02.01.31 Automated Nerve Conduction Tests

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Summary

Description

Note: This evidence review addresses the use of automated, noninvasive nerve conduction testing devices as an alternative to conventional methods of performing nerve conduction testing.

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

Summary of Evidence

For individuals who have entrapment carpal tunnel syndrome who received automated POC NCSs, the evidence includes studies on the diagnostic accuracy and clinical outcomes from industry-sponsored trials, nonrandomized trials, and registry data. Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. Four RCTs have reported on the diagnostic accuracy of automated POC nerve conduction testing to diagnose carpal tunnel syndrome. Sensitivity testing has suggested

there could be diagnostic value in detecting carpal tunnel syndrome; specificity testing was inconsistent across trials. No reference ranges were validated, and normative values were not defined in these studies. No validation testing by trained medical assistants vs trained specialist was reported in the studies. The evidence on clinical outcomes is limited to a single nonrandomized clinical trial and NeuroMetrix registry data. Neither reported health outcomes assessing individual symptoms or changes in functional status. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with lumbosacral radiculopathy who received automated POC NCSs, the evidence includes industry-sponsored trials and a nonrandomized study of diagnostic accuracy. Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. The evidence on the diagnostic accuracy of POC NCS in this population has shown variable test results across reported trials. No normative values were defined. Weaknesses of the studies included lack of applicable or valid reference ranges for testing, and variable test results validating or confirming pathology. The results of the 2 studies on diagnostic performance were inconclusive, with high false-positive results in a single trial. No trials on health outcomes assessing individual symptoms or changes in functional status were identified. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with diabetic peripheral neuropathy who received automated POC NCSs, the evidence includes industry sponsored observational trials and nonrandomized studies on the diagnostic accuracy. Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. Of 3 studies reporting evidence on diagnostic accuracy, 2 used NC-stat DPNCheck. Sensitivity testing has suggested there could be diagnostic value in detecting diabetic peripheral neuropathy in symptomatic individual; the evidence to detect individuals who are suspected of disease but who have mild symptoms was inconsistent. No reference ranges were validated, and normative values were not defined in 2 of the 3 studies. No validation testing by trained medical assistants vs trained specialist was reported in the studies. No trials on health outcomes assessing individual symptoms or changes in functional status were identified. The evidence is insufficient to determine the effects of the technology on health outcomes.

Additional Information

None

OBJECTIVE

The objective of this evidence review is to determine whether automated nerve conduction testing improves the net health outcome in individuals with conditions linked to peripheral nerve damage or disease.

PRIOR APPROVAL

Not applicable.

POLICY

Note: This evidence review addresses the use of automated, noninvasive nerve conduction testing devices as an alternative to conventional methods of performing nerve conduction testing.

Automated nerve conduction tests are considered **investigational** for all indications because the evidence is insufficient to determine the technology results in an improvement in the net health outcomes.

POLICY GUIDELINES

Coding

See the Codes table for details.

BACKGROUND

Electrodiagnostic Testing

Nerve conduction studies (NCSs) and needle electromyography (EMG), when properly performed by a trained practitioner, are considered the criterion standard of electrodiagnostic testing for the evaluation of focal and generalized disorders of peripheral nerves. However, the need for specialized equipment and personnel may limit the availability of electrodiagnostic testing for some individuals.

Nerve conduction velocity (NCV) studies are a type of electrodiagnostic study conducted to assess the integrity and function of the peripheral nervous system and to diagnose related diseases (e.g., carpal tunnel syndrome, Lumbosacral Radiculopathy, and diabetic peripheral neuropathy). NCV studies measure the velocity of nerve impulses, the amplitude, and the wave shapes of the motor responses. Another relevant measurement is that of nerve conduction latency. Abnormal results include slowing of the nerve conduction signal, a completely blocked conduction, failure to elicit a motor response from a nerve signal or a diminished motor response. The results of these tests may assist the physician to arrive at a differential diagnosis based on the degree of demyelination or loss of axon function in various portions of the nerve.

Carpal Tunnel Syndrome

Carpal tunnel syndrome is a pressure-induced entrapment neuropathy of the median nerve as it passes through the carpal tunnel, resulting in sensorimotor disturbances. This syndrome is defined by its characteristic clinical symptoms, which may include pain, subjective feelings of swelling, and nocturnal paresthesia.

Diagnosis

Diagnosis includes a variety of simple diagnostic tools that are available, and a positive response to conservative management (steroid injection, splints, modification of activity) can confirm the clinical diagnosis. Electrodiagnostic studies may also be used to confirm the presence or absence of median neuropathy at the wrist, assess the severity of the neuropathy, and assess associated diagnoses. Nerve conduction is typically assessed before the surgical release of the carpal tunnel, but the use of EMG in the diagnosis of carpal tunnel syndrome is controversial. One proposed use of automated nerve conduction devices is to assist in the diagnosis of carpal tunnel syndrome.

Lumbosacral Radiculopathy

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

Peripheral Neuropathy

Peripheral neuropathy is relatively common in individuals with diabetes, and the diagnosis is often made clinically through the physical examination. Diabetic peripheral neuropathy can lead to morbidity including pain, foot deformity, and foot ulceration.

Diagnosis

Diagnosis includes clinical practice guidelines which have recommended using simple sensory tools (e.g., 10-g Semmes-Weinstein monofilament or the 128-Hz vibration tuning fork for diagnosis). These simple tests predict the presence of neuropathy defined by electrophysiologic criteria with a high level of accuracy. Electrophysiologic testing may be used in research studies and may be required in cases with an atypical presentation. POC nerve conduction testing has been proposed as an alternative to standard electrodiagnostic methods for the diagnosis of peripheral neuropathy and for detecting neuropathy in individuals with diabetes.

Normative Values

NeuroMetrix (2009) published reference ranges for key nerve conduction parameters in healthy subjects. Data analyzed 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 article), the authors stated that clinicians could use the same method to develop their reference ranges. At this time, the proposed reference ranges have not been validated in a clinical patient population.

Due to the lack of uniform standards in nerve conduction testing in the United States, the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) identified 7 criteria that would identify high-quality NCS articles that would be appropriate for using as reference standards (2016). In March 2017, the American Academy of Neurology affirmed AANEM's recommendations.

Table 1. Criteria for Evaluating Published Sources for Normative Standards

Criteria	Description
Year published	Published during or after 1990, written in or translated from other languages into English
Sample size	>100 normal subjects
Subjects	Inclusion and exclusion criteria must be methodologically sound and reflect a true "normal" group of asymptomatic individuals
Testing factors	• Use of digital electromyographic equipment• Methods of temperature control stated• Testing techniques with electrode placement and distances between simulating and recording electrodes specified• Filter settings specified• Screen display parameters (milliseconds per division, microvolts/millivolts per division) specified
Age	Wide distribution of subject ages > 18 years with adequate sampling of the elderly
Statistical analyses	• Data distribution should be described and appropriate statistical methods used to account for non-Gaussian distributions• Cutoff values expressed and derived as percentiles of the distribution (the preferred method)• Percentage of subjects who have an absent response should be reported
Data presentation	Reference values and cutoff points for NCS parameters clearly presented in a useful format

Chen (2016) published reference values for upper and lower NCSs in adults, as a companion study to the Dillingham et al. (2016), to address the need for greater standardization in the field of electrodiagnostic medicine. Using the consensus-based criteria developed by AANEM, a comprehensive literature search was conducted for 11 routinely performed sensory and motor NCS from 1990 to 2012. Over 7500 articles were found, but after review, a single acceptable study meeting all criteria was identified for the 11 nerves. Reviewers determined there were multifactorial reasons that so few studies met the criteria. Large-scale normative studies are time intensive, requiring significant resources and cost. Data from many studies did not address the non-Gaussian distribution of NCS parameters and often derived cutoff values using the mean and standard deviations rather than percentiles.

Regulatory Status

Multiple devices have been approved by the U.S. Food and Drug Administration (FDA) for marketing through the 510(k) process for automated nerve conduction testing. For example:

- 1986, Neurometer® CPT/C (Neurotron®) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process (K853608).
    - The device evaluates and documents sensory nerve impairments at cutaneous or mucosal sites. The evaluation detects and quantifies hyperesthesia in early stages of progressive neuropathy and hypoesthesia in more advanced conditions.
- 1998 NC-stat® (NeuroMetrix) was cleared by FDA through the 510(k) process (K982359).
    - NC-stat® is intended "to measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies." This version is no longer commercially available. It is the predicate device for the NC-stat DPNCheck® (K041320), cleared in 2004.
- On January 23, 2017, Cadwell Sierra Summit and Cadwell Sierra Ascent (Cadwell Industries) was cleared for marketing by FDA through the 510K process (K162383). There are portable laptop versions and a desktop application with a handheld device. The system is used for acquisition, display, storage, transmission, analysis, and reporting of electrophysiologic and environmental data including EMG, NCS, evoked potentials, and autonomic responses (RR interval variability). The Cadwell Sierra Summit is used to detect the physiologic function of the nervous system, and to support the diagnosis of neuromuscular diseases or conditions.

FDA product code: JXE.

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

Table 2: Select FDA Cleared Devices for Neural Conduction Testing:

This is not intended to be an all-inclusive list.

Device	Manufacturer	Date Cleared	510 (k)	Indications
Axon II™	PainDX	1998	K980866	Part of a routine neurologic exam or screening procedure to detect peripheral neuropathy, which may be caused by various pathologic conditions or exposures to toxic substances.

Brevio®	Neurotron Medical	2001	K012069	To measure nerve response latency and amplitude in the diagnosis and monitoring of peripheral neuropathies.
Cadwell Sierra Ascent	Cadwell Industries	2017	K162383	Used as a portable laptop versions and a desktop application with a handheld device. The system is used for acquisition, display, storage, transmission, analysis, and reporting of electrophysiologic and environmental data including EMG, NCS, evoked potentials, and autonomic responses (RR interval variability).
Cadwell Sierra Summit	Cadwell Industries	2017	K162383	Used to detect the physiologic function of the nervous system, and to support the diagnosis of neuromuscular diseases or conditions
NC-stat®NC-statDPNCheck	NeuroMetrix	2004	K041320	To stimulate and measure neuromuscular signals in diagnosing and evaluating systemic and entrapment neuropathies. NC-stat DPNCheck is designed specifically for NCS of the sural nerve in the assessment of diabetic peripheral neuropathy.
NC-stat®	NeuroMetrix	2006	K060584	Addition of the modified median motor-sensory biosensor to stimulate and measure neuromuscular signals useful in diagnosing and evaluating systemic and entrapment neuropathies.
NeuroMetrix Advance™	NeuroMetrix	2008	K070109	To measure neuromuscular signals useful as an aid in diagnosing and evaluating individuals suspected of having focal or systemic neuropathies. If the elective needle EMG module is used, then the device is also intended to measure signals useful as an aid in evaluating disorders of muscles.
VT 3000	Virtual Medical Systems	2005	K052904	Approved by the FDA as Class II medical devices.

XLTEK NEUROPATH	Excel Tech	2006	K053058	To stimulate and measure neuromuscular signals useful in diagnosing and evaluating systemic and entrapment neuropathies.

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

RATIONALE

This evidence review was created in January 2007 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through July 2024.

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

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

Carpal Tunnel Syndrome (CTS)

Clinical Context and Test Purpose

The purpose of automated point-of-care (POC) nerve conduction testing in individuals who have carpal tunnel syndrome (CTS) is to inform the diagnosis of neuropathy.

The following PICO was used to select literature to inform this review.

Populations

The relevant populations of interest are individuals within individuals who have CTS.

Interventions

The test being considered is automated POC nerve conduction testing.

Comparators

The following tests are currently being used: standard clinical examination, needle electromyography (EMG), and standardized nerve conduction studies (NCS).

Outcomes

The primary outcomes of interest relate to diagnostic accuracy (i.e., test accuracy and validity) and health outcomes (i.e., symptoms, functional outcomes).

Diagnostic accuracy is a short-term outcome. Symptoms and functional outcomes would be measured over the long term after individuals have been diagnosed and treated.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Review of Evidence

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

In an early report of NC-stat technology using distal motor latency (DML) to diagnose CTS, Leffler et al (2000) 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%. In a report by Rotman et al (2004), the NC-stat DML had 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 POC study evaluating industrial workers for possible CTS using DML, Katz (2006) found that many patients who were identified with prolonged DML by NC-stat fell within the normal range (using a 95% cutoff point) as defined by this study population.

A report by Armstrong et al. (2008) assessed the diagnostic performance of NC-stat against the criterion standard NCS in patients referred for electrodiagnostic testing at one of the several academic medical centers. Of 47 patients invited to participate in the study, 12 declined to participate, and records from 1 patient were missing, resulting in data analysis of 33 patients. The goal of the study was to compare the diagnostic performance of both testing methods as they would be used in standard practice; thus, patients were not excluded by the particular diagnosis for which they were referred. The diagnosis being tested was CTS in 25 (76%) patients, with the remaining 8 patients having other potential diagnoses. NC-stat testing was independently performed by assistants (medical students, physical therapy assistants, occupational therapy assistants) trained to operate the device following the manufacturer's recommendations. NC-stat results could not be obtained for 2 patients for median nerve motor studies and 3 (15%) patients for median nerve sensory studies. 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% to 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 intraclass correlation coefficients had generally lower values than the Pearson coefficients, reflecting systematic bias due to methodologic differences in the 2 methods of NCS. The authors concluded that the recommended cutoff values for NC-stat might need to be adjusted, although specific study results were limited by the small sample size. Also, the authors noted that the study did not evaluate how well physicians could 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."

Section Summary: Clinically Valid

There are no randomized controlled trials. Several uncontrolled nonrandomized studies have reported on the diagnostic accuracy of NC-stat to evaluate symptoms suggestive of CTS. There were no clinical comparators. There was high sensitivity but low specificity using manufacturer reference standards. Specificity results were also inconsistent across the trials. No reference ranges were validated, and normative values were not defined in these studies. No validation of testing by trained medical assistants vs trained specialist was reported in the studies. Clinically Useful A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if individuals receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Clinically Useful

Direct evidence of clinical utility is provided by studies that have compared health outcomes for individuals managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

Tsamis et al. (2021) completed a study to evaluate the sensitivity of different NCSs' parameters for the diagnosis of median nerve mononeuropathy and the ability of different classifiers to automatically discriminate normal and pathological values. Machine learning techniques were employed to examine signal characteristics and compute the accuracy of automatic classification. This study included 38 volunteers that were examined prospectively, over a period of two months, at the Laboratory of Clinical Neurophysiology, Neurological Department of the University Hospital of Ioannina. Among them, 28 participants were patients with symptoms and signs suggestive of CTS, who were referred to the laboratory by hospital physicians not affiliated to the study (neurologists, orthopedics, and rheumatologists). Patients diagnosed with other neurological disorders apart from CTS (other neuropathies, radiculopathies, central nervous system lesions), as well as patients with other systemic diseases, were excluded from the study. The authors noted currently, NCS is considered the gold standard for the confirmation of median nerve mononeuropathy in the CTS. The aim of the present study is to find a methodology to enable automatic diagnosis through the analysis of conventional electrodiagnosis signals with machine learning techniques. This would facilitate and accelerate the electrodiagnosis, excluding the human error. The results show that the inclusion of the novel features described here can increase the accuracy of the automatic electrodiagnosis when they are used together with the common features. So, the inclusion of the novel features does not aim to replace the common features but to enhance their performance. The authors concluded the findings of this study show that an accurate automatic electrodiagnosis for median nerve mononeuropathy is possible. Apart from testing the accuracy of the common NCSs' features, several geometric features with indicated physiological meaning for median nerve compression were extracted and presented. These features are employed for the first time in the workup of CTS. The classification model proposed is unbiased and indicates that these features can play an important role in supporting the diagnosis of the syndrome and grading its severity. However, the evaluation of the results through a larger database of CTS patients would be useful, in order to establish an accurate grading scale and produce more robust generalizations. Such a grading scale could serve as a basis for an automatic electrodiagnosis, excluding the human error, implemented in costume electrophysiological testing or hand-held devices.

Bourke et al. (2011) reported on a nonrandomized study comparing clinic-based NC-stat testing with referral to standard electrodiagnostic testing to evaluate the efficiency of work up. The study included 142 patients being considered for decompression surgery for CTS at a hand clinic. Seventy-one patients who

accepted NCSs in a nurse-led clinic were compared with 71 historical controls who had been sent for NCSs at the regional neurophysiologic unit. Patients with known or suspected complex neurologic conditions were excluded from the study. Outcome measures were the time from presentation to carpal tunnel decompression and the practicalities of using the device in the clinic. In the NC-stat group, 43 (61%) patients had a diagnosis of CTS confirmed by NC-stat and underwent decompression surgery, and 28 (39%) patients had normal or inconclusive tests. Of these 28 patients, 12 were referred for electrodiagnostic testing, and 2 of them were recommended for decompression surgery (3% false negative). In the referred group, 44 (62%) patients 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. Health outcomes for both approaches were not assessed.

The NeuroMetrix data registry was analyzed by Megerian et al (2007) for all NC-stat studies performed by a primary care provider and coded for CTS over a period of 10 days. The initial data set consisted of studies on 1190 patients performed by 613 different physician practices; studies that met CTS testing guidelines (82% met strict guidelines, 93% met less restrictive guidelines) were further analyzed. Thus, in nearly 1 (18.4%) of 5 patients, the studies did not meet strict CTS testing guidelines. From the limited patient 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.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility. Because the evidence is insufficient to demonstrate clinical validity for automated POC nerve conduction testing, no inferences can be made about clinical utility.

Section Summary: Clinically Useful

One nonrandomized study has reported on the clinical outcomes of NC-stat vs referral to standard electrodiagnostic testing. Health outcomes assessing individual symptoms or changes in functional status outcomes were not assessed. A data set from a NeuroMetrix registry on NC-stat did not report on relevant clinical or health outcomes. Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility. Because the evidence is insufficient to demonstrate clinical validity for automated POC nerve conduction testing, no inferences can be made about clinical utility.

Lumbosacral Radiculopathy

Clinical Context and Test Purpose

The purpose of automated point-of-care (POC) nerve conduction testing in individuals who have lumbosacral radiculopathy is to inform the diagnosis of neuropathy.

The following PICO was used to select literature to inform this review.

Populations

The relevant populations of interest are individuals within individuals who have lumbosacral radiculopathy.

Interventions

The test being considered is automated POC nerve conduction testing.

Comparators
The following tests are currently being used: standard clinical examination, needle electromyography (EMG), and standardized nerve conduction studies (NCS).

Outcomes
The primary outcomes of interest relate to diagnostic accuracy (i.e., test accuracy and validity) and health outcomes (i.e., symptoms, functional outcomes). Diagnostic accuracy is a short-term outcome. Symptoms and functional outcomes would be measured over the long term after individuals have been diagnosed and treated.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Review of Evidence

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Fisher et al. (2008) assessed the relation between NC-stat and routine NCS plus needle EMG in 34 consecutive patients with a clinical history and/or examination consistent with lumbosacral radiculopathy. Inclusion in the study was based on a chart review of symptoms from clinical history and/or examination (including low back pain or buttock pain, numbness, and/or paresthesia 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 34 patients included in the study, 28 had magnetic resonance imaging of the lumbosacral spine within 6 months of electrodiagnosis, 2 had a postmyelogram computed tomography scan, and 3 had lumbosacral spine radiographs. A neuroradiologist blinded to the clinical evaluation and electrodiagnostic results determined from magnetic resonance imaging or computed tomography that lumbosacral root injury was likely at the L4-5 and/or L5-S1 levels in 18 (60%) patients. 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 amplitude abnormalities with NCstat testing. The clinical implications of this finding are uncertain.

A report by Schmidt et al. (2011) assessed the accuracy of NC-stat diagnosis of lumbosacral radiculopathy in 50 patients and 25 controls with no history of lumbosacral radiculopathy. The patient cohort included patients referred to a tertiary referral EMG laboratory for testing of predominantly unilateral leg symptoms (pain, numbness, weakness). Control subjects were recruited from clinic employees and patients referred to the EMG laboratory for upper-limb symptoms. All patients underwent a focused history and physical examination and both standard and automated electrodiagnostic testing. Automated testing was performed by experienced technicians unaware of the electrodiagnostic test results. 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 0% for L4 radiculopathy, 69%

for L5 radiculopathy, and 64% for S1 radiculopathy compared with standard electrodiagnostic testing. By standard electrodiagnostic evaluation, 22 (44%) of the 50 symptomatic patients had findings consistent with L4, L5, or S1 radiculopathy, and 28 (56%) 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, 14%). Standard electrodiagnostic testing also identified other important diagnoses in 9 (18%) patients 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, 32%). The study found that raw nerve conduction data were comparable for both 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 (2011) stated 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. England and Franklin (2011) also concluded that an overly sensitive but not very specific test for CTS, or other monoor polyneuropathies, cannot replace expert use and interpretation of conventional electrodiagnostic testing. Section Summary: Clinically Valid One nonrandomized study comparing results of NCT-stat with results of standard EMG plus NCSs to evaluate the potential diagnosis of lumbosacral radiculopathy found a poor correlation. A second nonrandomized study using an asymptomatic control group reported an unacceptably high false-positive rate in both the patient and control groups when definitive electrodiagnostic testing was performed. Reference ranges were not validated, and normative values were not defined in these studies.

Section Summary: Clinically Valid

One nonrandomized study comparing results of NCT-stat with results of standard EMG plus NCSs to evaluate the potential diagnosis of lumbosacral radiculopathy found a poor correlation. A second nonrandomized study using an asymptomatic control group reported an unacceptably high false-positive rate in both the individual and control groups when definitive electrodiagnostic testing was performed. Reference ranges were not validated, and normative values were not defined in these studies. No clinical outcome studies were identified to inform this review. Because the evidence is insufficient to demonstrate clinical validity for automated POC nerve conduction testing, no inferences can be made about clinical utility.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials. No clinical outcome studies were identified to inform this review.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility. Because the evidence is insufficient to demonstrate clinical validity for automated POC nerve conduction testing, no inferences can be made about clinical utility.

Diabetic Peripheral Neuropathy (DPN)

Clinical Context and Test Purpose
The purpose of automated point-of-care (POC) nerve conduction testing in individuals who have diabetic peripheral neuropathy (DPN) is to inform the diagnosis of neuropathy.

The following PICO was used to select literature to inform this review.

Populations
The relevant populations of interest are individuals within individuals who have diabetic peripheral neuropathy (DPN).

Interventions
The test being considered is automated POC nerve conduction testing.

Comparators
The following tests are currently being used: standard clinical examination, needle electromyography (EMG), and standardized nerve conduction studies (NCS).

Outcomes
The primary outcomes of interest relate to diagnostic accuracy (i.e., test accuracy and validity) and health outcomes (i.e., symptoms, functional outcomes). Diagnostic accuracy is a short-term outcome. Symptoms and functional outcomes would be measured over the long term after individuals have been diagnosed and treated.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Review of Evidence

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

A nonrandomized study has assessed the validity of NC-stat to diagnose DPN through sural nerve testing in patients from diabetes and diabetic neuropathy outpatient practices. Perkins et al (2006) enrolled 72 consecutive patients (64 with type 2 diabetes) who completed a clinical evaluation, a conventional NCS, and a POC NC-stat assessment. The POC assessment was independently conducted by nontechnologist research staff following a 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 reported that the sensitivity and specificity of NC-stat for diagnosis of diabetic sensorimotor polyneuropathy, as defined by clinical and conventional electrophysiologic evaluation, were 92% and 82%, respectively. The

Spearman correlation coefficient (vs 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.

Sharma et al. (2015) assessed the diagnostic accuracy of NC-stat DPNCheck in 162 patients with diabetes and 80 healthy controls. Based on the 10-point Neuropathy Disability Score (NDS), DPN was categorized as none, mild, moderate, or severe. Measurements with the POC device were conducted by blinded assessors. Receiver operating characteristic curves showed high overall accuracy in participants with either no neuropathy or severe neuropathy. However, for patients with mild neuropathy who would benefit most from early diagnosis, accuracy was substantially lower.

Chatzikosma et al. (2016) reported on the diagnostic accuracy of NC-stat DPNCheck by comparing sural nerve conduction in the diagnosis of peripheral neuropathy in 114 patients who had type 2 diabetes (58 men, 56 women) with an age- and sex-matched group of 46 healthy controls (24 men, 22 women). Diagnosis of DPN was based on the standardized NDS developed by Young et al. (1993). An NDS of 3 or more was considered diagnostic of DPN. DPN was diagnosed in 42 (36.84%) patients using the NDS. Examination with NC-stat DPNCheck exhibited 90.48% sensitivity, 86.11% specificity, 79.17% positive predictive value, and 93.94% negative predictive value. The positive likelihood ratio was 6.51, and the negative likelihood ratio was 0.11. In the control group, the NDS was normal in all subjects, while automated NCS was abnormal in 2 subjects. The investigators concluded that the NC-stat DPNCheck "exhibited a very good diagnostic performance" to rule in DPN and was "especially reliable as a screening tool to rule out DPN." Study limitations were identified as the inclusion of patients from a tertiary care setting and not the general diabetic population, exclusion of patients with type 1 diabetes, and no confirmation of the diagnosis of DPN by classical NCS.

Section Summary: Clinically Valid

Three nonrandomized studies have reported on the diagnostic accuracy of POC automated nerve conduction testing to evaluate a diagnosis of suspected DPN. Two studies used the NC-stat DPNCheck. The 2015 study using NC-stat DPNCheck used laser Doppler technology as a comparator. The 2016 study using NC-stat DPNCheck used standardized clinical examination as its comparator. High sensitivity indicated there might be potential diagnostic value to detect DPN in symptomatic individuals. However, specificity was low and inconsistent across trials. No reference ranges were validated, and normative values were not defined in 2 of the 3 studies. No validation of testing by trained medical assistants vs trained specialist was reported in the studies. No clinical outcome studies were identified to inform this review. Because the evidence is insufficient to demonstrate clinical validity for automated POC nerve conduction testing, no inferences can be made about clinical utility.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials. No clinical outcome studies were identified to inform this review.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility. Because the evidence is insufficient to

demonstrate clinical validity for automated POC nerve conduction testing, no inferences can be made about clinical utility.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Orthopaedic Surgeons (AAOS)

In 2024, the American Academy of Orthopaedic Surgeons released guidelines on the management of carpal tunnel syndrome. The guidelines were also endorsed by other specialty societies including the American Association for Hand Surgery on the management of carpal tunnel syndrome. The guidelines found, "strong evidence suggest that CTS-6 can be used to diagnose carpal tunnel syndrome, in lieu of routine use of ultrasonography or NCV/EMG: (Quality of evidence: High, Strength of Recommendation: Strong.)

The American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM)

In 2006, the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) issued a position statement that illustrated how standardized nerve conduction studies (NCSs) performed independently of needle electromyography studies may miss data essential for an accurate diagnosis. AANEM discussed 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. The American Association of Neuromuscular & Electrodiagnostic Medicine stated that, "the standard of care in clinical practice dictates that using a predetermined or standardized battery of NCSs for all patients is inappropriate," and concluded 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." This position statement was reviewed, updated, and approved by AANEM in 2014. No changes were made to the earlier statement on NCSs.

In February 2010, the AANEM published the Model Policy for Needle Electromyography and Nerve Conduction Studies last which was updated and re-approved December 2022 that stated, "Nerve Conduction Studies: Limitations: EDX testing with automated, noninvasive nerve conduction testing devices is considered investigational and not medically necessary for all indications, including as an alternative method of performing NCSs."

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	95095	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
HCPCS		
	G0255	Current perception threshold/sensory nerve conduction test, (SNCT) per limb, any nerve
Type of Service	Medicine	
Place of Service	Outpatient	

POLICY HISTORY

Date	Reason	Action
July 2025	Annual Review	Policy Renewed
June 2024	Annual Review	Policy Renewed
June 2023	Annual Review	Policy Revised
April 2022	Annual Review	Policy Revised
April 2021	Annual Review	Policy Revised
April 2020	Annual Review	Policy Renewed
April 2019	Annual Review	Policy Renewed
April 2018	Annual Review	Policy Renewed
April 2017	Annual Review	Policy Renewed
April 2016	Annual Review	Policy Revised
April 2014	Annual Review	Policy Renewed
June 2013	Annual Review	Policy Revised

July 2012	Annual Review	Policy Renewed
August 2011	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
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