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OVERVIEW

Portable devices have been developed to provide point-of-care nerve conduction studies (NCSs). These devices have computational 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.

MEDICAL CRITERIA

Not applicable.

PRIOR AUTHORIZATION

Prior Authorization is not required.

POLICY STATEMENT

BlueCHiP for Medicare

Automated point-of-care nerve conduction studies (portable hand-held devices like the NC-stat® and Brevio) are considered covered and medically necessary.

NOTE: Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates consideration of governmental regulations from the Centers for Medicare and Medicaid Services (CMS), such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than BCBSRI. Medicare and BCBSRI policies may differ. However, BlueCHiP for Medicare members must be offered, at least, the same services that Medicare offers.

Commercial

Automated point-of-care nerve conduction studies (portable hand-held devices like the NC-stat and Brevio) are considered not medically necessary as there is no peer-reviewed published medical literature on the use of voltage-actuated sensory nerve conduction tests and their impact on clinical outcomes. Overall, evidence remains insufficient to evaluate the effect of automated point-of-care nerve conduction tests on health outcomes.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable diagnostic imaging, lab, and machine tests benefits.

BACKGROUND

Nerve conduction studies and needle electromyography (EMG), when properly performed by a trained practitioner, are considered the criterion 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 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 alternate associated diagnoses. Nerve conduction is typically assessed before surgical release of the carpal tunnel, but the use of EMG in the diagnosis of CTS is controversial.

Point-of-care nerve conduction testing 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.⁽²⁾ 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.

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 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 discernible nerve impulse. Results are adjusted and compared with population means; the most severe hypoesthesia is considered the primary lesion.

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 nonspecialists at the point-of-care in comparison with the “criterion standard” of laboratory nerve conduction studies/electromyography. One study from a tertiary care clinic found high sensitivity but low specificity for the diagnosis of lumbosacral radiculopathy. Another 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 addressing the utility of point-of-care automated nerve conduction tests in a clinical setting is limited. There is no peer-reviewed published medical literature on the use of voltage-actuated sensory nerve conduction tests and their impact on clinical outcomes. Overall, evidence remains insufficient to evaluate the effect of automated point-of-care nerve conduction tests on health outcomes. Therefore, automated point-of-care nerve conduction tests are considered investigational.

Blue CHiP For Medicare

Current Perception Threshold/Sensory Nerve Conduction Threshold Test (sNCT) – is not covered by Medicare. *This procedure is different and distinct from assessment of nerve conduction velocity, amplitude and latency. It is also different from short-latency somatosensory evoked potentials. Codes designated for eliciting nerve conduction velocity, latency or amplitude, and those designed for short latency evoked potentials are not to be used for sNCT. The sNCT has a unique code G0255: Effective October 1, 2002, CMS initially concluded that there was insufficient scientific or clinical evidence to consider the sNCT test and the device used in performing this test reasonable and necessary within the meaning of section 1862(a)(1)(A) of the law. Therefore, sNCT was noncovered. Based on a reconsideration [in March, 2004] of current Medicare policy for sNCT, CMS concludes that there continues to be insufficient scientific or clinical evidence to consider the sNCT test and the device used in performing this test as reasonable and necessary within the meaning of section 1862(a)(1)(A) of the law.*

Examination using portable hand-held devices, or devices which are incapable of real-time wave-form display and analysis, and incapable of both NCS and EMG testing; will be included in the E/M service. They will not be paid separately. Examples include; The Axon II or delta fiber analysis testing and/or machines with other names.

Nerve conduction studies must provide a number of response parameters in a real-time fashion to facilitate provider interpretation. Those parameters include amplitude, latency, configuration and conduction velocity. Medicare does not accept diagnostic studies that do not provide this information or those that provide delayed interpretation as substitutes for Nerve conduction studies. Raw measurement data obtained and transmitted

CODING

BlueCHIP for Medicare

The following code is medically necessary

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

The following code is not medically necessary

G0255 Current perception threshold/sensory nerve conduction test, (SNCT) per limb, any nerve

Commercial Products

The following codes are not medically necessary

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

G0255 Current perception threshold/sensory nerve conduction test, (SNCT) per limb, any nerve

RELATED POLICIES

Not applicable.

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24. CMS Publication 100-3, *Medicare National Coverage Determinations Manual*, Chapter 1, Section 160.23

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