## INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify its policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

## CONDITIONS OF COVERAGE

<table>
<thead>
<tr>
<th>Applicable Lines of Business/ Products</th>
<th>This policy applies to Oxford Commercial plan membership.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benefit Type</td>
<td>General benefits package</td>
</tr>
<tr>
<td>Referral Required</td>
<td>Yes</td>
</tr>
<tr>
<td>(Does not apply to non-gatekeeper products)</td>
<td></td>
</tr>
<tr>
<td>Authorization Required</td>
<td>No&lt;sup&gt;1,2&lt;/sup&gt;</td>
</tr>
<tr>
<td>(Precertification always required for inpatient admission)</td>
<td></td>
</tr>
<tr>
<td>Precertification with Medical Director Review Required</td>
<td>No&lt;sup&gt;1,2&lt;/sup&gt;</td>
</tr>
<tr>
<td>Applicable Site(s) of Service</td>
<td>Office, Outpatient</td>
</tr>
<tr>
<td>(If site of service is not listed, Medical Director review is required)</td>
<td></td>
</tr>
</tbody>
</table>

<sup>1</sup>Precertification with Medical Director review is required for CPT codes 0106T-0110T, 95905, 95999, 96002-96004 and HCPCS codes S3900 and G0255.

<sup>2</sup>Precertification is required for CPT codes 0106T-0110T, 95905, 95999, and 96002-96004 and HCPCS codes S3900 and G0255, services which are covered under the Member's General Benefits package when performed in...
Special Considerations (continued)

the office of a participating provider. For Commercial plans, precertification is not required, but is encouraged for out-of-network services performed in the office that are covered under the Member’s General Benefits package. If precertification is not obtained, Oxford may review for medical necessity after the service is rendered.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Electromyography (EMG)

Surface electromyography (SEMG) is unproven and not medically necessary.
There is limited and insufficient evidence to support the use of SEMG. Studies varied considerably in SEMG instrumentation, SEMG protocol, and diagnostic algorithm. Depending on the study’s SEMG approach, diagnostic performance ranged from poor to fair. Further research is needed to standardize SEMG approaches and diagnostic algorithms, increase diagnostic performance, and to assess the role of SEMG in clinical practice.

Macro electromyography (macro-EMG) testing is unproven and not medically necessary.
There is limited and insufficient evidence to support the use of macro-EMG. Additional studies are needed to establish how this test improves diagnostic capabilities and physician decision-making.

Nerve Conduction Studies

Nerve Conduction Studies Performed in Conjunction with Needle Electromyography

Nerve conduction studies with or without late responses (e.g., F-wave and H-reflex tests) and neuromuscular junction testing are proven and medically necessary when performed in conjunction with needle electromyography for any of the following known or suspected disorders:

- Peripheral nerve entrapment syndromes
- Generalized neuropathies
- Hereditary, metabolic, or degenerative polyneuropathy
- Plexopathy (acquired disorder in tissue along nerves that causes motor and sensory dysfunction)
- Neuromuscular junction disorders
- Myopathies
- Motor neuron disease
- Spine disorder with nerve root impingement symptoms
- Cervical, thoracic, and/or lumbosacral radiculopathy
- Guidance for botulinum toxin injection for spasmodic dysphonia or segmental dystonia when it is difficult to isolate affected muscles
- Traumatic nerve lesions

Nerve Conduction Studies Performed without Needle Electromyography

Nerve conduction studies with or without late responses (e.g., F-wave and H-reflex tests) are proven and medically necessary when performed without needle electromyography for patients who have any of the above known or suspected disorders with any of the following clinical indications:

- Patients treated with anticoagulants; or
- Patients with lymphedema; or
- Patients being evaluated for carpal tunnel syndrome
The American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) states that it is in the best interest of patients, in the majority of situations, for the needle EMG and the NCS examination to be conducted and interpreted on-site in real time. According to the AANEM, the use of the term "real time" with regard to nerve conduction studies indicates that information from the history and physical examinations are integrated, the specific and tailored electrodiagnostic (EDX) study is performed, and the analysis of the waveforms are all done at the same time and while the patient is present in the EDX laboratory. (AANEM, Proper Performance and Interpretation of Electrodiagnostic Studies, 2014; AANEM, What does ‘On Site’ and ‘Real Time’ Mean?, 2014)

**Nerve conduction studies are unproven and not medically necessary for all conditions other than those listed above as proven and medically necessary.**

There is limited and insufficient evidence to conclude that nerve conduction studies are beneficial for health outcomes in patients with disorders other than those listed above as proven and medically necessary.

**Non-invasive automatic, portable, or automated point of care nerve conduction monitoring systems (e.g., the NC-stat® System, the Brevio® NCS-Monitor, and the Advance™ System) that test only distal motor latencies and conduction velocities are unproven and not medically necessary for the purpose of electrodiagnostic testing.**

Studies of these devices are primarily small case series comparing portable with conventional nerve conduction studies in the same patient. Studies that did use controls did not always report the patients' conditions. Large, robust randomized, controlled studies are needed to prove the safety and efficacy of this technology.

**Physiologic Recording of Tremor**

**Physiologic recording of tremor using accelerometers is unproven and not medically necessary.**

There is insufficient evidence and too few studies to conclude that these devices improve therapeutic responses for the purpose of decreasing tremor in patients with tremor. Well-designed controlled studies are needed to determine the usefulness of these devices.

**Quantitative Sensory Testing**

**Quantitative sensory testing, including monofilament testing, pressure-specified sensory testing, computer assisted sensory examinations, and current perception threshold (CPT) testing is unproven and not medically necessary.**

Definitive conclusions for current perception threshold (CPT) testing cannot be drawn due to evidence that is inconsistent. Furthermore, in the absence of other testing, CPT tests do not include sensory nerve conduction amplitudes or other critical data to reach conclusions on diagnoses. Further research is needed to validate the clinical utility of pressure-specified sensory testing.

**Seizure Monitoring Systems**

**Surface electromyography (SEMG) based seizure monitoring systems are unproven and not medically necessary.**

There is insufficient evidence to conclude that SEMG based seizure monitoring systems improve care and health outcomes in patients with seizures. Well-designed controlled studies are needed to determine the efficacy of these devices.

**Visual Evoked Potentials for Glaucoma**

**Visual evoked potential testing is unproven and not medically necessary for diagnosing and evaluating glaucoma.**

Visual evoked potentials (VEPs) show some promise as a tool for diagnosing glaucoma, but definitive conclusions cannot be drawn due to evidence that is limited and inconsistent. Evidence regarding the use of VEP testing for monitoring progression in patients at risk for glaucoma is too limited to allow evaluation of sensitivity or positive predictive value. VEP has not been shown to be as good or better than standard visual testing in managing patients with glaucoma.

This policy does not address intraoperative neurophysiologic testing.

**APPLICABLE CODES**

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.
<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0106T</td>
<td>Quantitative sensory testing (QST), testing and interpretation per extremity; using touch pressure stimuli to assess large diameter sensation</td>
</tr>
<tr>
<td>0107T</td>
<td>Quantitative sensory testing (QST), testing and interpretation per extremity; using vibration stimuli to assess large diameter fiber sensation</td>
</tr>
<tr>
<td>0108T</td>
<td>Quantitative sensory testing (QST), testing and interpretation per extremity; using cooling stimuli to assess small nerve fiber sensation and hyperalgesia</td>
</tr>
<tr>
<td>0109T</td>
<td>Quantitative sensory testing (QST), testing and interpretation per extremity; using heat-pain stimuli to assess small nerve fiber sensation and hyperalgesia</td>
</tr>
<tr>
<td>0110T</td>
<td>Quantitative sensory testing (QST), testing and interpretation per extremity; using other stimuli to assess sensation</td>
</tr>
<tr>
<td>0464T</td>
<td>Visual evoked potential, testing for glaucoma, with interpretation and report</td>
</tr>
<tr>
<td>95860</td>
<td>Needle electromyography; 1 extremity with or without related paraspinal areas</td>
</tr>
<tr>
<td>95861</td>
<td>Needle electromyography; 2 extremities with or without related paraspinal areas</td>
</tr>
<tr>
<td>95863</td>
<td>Needle electromyography; 3 extremities with or without related paraspinal areas</td>
</tr>
<tr>
<td>95864</td>
<td>Needle electromyography; 4 extremities with or without related paraspinal areas</td>
</tr>
<tr>
<td>95865</td>
<td>Needle electromyography; larynx</td>
</tr>
<tr>
<td>95866</td>
<td>Needle electromyography; hemidiaphragm</td>
</tr>
<tr>
<td>95867</td>
<td>Needle electromyography; cranial nerve supplied muscle(s), unilateral</td>
</tr>
<tr>
<td>95868</td>
<td>Needle electromyography; cranial nerve supplied muscles, bilateral</td>
</tr>
<tr>
<td>95869</td>
<td>Needle electromyography; thoracic paraspinal muscles (excluding T1 or T12)</td>
</tr>
<tr>
<td>95870</td>
<td>Needle electromyography; limited study of muscles in 1 extremity or non-limb (axial) muscles (unilateral or bilateral), other than thoracic paraspinal, cranial nerve supplied muscles, or sphincters</td>
</tr>
<tr>
<td>95872</td>
<td>Needle electromyography using single fiber electrode, with quantitative measurement of jitter, blocking and/or fiber density, any/all sites of each muscle studied</td>
</tr>
<tr>
<td>95873</td>
<td>Electrical stimulation for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>95874</td>
<td>Needle electromyography for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>95885</td>
<td>Needle electromyography, each extremity, with related paraspinal areas, when performed, done with nerve conduction, amplitude and latency/velocity study; limited (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>95886</td>
<td>Needle electromyography, each extremity, with related paraspinal areas, when performed, done with nerve conduction, amplitude and latency/velocity study; complete, five or more muscles studied, innervated by three or more nerves or four or more spinal levels (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>95887</td>
<td>Needle electromyography, non-extremity (cranial nerve supplied or axial) muscle(s) done with nerve conduction, amplitude and latency/velocity study (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>95905</td>
<td>Motor and/or sensory nerve conduction, using preconfigured electrode array(s), amplitude and latency/velocity study, each limb, includes F-wave study when performed, with interpretation and report</td>
</tr>
<tr>
<td>95907</td>
<td>Nerve conduction studies; 1-2 studies</td>
</tr>
<tr>
<td>95908</td>
<td>Nerve conduction studies; 3-4 studies</td>
</tr>
<tr>
<td>95909</td>
<td>Nerve conduction studies; 5-6 studies</td>
</tr>
<tr>
<td>95910</td>
<td>Nerve conduction studies; 7-8 studies</td>
</tr>
<tr>
<td>95911</td>
<td>Nerve conduction studies; 9-10 studies</td>
</tr>
<tr>
<td>95912</td>
<td>Nerve conduction studies; 11-12 studies</td>
</tr>
<tr>
<td>95913</td>
<td>Nerve conduction studies; 13 or more studies</td>
</tr>
<tr>
<td>95937</td>
<td>Neuromuscular junction testing (repetitive stimulation, paired stimuli), each nerve, any 1 method</td>
</tr>
<tr>
<td>95999</td>
<td>Unlisted neurological or neuromuscular diagnostic procedure</td>
</tr>
</tbody>
</table>
### Neurophysiologic Testing and Monitoring

Neurophysiologic studies are used to evaluate and monitor patients with suspected or known central and peripheral nervous system disorders. This policy includes information on the following tests:

**Electromyography (EMG)**

EMG measures muscle response to electrical or nerve stimulation. The test is used to evaluate the function of individual nerves and muscles and has various applications in sports, ergonomics, rehabilitation, orthopedics, psychology, and neurology. Two main types of EMG exist: needle EMG (NEMG) and surface EMG (SEMG).

SEMG is a diagnostic technique in which electrodes are placed on the skin and used to measure the electrical activity of the underlying muscle in response to electrical or nerve stimulation. The SEMG recordings, also referred to as the electromyogram, differ among patients and healthy persons and can potentially be used to detect impairments in nerve and/or muscle function. Paraspinal EMG is a type of surface EMG that is used to evaluate back pain.

Needle electromyography requires insertion of needles through the patient’s skin and is helpful in determining whether muscle weakness results from an injury or a disorder in the nerves that control the muscles, the neuromuscular junction or the muscle itself.

Macroelectromyography (macro-EMG) is an electrodiagnostic technique that is used to assess the size of the entire motor unit. It is performed by inserting a special type of needle into the muscle being studied.

**Nerve Conduction Studies (NCSs)**

Nerve conduction studies are performed to assess the integrity and diagnose diseases of the peripheral nervous system. Specifically, they assess the speed (conduction velocity, and/or latency), size (amplitude), and shape of the response. In most circumstances, a properly performed electrodiagnostic (EDX) evaluation involves using both NCS and needle EMG. (AANEM, Proper Performance and Interpretation of Electrodiagnostic Studies, 2014)

Another type of NCS is late response testing (F wave and H-reflex testing). Late response studies are complementary to NCV and are performed during the same patient evaluation. In some cases, the late response may be the only abnormality. (AANEM, Recommended policy for electrodiagnostic medicine, 2014) The F-wave is a late response evoked by maximal stimulation during a motor nerve conduction study. The H-reflex is the electrophysiological component of the ankle reflex. The H-reflex is obtained from the calf muscle after stimulation of the posterior tibial nerve. In S-1 radiculopathy, the H-reflex is often absent or prolonged in latency. The H-reflex may also be recorded from other sites such as the quadriceps in the leg following femoral nerve stimulation and the flexor carpi radialis in the arm with median nerve stimulation.

The NC-stat is a non-invasive, automatic, portable nerve conduction monitoring system used for electrodiagnostic testing at the point of care setting. Other devices used for non-invasive nerve conduction measurement include the Brevio NCS-Monitor and the Advance System. A distinguishing feature of these devices is that they test distal motor latencies response amplitudes and conduction velocities but do not produce real time wave forms.
Neuromuscular Junction Testing

Neuromuscular junction testing also known as repetitive nerve stimulation is a type of electrodiagnostic test that is used to diagnose myasthenia gravis, Lambert-Eaton myasthenic syndrome, and other neuromuscular junction disorders. The test consists of recording muscle responses to a series of nerve stimuli and may be used in association with nerve conduction studies of the same nerves. At least one motor and one sensory nerve conduction study should be performed in a clinically involved limb, preferably in the distribution of a nerve studied with repetitive stimulation or single fiber electromyography (SFEMG). At least one distal and one proximal muscle should be studied by a needle EMG examination to exclude a neuropathy or myopathy that can be associated with abnormal repetitive stimulation studies or SFEMG. (AANEM Recommended policy for electrodiagnostic medicine, 2014)

Physiologic Recording of Tremor

Physiologic recording of tremors using accelerometers and gyroscopes includes the use of devices such as Kinesia™ or Tremorometer™. Kinesia integrates accelerometers and gyroscopes in a compact patient-worn unit to capture kinematic movement disorder features. The Tremorometer is a physiologic recording system using accelerometers that generates precision tremor frequency and amplitude information. TremReport™ is a utility for generating comprehensive reports from tremor records and written interpretations. The current standard in evaluating Parkinson's disease (PD) tremor is the Unified Parkinson's Disease Rating Scale (UPDRS), a qualitative ranking system typically completed during an office visit.

Quantitative Sensory Testing (QST)

QST is a testing method for objective assessments of peripheral sensory functions. QST usually evaluates the response to one particular stimulus, such as vibration, touch-pressure, heat or cold, and these tests are used to provide information about the function of specific types of nerve fibers. This type of testing includes monofilament stimuli like the Weinstein-Semmes filaments and computer assisted sensory examinations like the CASE IV, the Medoc systems, and the Vibratron or Biothesiometer. These tests have been used to detect and quantitate sensory deficits in diabetic ulcers and diabetic neuropathy in population bases studies and in drug treatment trials.

Two types of QST which use electrical current for stimulation of sensory axons are available. One is the current perception threshold (CPT) instrument [also called sensory nerve conduction threshold (sNCT) testing] and the other is the voltage actuated sensory nerve conduction threshold (V-sNCT) tests.

The pressure-specified sensory testing is another type of QST instrument and is used to assess nerve function by quantifying the sensory thresholds of skin by using with light quantifiable static, or moving cutaneous pressure stimuli. The NK Pressure-Specified Sensory Device is a pressure-specified sensory testing device that measures sensation using two rounded prongs that are pressed against the skin. The pressure of the stimuli is measured along with the patient's response to the stimulus. Move the following to the first paragraph of this section. The term sensory nerve conduction threshold (sNCT) tests should not be confused with the term motor and sensory nerve conduction studies (NCS), the latter type of tests include measurement of conduction velocity, onset latency and amplitude.

Seizure Monitoring Systems

Seizure monitoring systems such as the SPEAC® System (Brain Sentinel® Seizure Monitoring and Alerting System) is a non-invasive monitor that is placed on the biceps muscles to analyze surface electromyography (SEMG) signals that may be associated with generalized tonic-clonic (GTC) seizures. The system provides an alarm to alert caregivers of a possible GTC seizure.

Visual Evoked Potentials (VEPs) for Glaucoma

VEPs measure the brain’s electrical response to a visual stimulus and can be used for neurological assessment of the visual system. Measurement of VEPs has been investigated as a method of diagnosing and monitoring glaucoma. Variations in VEP testing include multifocal VEP (mfVEP) testing, which allows assessment of many visual field locations independently and concurrently and produces a topographical representation of defects.

Performance and Supervision of Testing

The American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) recommends that needle EMG examination must be performed by a physician specially trained in electrodiagnostic (EDX) medicine, as these tests are simultaneously performed and interpreted. (AANEM Recommended Policy for Electrodiagnostic Medicine, 2014; AANEM, Who is Qualified to Practice Electrodiagnostic Medicine? 1999. Updated and re-approved May 2012)

In a position statement for Electrodiagnostic Services: Pay for Quality, the AANEM recommends that providers have demonstrable training and experience in electrodiagnostic (EDX) testing. According to AANEM, this can be demonstrated by appropriate training in a neurology or physical medicine and rehabilitation (PMR) residency/fellowship program and certification by a nationally recognized organization. The American Board of Electrodiagnostic Medicine (ABEM) is a certifying organization specifically for physicians interested in EDX medicine.
The AANEM also has developed an Electrodiagnostic Laboratory Accreditation Program to identify and acknowledge EDX laboratories for achieving and maintaining the highest level of quality, integrity, and patient safety. Accreditation of an EDX laboratory is a voluntary, peer review process that assesses the expertise of the staff, evaluates the policies and procedures utilized, and ensures the safety of the laboratory and equipment to improve accuracy and reliability of the EDX testing and the patient care being provided. (AANEM Position Statement, Electrodiagnostic Services: Pay for Quality, 2016)

It is the AANEM's position that EDX evaluations should be performed by a physician (a neurologist or physiatrist) who has special training in the diagnosis and treatment of neuromuscular diseases and in the application of neurophysiologic techniques. (AANEM, Who is Qualified to Practice Electrodiagnostic Medicine? 1999. Updated and re-approved May 2012) According to the AANEM, nerve conduction studies should be performed by a trained physician or a trained individual under direct supervision of a physician. Direct supervision indicates that the physician is in close physical proximity to the electrodiagnostic laboratory while testing is being done and is immediately available to provide assistance and direction. (AANEM Recommended Policy for Electrodiagnostic Medicine 2014)

Collection of the clinical and electrophysiologic data should be entirely under the supervision of the electrodiagnostic (EDX) physician. The physician may collect all of the data directly from the patient or may delegate collection of some data to a specifically trained technologist. Data collection may also be delegated to a physician in a residency training program related to neurology or physical medicine and rehabilitation or fellowship related to electrodiagnostic and/or neuromuscular medicine. In the case of NCSs and somatosensory evoked potential (SEP) testing, the EDX physician may be absent from the room when the procedure is performed but should be immediately available. Once the physician has determined the preliminary differential diagnosis on the basis of the patient's history and examination, a technologist may perform the NCS and/or SEP tests selected by the physician. The physician should be alerted immediately during the testing if any results appear to be unusual or unexpected, so that there is opportunity to reassess the differential diagnosis and develop alternative testing strategies. The patient should remain in the room until the supervising EDX physician has reviewed NCS and diagnostic SEP results. SEPs are also frequently performed for preoperative baselines or prognosis after nerve trauma; those results can be reviewed by the physician at a later time. (AANEM, Technologists Conducting Nerve Conduction Studies and Somatosensory Evoked Potential Studies Independently to be Reviewed by a Physician at a Later Time, 2009, modified November 2014)

**CLINICAL EVIDENCE**

**Surface Electromyography (SEMG)**

Wang et al. (2016) performed a systematic review and meta-analysis of the published literature on the effect of surface electromyography (SEMG) as a measure of trunk muscle activity in patients with spinal cord injury (SCI). Eleven case-control, cohort, and cross-sectional studies were included in the review. Trunk muscle activities for the sitting condition were greater in patients with SCI than normal subjects. SEMG activity of trunk muscles for the sitting condition and posterior transfer was greater in patients with high level (HL)-SCI compared to those with low level (LL)-SCI. In addition, across studies, the level of trunk muscle activity for various difficulty settings was different for a given SCI group. According to the authors, this systematic review evaluated the value of trunk muscles for patients with SCI. There is no evidence from this study that this information will affect patient management.

In a meta-analysis, Geisser et al. (2005) evaluated diagnostic performance of SEMG for low back pain among 44 studies that were published during the years 1988 to 2002. The mean sensitivity and specificity was 39.6% and 90.8% for static SEMG, 88.8% and 81.3% for dynamic SEMG, and 84.4% and 89.8% for static SEMG during isometric exertion, respectively. While SEMG could differentiate between patients with low back pain and healthy persons, effect sizes were small to moderate and sensitivity and specificity were poor to fair for all types of SEMG and varied considerably among studies.

Berni et al. (2015) evaluated the accuracy of surface electromyography (sEMG) activity in the diagnosis of temporomandibular disorder (TMD). One hundred twenty-three volunteers were evaluated using the Research Diagnostic Criteria for Temporomandibular Disorders and placed into two groups: women with myogenous TMD (n=80) and women without TMD (n=43). The volunteers were then submitted to sEMG evaluation of the anterior temporalis, masseter and suprahyoid muscles at rest and during maximum voluntary teeth clenching (MVC) on parafilm. The accuracy, sensitivity and specificity of the muscle activity were analyzed. Differences between groups were found in all muscles analyzed at rest as well as in the masseter and suprahyoid muscles during MVC on parafilm. Moderate accuracy of the root mean square (RMS) sEMG was found in all muscles regarding the diagnosis of TMD at rest and in the suprahyoid muscles during MVC on parafilm. Sensitivity ranged from 71.3% to 80% and specificity from 60.5% to 76.6%. In contrast, RMS sEMG did not exhibit acceptable degrees of accuracy in the other masticatory muscles during MVC on parafilm. According to the authors, sEMG activity of the masticatory muscles at rest and the suprahyoid muscles during MVC on parafilm demonstrated a moderate degree of accuracy for the diagnosis of myogenous TMD and should be used as a complementary tool in the diagnosis of this disorder as well as during the treatment follow up. The authors also indicated that the diagnosis by RMS sEMG is limited, as the specificity and sensitivity ranged from
60% to 80%, an ideal diagnostic test should have accuracy ranging from 0.9 to 1.0 as well as specificity and sensitivity close to 100%.

Manfredini et al. (2011) assessed the diagnostic accuracy of commercially available surface electromyography (sEMG) and kinesiology (KG) devices for myofascial pain of jaw muscles. Thirty-six consecutive patients with diagnostic criteria for temporomandibular disorders (TMD) axis I diagnosis of myofascial pain and an age- and sex-matched group of 36 TMD-free asymptomatic subjects underwent sEMG and KG assessments. Receiver operating characteristics curve analysis showed that for most outcomes, sEMG and KG measures did not reach acceptable levels of sensitivity and specificity, with a 30-6-88.9% percentage of false-positive results. According to the authors, clinicians should not use sEMG and KG devices as diagnostic tools for individual patients who might have myofascial pain in the jaw muscles. Whether intended as a stand-alone measurement or as an adjunct to making clinical decisions, such instruments do not meet the standard of reliability and validity required for such usage.

**Professional Societies**

**American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM)**

According to an AANEM practice topic titled, Use of Surface Electromyography in the Diagnosis and Study of Neuromuscular Disorders, the data are insufficient to determine the clinical utility of surface electromyography (sEMG) for distinguishing between neuropathic and myopathic conditions or for detecting the more specific neuromuscular conditions of post-polioymyelitis syndrome, pathologic fasciculations, acquired demyelinating peripheral neuropathy, amyotrophic lateral sclerosis, myotonic dystrophy, and hypokalemic periodic paralysis (level U - data inadequate or conflicting). The AANEM states that on the basis of two class III studies, sEMG may be useful to detect the presence of neuromuscular disease (level C - possibly effective, ineffective, or harmful for the given condition in the specified population; level C rating requires at least one class II study or two consistent class III studies). (Meekins, 2008)

**Macrolelectromyography (Macro-EMG) Testing**

A small number of studies have evaluated the use of macro-EMG. Sartucci et al. (2011) assessed changes in Motor Units (MU) and extent of MU loss using macro-electromyography (macro-EMG) and Motor Unit Number Estimation (MUNE) in 61 Amyotrophic Lateral Sclerosis (ALS) patients. Macro-EMG increased and fiber density decreased after 8 months of tracking the disease course. The authors concluded that combined use of macro-EMG and MUNE techniques in ALS patients allows the tracking of changes in muscle MU features and number in face of progressive anterior horn cells death over time during disease's evolution. However, it is not clear how this information will affect patient management.

**Nerve Conduction Studies (NCS)**

Nerve conduction studies with or without late responses are indicated for the following conditions: peripheral nerve entrapment (Galmab et al., 2015; Omejec et al., 2014; Park et al., 2014; Calfee et al., 2012); generalized neuropathies (Holiner et al., 2013) polyneuropathies (Koo et al., 2016; de Souza et al., 2015); neuromuscular junction disorders (Merighioli and Sanders, 2005); myopathies including polymyositis, dermatomyositis, and congenital myopathies (Wang et al., 2010); motor neuron disease (Reniers et al., 2017); spine disorders and radiculopathy (Pawar et al., 2013); and guidance for botulinum toxin injection for spasmodic dysphonia or segmental dystonia, when it is difficult to isolate affected muscles. (Albanese et al., 2011, reaffirmed 2016)

**Point of Care Nerve Conduction Tests**

The results of preliminary studies for automatic or portable nerve conduction monitoring systems are promising; however the studies are primarily small case series comparing portable with conventional nerve conduction studies or clinical examination in the same patient. (Chatzikosma et al., 2016; Dale et al., 2015; Fisher et al., 2008; Perkins et al., 2008; Armstrong et al., 2008)

Sharma et al. (2015) evaluated a point-of-care nerve conduction device (POCD; NC-stat® DPNCheck™) for the assessment of diabetes polyneuropathy (DPN) and compared it with the LDIFLARE technique—which uses a laser-Doppler-imager for early detection of small fibre dysfunction. A total of 162 patients with diabetes (DM) and 80 healthy controls (HC) were recruited. Based on the 10-point Neuropathy Disability Score (NDS), (DPN) was categorized into none (<2), mild (3-5) moderate (6-7), and severe (8-10). The associations between POCD outcomes and the LDIFLARE within the NDS categories were evaluated using regression analysis. In HC and DM, SNCV measured with the POCD correlated significantly with the LDIFLARE technique; in addition, significance was found in all categories of DPN. ROC curves within each category of DPN showed that the POCD was sensitive in the assessment of DPN. The authors concluded that the NC-stat®DNPCheck™ system appears to be an excellent adjunctive diagnostic tool for diagnosing DPN in the clinical setting. According to the authors, the NC-stat may be limited because it is dependent on the presence of an accessible sural nerve which can be anatomically absent in up to 9% of healthy subjects. This study was limited because the sample size was too small to draw clear conclusions.
Bourke et al. (2011) investigated the use of a clinic-based, handheld, non-invasive electrophysiological device (NC-stat®) in 71 patients with suspected carpal tunnel syndrome. These patients were compared to a similar cohort of 71 age-matched patients in whom formal nerve conduction studies were performed at a local neurophysiology unit. Outcome measures were time from presentation to carpal tunnel decompression, the cost of each pathway and the practicalities of using the device in a busy hand unit. According to the authors, the NC-stat® proved to be a successful device when compared with referring patients out for more formal nerve conduction studies, shortening the time from presentation to surgery from 198 days to 102 days. These findings need confirmation in a larger study.

Tan et al. (2012) assessed the clinical impact of replacing standard neurophysiologic testing with a hand-held device (Mediracer) for diagnosis of carpal tunnel syndrome (CTS). One hundred patients (200 hands) with suspected CTS were studied by blinded assessors [Hand-therapist (HT1) and Consultant Neurophysiologist] using the Mediracer, followed by standard neurophysiologic testing. To simulate testing by personnel without neurological training, Mediracer recordings were analyzed separately by an assessor who had not seen the patients (HT2). Correlation of the CTS grades was 0.94 for the results obtained by HT1, and 0.87 for HT2. The sensitivity and specificity of the Mediracer was 0.85 and 0.9, respectively, by HT1, and 0.84 and 0.89 for HT2. Nine patients had conditions other than CTS, and 35 patients were judged to require further investigation. The authors concluded that the Mediracer should only be used in patients with typical CTS symptoms and signs and no muscle wasting who have had careful neurological assessment. These findings need confirmation in a larger randomized controlled trial.

Schmidt et al. (2011) compared the specificity and sensitivity of a hand-held nerve conduction study (NCS) device for the detection of lumbosacral radiculopathy (LSR) with standard electrodiagnostic study (EDX). Fifty patients referred to a tertiary referral electromyography (EMG) laboratory for testing of predominantly unilateral leg symptoms (weakness, sensory complaints, and/or pain) were included in the investigation. Twenty-five normal "control" subjects were later recruited to calculate the specificity of the automated protocol. All patients underwent standard EDX and automated testing. Raw NCS data were comparable for both techniques; however, computer-generated interpretations delivered by the automated device showed high sensitivity with low specificity (i.e., many false positives) in both symptomatic patients and normal controls. The authors concluded that the automated device accurately recorded raw data, but the interpretations provided were overly sensitive and lacked the specificity necessary for a screening or diagnostic examination.

**Professional Societies**

**American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM)**

The AANEM recommends that a typical examination performed for nerve conduction studies (NCSs) include:

- Development of a differential diagnosis based upon appropriate history and physical examination,
- Nerve conduction studies of a number of nerves by recording and studying the electrical responses from peripheral nerves or the muscles they innervate,
- The completion of indicated needle EMG studies to evaluate the differential diagnosis and to complement the nerve conduction study.

The minimum standards for NCV testing are as follows:

- The testing is medically indicated.
- It is performed using equipment that provides assessment of all parameters of the recorded signals (equipment designed for screening purposes is not acceptable).
- The test is performed by a physician, or by a trained technician under the direct supervision of a physician.
- The EMG must be performed by a trained physician.
- One physician supervises and performs all components of the exam.

(AANEM Recommended policy for electrodiagnostic medicine, 2014)

A task force of the AANEM (Charles Cho et al., 2010) evaluated the evidence and made recommendations regarding the use of electrodiagnostic (EDX) testing of patients with suspected lumbosacral radiculopathy. The task force concluded the following:

- In patients with suspected lumbosacral radiculopathy, the following EDX studies probably aid the clinical diagnosis:
  - Peripheral limb EMG (Class II evidence, Level B (probably effective) recommendation).
  - Paraspinal mapping (PM) with needle EMG in lumbar radiculopathy (Class II evidence, Level B recommendation).
  - H-reflex in S1 radiculopathy (Class II and III evidence, Level C (possibly effective) recommendation).
- Evidence suggests a low sensitivity of peroneal and posterior tibial F-waves (Class II and III evidence, Level C recommendation).
- There is inadequate evidence to reach a conclusion on the utility of the following EDX studies:
  - Dermatomal/segmental somatosensory evoked potentials (SEP) of the L5 or S1 dermatomes (Class III evidence, Level C recommendation).
  - Paraspinal mapping (PM) with needle EMG in sacral radiculopathy (one small Class II study, Level U (data inadequate or conflicting).
The position statement of the AANEM regarding the performance and interpretation of electrodiagnostic studies states that the performance or interpretation of NCS separately from the needle EMG component of the testing should clearly be the exception. The AANEM states that when NCSs are performed without needle EMG, the additional and complementary information provided by the needle EMG results (except in limited circumstances) is not available. Without the information provided by the needle EMG examination, valuable data that may be essential in establishing an accurate diagnosis is missing. For example, performing both studies together is critically important when evaluating patients with suspected radiculopathy, plexopathy, and motor nerve or motor neuron disease. According to the AANEM, NCS and EMG may be performed for carpal tunnel syndrome to ensure that an underlying medical condition is not missed. (AANEM, Proper performance and interpretation of electrodiagnostic studies, 2014)

A 2002 practice parameter for electrodiagnostic studies in carpal tunnel syndrome developed by the AANEM, American Academy of Neurology, and the American Academy of Physical Medicine and Rehabilitation, lists NCS as a standard diagnostic test for carpal tunnel syndrome and NEMG as an optional test for diagnosing carpal tunnel syndrome. (Jablecki et al., 2002)

In a policy for electrodiagnostic medicine, the AANEM recommends that a typical EMG examination includes all of the following: development of a differential diagnosis based upon appropriate history and physical examination, completion of indicated nerve conduction studies (recording and studying of electrical responses from peripheral nerves or muscles), and the completion of indicated needle EMG studies for selected muscles. The needle EMG studies are interpreted in real time as they are being performed. In addition, the AANEM recommends that one attending physician perform and supervise all components of the electrodiagnostic testing and that the testing occur on the same day. Reporting NCS and EMG results into separate reports is inappropriate and would be an exception to clinical practice. (AANEM Recommended Policy for Electrodiagnostic Medicine, 2014)

Based on the literature, the AANEM's position is that there are no contraindications to EMG in patients with lymphedema. However, the AANEM believes that reasonable caution should be taken in performing needle examinations in lymphedematous regions to avoid complications. Clinical judgment should be used in deciding whether the risk of complication is greater than the value of the information to be obtained from the EMG. (AANEM, Needle EMG in certain uncommon clinical contexts, 2005)

According to the AANEM, nerve conduction studies may be performed without needle electromyography in patients on anticoagulants, patients who have lymphedema, or patients who are being evaluated for carpal tunnel syndrome. (AANEM, Needle EMG in certain uncommon clinical contexts, 2005; Jablecki et al., 2002)

According to a literature review prepared for the AANEM, the Nervepace Digital Electroneurometer (NDE) is experimental and is not an effective substitute for standard electrodiagnostic studies in clinical evaluation of patients with suspected carpal tunnel syndrome. (David, 2003)

According to a model policy for needle electromyography and nerve conduction studies developed by AANEM, electrodiagnostic testing is indicated for the following:
- Focal neuropathies, entrapment neuropathies, or compressive lesions/syndromes such as carpal tunnel syndrome, ulnar neuropathies, or root lesions, for localization
- Traumatic nerve lesions, for diagnosis and prognosis
- Generalized neuropathies, such as diabetic, uremic, metabolic, toxic, hereditary, or immune-mediated
- Neuromuscular junction disorders such as myasthenia gravis, myasthenic syndrome or botulism
- Symptom-based presentations such as "pain in limb," weakness, disturbance in skin sensation or "paraesthesia" when appropriate pre-test evaluations are inconclusive and the clinical assessment unequivocally supports the need for the study
- Radiculopathy-cervical, lumbosacral
- Plexopathy-idiopathic, trauma, inflammatory or infiltrative
- Myopathy-including polymyositis and dermatomyositis, myotonic disorders, and congenital myopathies
- Precise muscle location for injections such as botulinum toxin, phenol, etc

The American Academy of Orthopaedic Surgeons (AAOS)
The AAOS Clinical Practice Guideline on the management of carpal tunnel syndrome states that limited evidence supports the use of a hand-held nerve conduction study (NCS) device for the diagnosis of carpal tunnel syndrome. (AAOS 2016)
Physiologic Recording of Tremor

Godinho et al. (2016) performed a systematic review in order to list, compare and classify technological-based devices used to measure motor function in individuals with Parkinson's disease into three groups, namely wearable, non-wearable and hybrid devices. A systematic literature search of the PubMed database resulted in the inclusion of 168 studies. These studies were grouped based on the type of device used. For each device the authors reviewed availability, use, reliability, validity, and sensitivity to change. The devices were then classified as recommended, suggested or listed based on the following criteria: (1) used in the assessment of Parkinson's disease (yes/no), (2) used in published studies by people other than the developers (yes/no), and (3) successful clinimetric testing (yes/no). The authors reviewed the Kinesia system which they classified as recommended. The authors based the clinimetric properties on one study (Giuffrida et al., 2009) which evaluated individuals with PD who performed the tremor subset of the UPDRS III while wearing Kinesia. Quantitative kinematic features were processed and highly correlated to clinician scores for rest tremor ($r^{(2)} = 0.89$), postural tremor ($r^{(2)} = 0.90$), and kinetic tremor ($r^{(3)} = 0.69$). According to the authors, the Kinesia device has been shown to be able to successfully ascertain tremor. However, it suffered from poor subject acceptability. The authors indicated that a limitation of the review was grouping all types of validity in to a single yes/no binary answer since this may not accurately reflect the maturity(validity) of a certain system given the different types of validity and many degrees of validity that exist.

Ghassemi et al. (2016) attempted to differentiate patients with essential tremor (ET) from tremor dominant Parkinson disease (PD). Accelerometer and electromyographic signals of hand movement from standardized upper extremity movement tests (resting, holding, carrying weight) were extracted from 13 PD and 11 ET patients. The signals were filtered to remove noise and non-tremor high frequency components. A set of statistical features was then extracted from the discrete wavelet transformation of the signals. Principal component analysis was utilized to reduce dimensionality of the feature space. Classification was performed using support vector machines. The proposed method was evaluated by using leave one out cross validation and the overall accuracy of the classification was reported. With this method, it was possible to discriminate 12/13 PD patients from 8/11 patients with ET with an overall accuracy of 83%. In order to individualize this finding for clinical application the authors generated a posterior probability for the test result of each patient and compared the misclassified patients, or low probability scores to available clinical follow up information for individual cases. This non-standardized post hoc analysis revealed that not only the technical accuracy but also the clinical accuracy limited the overall classification rate. The authors indicated that in addition to the successful isolation of diagnostic features, longitudinal and larger sized validation is needed in order to prove clinical applicability.

Fraiwan et al. (2016) evaluated a new system for mobile phone applications based on measuring the acceleration from the Parkinson's disease patient's hand using a mobile cell phone accelerometer. Recordings from 21 Parkinson's disease patients and 21 healthy subjects were used. These recordings were analyzed using a two level wavelet packet analysis and features were extracted forming a feature vector of 12 elements. The features extracted from the 42 subjects were classified using a neural networks classifier. The results obtained showed an accuracy of 95% and a Kappa coefficient of 90%. According to the authors, these results indicate that a cell phone accelerometer can accurately detect and record rest tremor in Parkinson's disease patients. The study did not confirm the utility of such findings in improving care and outcome of patients.

Heldman et al. (2014) evaluated the reliability and responsiveness of a portable kinematic system for quantifying Parkinson's disease (PD) motor deficits as compared to clinical ratings. Eighteen PD patients with subthalamic nucleus deep-brain stimulation (DBS) performed three tasks for evaluating resting tremor, postural tremor, and finger-tapping speed, amplitude, and rhythm while wearing a wireless motion-sensor unit (Kinesia) on the more-affected index finger. These tasks were repeated three times with DBS turned off and at each of 10 different stimulation amplitudes chosen to yield small changes in treatment response. Each task performance was video-recorded for subsequent clinician rating in blinded, randomized order. Test-retest reliability was calculated as intraclass correlation (ICC) and sensitivity was calculated as minimal detectable change (MDC) for each DBS amplitude. ICCs for Kinesia were significantly higher than those for clinician ratings of finger-tapping speed, amplitude, and rhythm, but were not significantly different for evaluations of resting or postural tremor. Similarly, Kinesia scores yielded a lower MDC as compared with clinician scores across all finger-tapping sub-scores, but did not differ significantly for resting and postural tremor. The authors concluded that the Kinesia portable kinematic system can provide greater test-retest reliability and sensitivity to change than conventional clinical ratings for measuring bradykinesia, hypokinesia, and dysrhythmia in PD patients. The study did not confirm the utility of such findings in improving care and outcome of patients.

Quantitative Sensory Testing (QST)

Marcuzzi et al. (2016) conducted a systematic review to summarize the emerging body of evidence investigating the prognostic value of QST measures in people with low back pain (LBP). An electronic search of six databases was conducted from inception to October 2015. Experts in the field were contacted to retrieve additional unpublished data. Studies were included if they were prospective longitudinal in design, assessed at least one QST measure in people with LBP, assessed LBP status at follow-up, and reported the association of QST data with LBP status at follow-up. Statistical pooling of results was not possible due to heterogeneity between studies. Of 6,408 references screened
Neurophysiologic Testing and Monitoring

identified 54 potentially eligible studies, of which 3 were quality was assessed using the Quality Assessment of Diagnostic Accuracy Studies (QUADAS) tool. The investigators Dros et al. (2009) conducted a systematic review of studies in which the accuracy of monofilament testing was determine the clinical utility of QST.

differentiate between people with OA a and healthy controls. The authors concluded that QST of PPTs demonstrated good ability to

Suokas et al. (2012) systematically reviewed the use of quantitative sensory testing (QST) in pain characterization in osteoarthritis (OA). Of 20 studies comparing people with OA and healthy controls, seven provided sufficient information for meta-analysis. Compared with controls, people with OA had lower pressure pain thresholds (PPTs) both at the affected joint and at remote sites. The authors concluded that QST of PPTs demonstrated good ability to
determine between people with OA and healthy controls. The authors stated that more research is needed to

determining the clinical utility of QST.

Dros et al. (2009) conducted a systematic review of studies in which the accuracy of monofilament testing was evaluated to detect peripheral neuropathy of any cause using nerve conduction as reference standard. Methodological quality was assessed using the Quality Assessment of Diagnostic Accuracy Studies (QUADAS) tool. The investigators identified 54 potentially eligible studies, of which 3 were finally selected for data synthesis. All studies were limited to
patients with diabetes mellitus and showed limitations according to the QUADAS tool. Sensitivity ranged from 41% to 93% and specificity ranged from 68% to 100%. Because of the heterogenous nature of the studies, a meta-analysis could not be accomplished. According to the investigators, despite the frequent use of monofilament testing, little can be said about the test accuracy for detecting neuropathy in feet without visible ulcers. Optimal test application and defining a threshold should have priority in evaluating monofilament testing, as this test is advocated in many clinical guidelines. Accordingly, the investigators do not recommend the sole use of monofilament testing to diagnose peripheral neuropathy.

Cettomai et al. (2013) investigated the utility of screening tools administered by non-physician healthcare workers (HCW) and quantitative sensory testing (QST) administered by trained individuals for identification of moderate/severe neuropathy. The study included 240 HIV-infected outpatients using 2-stage cluster randomized sampling. HCWs administered several screening tools. Tools were validated against a clinical diagnosis of neuropathy. Sixty-five percent of the participants were taking antiretrovirals, and 18% had moderate/severe neuropathy. The screening tests were 76% sensitive in diagnosing moderate/severe neuropathy with negative predictive values of 84-92%. QST was less sensitive but more specific. The authors concluded that QST showed promise for research use.

Yildirim and Gunduz (2015) investigated the ability of Semmes-Weinstein Monofilament testing to detect carpal tunnel syndrome, as well as moderate-to-severe carpal tunnel syndrome using varying thresholds and methods. Clinical and electrophysiological data of 62 patients (124 hands) with a mean age of 49.09±10.5 years were evaluated in this study. The criteria of 2.83-conventional method yielded a sensitivity of 98% and a specificity of 17% in the diagnosis of carpal tunnel syndrome. The threshold value of 3.22 using a conventional method was found to detect moderate-to-severe carpal tunnel syndrome with high sensitivity (80%) and excellent specificity (93%). A statistically significant difference was observed in the mean strength values of the monofilaments in moderate-to-severe carpal tunnel syndrome hands and hands without carpal tunnel syndrome. The authors concluded that Semmes-Weinstein monofilament testing might be a valuable quantitative method for detecting moderate-to-severe carpal tunnel syndrome. According to the authors, future studies with a larger sample size, as well as further analyses of different threshold abnormalities of moderate-to-severe CTS hands, are needed.

According to a National Institute for Health and Care Excellence (NICE) Guidance for VibraTip for testing vibration perception to detect diabetic peripheral neuropathy, the current evidence does not support the case for routine adoption of this device. (NICE 2014, updated March 2015)

**Professional Societies**

**American Academy of Neurology (AAN)**

In a 2003 report, reaffirmed in July 2013, the AAN noted quantitative sensory testing (QST) is a potentially useful tool for measuring sensory impairment for clinical and research studies. However, QST results should not be used as a sole method for diagnosis of pathology. The authors identified no adequately powered class I studies demonstrating the effectiveness of QST in evaluating any particular disorder. Lesser quality studies indicated that QST may be useful in identifying small or large fiber sensory abnormalities in some clinical conditions. The AAN indicated QST poses technical challenges in the methodology of testing, reproducibility, and psychophysical factors which limit the objectivity of testing results. The recommendations for use of QST include:

- Based on Class II evidence, QST measuring vibration and thermal perception thresholds is probably an effective tool in the documentation of sensory abnormalities in patients with diabetic neuropathy (Level B recommendation).
- Based on several Class II studies, QST is probably useful in documenting changes in sensory thresholds in longitudinal evaluation of patients with diabetic neuropathy (Level B recommendation).
- Although there is data to suggest that QST abnormalities may be detectable in the absence of clinical evidence of neuropathy in diabetic patients, there is no credible prospective evidence that patients with these abnormalities will ultimately go on to develop clinical neuropathy. Thus, whether QST is useful in preclinical neuropathy detection is unproven (Level U recommendation - current knowledge is conflicting, unproven, or inadequate). (Shy et al., 2003; reaffirmed in July 2013)

In a practice topic for the evaluation of distal symmetric polyneuropathy, Definition for Clinical Research, the American Academy of Neurology, American Association of Neuromuscular and Electrodiagnostic Medicine, and American Academy of Physical Medicine and Rehabilitation state that the sensitivities and specificities of quantitative sensory testing (QST) varied widely among studies. These psychophysical tests have greater inherent variability, making their results more difficult to standardize and reproduce. Reproducibility of QST varied from poor to excellent. The practice parameter indicated that there is too much inconsistency among the studies describing the accuracy of QST for its incorporation into the case definition. (England et al., 2009)

**American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) formerly known as the American Association of Electrodiagnostic Medicine (AAEM)**

In 2004, AAEM reviewed the technical aspects and reproducibility of different methods to determine threshold for light touch-pressure, vibration, thermal, and pain stimuli. Clinical uses and limitations of QST were also reviewed. The
report found that the results of QST are highly dependent on methodology and the full cooperation of the subject. QST has been shown to be reasonably reproducible over a period of days or weeks in normal subjects. The use of QST in research and patient care should be limited to instruments and their corresponding methodologies that have been shown to be reproducible. Literature data do not allow conclusions regarding the relative merits of individual QST instruments (Chong and Cros, 2004). AAEM concluded the following:

- QST is a reliable psychophysical test of large-and small-fiber sensory modalities.
- QST tests the integrity of the entire sensory axis from receptors to brain. Abnormalities do not localize dysfunction to the central or peripheral nervous system, or any particular location along the peripheral nervous system.
- QST is highly dependent on the full cooperation of the patient and may be falsely abnormal if the patient is biased toward an abnormal result or is cognitively impaired. No algorithm can reliably distinguish between psychogenic and organic abnormality.
- QST has been shown to be reasonably reproducible over a period of days or weeks in normal subjects. Since longitudinal QST studies of patients in drug trials are usually done over a period of several months to a few years, reproducibility studies on the placebo-controlled group should be included.
- The reproducibility of thermal thresholds may not be as good as that of vibration threshold.
- For individual patients, more studies are needed to determine the maximum allowable difference between two QSTs that can be attributed to experimental error.
- Different commercially available QST instruments have different specifications (thermode size, stimulus characteristics), testing protocols, algorithms, and normal values. Only QST instruments and their corresponding methodologies that have been shown to be reproducible should be used for research and patient care.
- The results of QST can only be interpreted properly if machine calibration and testing protocol are strictly followed.
- The published evidence does not allow a conclusion to be made regarding whether any QST instrument is better than another.

According to a model policy for needle electromyography and nerve conduction studies developed by American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM), the current perception threshold/sensory nerve conduction threshold test (sNCT) is investigational. (American Association of Neuromuscular and Electrodiagnostic Medicine Model Policy for Needle Electromyography and Nerve Conduction Studies Updated January 2016)

**American College of Foot and Ankle Surgeons**

In 2010, the American College of Foot and Ankle Surgeons revised a clinical practice guideline for the diagnosis and treatment of heel pain, which states that diagnostic studies [for heel pain] may include electromyography (EMG), nerve conduction velocity (NCV) test, magnetic resonance imaging (MRI), and the pressure-specified sensory device test. (Thomas et al., 2010)

**The International Association for the Study of Pain**

The International Association for the Study of Pain published guidelines for the assessment of patients with neuropathic pain. According to the guideline, clinical examination, including accurate sensory examination, is the basis of neuropathic pain diagnosis. For more accurate sensory profiling, quantitative sensory testing is recommended for selected cases in clinic, including the diagnosis of small fiber neuropathies and for research purposes. The associations states that QST can be used in clinic along with bedside testing, but it cannot allow for estimation of the level of the lesion within the neuraxis. The relevance of QST to predict therapeutic outcome has yet to be established in prospective studies. (Haanpaa et al. 2011)

**Seizure Monitoring Systems**

Szabo et al. (2015) evaluated the surface electromyography (sEMG) seizure-detection algorithm developed by Brain Sentinel using inpatient video-electroencephalography (EEG) monitoring. sEMG was recorded unilaterally from the biceps/triceps muscles in 33 patients (17white/16 male) with a mean age of 40 (range 14-64) years who were admitted for video-EEG monitoring. Maximum voluntary biceps contraction was measured in each patient to set up the baseline physiologic muscle threshold. A seizure-detection algorithm utilizing Hotelling’s T-squared power analysis of compound muscle action potentials was used to identify generalized tonic-clonic seizures (GTCS) and correlated with video-EEG recordings. In 1,399 h of continuous recording, there were 196 epileptic seizures (21 GTCS, 96 myoclonic, 28 tonic, 12 absence, and 42 focal seizures with or without loss of awareness) and 4 nonepileptic spells. During retrospective, offline evaluation of sEMG from the biceps alone, the algorithm detected 20 GTCS (95%) in 11 patients, averaging within 20 s of electroclinical onset of generalized tonic activity, as identified by video-EEG monitoring. One false-positive detection occurred during the postictal period following a GTCS, but false alarms were not triggered by other seizure types or spells. The authors concluded that Brain Sentinel’s seizure detection algorithm demonstrated excellent sensitivity and specificity for identifying GTCS recorded in an epilepsy monitoring unit. According to the authors, further studies are needed in larger patient groups, including children, especially in the outpatient setting.

In a case-control study, Beniczky et al. (2014) investigated the characteristics of sustained muscle activation during convulsive epileptic and psychogenic nonepileptic seizures (PNES), as compared to voluntary muscle activation. The
main goal was to find surface electromyography (EMG) features that can distinguish between convulsive epileptic seizures and convulsive PNES. Surface EMG was recorded from the deltoid muscles during long-term video-electroencephalography (EEG) monitoring in 25 patients and in 21 healthy controls. A total of 46 clinical episodes were recorded: 28 generalized tonic-clonic seizures (GTCS) from 14 patients with epilepsy, and 18 convulsive PNES from 12 patients (one patient had both GTCS and PNES). The healthy controls were simulating GTCS. Duration of the seizure, and separation between the tonic and the clonic phases distinguished at group-level but not at individual level between convulsive PNES and GTCS. RMS, temporal dynamics of the high frequency (HF)/low frequency (LF) ratio, and the evolution of the silent periods differentiated between epileptic and nonepileptic convulsive seizures at the individual level. A combination between HF/LF ratio and RMS separated all PNES from the GTCS. A blinded review of the EMG features distinguished correctly between GTCS and convulsive PNES in all cases. The HF/LF ratio and the RMS of the PNES were smaller compared to the simulated seizures. According to the authors, this study suggests that surface EMG features can accurately distinguish convulsive epileptic from nonepileptic psychogenic seizures, even in PNES cases without rhythmic clonic movements. Further research with randomized controlled trials is needed to validate these findings.

Visual Evoked Potentials for Glaucoma

Chen and Zhao (2017) compared the diagnostic performance of isolated-check visual evoked potential (icVEP) and standard automated perimetry (SAP), for evaluating the application values of icVEP in the detection of early glaucoma. In total, 144 subjects (288 eyes) were enrolled in this study. icVEP testing was performed with the Neucodia visual electrophysiological diagnostic system. A 15% positive-contrast (bright) condition pattern was used in this device to differentiate between glaucoma patients and healthy control subjects. SAP testing was performed with the Humphrey Field Analyzer II. The authors found there was no statistical significance between the sensitivity or specificity of SAP and icVEP, regardless of which diagnostic standard was based on. The authors concluded that the diagnostic performance of icVEP is not better than that of SAP in the detection of early glaucoma.

Mousa et al. (2014) evaluated the validity of multifocal visual evoked potential (mfVEP) and whether it could be used effectively for early detection of visual field defects in glaucoma. Three groups were tested: normal controls (38 eyes), glaucoma patients (36 eyes) and glaucoma suspect patients (38 eyes). All subjects had a two standard Humphrey field analyzer (HFA) test 24-2 and a single mfVEP test undertaken in one session. Analysis of the mfVEP results was done using a new analysis protocol: the hemifield sector analysis (HSA) protocol. Analysis of the HFA was done using the standard grading system. Analysis of mfVEP results showed that there was a statistically significant difference between the three groups in the mean signal to noise ratio. Sensitivity and specificity of the HSA protocol in detecting glaucoma was 97% and 86%, respectively, and for glaucoma suspect patients the values were 89% and 79%, respectively. According to the authors, the new HSA protocol used in the mfVEP testing can be applied to detect glaucomatous visual field defects in both glaucoma and glaucoma suspect patients. Using this protocol can provide information about focal visual field differences across the horizontal midline, which can be utilized to differentiate between glaucoma and normal subjects. The authors indicated that the sensitivity and specificity of the mfVEP test showed very promising results and correlated with other anatomical changes in glaucoma field loss. According to the authors, there are significant reasons which made the use of mfVEP as a primary tool for objective visual field testing limited. The test is lengthy, specifically which in the two runs mode which is the one used for diagnosis and monitoring, and performing the test needs qualified and well-trained technical staff that can connect the electrodes accurately and monitor for any intra- test errors. Despite this, many patients prefer the mfVEP test over standard HFA testing protocols because it is less dependent on patients’ responses. However, for clinicians it cannot be performed on all glaucoma patients in daily practice because of its lengthy testing duration. The interpretation of mfVEP test results is another limiting factor, as it requires the clinician to possess a good knowledge of VEP testing and potential sources of testing error. All these factors have put the mfVEP test behind where it should be as a highly sensitive and repeatable objective perimetry testing tool.

Kanadani et al. (2014) evaluated the sensitivity and specificity of frequency-doubling perimetry (FDT) and multifocal visual evoked potential (mfVEP) tests in normal, suspect, and glaucomatous eyes and compare the monocular and interocular mfVEP. Ninety-five eyes from 95 individuals (23 controls, 33 glaucoma suspects, 39 glaucomatous) were enrolled. All participants underwent a full ophthalmic examination, followed by SAP, FDT, and mfVEP tests. The area under the curve for mean deviation and pattern standard deviation were 0.756 and 0.761, respectively, for FDT, 0.564 and 0.512 for signal and alpha for interocular mfVEP, and 0.568 and 0.538 for signal and alpha for monocular mfVEP. This difference between monocular and interocular mfVEP was not significant. The authors concluded that the FDT Matrix was superior to mfVEP in glaucoma detection. The difference between monocular and interocular mfVEP in the diagnosis of glaucoma was not significant. The authors could not confirm the efficacy of mfVEP in detecting early glaucomatous defects, and found no difference in area under curve (AUC) between the interocular and monocular mfVEP analysis.

Pillai et al. (2013) evaluated the ability of the short-duration transient visual evoked potential (SD-tVEP) to discriminate between healthy eyes and eyes with early to advanced glaucomatous visual field loss. The study included 30 eyes of 30 healthy controls and 45 eyes of 35 glaucoma patients. Normal eyes had 20/30 or better visual acuity
and normal 24-2 Swedish interactive thresholding algorithm (SITA) Standard visual fields. There were 15 eyes in each group. SD-tVEPs were recorded using the Diopsys NOVA-LX System. Each eye was stimulated with a low (Lc) and a high (Hc) Michelson contrast checkerboard pattern. Each test resulted in an Lc and an Hc SD-tVEP response. Each response was evaluated for overall waveform quality, P100 latency, and P100 amplitude referenced to the N75. The sensitivity, specificity, negative predictor value (NPV), and positive predictor value (PPV) were calculated. Lc latency showed the highest accuracy for discrimination using receiver operating characteristic curves for high and low contrast parameters. The analysis for all subjects resulted in a 91.1% sensitivity, 93.3% specificity, 95.3% PPV, and an 87.5% NPV. Evaluating the mean Lc latency of the mild, moderate, and severe glaucoma patients against controls showed discrimination consistent with the glaucoma severity. The authors concluded that short-duration transient VEP objectively identified decreased visual function and discriminated between healthy and glaucomatous eyes, and also showed good differentiation between healthy eyes and those with early visual field loss. According to the authors, further studies are warranted to determine if modifications to the present protocol could better isolate the M and P pathways VEP responses. This study is limited by a small study population.

De Moraes et al. (2012) tested a framework that describes how the multifocal visual-evoked potential (mfVEP) technique is used in a particular glaucoma practice. In this prospective, descriptive study, glaucoma suspects, ocular hypertensives and glaucoma patients were referred for mfVEP testing by a single glaucoma specialist over a 2-year period. All patients underwent standard automated perimetry (SAP) and mfVEP testing within 3 months. Two hundred and ten patients (420 eyes) were referred for mfVEP testing for the following reasons: (1) normal SAP tests suspected of early functional loss (ocular hypertensives, n = 43; and glaucoma suspects on the basis of suspicious optic disks, n = 52); (2) normal-tension glaucoma patients with suspected central SAP defects (n = 33); and (3) SAP abnormalities needing confirmation (n = 82). All the glaucoma suspects with normal SAP and mfVEP results remained untreated. Of those with abnormal mfVEP results, 68 % (15/22) were treated because the abnormal regions on the mfVEP were consistent with the abnormal regions seen during clinical examination of the optic disk. The mfVEP was abnormal in 86 % (69/80) of eyes with glaucomatous optic neuropathy and SAP damage, even though it did not result in an altered treatment regimen. In NTG patients, the mfVEP showed central defects in 44 % (12 of 27) of the eyes with apparently normal central fields and confirmed central scotomata in 92 % (36 of 39), leading to more rigorous surveillance of these patients. The authors concluded that in a clinical practice, the mfVEP was used when clinical examination and subjective visual fields provided insufficient or conflicting information and this information influenced clinical management. According to the authors, it was not their purpose to compare the diagnostic ability of the mfVEP to that of other technologies, nor can they rule out that the possibility that the diagnostic power of detecting glaucoma could be increased by replacing the mfVEP test with other diagnostic tests (e.g., SWAP) or even repeated conventional perimetry. Instead, the authors sought to describe how the mfVEP was used in a clinical practice, as despite extensive debate on the performance of each technique, little is known on how they are used in practice and how they influence clinical decisions. This study did not confirm the usefulness of multifocal visual-evoked potential (mfVEP) in improving care and outcome of patients.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Electromyography (EMG)
EMG devices are approved by the FDA as Class II medical devices. See the following website for more information (use product code IKN): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed July 16, 2017)

Seizure Monitoring Systems
The FDA granted a de novo classification to market the SPEAC® System, the Brain Sentinel® Seizure Monitoring and Alerting System (Brain Sentinel, Inc.) on February 16, 2017. The SPEAC System is indicated for adjunctive seizure monitoring in adults at home or in healthcare facilities during periods of rest. The monitor analyzes surface electromyography (sEMG) signals that may be associated with generalized tonic-clonic seizures. It is worn over the bicep muscle belly of the upper arm. The SPEAC System records and stores sEMG data for subsequent review by a trained healthcare professional. See the following website for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf14/DEN140033.pdf. (Accessed July 18, 2017)

Quantitative Sensory Testing and Nerve Conduction Studies
Devices used for current perception threshold and sensory nerve conduction threshold testing are classified under product codes LLN, GXB, LOW, and GWI. Note that there are numerous 510(k) marketing clearances for these codes and that not all of these clearances are for devices indicated for nerve threshold testing. Neurosensory testing systems such as the NK Pressure-Specified Sensory Device (PSSD) are regulated by the FDA as Class II devices. The PSSD was approved via the FDA 510(k) process (K934368) on August 11, 1994. See the following website for more information: (use product codes LLN, GXB, LOW or GWI) http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed July 16, 2017)

The FDA classifies instruments for quantitative sensory testing (QST) as Class II devices under the generic names “esthesiometer” (product code GXB), “2-point discriminator” (product code GWI), “vibration threshold measurement

The Neurometer® approved for marketing in June 1986. A similar device, the Medi-Dx 7000TM Single-Electrode Sensory Nerve Conduction Threshold Device (NDA Inc, Laguna Beach, CA) received marketing approval from the FDA in December 1997. See the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf/K964622.pdf. (Accessed July 16, 2017)

**Automated Point of Care Nerve Conduction Tests**

Several point of care nerve conduction devices have received FDA 510(k) clearance. These devices are regulated as Class II devices. Examples of FDA approved devices include, but are not limited to, the NC-stat® System, the Brevio® NCS-Monitor, and the Advance™ System.

Point of care nerve conduction devices are classified under the product code JXE. See the following website for more information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed July 16, 2017)

**Accelerometers**

Kinesia (Cleveland Medical Devices Inc.) received FDA approval in April 2007 to be used for monitoring physical motion and muscle activity to quantify kinematics of movement disorder symptoms such as tremor and assess activity in any instance where quantifiable analysis of motion and muscle activity is desired. Kinesia, a quantitative motor assessment system, is a compact wireless system that uses accelerometers and gyroscopes to monitor three-dimensional motion. The device is worn on the wrist and finger of the patient and can be used to monitor upper extremity movement disorder symptoms and their fluctuations. See the following website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf6/K063872.pdf. (Accessed July 16, 2017)

**Visual Evoked Potentials (VEPs) for Glaucoma**

Numerous evoked response photic stimulators have been approved by the FDA (Class II, product codes GWE and HLX). These devices may also have recording/measuring capabilities, or the visual signals produced by these devices may be recorded and measured by standard EEG recording devices (product code GWQ).

**Additional Products**

**Electromyography (EMG)**

A number of EMG devices are available that are too numerous to mention here. Surface EMG devices include but are not limited to the following: Spinoscope (Spinex Corp.).

**Quantitative Sensory Testing and Nerve Conduction Studies**

Testing devices include but are not limited to the following: Medi-Dx 7000TM Single-Electrode Sensory Nerve Conduction Threshold Device (NDA Inc, Laguna Beach, CA), Neurometer® CPT Electrodagnostic Neurostimulator (Neurotron Inc, Baltimore, MD), NC-stat System (NeuroMetrix, Inc.), Brevio (NeuMed, Inc.), Neurometer (Neurotron, Inc.); Neural-Scan, formally known as Medi-Dx 7000® (Neuro-Diagnostic Associates); Nk Pressure-Specified Sensory Device (Nk Biotechnical Engineering); Vibration Perception Threshold (VPT) Meter® (Xilas Medical Inc.); Medi-Dx 7000 (Neuro-Diagnostic Assoc. (NDA) Inc.); CASE™ IV System: Computer Aided Sensory Evaluator (WR Medical Electronics Co.); Neurometer® (Neurotron Inc.); Vibrameter™ (Somedic AB, Sweden); Thermal sensitivity tester (Sensortek, Inc., Clifton, NJ); Axon-II™ NCSS System™.

**REFERENCES**

The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2017T0493U]


With Diabetes:

UnitedHealthcare Oxford Clinical Policy

Neurophysiologic Testing and Monitoring

updated: March 2015.

testing vibration perception in the detection of diabetic peripheral neuropathy: Published date: December 2014. Last


<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/01/2017</td>
<td>• Changed policy title; previously titled Neurophysiologic Testing</td>
</tr>
<tr>
<td></td>
<td>• Revised coverage rationale:</td>
</tr>
<tr>
<td></td>
<td>o Replaced language indicating “nerve conduction studies with or without late</td>
</tr>
<tr>
<td></td>
<td>responses (e.g., F-wave and H-reflex tests) are proven and medically</td>
</tr>
<tr>
<td></td>
<td>necessary when performed in conjunction with needle electromyography for</td>
</tr>
<tr>
<td></td>
<td>any of the [listed] known or suspected disorders” with “nerve conduction</td>
</tr>
<tr>
<td></td>
<td>studies with or without late responses (e.g., F-wave and H-reflex tests) and</td>
</tr>
<tr>
<td></td>
<td>neuromuscular junction testing are proven and medically necessary when</td>
</tr>
<tr>
<td></td>
<td>performed in conjunction with needle electromyography for any of the [listed]</td>
</tr>
<tr>
<td></td>
<td>known or suspected disorders”</td>
</tr>
<tr>
<td></td>
<td>o Added language to indicate surface electromyography (SEMG) based seizure</td>
</tr>
<tr>
<td></td>
<td>monitoring systems are unproven and not medically necessary</td>
</tr>
</tbody>
</table>

POLICY HISTORY/REVISION INFORMATION
There is insufficient evidence to conclude that SEMG based seizure monitoring systems improve care and health outcomes in patients with seizures.

- Well-designed controlled studies are needed to determine the efficacy of these devices.

- Updated list of applicable HCPCS codes:
  - Added A9279 and A9280
  - Revised description for G0255

- Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references.

- Archived previous policy version DIAGNOSTIC 047.16 T2