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Medical Policy

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Title: Automated Point-of-Care Devices for Nerve Conduction Testing

See also: EMG, NCS, and Other Electrodiagnostic (EDX) Related Services

Professional
Original Effective Date: October 13, 2008
Revision Date(s): June 16, 2009; August 11, 2009; January 1, 2010; July 19, 2011; August 13, 2012; November 24, 2015; October 26, 2018; August 14, 2019
Current Effective Date: October 26, 2018
Archived Date: May 14, 2021

Institutional
Original Effective Date: October 13, 2008
Revision Date(s): June 16, 2009; August 11, 2009; January 1, 2010; July 19, 2011; August 13, 2012; November 24, 2015; October 26, 2018; August 14, 2019
Current Effective Date: October 26, 2018
Archived Date: May 14, 2021

Populations	Interventions	Comparators	Outcomes
Individuals: • With carpal tunnel syndrome	Intervention of interest is: • Automated point-of-care nerve conduction tests	Comparators of interest are: • Standard clinical evaluation, electromyography, and standardized nerve conduction studies	Relevant outcomes include: • Test accuracy • Test validity • Symptoms • Functional outcomes
Individuals:	Intervention of interest is:	Comparators of interest are:	Relevant outcomes include: • Test accuracy

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Populations	Interventions	Comparators	Outcomes
• With lumbosacral radiculopathy	• Automated point-of-care nerve conduction tests	• Standard clinical evaluation, electromyography, and standardized nerve conduction studies	• Test validity • Symptoms • Functional outcomes
Individuals: • With diabetic peripheral neuropathy	Intervention of interest is: • Automated point-of-care nerve conduction tests	Comparators of interest are: • Standard clinical evaluation, electromyography, and standardized nerve conduction studies	Relevant outcomes include: • Test accuracy • Test validity • Symptoms • Functional outcomes

DESCRIPTION

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.

Objective

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

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 patients.

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

A variety of simple diagnostic tools are available, and a positive response to conservative management (steroid injection, splints, modification of activity) can confirm the clinical diagnosis.[1] Electrodiagnostic studies may also be used to confirm the presence or

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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 patients with persistent disabling symptoms when neuroimaging findings are inconsistent with clinical presentation. Comparisons of automated point-of-care (POC) NCSs with EMGs and standardized NCSs have been evaluated as alternative electrodiagnostic tools.

Peripheral Neuropathy

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

Diagnosis

Clinical practice guidelines have recommended using simple sensory tools such as the 10-g Semmes-Weinstein monofilament or the 128-Hz vibration tuning fork for diagnosis.[2] 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, in particular, for detecting neuropathy in patients with diabetes.

Normative Values

NeuroMetrix (2009) published reference ranges for key nerve conduction parameters in healthy subjects.[3] 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.

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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 referent standards (2016).[4] AANEM identified normative criteria for nerve conduction velocity tests based on a review of high-quality published studies (see Table 1). In March 2017, the American Academy of Neurology affirmed AANEM's recommendations.[4]

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

Adapted from Dillingham et al (2016).[5]
NCS: nerve conduction study.

Chen (2016) published reference values for upper and lower NCSs in adults, as a companion study to the Dillingham et al (2016) report (above), to address the need for greater standardization in the field of electrodiagnostic medicine.[6] 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

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distribution of NCS parameters and often derived cutoff values using the mean and standard deviations rather than percentiles.

Regulatory Status

Multiple devices have been cleared for POC neural conduction testing. For example, in 1986, Neurometer® CPT/C (Neurotron®) was cleared for marketing by the U.S. 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.

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

On January 23, 2017, Cadwell Sierra Summit 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.

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Table 2. Select FDA Cleared Devices for Neural Conduction Testing

Device	Manufacturer	Date Cleared	510(k)	Indications
Axon II™	PainDX	1998	K980866	Part of a routine neurologic exam or screening procedure 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
NC-stat®, NC-stat DPNCheck	NeuroMetrix	2004	K041320	To stimulate and measure neuromuscular signals in diagnosing and evaluating systemic and entrapment neuropathies. Added the sural biosensor for use in diagnosing neuropathies affecting the sural nerve.
NC-stat®	NeuroMetrix	2006	K060584	Addition of the modified median motor-sensory biosensor to stimulate and measure neuromuscular signals useful in diagnosing and evaluating systemic and entrapment neuropathies
XLTEK NEUROPATH	Excel Tech	2006	K053058	To stimulate and measure neuromuscular signals useful in diagnosing and evaluating systemic and entrapment neuropathies
NeuroMetrix Advance™	NeuroMetrix	2008	K070109	To measure neuromuscular signals useful as an aid in diagnosing and evaluating patients suspected of having focal or systemic neuropathies. If the elective needle EMG module is used, then the device is also intended to measure signals useful as an aid in evaluating disorders of muscles.

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

POLICY

Automated point-of-care nerve conduction tests are considered **experimental / investigational**.

RATIONALE

This evidence review has been updated with searches of the MEDLINE database. The most recent literature update was performed through April 1, 2019.

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Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

Carpal Tunnel Syndrome
Clinical Context and Test Purpose
The purpose of automated point-of-care (POC) nerve conduction testing in patients who have carpal tunnel syndrome (CTS) is to inform the diagnosis of neuropathy.

The question addressed in this evidence review is: Does use of automated POC nerve conduction testing improve health outcomes in patients who have CTS?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant populations of interest are individuals with 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 (ie, test accuracy and validity) and health outcomes (ie, symptoms, functional outcomes).

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

Technically Reliable
Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review, and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

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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%.[7] 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.[8] 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.[9]

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.[7,] 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 excludedby 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

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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 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.

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.[8,] 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.[9,] 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.

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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 patient 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.

Lumbosacral Radiculopathy
Clinical Context and Test Purpose
The purpose of automated POC nerve conduction testing in patients who have lumbosacral radiculopathy is to inform the diagnosis of neuropathy.

The question addressed in this evidence review is: Does use of automated POC nerve conduction testing improve health outcomes in patients who have lumbosacral radiculopathy?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest is individuals with 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 EMG, and standardized NCSs.

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

Technically Reliable
Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review, and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

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).

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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.[13] 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 NC-stat 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.[10,] 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.[11,] England and Franklin (2011) also concluded 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.

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.

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

The question addressed in this evidence review is: Does use of automated POC nerve conduction testing improve health outcomes in patients who have DPN?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant populations of interest are individuals with suspected DPN.

Interventions

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The test being considered is automated POC nerve conduction testing.

Comparators
The following tests are currently being used: standard clinical examination, needle EMG, and standardized NCS.

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

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

Technically Reliable
Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review, and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

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 fromdiabetes 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.[12,]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.[13,] 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.

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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).[14,] Diagnosis of DPN was based on the standardized NDS developed by Young et al (1993).[15,] 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 patients. 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.

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.

No review or update is scheduled on this Medical Policy as it is unlikely that further published literature would change the policy position. If there are questions about coverage of this service, please contact Blue Cross and Blue Shield of Kansas customer service, your professional or institutional relations representative, or submit a predetermination request.

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 patient symptoms or changes in functional status. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with lumbosacral radiculopathy who received automated POC NCSs, the evidence includes industry-sponsored trials and a nonrandomized study of 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 patient symptoms or changes in functional status were identified. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

Practice Guidelines and Position Statements

American Association of Neuromuscular & Electrodiagnostic Medicine

The American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) issued a position statement (2006) that illustrated how standardized nerve conduction studies (NCSs) performed independently of needle electromyography studies may miss data essential for an accurate diagnosis.[20] 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

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interpreting the data, making a diagnosis, and establishing a treatment plan.The Association 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.[16,] No changes were made to the earlier statement on NCSs.

American Academy of Orthopaedic Surgeons
The American Academy of Orthopaedic Surgeons (2016) released guidelines on the management of carpal tunnel syndrome.[17,] The guidelines were endorsed by other specialty societies including the American College of Radiology and American College of Surgeons. The guidelines found "limited evidence" for a "hand-held nerve conduction study."

U.S. Preventive Services Task Force Recommendations
Not applicable.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in May 2019 did not identify any ongoing or unpublished trials that would likely influence this review.

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

- 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.

DIAGNOSES
Experimental / Investigational for all diagnoses related to this medical policy.

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REVISIONS	
10-13-2008	The Automated Point-of-Care Devices for Nerve Conduction Testing medical policy is a new free-standing policy developed from one indication discussed in the Electrodiagnostic (EDX) Medicine and Related Services medical policy – effective date December 1, 2006 (revised and retitled Electromyography, Nerve Conduction Studies and Other Electrodiagnostic Related Services – effective November 12, 2008).
06-16-2009	Listed examples of Automated Point-of-Care devices.
08-11-2009	In Description section: ▪ Removed ADVANCE NCS/EMG System (NeuroMetrix) as this device is not an automated point-of-care device.
01-01-2010	In Coding Section: ▪ Added CPT Code: 95905
07-19-2011	In Professional and Institutional Dates section: Corrected a revision date from April 21, 2009 to June 16, 2009
	Updated Description section
	In Coding section: ▪ Added CPT/HCPCS Codes: 95999, G0255?? ▪ Removed CPT Code: S3905 (discontinued from use 04/01/11)
	Updated Rationale section
	In Revision section: Corrected a revision date from April 21, 2009 to June 16, 2009
	Updated References section
08-13-2012	Description section updated
	Rationale section updated
	References updated
11-24-2015	Description section updated
	Rationale section updated
	In Coding section: Added the statement "Experimental / Investigational for all diagnoses related to this medical policy", which had been erroneously left off the policy in past updates. Updated Coding notations.
	References updated
10-26-2018	Description section updated
	Rationale section updated
	References updated
08-14-2019	Description section updated
	Rationale section updated
	References updated
05-14-2021	ARCHIVED

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