I. POLICY

A nerve conduction velocity study (NCV) when indicated with needle electromyography (EMG) may be considered medically necessary to confirm a suspected diagnosis. Suspected diagnoses include, but are not limited to, these conditions:

- Carpal tunnel syndrome
- Muscular dystrophy
- Myasthenia gravis
- Nerve root compression
- Peripheral neuropathy
- Spinal cord injury
- Other neurological conditions.

Note: Both nerve conduction studies and electromyography are required for a clinical diagnosis of peripheral nervous system disorders. Except for limited circumstances, nerve conduction studies and needle electromyography (EMG) should be performed together. When only one study is performed, an explanation should be provided in the clinical documentation.

The following electrodiagnostic tests are considered investigational:

- Nerve conduction studies performed without needle electromyography;
- Automated, non-invasive nerve conduction testing (e.g., NC-stat system);
- Quantitative sensory testing (QST), including but not limited to pressure-specified sensory device testing, current perception threshold testing (also referred to as sensory nerve conduction threshold [sNCT]) testing, vibration perception threshold testing, and thermal threshold testing; and
- Surface electromyography (SEMG), including paraspinal SEMG.

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these procedures.
II. PRODUCT VARIATIONS

[N] = No product variation, policy applies as stated
[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids  
[N] PPO  
[N] HMO  
[Y] SeniorBlue HMO**  
[Y] SeniorBlue PPO**

[N] Indemnity  
[N] SpecialCare  
[N] POS  
[Y] FEP PPO*

* Refer to FEP Medical Policy Manual MP-2.01.77 Automated Point-of-Care Nerve Conduction Tests, MP 2.01.35 Paraspinal Surface Electromyography (SEMG) to Evaluate and Monitor Back Pain, and MP 2.01.39 Quantitative Sensory Testing. The FEP Medical Policy manual can be found at: www.fepblue.org

** Refer to the following Novitas Local Coverage Determinations (LCD)

- L29547 Electromyography (EMG) and Nerve Conduction Studies,
- L32239 Neuromuscular Junction Testing
- L32943 Anorectal Manometry, Anal Electromyography, and Biofeedback Training for Perineal Muscles and Anorectal or Urethral Sphincters

III. DESCRIPTION/BACKGROUND

Electromyography and Nerve Conduction Velocity Studies

Electromyography (EMG) is a diagnostic test that measures muscle response to nerve stimulation in order to evaluate muscle disorders. A conventional EMG involves placement of a needle electrode to record electrical activity. The electromyographic nerve conduction (EMG-NCV) test is a diagnostic study designed to evaluate the function of large myelinated nerve fibers, i.e., the motor nerves, and thus does not evaluate the function of smaller myelinated and unmyelinated sensory nerves, which may show pathologic changes before the involvement of the motor nerves. An EMG and a NCV are often performed to confirm a suspected diagnosis. These two tests are often done at the same time; however, depending on the suspected diagnosis, they can be performed independently.

Automated Point-of-Care Nerve Conduction Tests

Portable devices have been developed to provide point-of-care nerve conduction studies. These devices have computational algorithms that are able to 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.

Nerve conduction studies (NCS) and needle electromyography (EMG), when properly performed by a trained practitioner, are considered the gold standard of electrodiagnostic testing. 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 (CTS). CTS 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, and 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 alternate associated diagnoses. Nerve conduction is typically assessed prior to surgical release of the carpal tunnel, but the use of electromyography in the diagnosis of CTS is controversial.

Point-of-care nerve conduction testing has also been proposed 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 mellitus, and the diagnosis is often made clinically through the physical examination. Diabetic peripheral neuropathy can lead to important morbidity including pain, foot deformity, and foot ulceration. Clinical practice guidelines recommend 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 electrophysiological criteria with a high level of accuracy. Electrophysiological testing may be used in research studies and may be required in cases with an atypical presentation.

NC-stat® by NeuroMetrix is a portable nerve conduction test device designed to be used at the point-of-care. The system comprises a biosensor array, an electronic monitor, and a remote report generation system. The biosensor is a single use, preconfigured array consisting of a stimulation anode and cathode, skin surface digital thermometer, and response sensor. Biosensor arrays are available for assessment of sensory and motor nerves of the wrist (median and ulnar), and for the foot (peroneal, posterior tibial, and sural). A chip embedded in the biosensor panel measures skin surface temperature, the analysis algorithm adjusts for differences in temperature from 30º C, or if skin surface temperature is less than 23º C, the monitor will indicate that limb warming is necessary. Data are sent to a remote computer via a modem in the docking station, and the remote computer generates a report based on the average of 6 responses that is sent back by fax or email. In addition to the automated stimulus delivery and reporting, NC-stat analysis adjusts the calculation for body temperature, height, and weight, and uses the average of 6 responses. Sensitivity of the device for sensory nerve
amplitude potentials is 2.1 µV; values lower than this are analyzed as zero, and responses with artifact are automatically eliminated from the analysis.

The Axon-II™ (PainDx) is an automated system that is being marketed for the detection of various sensory neurologic impairments caused by various pathologic conditions or toxic substance exposures, including signs of sympathetic dysfunction and detection of down-regulated A-delta function to locate injured nerve(s). The Axon-II software works with the Neural-Scan™ system (Neuro Diagnostics) and lists 7 automated studies (Cervical, Thoracic, Lumbar, Upper Extremities, Lower Extremities, Neuroma, Trigeminal), as well as a custom study. The Neural-Scan™ is a voltage-actuated sensory nerve conduction test device, which measures the voltage amplitude necessary to cause a discernable nerve impulse. Results are adjusted and compared to population means; the most severe hypoesthesia is considered the primary lesion.

**Regulatory Status**

Several devices are now being marketed for point-of-care neural conduction testing. NeuroMetrix received specific clearance to market NC-stat® via the U.S. Food and Drug Administration’s (FDA) 510(k) process in 1998, listing as predicate devices the TECA model-10 electromyograph and the Neurometer by Neurotron, which measures vibration threshold. The FDA-listed intended use was “to measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies.” In addition, the approved application stated that “The NC-stat is intended to be used as an adjunct to and not a replacement for conventional electrodiagnostic measurements.” NeuroMetrix subsequently received FDA clearance to market newer models with biosensors and engineering changes that enable the NC-stat to be used for motor and sensory nerves of the wrist (median and ulnar) and foot (peroneal, tibial, and sural). The intended use as listed on the 510(k) approval from 2006 (K060584) is “to stimulate and measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies.” The NeuroMetrix ADVANCE™ system received marketing clearance in 2008 (K070109). It is intended to perform nerve conduction studies using disposable surface electrodes (similar to NC-stat) with an additional module for invasive needle EMG. The ADVANCE™ system includes a real-time display of nerve conduction waveforms with a stylus for assignment of waveforms.

The Brevio® from Neurotron Medical received marketing clearance from the FDA in 2001. The Brevio® is intended “for use for the measurement of nerve response latency and amplitude in the diagnosis and monitoring of peripheral neuropathies.” The XLTek Neuropath (Excel-Tech) received clearance for marketing through the FDA’s 510(k) process in 2006; the indications are the same as those for NC-stat®. The Neural-Scan™ NCS (Neuro Diagnostics) is a Class I diagnostic device (FDA clearance not usually required) that is being marketed “as part of the [sic] neurological examination or for screening to detect peripheral neuropathies.”
Paraspinal Surface Electromyography (SEMG)

Surface electromyography (SEMG), a noninvasive procedure that records the summation of muscle electrical activity, has been investigated as a technique to evaluate the physiologic functioning of the back. In addition, 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 (ROM), or postural disorders.

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. For example, 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. The majority of cases of acute low back pain will resolve with conservative therapy, such as physical therapy, and continuing normal activities within limits permitted by the pain. Thus, initial imaging or other diagnostic testing is generally not recommended unless “red flag” warning signs are present or the pain persists for longer than 4-6 weeks. Red flag findings include significant trauma, history of cancer, unremitting night pain, fevers or chills, and progressive motor or sensory deficits.

Aside from physical examination, diagnostic tests include imaging technologies, such as magnetic resonance imaging (MRI), designed to identify pathology (e.g., bulging discs) or tests such as discography to localize the abnormality by reproducing the pain syndrome. However, due to their lack of specificity, all diagnostic tests must be carefully interpreted in the context of the clinical picture. For example, 5% of asymptomatic patients will have bulging discs as identified by MRI. Therefore, the presence of a bulging disc may only be clinically significant if well correlated with symptoms. Assessment of the musculature may focus on ROM 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 is contrasted with needle electromyography, an invasive procedure in which the electrical activity of individual muscles is recorded. Paraspinal SEMG, also referred to as paraspinal EMG scanning, has been explored 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 ROM, or postural disorders. The technique is performed using 1 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 can be assessed by computer analysis of the frequency spectrum (i.e., spectral analysis), amplitude, or root mean square of the electrical action.
potentials. In particular, 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 also 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 (i.e., 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

Regulatory Status

SEMG devices approved by the U.S. Food and Drug Administration (FDA) include those that
use a single electrode or a fixed array of multiple surface electrodes.

Several FDA-approved devices combine surface EMG 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, 1 of which is
surface EMG. The indications include measuring bilateral differences in surface EMG along
the spine and measuring surface EMG along the spine during functional tasks. (Earlier Insight
models had fewer sensor types.)

Quantitative Sensory Testing

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. Pain conditions evaluated may include diabetic neuropathy and
uremic and toxic neuropathies, complex regional pain syndrome, carpal tunnel syndrome, and
other nerve entrapment/compression disorders or damage.

Quantitative sensory testing (QST) has been investigated for a broad range of clinical
applications, including evaluation of peripheral neuropathies, detection of carpal tunnel
syndrome, spinal radiculopathy, evaluation of the effectiveness of peripheral nerve blocks,
quantification of hypoesthetic and hyperesthetic conditions, and differentiation of psychogenic
from neurologic disorders.
QST systems measure and quantify the amount of physical stimuli required for sensory perception to occur in the patient. 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 in conjunction with standard evaluation and management procedures (e.g., physical and neurologic examination, monofilament testing, pinprick, grip and pinch strength, Tinel’s sign and Phalen’s and Roos’ test) to enhance the diagnosis and treatment-planning process and confirm physical findings with quantifiable data. Stimuli used in QST includes touch, pressure, pain, thermal (warm and cold), or vibratory stimuli.

The gold standard for evaluation of myelinated large fibers is the electromyographic nerve conduction study (EMG-NCS). 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 (PSSD) 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 different frequencies are tested: 5 Hz, designed to assess C fibers; 250 Hz, designed to assess A-delta fibers; and 2,000 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 be standardized with 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 standardize and reproduce.

Regulatory Status

Devices cleared for marketing by the FDA through the 510(k) process include:

1987: Thermal Threshold Tester (TTT) (Teca, Inc., Pleasantville, NY)
1992: CASE IV Computer Aided Sensory Evaluator (WR Medical Electronics, Stillwater, MN) (vibration and thermal threshold testing)
1993: Thermal Sensory Analyzer (TSA) (Medoc Corp., Israel)
1994: Nk Pressure-Specified Sensory Device™ (NK Biotechnical Corporation)
1994: Pressure-Specified Sensory Device™ (Sensory Management Services LLC, Baltimore, MD)
1997: Medi-Dx 7000® Current Perception Threshold (Neuro Diagnostic Associates)
2003: Vibration Perception Threshold (VPT) meter (Xilas Medical)

IV. DEFINITIONS

510 (k) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims.

NEUROPATHY refers to any disease of the nerves.

PERIPHERAL refers to something that occurs away from the center.

TRANSCUTANEOUS refers to a procedure that is performed through the skin.

V. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member’s contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

VI. DISCLAIMER

Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.
VII. REFERENCE


Electromyography and Nerve Conduction Velocity Studies
American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM).

Automated Point-of-Care Nerve Conduction Tests

Paraspinal Surface Electromyography


Quantitative Sensory Testing


Other sources:


VIII. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

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Investigational; therefore not covered:

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**IX. POLICY HISTORY**

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8/1/13 administrative change. Added reference to L32943 Anorectal Manometry, Anal Electromyography, and Biofeedback Training for Perineal Muscles and Anorectal or Urethral Sphincters in the Medicare variation and in reference list.
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CAC 1/28/14 Consensus. Policy statement on quantitative sensory testing updated to include vibration threshold testing and thermal threshold testing as investigational. Updated Background/Description. Changes to statement did not result in any coding changes therefore reviewed as consensus. Administrative coding changes 51784 added.