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. (1) 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 (2). 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, pre configured 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 e-mail. 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 XL Tek 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.”
Examples of Automated Point-of-Care devices not eligible for coverage as discussed in this policy:
  - NC-stat System (NeuroMetrix)
  - Neural-Scan NCS (Neuro Diagnostics)
  - Neural Scan Axon II
  - Brevio (NeuMed)
  - Neurometer (Neurotron)
  - Axon-II ™ (PainDx)
  - XLTek Neuropath (Excel- Tech)
Automated Point-of-Care devices not listed, but equivalent to the devices listed are also not eligible for coverage as discussed in this policy.

**POLICY**
Automated nerve conduction tests are considered experimental / investigational.

**RATIONALE**
Assessment of a diagnostic technology typically focuses on 3 parameters: 1) technical performance; 2) diagnostic performance (sensitivity, specificity, and positive and negative predictive value) in appropriate populations of patients; and 3) demonstration that the diagnostic information can be used to improve patient outcomes. This evaluation will focus on the technical performance of NC-stat, the first automated nerve conduction test device to be marketed, and its reported performance in diagnosing patients (validity) with suspected deficits of neuronal transmission (e.g., diabetic neuropathy, carpal tunnel syndrome (CTS), and lumbosacral radiculopathy).

Technical performance of a device is typically assessed with 2 types of studies, those that compare test measurements with a gold standard and those that compare results taken with the same device on different occasions (test-retest). The gold standard for nerve conduction testing is the electrophysiologic nerve conduction study (NCS) combined with needle electromyography (EMG). Several studies have assessed the reliability and validity of NC-stat when used by personnel trained in electrophysiology. These studies, the majority of which are company-sponsored, are described below.

Diagnostic performance is evaluated by the ability of a test to accurately diagnose a clinical condition in comparison with a gold standard. The sensitivity of a test is the ability to detect a disease when the condition is present (true positive), while specificity indicates the ability to detect patients who are suspected of disease but who do not have the condition (true negative). Evaluation of diagnostic performance, therefore, requires independent assessment by the two methods in a population of patients who are suspected of disease but who do not all have the disease. An additional issue with NC-stat is that this device is designed to be used by minimally trained personnel (approximately 1 day for device-specific training), while the comparison standard is performed by specialists with extensive training in electromyography (EMG) and electrophysiology. Studies that do not meet these criteria (broad patient population and comparison of point-of-care use with the standard laboratory EMG) may be considered relevant.
Evidence related to improvement of clinical outcomes with use of point-of-care automated nerve testing is also reviewed.

**Literature Review**

**Technical Performance**

**Comparison to the Reference Standard:** A 2006 study compared results for sensory nerve testing from NC-stat and the reference standard in median and ulnar nerves in 60 patients referred to an EMG laboratory for neck and shoulder pain who also volunteered to undergo testing with NC-stat. (3) The reported correlations (Pearson correlation) between the NC-stat and the reference standard were high (0.91 for median nerve distal sensory latency [DSL], 0.70 for ulnar DSL, and 0.88 for the median ulnar difference of the DSL). However, this final correlation was calculated only with the responses obtained for 81 of 120 possible nerve pairs. The authors of this study report systematic differences between the two techniques and indicate that use of the NC-stat would require applicable reference ranges.

A study of motor nerve function compared NC-stat with standard nerve conduction tests of the wrist in a small study of 17 subjects with diabetes mellitus who had clinical evidence of peripheral neuropathy in either the upper or lower extremity. (4) Again, Pearson correlation coefficients were relatively high and ranged from 0.70 for ulnar distal motor latency (DML) to 0.96 for median nerve DML.

Another NeuroMetrix-sponsored trial compared NC-stat and standard EMG results for peroneal and posterior tibial nerve conduction in 60 patients referred to an EMG laboratory. (5) The report indicates that all patients referred to the laboratory were offered the opportunity to participate but does not provide the total number of referrals. F-wave latency (FLAT) was found to have the highest correlation (0.91, 0.90 Spearman correlation coefficient for peroneal and posterior tibial nerves, respectively), with moderate correlations for amplitude (0.86, 0.73) and distal motor latency (0.70, 0.45). The authors concluded that there was excellent criterion validity for the peroneal and posterior tibial FLAT and the peroneal amplitude; acceptable criterion validity for the peroneal DML and posterior tibial amplitude; but the validity of the posterior tibial DML could not be demonstrated. Although NC-stat results were significantly correlated with standard EMG tests in the study population as a whole, in a subgroup analysis of the most abnormal half of responses, the correlation coefficient for amplitude of the peroneal response was 0.62, and the correlation coefficient for distal motor latency was reduced to 0.32 for the posterior tibial nerve and 0.10 for the peroneal nerve. Thus, in this pathological subgroup analysis, criterion validity was lost for the peroneal distal motor latency and decreased from “excellent” to “acceptable” for the other parameters. The authors note that “this study did not address interpretations performed by physicians using NC-stat data, nor the validity of the reference ranges used or the way these were collected.”

A Pearson correlation coefficient of 0.944 was reported for DML for 46 patients with CTS who had a nerve conduction study at a different time (average of 28 days’ difference). (6) Another study compared results from NC-stat and standard NCS in a previously diagnosed patient population. (7) This study compared DML of the median nerve in 72 patients (of 400 treated) with
established CTS before and after surgical intervention, finding a correlation coefficient of 0.88 for the median nerve DML. However, a scatter plot indicates a poor correlation for longer latencies.

**Test-Retest:** NeuroMetrix reported intra-operator reliability in 15 healthy subjects who underwent measurements 7 days apart. (8) The report states that “each upper and lower extremity nerve was tested twice by the same technician” and that 9 subjects participated in both upper and lower extremity studies. It is not clear from the report whether the upper and lower extremities were designed as separate studies, or if 12 of 42 (29%) measurements did not provide usable data. Of the data reported, the coefficient of variation ranged from 0.013 for F-wave latency to 0.298 for the compound muscle action potential amplitude of the peroneal nerve. A 2010 publication by NeuroMetrix reported test-retest reproducibility with the ADVANCE™ system in 30 subjects with symptoms suggestive of neuropathies; 29 subjects completed the study. (9) Coefficients of variation ranged from 4.2% to 9.8% for tests measured 3-7 days apart. Between session intraclass correlation coefficients (ICCs) ranged from 0.98 for F-wave latency to 0.77 for sural sensory conduction velocity.

**Diagnostic Performance**

**Carpal Tunnel Syndrome:** In an early report of the NC-stat technology using DML to diagnose CTS, Leffler and colleagues reported that in 248 symptomatic hands (apparently a combination of an initial and validation group), compared with conventional diagnosis, testing using this device had a sensitivity of 86% and specificity of 90%. (10) In the report by Rotman et al., (6) the NC-stat DML was shown to have a sensitivity of 89% “at the predetermined specificity of 95%” for the diagnosis of CTS for “70 hands” that met the standardized CTS case definition. However, in a point-of-care study evaluating industrial workers for possible CTS using DML, many individuals who were identified with prolonged DML by NC-stat fell within the normal range (using 95% cutoff point) as defined by this study population. (11) This study also comments on the importance of sensory nerve findings in the diagnosis of CTS, suggesting a need to better define “normal” values.

**Diabetic Peripheral Neuropathy:** Another study assessed the validity of NC-stat to diagnose diabetic peripheral neuropathy through sural nerve testing in patients from diabetes and diabetic neuropathy outpatient practices. (12) Seventy-two consecutive patients (64 with type 2 diabetes) who completed a clinical evaluation, a conventional nerve conduction study, and a point-of-care NC-stat assessment were enrolled. The point-of-care assessment was independently conducted by non-technologist research staff following a single 1-hour lesson in the NC-stat protocol. The amplitude potential of the sural nerve was tested as an early indicator of diabetic neuropathy. Using a threshold of 6 µV, the authors report that the sensitivity and specificity of NC-stat for diagnosis of diabetic sensorimotor polyneuropathy, as defined by clinical and conventional electrophysiological evaluation, was 92% and 82%, respectively. The Spearman correlation coefficient (compared with the reference standard) was 0.95. Further study is needed in a broad spectrum of patients, including those who present with atypical neuropathy in a clinical setting. Further investigation is also needed into specific approaches that include the point-of-care nerve conduction study as a component of the clinical care of those with polyneuropathy.

**Lumbosacral Radiculopathy:** Fisher and colleagues explored the relationship between NC-stat and routine NCS/needle EMG in 34 consecutive patients with a clinical history and/or examination consistent with lumbosacral radiculopathy. (13) Inclusion in the study was based on chart review of symptoms from clinical history and/or examination (including low back pain or buttock pain,
numbness, and/or paresthesias of one or both lower extremities) and having undergone testing with both NC-stat and routine electrodiagnostic studies. All testing was conducted by the principal investigator, and the reason for and timing of NC-stat testing was not specified. Of the 34 patients included in the study, 28 had magnetic resonance imaging (MRI) of the lumbosacral spine within 6 months of electrodiagnosis, 2 had a post-myelogram computed tomography (CT) scan, and 3 had lumbosacral spine radiographs. A neuroradiologist who was blinded to the clinical evaluation and electrodiagnostic results determined from MRI or CT that lumbosacral root injury was likely at the L4-5 and/or L5-S1 levels in 18 patients (60%). The study found some correlation between the electrodiagnostic testing and NC-stat. However, 6 of 10 patients who had unremarkable routine electrodiagnostic results had abnormal F-wave and compound muscle action potential (CMAP) amplitude abnormalities with NC-stat testing. The clinical implications of this finding are uncertain.

A 2011 report by Schmidt and colleagues assessed the accuracy of NC-stat diagnosis of lumbosacral radiculopathy in 50 patients and 25 controls with no prior history of lumbosacral radiculopathy. (14) The patient cohort included patients referred to a tertiary referral EMG laboratory for testing of predominantly unilateral leg symptoms (pain, numbness, or weakness). Control subjects were recruited from clinic employees and from patients referred to the EMG laboratory for upper limb symptoms. All patients underwent focused history and physical examination and both standard and automated electrodiagnostic testing. Automated testing was performed by experienced technicians who were unaware of the electrodiagnostic test results. The data were transmitted to the manufacturer and compared with a large database of previously recorded data, which were adjusted for the age and height of the patient and subsequently determined to be normal or abnormal. In the patient cohort, the sensitivity of NC-stat was found to be 0% for L4 radiculopathy, 69% for L5 radiculopathy, and 64% for S1 radiculopathy compared with standard electrodiagnostic testing. By standard electrodiagnostic evaluation, 22 of the 50 symptomatic patients had findings consistent with L4, L5, or S1 radiculopathy, and 28 patients were found to be normal or to have a diagnosis other than lumbosacral radiculopathy; NC-stat identified only 4 of these 28 cases (specificity of 14%). Standard electrodiagnostic testing also identified other important diagnoses in 9 patients (18%) that were not identified by the automated test, while NC-stat reported 6 other diagnoses in patients found to be normal by standard electrodiagnostic testing. All standard electrodiagnostic tests in the control group were normal, but the automated test found that 18 of these subjects were abnormal (specificity of 32%). The study found that the raw nerve conduction data were comparable for the 2 techniques; however, computer-generated interpretations by the automated device showed low specificity (numerous false-positives) in both symptomatic patients and normal control subjects. An accompanying editorial by England and Franklin states that the use of automated nerve conduction devices is controversial and that the use of NC-stat for lumbosacral radiculopathy would likely lead to a high misdiagnosis rate and potentially inappropriate treatment, including surgery. (15) England and Franklin also conclude that an overly sensitive but not very specific test for CTS, or other mono- or polyneuropathies, cannot replace expert use and interpretation of conventional electrodiagnostic testing.

Mixed Population: A 2008 report assessed the diagnostic performance of NC-stat against the gold standard NCS in patients who had been referred for electrodiagnostic testing at one of several academic medical centers. (16) Of 47 patients who were invited to participate in the study, 12 declined to participate, and records from 1 patient were missing, resulting in data analysis on 33 patients. The goal of the study was to compare the measurements of the two
methods of nerve conduction testing as they would be used in standard practice, thus, patients
were not excluded on the basis of the particular diagnosis for which they were referred. The
diagnosis being tested was CTS in 25 patients (76%), with the remaining 8 patients having 8
other potential diagnoses, including ulnar neuropathy, upper extremity paresthesias, and C6
radiculopathy. NC-stat testing was independently performed by assistants (medical student,
physical therapy assistant, or occupational therapy assistant) who were trained to operate the
device following the manufacturer’s recommendations. NC-stat results could not be obtained for
2 patients for median motor studies and 3 patients for median sensory studies (15%). Based on
the manufacturer’s suggested cutoff for abnormal nerve conduction, sensitivity was 100% for
both the motor and sensory median-ulnar difference; specificity was 62–69% for the motor
median-ulnar difference and 41% to 47% for the sensory median-ulnar difference. Pearson
correlation coefficients ranged from 0.40 for the ulnar nerve to 0.91 for the median dorsal motor
nerve. The ICCs had generally lower values than the Pearson coefficients, reflecting systematic
bias due to methodologic differences in the two methods of NCS. The authors concluded that the
recommended cutoff values for NC-stat may need to be adjusted, although the specific study
results were limited by the small sample size. In addition, the authors noted that the study did
not evaluate how well physicians can assign clinical relevance to the results and that while the
device may be suited for research studies or screening of symptomatic patients, “in many clinical
situations referral to a specialist for a more comprehensive evaluation would be prudent.”

**Normative Values**: In 2009, NeuroMetrix published a study of reference ranges for key nerve
conduction parameters in healthy subjects. (17) Data analyzed in the paper were pooled from 5
studies, including from 92 to 848 healthy subjects with data on the median, ulnar, peroneal,
tibial, and sural nerves. Subject age and height were found to affect the parameters. In addition
to providing reference ranges for clinicians to use (providing that NCS techniques are consistent
with those described in the paper), the authors stated that clinicians could use the same method
to develop their own reference ranges. At this time, the proposed reference ranges have not
been validated in a clinical patient population.

**Clinical Outcomes**

In 2011, Bourke et al. reported a nonrandomized comparison of clinic-based NC-stat versus
referral to standard electrodiagnostic testing that evaluated efficiency of workup and costs. The
study included 142 patients being considered for decompression surgery for CTS at a hand clinic.
(18) Seventy-one patients who accepted nerve conduction studies in a nurse-led clinic were
compared with 71 historical controls who had been sent for nerve conduction studies at the
regional neurophysiological unit. Patients with known or suspected complex neurological
conditions were excluded from the study. Outcome measures were time from presentation to
carpal tunnel decompression, the cost of each pathway, and the practicalities of using the device
in the clinic. In the NC-stat group, 43 patients (61%) had a diagnosis of CTS confirmed by NC-
stat and underwent decompression surgery, and 28 patients (39%) had normal or inconclusive
tests. Of the 28, 12 were referred for electrodiagnostic testing, and 2 of the 12 were
recommended for decompression surgery (3% false negative). In the referred group, 44 patients
(62%) had confirmation of CTS and underwent decompression surgery. Use of NC-stat in the
clinic reduced the time from presentation to surgery from 198 days to 102 days. Cost saving for
NC-stat was reduced by the need to refer nearly 20% of patients for standard
electrophysiological testing, but still favored the clinic-based approach. Health outcomes for the 2
approaches were not assessed.
The NeuroMetrix data registry was analyzed for all NC-stat studies performed over a period of 10 days that were coded for CTS and performed by a primary care provider. (19) The initial data set consisted of studies on 1,190 patients performed by 613 different physician practices; studies that met CTS testing guidelines (82% met strict guidelines and 93% met less restrictive guidelines) were further analyzed. Thus, in nearly 1 of 5 patients (18.4%), the studies did not meet strict CTS testing guidelines. From the limited set, 31% were identified as normal, 53% exhibited CTS, 5% demonstrated an ulnar neuropathy, and 11% showed a nonspecific neuropathy. No comparison was made with standard nerve conduction testing nor was an assessment made of the impact of this testing on relevant clinical outcomes.

A 2007 study was identified that used NC-stat to assess the effect of a pharmaceutical agent on nerve conduction in patients with diabetic peripheral neuropathic pain. (20)

**Summary**

Studies have shown the correlation of portable automated nerve conduction test results with standard testing; however, questions remain about the diagnostic performance and clinical utility (i.e., impact on outcomes) of point-of-care automated testing. Particularly needed are data on the sensitivity and specificity of automated nerve conduction tests performed by non-specialists at the point-of-care in comparison with the “gold standard” of laboratory NCS/EMG. One study from a tertiary care clinic found high sensitivity but low specificity for the diagnosis of lumbosacral radiculopathy. Another potential clinical use could be early identification of asymptomatic diabetic neuropathy to institute-appropriate clinical management before the onset of ulcerations, but no studies were identified that assessed the influence of point-of-care nerve conduction tests on clinical outcomes in this population. Overall, evidence addressing the utility of point-of-care automated nerve conduction tests in a clinical setting is limited. There is no peer-reviewed published medical literature on the use of voltage-actuated sensory nerve conduction tests and their impact on clinical outcomes. Overall, evidence remains insufficient to evaluate the effect of automated point-of-care nerve conduction tests on health outcomes. Therefore, automated point-of-care nerve conduction tests are considered investigational.

**Practice Guidelines and Position Statements**

In 2006, the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) issued a position statement that illustrates how standardized nerve conduction studies performed independent of needle EMG studies may miss data essential for an accurate diagnosis and how nerve disorders are far more likely to be misdiagnosed or missed completely if a practitioner without the proper skill and training is interpreting the data, making a diagnosis, and establishing a treatment plan. (21) The organization states that, “the standard of care in clinical practice dictates that using a predetermined or standardized battery of NCSs for all patients is inappropriate,” and concludes that, “It is the position of the AANEM that, except in unique situations, NCSs and needle EMG should be performed together in a study design determined by a trained neuromuscular physician.”

Practice Parameters (2002) from the American Association of Electrodiagnostic Medicine, American Academy of Neurology, and American Academy of Physical Medicine and Rehabilitation recommended measuring sensory and motor nerve function in patients with suspected CTS. (22)
CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

95905  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

95999  Unlisted neurological or neuromuscular diagnostic procedure

G0255  Current perception threshold/sensory nerve conduction test, (SNCT) per limb, any nerve

- Effective in 2010, there is a specific CPT code for this testing: 95905.
- Automated nerve conduction testing using devices such as the Axon II, which does not have stimulus and recording electrodes on the same preconfigured electrode array, should be reported using the unlisted CPT code 95999 or HCPCS code G0255.
- Previously, these studies were reported under the CPT codes for standard nerve testing (95900, 95903, and 95904).

REVISIONS

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REFERENCES
