

Corporate Medical Policy

Automated Nerve Conduction Tests

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| File Name: | automated_nerve_conduction_tests |
| Origination: | 6/2007 |
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| Next CAP Review: | 5/2012 |
| Last Review: | 8/2011 |

Description of Procedure or Service

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

Nerve conduction studies (NCS) and needle electromyography (EMG), when properly performed by a trained practitioner, are considered the gold standard of electrodiagnostic testing. However, the need for specialized equipment and personnel may limit the availability of electrodiagnostic testing for some patients.

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

Point-of-care nerve conduction has also been proposed for the diagnosis of peripheral neuropathy and, in particular, for detecting neuropathy in patients with diabetes. Peripheral neuropathy is relatively common in patients with diabetes mellitus, and the diagnosis is often made clinically through the physical examination. Diabetic peripheral neuropathy can lead to important morbidity including pain, foot deformity, and foot ulceration. Clinical practice guidelines recommend using simple sensory tools such as the 10-g Semmes-Weinstein monofilament or the 128-Hz vibration tuning fork for diagnosis. These simple tests predict the presence of neuropathy defined by electrophysiological criteria with a high level of accuracy. Electrophysiological testing may be used in research studies and may be required in cases with atypical presentation.

NC-stat® by NeuroMetrix is a portable nerve conduction test device designed to be used at the point-of-care. The system comprises a biosensor array, an electronic monitor, and a remote report generation system. The biosensor is a single use, preconfigured array consisting of a stimulation anode and cathode, skin surface digital thermometer, and response sensor. Biosensor arrays are available for assessment of sensory and motor nerves of the wrist (median and ulnar), and for the foot (peroneal, posterior tibial, and sural). A chip embedded in the biosensor panel measures skin surface temperature, the analysis algorithm adjusts for differences in temperature from 30° C, or if skin surface temperature is less than 23° C the monitor will indicate that limb warming is necessary. Data are sent to a remote computer via a modem in the docking station, and the remote computer generates a report based on the average of 6 responses that

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is sent back by fax or email. In addition to the automated stimulus delivery and reporting, NC-stat® analysis adjusts the calculation for body temperature, height, and weight, and uses the average of 6 responses. Sensitivity of the device for sensory nerve amplitude potentials is 2.1 µV, values lower than this are analyzed as zero, and responses with artifact are automatically eliminated from the analysis.

The Axon-II™ (PainDx) is an automated system that is being marketed for the detection of various sensory neurologic impairments caused by various pathologic conditions or toxic substance exposures, including signs of sympathetic dysfunction and detection of down-regulated A-delta function to locate injured nerve(s). The Axon-II software works with the Neural-Scan™ system (Neuro Diagnostics) and lists 7 automated studies (Cervical, Thoracic, Lumbar, Upper Extremities, Lower Extremities, Neuroma, Trigeminal), as well as a custom study. The Neural-Scan™ is a voltage-actuated sensory nerve conduction test device, which measures the voltage amplitude necessary to cause a discernable nerve impulse. Results are adjusted and compared to population means; the most severe hypoesthesia is considered the primary lesion.

Regulatory Status

Several devices are now being marketed for point-of-care neural conduction testing. NeuroMetrix received specific clearance to market NC-stat® via the U.S. Food and Drug Administration's FDA 510(k) process in 1998, listing as predicate devices the TECA model-10 electromyograph and the Neurometer by Neutron, which measures vibration threshold. The FDA-listed intended use was "to measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies." In addition, the approved application stated that "The NC-stat® is intended to be used as an adjunct to and not a replacement for conventional electrodiagnostic measurements." NeuroMetrix subsequently received FDA clearance to market newer models with biosensors and engineering changes that enable the NC-stat® to be used for motor and sensory nerves of the wrist (median and ulnar) and foot (peroneal, tibial, and sural). The intended use as listed on the 510(k) approval from 2006 (#K060584) is "to stimulate and measure neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies." The NeuroMetrix ADVANCE™ system received marketing clearance in 2008 (K070109). It is intended to perform nerve conduction studies using disposable surface electrodes (similar to NC-stat) with an additional module for invasive needle EMG. The ADVANCE™ system includes a real-time display of nerve conduction waveforms with a stylus for assignment of waveforms.

The XLTek Neuropath (Excel- Tech) received clearance for marketing through the FDA's 510(k) process in 2006; the indications are the same as those for NC-stat. The Neural-Scan™ NCS (Neuro Diagnostics) is a Class I diagnostic device (FDA clearance not usually required) that is being marketed "as part the [sic] neurological examination or for screening to detect peripheral neuropathies."

Related Policies:

Quantitative Sensory Testing

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

Automated nerve conduction tests are considered investigational. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Automated Nerve Conduction Tests

When automated nerve conduction tests are covered

Not applicable.

When automated nerve conduction tests are not covered

BCBSNC **does not** provide coverage for automated nerve conduction tests. They are considered investigational. BCBSNC does not provide coverage for investigational services.

Policy Guidelines

Studies have shown the correlation of portable automated nerve conduction test results with standard testing; however, questions remain about the diagnostic performance and clinical utility (i.e., impact on outcomes) of point-of-care automated testing. Particularly needed are data on the sensitivity and specificity of automated nerve conduction tests performed by non-specialists at the point-of-care in comparison with the “gold standard” of laboratory NCS/EMG. One potential clinical use could be early identification of asymptomatic diabetic neuropathy to institute appropriate clinical management before the onset of ulcerations, but no studies were identified that assessed the influence of point-of-care nerve conduction tests on clinical outcomes in this population. Overall, evidence remains insufficient to evaluate the effect of automated point-of-care nerve conduction tests on health outcomes.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 95905, G0255

Based on CPT Assistant, December 2008/Volume 18, Issue 12; CPT codes 95900, 95903 or 95904 should not be used for this service.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM). Proper performance and interpretation of electrodiagnostic studies. *Muscle Nerve* 2006; 33(3):436-9.

BCBSNC Medical Policy Reference Manual [Electronic Version]. 2.01.77, 2/15/2007

Specialty Matched Consultant Advisory Panel - 5/2007

BCBSNC Medical Policy Reference Manual [Electronic Version]. 2.01.77, 4/9/2008

Specialty Matched Consultant Advisory Panel - 5/2009

BCBSNC Medical Policy Reference Manual [Electronic Version]. 2.01.77, 6/10/2010

Specialty Matched Consultant Advisory Panel – 5/2011

Automated Nerve Conduction Tests

BCBSNC Medical Policy Reference Manual [Electronic Version]. 2.01.77, 6/9/11
Medical Director – 8/2011

Policy Implementation/Update Information

- 6/18/07 New policy adopted. Specialty Matched Consultant Advisory Panel review 5/23/2007. Automated nerve conduction tests are considered investigational. BCBSNC does not provide coverage for investigational services. Notification given 6/18/2007. Effective date 8/27/2007.
- 7/6/09 Specialty Matched Consultant Advisory Panel review 5/28/2009. "Description" section revised. No change to policy statement. Added additional rationale to the "Policy Guidelines" section. Added statement to "Billing/Coding" section to indicate; "Based on CPT Assistant, December 2008/Volume 18, Issue 12; CPT codes 95900, 95903 or 95904 should not be used for this service." References added. (btw)
- 1/5/10 Added new CPT code, 95905, to "Billing/Coding" section. (btw)
- 6/22/10 Policy Number(s) removed. (amw)
- 3/29/11 Removed deleted HCPCS code, "S3905", from "Billing/Coding" section. (btw)
- 6/21/11 Specialty Matched Consultant Advisory Panel review 5/25/11. Revised "Description" section. No change to policy statement. "Policy Guidelines" updated with rationale. References added. (btw)
- 8/30/11 "Description" section updated. Added HCPCS code G0255 to "Billing/Coding" section. Medical Director review 8/6/11. Reference added. (btw)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.