Automated Point-of-Care Nerve Conduction Tests

Introduction

A nerve conduction test looks at how well nerves work. The purpose of the test is to see if a nerve is damaged. Two electrodes — patches attached to the skin that can transmit electrical signals — are placed along the path of the nerve being tested. An electrical signal is sent to the first electrode, with the second electrode receiving and recording the signal. The time it takes the electrical signal to travel between the two electrodes indicates how well the signal travels along the nerve. Specialized equipment is needed to do these tests. Newer types of portable equipment have been developed to try to do nerve conduction tests. Portable equipment is not as specialized and doesn’t require special training to use it. Portable equipment for nerve conduction studies is considered unproven. More studies are needed to show if the nerve conduction studies done on portable equipment by non-specialists gives information that is the same as or better information than standard nerve conduction studies.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Automated point-of-care (POC) nerve conduction tests are considered investigational.

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
<td>Motor and/or sensory nerve conduction, using preconfigured electrode array(s), amplitude and latency/velocity study, each limb, includes F-wave study when performed, with interpretation and report</td>
</tr>
<tr>
<td>HCPCS</td>
<td>Current perception threshold/sensory nerve conduction test (SNCT), per limb</td>
</tr>
</tbody>
</table>

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### Related Information

N/A

### Evidence Review

**Description**

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

Electrodiagnostic Testing

Nerve conduction studies (NCSs) and needle electromyography (EMG), when properly performed by a trained practitioner, are the standard electrodiagnostic tests for evaluating 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

Automated nerve conduction devices have been used to help in the diagnosis of carpal tunnel syndrome. Carpal tunnel syndrome is a pressure-induced entrapment neuropathy of the median nerve as it passes through the carpal tunnel in the wrist, resulting in sensorimotor disturbances. This syndrome is defined by its characteristic clinical symptoms, which may include pain, subjective feelings of swelling, and nocturnal paresthesia. A variety of simple diagnostic tools are available, and a positive response to conservative management (steroid injection, splints, modification of activity) can confirm the clinical diagnosis.¹ Electrodiagnostic studies may also be used to confirm the presence or absence of a median neuropathy at the wrist, assess the severity of the neuropathy, and assess associated diagnoses. Nerve conduction is typically assessed before the surgical release of the carpal tunnel, but the use of electromyography (EMG) in the diagnosis of carpal tunnel syndrome is controversial.

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

POC nerve conduction testing has been proposed as an alternative to standard electrophysiological methods for the diagnosis of peripheral neuropathy and, in particular, for detecting neuropathy in patients with diabetes. Peripheral neuropathy is relatively common in patients with diabetes, 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. 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. These simple tests show the presence of neuropathy as 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.

Summary of Evidence

For individuals who have entrapment carpal tunnel syndrome who received automated POC NCSs, the evidence includes studies on the technical accuracy, 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, but 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 specialists was reported in the studies. The evidence on clinical outcomes was 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 technical accuracy and diagnostic accuracy. Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. The evidence on the technical and 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 technical accuracy and diagnostic accuracy. Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. The evidence on the technical accuracy for 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 to validate or confirm pathology. Of 3 studies reporting evidence on diagnostic accuracy, two used NC-stat DPN-Check. Sensitivity testing has suggested there could be diagnostic value in detecting diabetic peripheral neuropathy in symptomatic patients. However, 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 specialists 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.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in July 2017 did not identify any ongoing or unpublished trials that would likely influence this review.

Practice Guidelines and Position Statements

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) that were performed independently of needle electromyography (EMG) 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 the person 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 2014.27 No changes were made to the earlier statement on NCSs.

**Medicare National Coverage**

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**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 conduction velocity and amplitude of the action potential going down the sural nerve of the leg. 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, Cadwell Sierra Ascent (Cadwell Industries) was cleared for marketing by FDA through the 510K process (K162383). There is a portable laptop version 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 1.

Table 1. Examples of FDA Cleared Devices for Neural Conduction Testing

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k)</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Axon II™</td>
<td>PainDX</td>
<td>1998</td>
<td>K980866</td>
<td>Part of a routine neurologic exam or screening procedure for detection of peripheral neuropathy, which may be caused by various pathologic conditions or exposures to toxic substances</td>
</tr>
<tr>
<td>Brevio®</td>
<td>Neurotron Medical</td>
<td>2001</td>
<td>K012069</td>
<td>To measure nerve response latency and amplitude in the diagnosis and monitoring of peripheral neuropathies</td>
</tr>
<tr>
<td>NC-stat®, NC-stat DPN-Check</td>
<td>NeuroMetrix</td>
<td>2004</td>
<td>K041320</td>
<td>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.</td>
</tr>
<tr>
<td>NC-stat®</td>
<td>NeuroMetrix</td>
<td>2006</td>
<td>K060584</td>
<td>Addition of the modified median motor-sensory biosensor to stimulate and measure neuromuscular signals useful in diagnosing and evaluating systemic and entrapment neuropathies</td>
</tr>
<tr>
<td>XLTEK NEUROPATH</td>
<td>Excel Tech</td>
<td>2006</td>
<td>K053058</td>
<td>To stimulate and measure neuromuscular signals useful in diagnosing and evaluating systemic and entrapment neuropathies</td>
</tr>
<tr>
<td>NeuroMetrix Advance™</td>
<td>NeuroMetrix</td>
<td>2008</td>
<td>K070109</td>
<td>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</td>
</tr>
<tr>
<td>Device</td>
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intended to measure signals useful as an aid in evaluating disorders of muscles.

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

References


### History

<table>
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<th>Date</th>
<th>Comments</th>
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<td>06/12/07</td>
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<td>05/13/08</td>
<td>Replace Policy - Policy updated with literature search; no change to the policy statement. Reference and code added.</td>
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<tr>
<td>09/15/09</td>
<td>Replace Policy - Policy updated with literature search; no change to the policy statement. References added.</td>
</tr>
<tr>
<td>08/10/10</td>
<td>Replace Policy - Policy updated with literature search through April 2010; references have been added and reordered. The policy statement remains unchanged. Code 95905 has been added.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
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<td>08/09/11</td>
<td>Replace Policy – Policy updated with literature review through April 2011; references 15 and 16 added and references reordered; policy statement unchanged. Codes updated.</td>
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<td>08/20/12</td>
<td>Replace policy. Policy updated with literature review through March 2012; reference 18 added and references reordered; policy statement unchanged.</td>
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<td>08/16/13</td>
<td>Replace policy. Policy updated with literature review through April 29, 2013; policy statement unchanged.</td>
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<tr>
<td>08/11/15</td>
<td>Annual Review. Policy updated with literature review through May 12, 2015; references 13 and 23 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>12/16/15</td>
<td>Update Related Policies. Remove 2.01.39 as it is archived.</td>
</tr>
</tbody>
</table>

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  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at
https://ocrportal.hhs.gov/ocr/portal/lobby.jsf or by mail or phone at:

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https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

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