MEDICAL POLICY

POLICY TITLE	AUTOMATED POINT-OF-CARE NERVE CONDUCTION TESTS
POLICY NUMBER	MP 2.099

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**2/1/2024**

I. Policy

Automated nerve conduction tests are considered **investigational** as there is insufficient evidence to support a general concerning the health outcomes or benefits associated with this procedure.

Cross-references:

MP 2.063 Electromyography and Nerve Conduction Studies
MP 2.100 Autonomic Nervous System Testing

II. Product Variations

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy Manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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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.

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Nerve conduction studies are a type of electrodiagnostic study conducted to evaluate the function of the peripheral nervous system and to diagnose related diseases (e.g., carpal tunnel syndrome, Lumbosacral Radiculopathy, and diabetic peripheral neuropathy). NCS measures the velocity of nerve impulses. Abnormal results include slowing of the nerve conduction signal, a completely blocked conduction, failure to elicit a motor response from a nerve signal or a diminished motor response. The results of these tests may assist in a differential diagnosis based on the degree of demyelination or loss of axon function in various portions of the nerve.

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. Electrodiagnostic studies may also be used to confirm the presence or 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 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. 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. 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.

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). 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.

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. 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 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.

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
Cadwell Sierra Ascent	Cadwell Industries	2017	K162383	Used as a 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)
Cadwell Sierra Summit	Cadwell Industries	2017	K162383	Used to detect the physiologic function of the nervous system, and to support the diagnosis of neuromuscular diseases or conditions
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
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.
XLTEK NEUROPATH	Excel Tech	2006	K053058	To stimulate and measure neuromuscular signals useful in diagnosing and evaluating systemic and entrapment neuropathies

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

IV. Rationale

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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.

V. DEFINITIONS

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N/A

VI. Benefit Variations

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member’s health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member’s health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member’s plan of benefits, please contact Capital Blue Cross’ Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. Coding Information

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore, not covered:

Procedure codes								
95905	95999	G0255						

IX. REFERENCES

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X. POLICY HISTORY

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MP 2.099	**CAC 1/27/15** New policy created however content was previously addressed in MP 2.063 Electromyography, Nerve Conduction Velocity Studies, and Quantitative Sensory Testing. No changes to the policy statement. References and rationale updated. Medicare variation added. Policy coded.
	CAC 1/26/16 Consensus review. No change to the policy statement. Reference and rationale update**.** Medicare variation revised to also refer to

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	LCD L35081 Nerve Conduction Studies and Electromyography. Coding reviewed.
	Administrative update 1/1/17. Product variation section reformatted.
	CAC 3/28/17 Consensus review. No change to the policy statement. References reviewed.
	1/1/18 Administrative update. Medicare variations removed from Commercial Policies.
	1/16/18 Consensus review. No change to the policy statement. Background, rationale, and references updated**.**
	1/14/19 Consensus review. No change to policy statements. Background and references updated. Rationale condensed.
	12/18/19 Consensus review. Literature, references updated. No change to policy statement.
	11/16/20 Consensus review. No references added. Policy statements unchanged.
	10/1/21 Consensus review. Policy statement unchanged. References updated, FEP language revised.
	07/01/2022 Consensus review. No change to policy statement. MP 2.098 removed as Cross-Referenced policy as now retired. Background updated.
	10/06/2023 Consensus review. No change to policy statement. Added Cross Referenced policy 2.100. References added.

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