Sierra Ascent (Cadwell Industries) was cleared for marketing by FDA through the 510K process (K162383). There is a portable laptop version and a desktop application with a handheld device. The system is used for acquisition, display, storage, transmission, analysis, and reporting of electrophysiologic and environmental data including EMG, NCS, evoked potentials, and autonomic responses (RR interval variability). The Cadwell Sierra Summit is used to detect the physiologic function of the nervous system, and to support the diagnosis of neuromuscular diseases or conditions.

FDA product code: JXE.
Other examples of devices cleared for marketing by FDA through the 510(k) process are noted in Table 2.

Table 2. Examples of FDA Cleared Devices for Neural Conduction Testing

Device	Manufacturer	Date Cleared	510(k)	Indications
Axon II™	PainDX	1998	K980866	Part of a routine neurologic exam or screening procedure for detection of peripheral neuropathy, which may be caused by various pathologic conditions or exposures to toxic substances
Brevio®	Neurotron Medical	2001	K012069	To measure nerve response latency and amplitude in the diagnosis and monitoring of peripheral neuropathies
NC-stat®, NC-stat DPN-Check	NeuroMetrix	2004	K041320	To stimulate and measure neuromuscular signals in diagnosing and evaluating systemic and entrapment neuropathies. Added the sural biosensor for use in diagnosing neuropathies affecting the sural nerve.
NC-stat®	NeuroMetrix	2006	K060584	Addition of the modified median motor-sensory biosensor to stimulate and measure neuromuscular signals useful in diagnosing and evaluating systemic and entrapment neuropathies
XLTEK NEUROPATH	Excel Tech	2006	K053058	To stimulate and measure neuromuscular signals useful in diagnosing and evaluating systemic and entrapment neuropathies

NeuroMetrix Advance™	NeuroMetrix	2008	K070109	To measure neuromuscular signals useful as an aid in diagnosing and evaluating patients suspected of having focal or systemic neuropathies. If the elective needle EMG module is used, then the device is also intended to measure signals useful as an aid in evaluating disorders of muscles.

EMG: electromyography; FDA: U.S. Food and Drug Administration.

Quantitative Sensory Testing

A number of QST devices have been cleared for marketing by the U.S. FDA through the 510(k) process. Examples are listed in Table 3.

Table 3. FDA-Approved Quantitative Sensory Testing Devices

Device	Manufacturer	Date Cleared	510(k)	Indications
FDA product code: LLN				
Neurometer®	Neurotron	Jun 1986	K853608	Current perception threshold testing
NK Pressure-Specified Sensory Device, Model PSSD	NK Biotechnical Engineering	Aug 1994	K934368	Pressure specified sensory testing
AP-4000, Air Pulse Sensory Stimulator	Pentax Precision Instrument	Sep 1997	K964815	Pressure specified sensory testing
Neural-Scan	Neuro-Diagnostic Assoc.	Dec 1997	K964622	Current perception threshold testing
Vibration Perception Threshold (VPT) METER	Xilas Medical	Dec 2003	K030829	Vibration perception testing
FDA product code: NTU				
Contact Heat-Evoked Potential Stimulator (Cheps)	Medoc, Advanced Medical Systems	Feb 2005	K041908	Thermal sensory testing

FDA: Food and Drug Administration.

Paraspinal Surface Electromyography to Evaluate and Monitor Back Pain

SEMG devices approved by the U.S. FDA include those that use a single electrode or a fixed array of multiple surface electrodes. Examples include the CMAP Pro (Medical Technologies) and Model 9200 EMG System (Myotronics-Noromed).

Several U.S. FDA–approved devices combine SEMG along the spine with other types of monitors. For example, in 2007, the Insight Discovery (Fasstech, Burlington, MA) was cleared for marketing through the 510(k) process. The device contains 6 sensor types, one of which is for SEMG. The indications include measuring bilateral differences in SEMG along the spine and measuring SEMG along the spine during functional tasks. (Earlier Insight models had fewer sensors.) U.S. FDA product code: IKN.

Centers for Medicare and Medicaid Services (CMS)

Electromyography and Nerve Conduction Studies
Sensory nerve conduction threshold tests (sNCTs) (160.23) are distinct from "assessment of nerve conduction velocity, amplitude and latency" and from "short-latency somatosensory evoked potentials."

In 2002, the CMS "initially concluded that there was insufficient scientific or clinical evidence to consider the sNCT test and the device used in performing this test reasonable and necessary" and therefore "sNCT was noncovered."

In 2004, after reconsideration, "CMS conclude[d] that the use of any type of sNCT device (e.g., 'current output' type device used to perform current perception threshold [CPT], pain perception threshold [PPT], or pain tolerance threshold [PTT] testing or 'voltage input' type device used for voltage-nerve conduction threshold (v-NCT) testing) to diagnose sensory neuropathies or radiculopathies in Medicare beneficiaries is not reasonable and necessary."

Automated Point-of-Care Nerve Conduction Tests
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.

Quantitative Sensory Testing
In 2002, Medicare announced a national noncoverage policy on sensory nerve conduction threshold testing. Medicare reconsidered its policy, but affirmed it, concluding that any use of sensory nerve conduction threshold testing to diagnose sensory neuropathies or radiculopathies is not reasonable and necessary. This decision was reaffirmed in 2004. Medicare has not addressed coverage for other types of QST.

Paraspinal Surface Electromyography to Evaluate and Monitor Back Pain
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.

Rationale/Source

Electromyography and Nerve Conduction Studies
EMG and NCS, also collectively known as electrodiagnostic assessment, evaluate the electrical functioning of muscles and peripheral nerves. These tests are diagnostic aids for the evaluation of myopathy and peripheral neuropathy by identifying, localizing, and characterizing electrical abnormalities in the skeletal muscles and peripheral nerves.

For individual with suspected peripheral neuropathy or myopathy who receive electrodiagnostic assessment including electromyography and nerve conduction studies, the evidence includes scattered small studies on a few diagnoses, such as carpal tunnel syndrome, radiculopathy, and myopathy. Relevant outcomes are test accuracy, symptoms, functional outcomes, and quality of life. We have several challenges obtaining high-quality evidence on electrodiagnostic testing. Most prominently, electrodiagnostic assessment is

considered the criterion standard for evaluating the electrical function of peripheral nerves and muscles. Because of the lack of a true alternative reference standard, it is difficult to perform high-quality studies on diagnostic accuracy. As a result, we cannot determine the sensitivity and specificity of particular EMG/NCS abnormalities for particular clinical disorders. In general, these tests are considered more specific than sensitive, and normal results do not rule out disease. For the available evidence on specific diagnoses, studies have reported a wide range of sensitivities, which are often less than 50%. The specificity is expected to be considerably higher, but the data insufficient to provide precise estimates of either sensitivity or specificity. The evidence is insufficient to determine the effects of the technology on health outcomes.

Based on the limitations of clinical exam, established practice patterns, and guidelines from specialty societies, it is likely that these electrodiagnostic tests improve the ability to diagnose neuropathy and myopathy above that of clinical examination alone. Many disorders diagnosed have specific treatments available; therefore, the use of EMG/NCS is likely to improve outcomes by initiating effective or terminating ineffective treatments in patients correctly diagnosed. As a result, the use of EMG/NCS may be considered medically necessary as a diagnostic aid in the evaluation of signs and symptoms suggestive of a peripheral neuropathy or myopathy. For other uses, such as monitoring disease progression and screening asymptomatic individuals, the use of EMG/NCS is considered investigational.

Automated Point-of-Care Nerve Conduction Tests
Portable devices have been developed to provide POC NCSs. These devices have computational algorithms that can drive stimulus delivery, measure and analyze the response, and provide a report of study results. Automated nerve conduction could be used in various settings, including primary care, without the need for specialized training or equipment.

For individuals who have entrapment carpal tunnel syndrome who received automated POC NCSs, the evidence includes studies on the technical accuracy, diagnostic accuracy, and clinical outcomes from industry-sponsored trials, nonrandomized trials, and registry data. Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. Four RCTs have reported on the diagnostic accuracy of automated POC nerve conduction testing to diagnose carpal tunnel syndrome. Sensitivity testing has suggested there could be diagnostic value in detecting carpal tunnel syndrome; specificity testing was inconsistent across trials. No reference ranges were validated, and normative values were not defined in these studies. No validation testing by trained medical assistants vs trained specialist was reported in the studies. The evidence on clinical outcomes was limited to a single nonrandomized clinical trial and NeuroMetrix registry data. Neither reported health outcomes assessing patient symptoms or changes in functional status. The evidence is insufficient to determine the effects of the technology on health outcomes. For individuals with lumbosacral radiculopathy who received automated POC NCSs, the evidence includes industry-sponsored trials and a nonrandomized study of technical accuracy and diagnostic accuracy. Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. The evidence on the technical and diagnostic accuracy of POC NCS in this population has shown variable test results across reported trials. No normative values were defined. Weaknesses of the studies included lack of applicable or valid reference ranges for testing, and variable test results validating or confirming pathology. The results of

the 2 studies on diagnostic performance were inconclusive, with high false-positive results in a single trial. No trials on health outcomes assessing patient symptoms or changes in functional status were identified. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with diabetic peripheral neuropathy who received automated POC NCSs, the evidence includes industry-sponsored observational trials and nonrandomized studies on the technical accuracy and diagnostic accuracy. Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. The evidence on the technical accuracy for POC NCS in this population has shown variable test results across reported trials. No normative values were defined. Weaknesses of the studies included lack of applicable or valid reference ranges for testing to validate or confirm pathology. Of 3 studies reporting evidence on diagnostic accuracy, two used NC-stat DPN-Check. Sensitivity testing has suggested there could be diagnostic value in detecting diabetic peripheral neuropathy in symptomatic patients; the evidence to detect patients who are suspected of disease but who have mild symptoms was inconsistent. No reference ranges were validated, and normative values were not defined in 2 of the 3 studies. No validation testing by trained medical assistants vs trained specialist was reported in the studies. No trials on health outcomes assessing patient symptoms or changes in functional status were identified. The evidence is insufficient to determine the effects of the technology on health outcomes.

Quantitative Sensory Testing
QST systems are used for the noninvasive assessment and quantification of sensory nerve function in patients with symptoms of or the potential for neurologic damage or disease. Types of sensory testing include current perception threshold testing, pressure-specified sensory testing (PSST), vibration perception testing, and thermal sensory testing. Information on sensory deficits identified using QST has been used in research settings to understand neuropathic pain better. It could be used to diagnose conditions linked to nerve damage and disease, and to improve patient outcomes by impacting management strategies.

For individuals who have conditions linked to nerve damage or disease (eg, diabetic neuropathy, carpal tunnel syndrome) who receive current perception threshold testing, the evidence includes several studies on technical performance and diagnostic accuracy. Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. A technology assessment found insufficient evidence on the technical performance of current perception QST devices (eg, reproducibility) and there is a lack of standardization for what constitutes values in a normal range. The existing evidence does not support the accuracy of current perception threshold testing for diagnosing any condition linked with nerve damage or disease. Studies comparing current perception threshold testing with other testing methods have not reported on sensitivity or specificity. In addition, there is a lack of direct evidence on the clinical utility of current perception testing and, because there is insufficient evidence on test performance, an indirect chain of evidence on clinical utility cannot be constructed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have conditions linked to nerve damage or disease (eg, diabetic neuropathy, carpal tunnel syndrome) who receive PSST, the evidence includes several studies on diagnostic accuracy.

Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. We did not identify any studies evaluating the technical performance of PSST. Current evidence does not support the accuracy of PSST for diagnosing any condition linked with nerve damage or disease. A systematic review found that PSST had low accuracy for diagnosing spinal conditions. In addition, there is a lack of direct evidence on the clinical utility of current perception testing and, because there is insufficient evidence on test performance, an indirect chain of evidence on clinical utility cannot be constructed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have conditions linked to nerve damage or disease (eg, diabetic neuropathy, carpal tunnel syndrome) who receive vibration perception testing, the evidence includes a study on technical performance and several studies on diagnostic accuracy. Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. A study evaluating the technical performance of vibration testing found that results were highly reproducible. A few studies have assessed the diagnostic performance of vibration testing using devices not cleared by the FDA. In addition, there is a lack of direct evidence on the clinical utility of vibration perception testing and, in the absence of sufficient evidence on test performance, an indirect chain of evidence on clinical utility cannot be constructed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have conditions linked to nerve damage or disease (eg, diabetic neuropathy, carpal tunnel syndrome) who receive thermal sensory testing, the evidence includes several studies on technical performance and diagnostic accuracy. Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. A systematic review of studies on the technical performance of thermal sensory found considerable variation in the reliability of thermal QST. Two studies identified evaluated the diagnostic accuracy of thermal QST using the same FDA–cleared device. Neither found a high diagnostic accuracy for thermal QST, but both studies found the test had potential when used with other tests. The optimal combination of tests is currently unclear. In addition, there is a lack of direct evidence on the clinical utility of thermal sensory testing and, because there is insufficient evidence on test performance, an indirect chain of evidence on clinical utility cannot be constructed. The evidence is insufficient to determine the effects of the technology on health outcomes.

Paraspinal Surface Electromyography (SEMG) to Evaluate and Monitor Back Pain
A noninvasive procedure that records the summation of muscle electrical activity, paraspinal SEMG has been investigated as a technique to evaluate the physiologic functioning of the back. Additionally, this procedure has been studied as a technique to evaluate abnormal patterns of electrical activity in the paraspinal muscles in patients with back pain symptoms, such as spasm, tenderness, limited range of motion, or postural disorders.

For individuals who have back pain who receive paraspinal SEMG for evaluation and monitoring, the evidence includes a systematic review of interrater reliability, a systematic review of validity and reliability, and several nonrandomized studies on using findings to classify back pain. Relevant outcomes are test accuracy and validity, symptoms, functional outcomes, quality of life, and resource utilization. Addressing

the technical performance of SEMG, systematic reviews of small nonrandomized studies have concluded that the validity and reliability of SEMG have not been established. Heterogeneity on how SEMG recordings of muscle activity are taken limit generalizability. Across studies, patients may be sitting or standing, and exercises are isometric or dynamic. Addressing diagnostic performance of SEMG, there have been no studies directly comparing SEMG with other noninvasive techniques for evaluating back pain, and standard criteria for normal and abnormal SEMG measurements have not been determined. Addressing clinical utility, SEMG has been proposed as a noninvasive technique providing objective measurements that would inform treatment decisions in patients with back pain. While the studies have shown that SEMG results have detected different pathologies in patients with back pain, none of the studies reported health outcomes. There are no data on the impact of SEMG for patient management or health outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

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Neurodiagnostics

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Original Effective Date: 05/15/2006
Current Effective Date: 07/11/2018

Policy History

Original Effective Date: 05/15//2006
Current Effective Date: 07/11/2018

01/04/2006	Medical Director review
01/17/2006	Medical Policy Committee review. Clarification of provider qualifications.
01/26/2006	Quality Care Advisory Council approval.
01/10/2007	Medical Director review
01/17/2007	Medical Policy Committee approval. NEMG without nerve conduction studies and nerve conduction without EMG are considered to be investigational was deleted. Not medically necessary statements added.
01/09/2008	Medical Director review
01/23/2008	Medical Policy Committee approval
01/07/2009	Medical Director review
01/14/2009	Medical Policy Committee approval. No change to coverage eligibility.
01/07/2010	Medical Policy Committee approval
01/20/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/06/2011	Medical Policy Committee review
01/19/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/01/2012	Medical Policy Committee review
03/21/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/23/2013	Coding updated
03/07/2013	Medical Policy Committee review
03/20/2013	Medical Policy Implementation Committee approval. Added "Based on review of available data, the Company considers automated nerve conduction tests to be **investigational.*"** **"**Based on review of available data, the Company considers office-based automated nerve conduction studies which are remotely interpreted such as NC-stat®‡ (NEUROMetrix®Inc.)‡ to be investigational" was removed from policy.
03/06/2014	Medical Policy Committee review
03/19/2014	Medical Policy Implementation Committee approval. No change to coverage.
04/02/2015	Medical Policy Committee review
04/20/2015	Medical Policy Implementation Committee approval. No change to coverage.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
04/07/2016	Medical Policy Committee review
04/20/2016	Medical Policy Implementation Committee approval. Investigational statement for NEMG or NCS for treatment of any diagnosis other than those listed in coverage statement.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
04/06/2017	Medical Policy Committee review
04/19/2017	Medical Policy Implementation Committee approval. No change to coverage.
07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 07/2019

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 2017 by the American Medical Association (AMA).

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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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Code Type	Code
CPT	0106T, 0107T, 0108T, 0109T, 0110T, 95860, 95861, 95863, 95864, 95865, 95866, 95867, 95868, 95869, 95870, 95872, 95875, 95885, 95886, 95887, 95905, 95907, 95908, 95909. 95910, 95911, 95912, 95913, 95925, 95926, 95927, 95999
HCPCS	G0255, S3900
ICD-10 Diagnosis	All related diagnoses

*****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.

**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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