FEP Medical Policy Manual

FEP 2.01.77 Automated Point-of-Care Nerve Conduction Tests

Effective Policy Date: January 1, 2021

Original Policy Date: December 2011

Related Policies:

2.01.39 - Quantitative Sensory Testing

Automated Point-of-Care Nerve Conduction Tests

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.

POLICY STATEMENT

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

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA 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 1.

Table 1. 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.

RATIONALE

Summary of Evidence

For individuals who have entrapment carpal tunnel syndrome who received automated point-of-care (POC) nerve conductions studies (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 randomized controlled trials (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, 2 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Association of Neuromuscular & Electrodiagnostic Medicine

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.[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 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.[20,] No changes were made to the earlier statement on NCSs.

American Academy of Orthopaedic Surgeons

In 2016, the American Academy of Orthopaedic Surgeons released guidelines on the management of carpal tunnel syndrome.[21,] 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.

Medicare National Coverage

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

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
June 2012	Replace policy	Policy statement changed to not medically necessary. Related policy added.
September 2013	Replace policy	Policy updated with literature review; reference 18 added; policy statement unchanged.
September 2014	Replace policy	Literature review/search through June 20, 2014. Policy statement is unchanged
September 2015	Replace policy	Policy updated with literature review through May 12, 2015; references 13 and 23 added; policy statement unchanged.

Date	Action	Description
December 2017	Replace policy	Policy updated with literature review through July 6, 2017; references 11- 13, 22, and 25-26 added. Rationale section revised. Policy statement unchanged.
September 2018	Replace policy	Policy updated with literature review through April 9, 2018; reference 22 added. Policy statement unchanged except "not medically necessary" corrected to "investigational" due to use of FDA 510(k) process.
September 2019	Replace policy	Policy updated with literature review through April 1, 2019, no references added. Policy statement unchanged.
December 2020	Replace policy	Policy updated with literature review through July 20, 2020; no references added. Policy statement unchanged.