Anthem

Medical Policy

Subject: Automated Nerve Conduction Testing
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Description/Scope

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

Note: Please see the following related document for additional information:

- CG-MED-24 Electromyography and Nerve Conduction Studies

Position Statement

Investigational and Not Medically Necessary:

Electrodiagnostic 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 nerve conduction velocity studies.

Rationale

Nerve conduction studies (NCS), along with other electrodiagnostic (EDX) studies such as needle electromyogram (EMG), neuromuscular junction studies and other specialized studies, are used to assess the integrity and diagnose diseases of the peripheral nervous system. Automated nerve conduction studies have also been proposed for use in evaluating the peripheral nervous system, and can be performed by office staff without the need for specialized equipment and trained personnel. Automated systems use anatomically configured biosensors to perform the nerve conduction studies. The responses are recorded by a hand-held device which transmits the data to the device company computer software for analysis and interpretation.

In 1998, the NC-stat® System (NEUROMetrix®, Inc., Waltham, MA) received United States Food and Drug Administration (FDA) clearance through the 510(k) clearance process, for measurement of neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies. This original clearance was for use as an adjunct to, and not as a replacement for, conventional EDX testing. Although the device has been modified since the original FDA review to extend its nerve testing capability, the intended use of the device has not changed. The NC-stat System is a portable, hand-held, noninvasive, automated nerve conduction testing device that has been marketed for use in an office or clinic setting to assess nerves of the upper and lower extremities to assist in the diagnosis of peripheral nerve disorders, such as carpal tunnel syndrome and diabetic peripheral neuropathy. Since the clearance of the NC-stat, several other devices have also received 510 (k) clearance by the FDA.

Schmidt and colleagues (2011) reported on the use of an automated hand-held nerve conduction device compared to NCS or needle electrode examination (standard EDX tests) in the evaluation of individuals with unilateral leg symptoms. A total of 50 participants with complaints of unilateral leg pain, numbness or weakness were included in the study and underwent history with physical exam and standard EDX testing. The participants were then tested using an automated hand-held nerve conduction device. A total of 22 participants had findings consistent with radiculopathy on standard EDX test and 28 participants had a normal EDX exam or evidence of another distinct neuromuscular diagnosis. During initial data analysis, a significant discrepancy was revealed between the results of standard EDX tests and the automated test. For this reason, another 25 participants were recruited to serve as the control group. The control group participants had upper limb symptoms such as cervical radiculopathy, carpal tunnel syndrome or ulnar neuropathy. Of the 50 participants initially recruited, 28 were found to have normal standard EDX tests. The automated tests corroborated the findings in 4 cases only. In the control group, all standard EDX tests were normal, but the automated testing showed 18 of 25 participants had findings consistent with radiculopathy or polyneuropathy. Automated and standard testing correlated in 14 of 75 participants studied (11 of whom had normal exams with both testing methods). While this study has a small number of participants, the authors stated that “it is unlikely that larger study numbers would have increased specificity to acceptable levels of a clinically useful test, given the 95% confidence levels for the current data.”

In a 2015 study by Dale and colleagues, the authors compared the validity of NC-stat testing to traditional testing in active workers participating in a longitudinal testing protocol. The authors hypothesized that median nerve conduction studies from the NC-stat device would produce similar results as traditional testing in a group of active workers. A total of 134 participants received traditional nerve conduction testing with 62 participants then also receiving automated nerve conduction testing with the NC-stat device. The majority of the participants reported no hand symptoms. Median motor and sensory latency comparisons showed agreement with intraclass correlations of 0.85 and 0.80 respectively. Areas under the receiver operator characteristic (ROC) curves were 0.97 and 0.96 respectively, with the optimal thresholds of 4.4 ms median motor latency (sensitivity 100%, specificity 86%) and 3.9 ms median sensory latency (sensitivity 100%, specificity 87%). The ROC values for the ulnar nerve showed 100% sensitivity for the ulnar distal motor latency and distal sensory latency, and specificity (74%) for the ulnar sensory latency. Most of the selected traditional thresholds used to detect abnormal results corresponded to the highest ROC area and showed a sensitivity of 100%. The median-ulnar sensory difference showed a specificity using a 0.80 threshold reference on the traditional test, but much lower sensitivity. Limitations of this study include few participants with abnormal findings. This study was nested in a longitudinal study measuring the incidence of new cases of carpal tunnel syndrome. The study was performed on a sample of workers employed in one of several industries, therefore the results may not be representative of different working populations. Also noted were differences in testing methods internal and external to the device that may have affected comparisons.

In an open, cross-sectional study of 100 participants with previously diagnosed diabetes, Vogt and colleagues (2017) reported on the comparison of different methods of diagnosing diabetic polyneuropathy in an African population and evaluated the NC-stat DPNCheck® (NEUROMetrix®, Inc., Waltham, MA) as a potential tool for detection of diabetic polyneuropathy. Evaluation of diabetic polyneuropathy was done by four methods: (1) self-reported numbness of the lower limbs, (2) monofilament test, (3) The Sibbald 60-s Tool, and (4) nerve conduction studies using the NC-stat DPN Check. Self-reported numbness of the feet resulted in 62% confirmatory answers, the monofilament test was positive in 61%, the Sibbald

60-s Tool was positive in 87%, and nerve conduction studies measured by NC-stat DPNCheck detected diabetic polyneuropathy in 45% of participants. Since the study was limited to an African population at one facility in Africa, cultural differences in the experience and reporting of symptoms may exist. Generalizability of findings remains to be seen. Further study is necessary with different ethnic and cultural populations.

In a 2019 study by Shibata and colleagues the authors reported on 57 individuals with diabetes who underwent both an EMG and an automated nerve conduction test (a point-of-care device) to examine the reliability and validity of nerve conduction parameters acquired by the automated nerve conduction device. Using simple diagnostic criteria, diabetic peripheral neuropathy was found in 16 participants, not found in 26 participants, and assessment was not completed in 15 participants. All participants received both the EMG and automated nerve conduction testing. Decreased amplitude of sensory nerve action potential was shown in participants with diabetic peripheral neuropathy, however no differences of nerve conduction velocities were found between participants with and without diabetic peripheral neuropathy. In the EMG group, for the total cohort the sural nerve conduction velocity was 45.0, 44.5 for those with diabetic peripheral neuropathy, and 45.7 for those without diabetic peripheral neuropathy. Sural nerve action potential was 7.1 in the total cohort, 5.7 in those with diabetic peripheral neuropathy, and 8.9 in those without peripheral neuropathy. The point-of-care device showed a sural nerve conduction velocity of 48.4 in the total cohort, 47.3 in those with diabetic peripheral neuropathy, and 48.8 in those without diabetic peripheral neuropathy. Sural nerve action potential was 9.6 in the total cohort, 8.6 in the diabetic peripheral neuropathy group, and 10.8 in those without diabetic peripheral neuropathy. While the parameters between the two types of devices correlated well, the point-of-care device is not sufficient for the assessment of systemic sensorimotor neuropathy in diabetes. It is only suitable for a screening of neuropathy, specifically testing of the sural nerve. A comprehensive nerve conduction study is necessary for a detailed assessment of diabetic peripheral neuropathy. This study also has limitations including the single institution.

In the 2020 American Association of Neuromuscular and Electrodiagnostic Medicine's (AANEM) position statement on the "Proper Performance and Interpretation of Electrodiagnostic Studies and the Recommended Use of Electrodiagnostic Medicine," the authors stated that "Because needle EMG studies offer information needed for an accurate diagnosis, except in unique situations, it is the AANEM's position that NCSs and needle EMGs should be performed together in the same setting." The document also notes that using only NCS may provide incomplete diagnostic information which could lead to inadequate or inappropriate treatment. There was no mention of automated nerve conduction studies for diagnostic purposes.

Although portable, automated, noninvasive testing of nerve conduction has been suggested as an easier method for providers to obtain rapid results, the AANEM recommended that EDX studies of EMG and NCS be performed "by physicians with medical education in neuromuscular disorders and special training in EDX testing" (AANEM, 2020).

Currently, there is insufficient evidence in peer-reviewed published literature to demonstrate that automated nerve conduction testing devices provide better measures in the diagnosis of peripheral nerve disease. In addition, it remains unclear how testing with portable devices improves clinical outcomes for populations such as those with diabetes compared to clinical detection through neurological examination.

Background/Overview

NCS provide information about the peripheral nervous system by assessing the speed (conduction velocity or latency), size (amplitude), and shape of the response. This requires specialized equipment and personnel which may not always be available. Automated and portable nerve conduction devices may be used by office staff thereby obviating the need for specialized equipment and personnel. The systems use anatomically configured biosensors that perform the nerve conduction studies. The responses are recorded by a hand-held device. The data is then transmitted to a company where computer software analyzes it and provides an interpretation.

Definitions

Electromyography (EMG): Refers to the recording and study of the electrical activity of specific muscles through the use of a needle electrode which is inserted directly into a skeletal muscle. EMG testing is used to exclude, diagnose, describe and follow-up on diseases of the peripheral nervous system and the associated muscles.

Nerve conduction studies (NCS): This involves the application of surface electrodes to diagnose diseases of the peripheral nervous system. NCS assess the speed (conduction velocity/latency), size (amplitude), and shape of the electrical responses elicited from the targeted nerve and the muscle stimulated by that nerve.

Coding

The following codes for treatments and procedures applicable to this document 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 policy. 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.

When services are Investigational and Not Medically Necessary:
For the procedure codes listed below, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT	
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 [when specified as other portable automated nerve conduction testing]
HCPCS	
G0255	Current perception threshold/sensory nerve conduction test (SNCT), per limb, any nerve [when specified as other portable automated nerve conduction testing]
ICD-10 Diagnosis	
	All diagnoses

References

Peer Reviewed Publications:

1. Dale AM, Agboola F, Yun A, et al. Comparison of automated versus traditional nerve conduction study methods for median nerve testing in a general worker population. PM R. 2015; 7(3):276-282.
2. Elkowitz SJ, Dubin NH, Richards BE, Wilgis EF. Clinical utility of portable versus traditional electrodiagnostic testing for diagnosing, evaluating and treating carpal tunnel syndrome. Am J Orthop. 2005; 34(8):362-364.
3. England JD, Franklin GM. Automated hand-held nerve conduction devices: raw data, raw interpretations. Muscle Nerve. 2011; 43(1):6-8.
4. Jabre JF, Salzsieder BT, Gnemi KE. Criterion validity of the NC-stat automated nerve conduction measurement instrument. Physiol Meas. 2007; 28(1):95-104.
5. Katz JN, Simmons BP. Carpal tunnel syndrome. N Engl J Med. 2002; 346(23):1807-1812.
6. Katz RT. NC-stat as a screening tool for carpal tunnel syndrome in industrial workers. J Occup Environ Med. 2006; 48(4):414-418.
7. Kong X, Gozani SN, Hayes MT, Weinberg DH. NC-stat sensory nerve conduction studies in the median and ulnar nerves of symptomatic patients. Clin Neurophysiol. 2006; 117(2):405-413.
8. Leffler CT, Gozani SN, Cros D. Median neuropathy at the wrist: diagnostic utility of clinical findings and an automated electrodiagnostic device. J Occup Environ Med. 2000; 42(4):398-409.
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10. Perkins BA, Grewal J, Ng E, et al. Validation of a novel point-of-care nerve conduction device for the detection of diabetic sensorimotor polyneuropathy. Diabetes Care. 2006; 29(9):2023-2027.
11. Schmidt K, Chinea NM, Sorenson EJ, et al. Accuracy of diagnoses delivered by an automated hand-held nerve conduction device in comparison to standard electrophysiological testing in patients with unilateral leg symptoms. Muscle Nerve. 2011; 43(1):9-13.
12. Shibata Y, Himeno T, Kamiya T, et al. Validity and reliability of a point-of-care nerve conduction device in diabetes patients. J Diabetes Investig. 2019; 10(5):1291-1298.
13. Vinik AL, Emley MS, Megerian JT, Gozani SN. Median and ulnar nerve conduction measurements in patients with symptoms of diabetic peripheral neuropathy using the NC-stat system. Diabetes Technol Ther. 2004; 6(6):816-824.
14. Vogt EC, Øksnes M, Suleiman F, et al. Assessment of diabetic polyneuropathy in Zanzibar: Comparison between traditional methods and an automated point-of-care nerve conduction device. J Clin Transl Endocrinol. 2017; 10:9-14.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM). Proper performance and interpretation of electrodiagnostic studies. Muscle Nerve. 2006; 33(3):436-439. Updated January 2020. Available at: https://www.aanem.org/clinical-practice-resources/position-statements/position-statement/proper-performance-and-interpretation-of-electrodiagnostic-studies. Accessed on September 20, 2023.
2. American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM). Recommended policy for Electrodiagnostic Medicine. American Association of Neuromuscular & Electrodiagnostic Medicine. September 1997 and updated November 2019. Available at: https://www.aanem.org/clinical-practice-resources/position-statements/position-statement/recommended-policy-for-electrodiagnostic-medicine. Accessed on September 20, 2023.
3. U.S. Food and Drug Administration 510(k) Premarket Notification Database. NeuroMetrix NC-stat. No. K060584. Rockville, MD: FDA. July 31, 2006. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf6/K060584.pdf. Accessed on September 20, 2023.

Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale and References sections.
Reviewed	11/10/2022	MPTAC review. Updated Rationale and References sections.
Reviewed	11/11/2021	MPTAC review. Updated Rationale and References sections.
Reviewed	11/05/2020	MPTAC review. Updated Rationale and References sections.
Reviewed	11/07/2019	MPTAC review. Updated Rationale and References sections.
Reviewed	01/24/2019	MPTAC review. Updated Rationale, References, and Index sections.
Reviewed	01/25/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Rationale, Background/Overview, References and Index sections.
Reviewed	02/02/2017	MPTAC review. Updated References section.
Reviewed	02/04/2016	MPTAC review. Updated References. Removed ICD-9 codes from Coding section.
Reviewed	02/05/2015	MPTAC review. Updated Rationale and References.
Reviewed	02/13/2014	MPTAC review. Updated Rationale.
Reviewed	02/14/2013	MPTAC review. Updated Rationale, Background/Overview, Coding, and Reference sections.
Revised	02/16/2012	MPTAC review. Updated Rationale, Background/Overview, and References. Removed device name from Position Statement.
Reviewed	02/17/2011	MPTAC review. Updated References, Index. Removed Web Sites for Additional Information. Updated Coding section with 04/01/2011 HCPCS changes; removed S3905 deleted 03/31/2011.

Reviewed	02/25/2010	MPTAC review. References were updated.
	01/01/2010	Updated Coding section with 01/01/2010 CPT changes.
Reviewed	02/26/2009	MPTAC review. References were updated.
Reviewed	02/21/2008	MPTAC review. The phrase “investigational/not medically necessary” was clarified to read “investigational and not medically necessary.” This change was approved at the November 29, 2007 MPTAC meeting. References were updated.
	07/01/2007	Updated Coding section with 07/01/2007 HCPCS changes.
New	03/08/2007	MPTAC review. Initial document development.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.