


<b>MEDICAL POLICY</b>	<b>Nerve Conduction Studies (All Lines of Business Except Medicare)</b>
<b>Effective Date: 6/1/2021</b>   <div style="text-align: right;">6/1/2021</div>	Medical Policy Number: 129
	Technology Assessment Committee Approved Date: 12/15  Medical Policy Review Committee Approved Date: 8/16; 10/17; 7/18; 8/19; 4/2020; 5/2020; 05/2021
Medical Officer _____ Date _____	

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

**SCOPE:**

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayn Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

**APPLIES TO:**

All lines of business except Medicare

**BENEFIT APPLICATION**

Medicaid Members

*Oregon:* Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**POLICY CRITERIA**

**Non-automated Nerve Conduction Studies**

- I. The use of non-automated nerve conduction studies may be considered **medically necessary and covered** for the clinical diagnosis of peripheral nervous system disorders.
- II. The use of non-automated nerve conduction studies is considered **not medically necessary and not covered** for either of the following:
  - A. Screening of asymptomatic individuals.
  - B. Monitoring of disease intensity or monitoring of treatment efficacy.

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- III. The use of non-automated nerve conduction studies is considered **investigational and not covered** when the above criterion (I.) is not met, including, but not limited to diagnosis of conditions other than peripheral nervous system disorders.

#### **Automated Nerve Conduction Studies**

- IV. The use automated nerve conduction studies (e.g., testing with hand-held/point-of-care devices such as the NC-stat® device) are considered **investigational and are not covered** for to diagnose, evaluate, or monitor any condition, including, but not limited to:
- A. Carpal tunnel
  - B. Chemotherapy-induced peripheral neurotoxicity
  - C. Diabetic neuropathy
  - D. Lumbosacral radiculopathies
  - E. Leprosy
  - F. Peripheral neuropathies of the lower extremities

#### **Quantitative Sensory Testing (QST)**

- V. Quantitative sensory testing (QST) is considered **investigational and not covered** to diagnose or evaluate any condition.

#### **Sensory Nerve Conduction Threshold Testing (SNCT)**

- VI. Sensory nerve conduction threshold testing (SNCT) is considered **investigational and not covered** to diagnose or evaluate any condition.

Link to [Policy Summary](#)

## **BILLING GUIDELINES**

### **Automated Nerve Conduction Studies**

- CPT code 95905 should be used when billing *automated* nerve conduction studies, such as NC-stat.
- CPT codes 95907 - 95913 should *not be used to bill automated* nerve conduction testing.

### **Non-automated Nerve Conduction Studies**

Each of the following codes 95907, 95908, 95909, 95910, 95911, 95912, and 95913, can be reimbursed only once per nerve, or named branch of a nerve, regardless of the number of sites tested or the number of methods used on that nerve.

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**CPT/HCPCS CODES**

All Lines of Business Except Medicare	
No Prior Authorization Required	
95907	Nerve conduction studies; 1-2 studies
95908	Nerve conduction studies; 3-4 studies
95909	Nerve conduction studies; 5-6 studies
95910	Nerve conduction studies; 7-8 studies
95911	Nerve conduction studies; 9-10 studies
95912	Nerve conduction studies; 11-12 studies
95913	Nerve conduction studies; 13 or more studies
Not Covered	
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
0106T	Quantitative sensory testing (QST), testing and interpretation per extremity; using touch pressure stimuli to assess large diameter sensation
0107T	Quantitative sensory testing (QST), testing and interpretation per extremity; using vibration stimuli to assess large diameter fiber sensation
0108T	Quantitative sensory testing (QST), testing and interpretation per extremity; using cooling stimuli to assess small nerve fiber sensation and hyperalgesia
0109T	Quantitative sensory testing (QST), testing and interpretation per extremity; using heat-pain stimuli to assess small nerve fiber sensation and hyperalgesia
0110T	Quantitative sensory testing (QST), testing and interpretation per extremity; using other stimuli to assess sensation
G0255	Current perception threshold/sensory nerve conduction test, (snct) per limb, any nerve
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then <b>prior-authorization is required.</b>	
95999	Unlisted neurological or neuromuscular diagnostic procedure

**DESCRIPTION**

Non-automated (Conventional) Nerve Conduction Studies (NCSs)

Non-automated nerve conduction studies are tests typically administered by physicians (typically neurologists) which are performed to diagnose peripheral neuropathies. According to the American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM), “they assess action potentials resulting from peripheral nerve stimulation which are recordable over the nerve or from an innervated

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muscle, the speed (conduction velocity and/or latency), size (amplitude), and shape of the response. Pathological findings include conduction slowing, conduction block, or reduced response. Results of the NCS reflect on the integrity and function of: (I) the myelin sheath, and (II) the axon of a nerve. Interruption of axon and dysfunction of myelin will both affect NCS results.”<sup>1</sup>

#### Automated Nerve Conduction Studies (NCS)

Automated NCS differ from conventional NCS/EMG testing in that they may be used in a variety of clinical settings, including a physician’s office, without the need for specialized training or equipment, theoretically obtaining results within minutes. Portable, automated devices are currently being investigated in the evaluation of several conditions, including carpal tunnel syndrome, diabetic peripheral neuropathy, and others, either as an alternative to or as an adjunct to conventional NCS.

There are several devices currently marketed as point of care devices for automated NCS. The first to be FDA approved, and the most-commonly studied device is the NC-stat device, described below.

#### *NC-stat System (NeuroMetrix, Inc.)*

The NC-stat device received FDA approval for the measurement of neuromuscular signals that are useful in diagnosing and evaluating systemic and entrapment neuropathies. The device has been approved for use as an adjunct to, and not as a replacement for, conventional electrodiagnostic measurements.<sup>2</sup>

The device consists of a hand-held, battery operated monitor and a disposable sensor. The device measures two median nerve electrophysiological parameters:

1. Distal motor latency (DML): the interval between the onset of the stimulus and the onset of the resultant compound muscle action potential (CMAP) in the thenar muscles.
2. F-wave latency (F-LAT): the median interval between the onset of the stimulus and the onset of a CMAP in the thenar muscle resulting from antidromic activation of the motor neurons in the spinal cord

Reports in the literature indicate that the original NC-stat device is limited by anatomical variations of sural nerve, severe edema, excessive adipose tissue, poor skin preparation and device misplacement, which might produce non-recordable measurements.<sup>3,4</sup> Therefore, in case of a ‘zero’ result using the NC-stat device, it is not possible to differentiate between a diseased state and nonclinical causes. In these cases conventional NCS must be performed. Nondiagnostic results, thereby necessitating re-testing, have been reported in 8-10% of patients while testing the sural, median and ulnar nerves.<sup>5,6</sup>

However, current devices marketed by NeuroMetrix, have been modified to address some of the shortcomings of the original NC-stat device.

1. The NC-stat® DPN-Check™ device has been modified from its predecessor and is intended to measure the sural nerve. Therefore, it is currently being evaluated to assess diabetic peripheral neuropathy (DPN).

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- The NeuroMetrix ADVANCE™ is intended to perform nerve conduction studies in a similar manner to its predecessor, but contains an additional module for invasive needle EMG, in an effort to provide a more complete evaluation.

### Quantitative Sensory Testing (QST)

QST techniques are being investigated as noninvasive tests to diagnose peripheral neuropathies. QST involves a variety of testing techniques to assess a patient's perception of pressure, vibration, and temperature. These tests have the potential to provide more detailed information about nerve function than conventional NCS, since QST is performed across the ranges of normal sensation, to determine whether the thresholds for capacity to perceive pressure, vibration, and/or temperature have become abnormal.<sup>7</sup>

Several different types of QST exist:<sup>7</sup>

- Pressure sensation QST, which includes two types of tests:
  - Tests which measure the threshold for pressure sensation (e.g., monofilament QST)
  - Tests which measure the density of pressure-sensing nerves (e.g., 2-point and circumferential discrimination QST)
- Vibration QST (e.g., Rydel-Seiffer tuning fork)
- Thermal QST (e.g., devices which heat and cool a metal probe)

One disadvantage of QST compared to conventional NCS is that QST is subjective, relying on self-reporting of the sensations they experience during testing. In contrast, conventional NCS measure nerve function directly and requires no reporting from the patient.<sup>7</sup>

QST has several important limitations:<sup>7-9</sup>

- QST consists of psychophysiological tests that require normal cognition on the part of the patient. Therefore, cognitive impairment or the desire for an abnormal test may introduce bias.
- QST provides no information on whether sensory dysfunction is due to peripheral or central pathology.
- The test may lack objectivity due to patient status (e.g., distraction, boredom, inattention, fatigue, drowsiness) and reaction time.
- Variables such as electrode size, site of stimulation, method and rate of change of the stimulation, method of obtaining patient's response, and variations in testing devices, make reproducibility of the test results difficult.
- There is a lack of standardization for testing procedures and reporting outcomes.

Due to these variables, QST lacks the objectivity of conventional NCS.

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Sensory Nerve Conduction Threshold (SNCT) Testing

Sensory nerve conduction threshold (SNCT or sNCT) testing, also known as perception sensory threshold testing or current perception threshold (CPT) testing, is a procedure that is different and distinct from the conventional assessment of nerve conduction velocity, amplitude, and latency used in non-automated NCS.<sup>1</sup>

SNCT tests are marketed as noninvasive and are intended to be used in combination with other tests, to diagnose suspected neurologic disorders, such as carpal tunnel syndrome and diabetic neuropathy, and to monitor patients with existing deficits.<sup>10</sup>

SNCT uses electrical stimulation rather than touch alone to measure and quantify the amount of physical stimulation required for a patient to perceive sensory stimulation. SNCT testing evaluates the function of the C, A-delta, and A-beta nerve fibers. In SNCT testing, three different levels of electrical stimulation are applied to an area of the skin that corresponds to the specific nerve being studied. The minimal amount of electrical stimulation needed to elicit a sensation is noted, based on patient responses, making these tests subjective in nature.<sup>10</sup>

**REVIEW OF EVIDENCE**

Conventional non-automated nerve conduction studies (NCSs) are standard of care for diagnosing peripheral nervous system disorders. Therefore, the following evidence review will focus on the investigational types of nerve conduction testing, including automated NCS, quantitative sensory testing (QST) and sensory nerve conduction threshold testing (SNCT). A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of these three investigational types of nerve conduction testing for the diagnosis, evaluation or monitoring of any nervous system disorders. Below is a summary of the available evidence identified through April 2021.

**Automated Nerve Conduction Studies**

Analytical and Clinical Validity

*Carpel Tunnel Syndrome (CTS)*

The NC-stat system has been used to evaluate carpel tunnel syndrome (CTS). Studies comparing automated NCS using the NC-Stat device to traditional electrodiagnostic studies have reported significant correlations between the two tests in cohorts of patients being evaluated for CTS.<sup>11-13</sup> However, these studies were poorly designed, involved small sample sizes (n=33 and 62) and lack generalizability due to study populations studied. In addition, evidence regarding measures of diagnostic performance (sensitivity and specificity) of the NC-stat system compared to standard testing for CTS is conflicting and does not permit strong conclusions regarding the usefulness of this type of NCS.<sup>11,14,15</sup>

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*Diabetic Neuropathy*

Hand-held devices for automated NCSs have also been evaluated in the context of diabetic neuropathy, where case-control studies have reported significant correlations when comparing these devices with reference standards.<sup>4,16,17</sup> However, evidence regarding measures of diagnostic performance (sensitivity and specificity) of these devices compared to standard testing for diabetic neuropathy is conflicting.<sup>16,18-22</sup>

In one of the largest case series that compared the diagnostic utility of the NC-stat device to a number of standard nerve conduction tests for diabetic neuropathy in patients with type 1 diabetes, Pambianco et al. evaluated 195 patients.<sup>22</sup> Sensitivity and specificity of the NC-stat device were reported as 79% and 48%, respectively, for detection of diabetic peripheral neuropathy, and 77% and 38% for the detection of amputation/ulcer/ or neuropathic pain. The Michigan Neuropathy Screening Index (MNSI) had the highest sensitivity (87% and 80%) and specificity (49% and 36%) for diabetic peripheral neuropathy and amputation/ ulcer/ or neuropathic pain. The authors concluded that the reduced specificity of the NC-stat device limits its use as a diagnostic tool for individuals with type 1 diabetes.

In a recent case-control study on diabetic neuropathy by Sharma et al. in 2015, 162 patients with diabetes (80 with type 1 and 82 with type 2 diabetes) and 80 healthy controls were tested with the NC-stat system.<sup>4</sup> The authors reported significant correlations between NC-stat results and those of two different conventional nerve conduction tests (conduction and amplitude potential), but the correlations were lower in the diabetics than in the healthy controls ( $r=0.73-0.78$  versus  $0.83-0.90$ , respectively). In addition, although the authors reported that the NC-stat device was able to distinguish between diabetics and healthy controls, the confidence intervals were wide, making it difficult to draw conclusions due to insufficient power. Lastly, in patients with mild neuropathy who would benefit most from early diagnosis, the sensitivity of the NC-stat device was substantially lower than patients with moderate to severe disease.

Overall, the case-control studies evaluating the use of the NC-stat device for diabetic neuropathy suffer from limitations including small sample size and heterogeneity in the types of diabetics included in each study (e.g., type I only, type II only, mixed patient populations, patients with abnormal glycemia).

*Other Conditions*

Several other indications have been evaluated using the NC-stat system in small case series ( $n<100$  patients), including lumbosacral radiculopathies,<sup>23</sup> leprosy,<sup>24</sup> lower extremity symptoms,<sup>25,26</sup> and chemotherapy-induced peripheral neurotoxicity.<sup>27</sup> However, there is not enough evidence on these indications to permit conclusions regarding the diagnostic utility of automated NCS.

Clinical Utility

No studies were identified that reported on measures of clinical utility, such as improved health outcomes and functional status, in patients who underwent automated NCSs compared to those who

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underwent conventional testing. In addition, no studies were identified that relied on automated NSCs to guide patient management for any indication.

Automated Nerve Conduction Evidence Summary

The body of evidence evaluating hand-held, point-of-care devices for automated nerve conduction testing consists entirely of case series, retrospective reviews, and nonrandomized case-control studies that have evaluated the diagnostic utility of these devices for a number of indications. The majority of studies have evaluated the NC-stat device or its successor, the DPN-Check device. No systematic reviews or randomized controlled trials comparing the results of these automated devices to those of conventional nerve conduction tests were identified for any indication. There is insufficient evidence that automated nerve conduction testing devices are valid tools to diagnose peripheral neuropathies and a paucity of evidence that the use of these devices alters management or improves patient outcomes.

**Quantitative Sensory Testing (QST)**

Analytical and Clinical Validity

*Migraine*

In 2018, Nahman-Averbuch and colleagues conducted a systematic review evaluating QST’s testing in patients with migraine to identify QST parameters that are reliably different between patients with migraine and healthy controls.<sup>28</sup> Independent investigators systematically searched the literature through January 2017, identified eligible studies, assessed study quality and extracted data. In total, 65 studies were included for meta-analysis. For each QST modality, investigators calculated up to 3 meta-analyses for combined (combined data from multiple testing locations), local (head and neck), and nonlocal (outside the head or neck) locations. Meta-analysis revealed no evidence of significant differences in detection thresholds between patients with migraine and healthy controls across studies. Lower heat and pressure pain thresholds were observed in patients with migraine compared with healthy controls in the combined locations. Importantly, lower pressure pain threshold in patients with migraine was found in local areas but not in nonlocal areas. In addition, patients with migraine had higher pain ratings to cold suprathreshold stimuli for combined and nonlocal areas, and higher pain ratings to electrical suprathreshold stimuli for nonlocal areas. Limitations included the substantial heterogeneity across subjects, which may have confounded results. While authors stated that alterations in nociceptive processing of patients with migraine may be modality, measure, and location specific, additional studies are needed that use more than 1 QST stimulus modality or measure.

*Diabetes*

In 2012, Moloney et al. published a systematic review that examined the reliability of thermal QST.<sup>29</sup> Twenty-one studies were included, eight of which evaluated thermal QST in diabetic patients, and nine studies recruiting only healthy subjects. Other studies included patients with spinal cord injury (n=2), sciatica (n=1) and complex regional pain syndrome type I (n=1). Only five studies were considered high



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quality. The review authors found considerable variation in the reliability of thermal QST between studies, stating that methodologic limitations included incomplete information on the qualifications/training of those administering the tests, a lack of blinding and randomization, and lack of standardization of test protocols.

*Lower Extremity Peripheral Neuropathy*

In 2014 (reviewed 2018; archived 2019), Hayes published a review of QST for the diagnosis of lower extremity peripheral neuropathy, including 29 prospective or retrospective cohort, cross-sectional, matched-group, or case-control studies evaluating QST for detection of neuropathy or foot ulcer and/or amputation susceptibility.<sup>7</sup> The studies included in the review only reported on measures of analytical and clinical validity, and no clinical utility studies were identified. This review included heterogeneous studies in terms of size (n=30 to 1441 patients), patient age (pediatric and adult patients), the type of QST used, and the etiology of the neuropathy (diabetes, human immunodeficiency virus (HIV) infection, alcohol use, rheumatologic disease, chemotherapy-induced).

Overall, all of the included studies were determined to be of poor to very poor quality. The amount and consistency of evidence concerning QST for the diagnosis of neuropathy varied widely, depending on the type of QST and the indication for testing. Overall, low quality evidence suggested that vibration QST had moderate to high accuracy for the diagnosis of neuropathy (rating of “C”) and that monofilament QST and vibration QST have moderate to high accuracy for the diagnosis of loss of protective sensation (Hayes rating of “C”). However, the review stated that there was, “uncertainty due to the lack of uniformity in cutoff values used to interpret QST results and insufficient comparison with simpler methods for the diagnosis of neuropathy.”

The review concluded “there is insufficient evidence (rating of “D2”) to evaluate monofilament QST for the diagnosis of neuropathy or to evaluate monofilament QST for the diagnosis of neuropathy or to evaluate thermal QST, ball bearing QST, 2-point discrimination QST, or tactile circumferential QST for the diagnosis of neuropathy or susceptibility to foot ulcer and/or amputation.” The review stated that there was either a small number or lack of studies for all types of QST except vibrational QST, “divergent results, differing methodologies, and/or incomplete reporting of methodology in studies of these forms of QST for the diagnosis of neuropathy.”

*Spinal Pain*

In 2013, Hubscher et al. published the results of a systematic review that evaluated the association between QST and self-reported pain and disability in patients with spinal pain, including 40 studies (28 of which used pressure QST). The overall analysis found low or no correlations between pain thresholds, as assessed by QST and self-reported pain intensity or disability. The review concluded that QST provided low accuracy for diagnosing patients’ level of spinal pain and disability.<sup>30</sup>

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*Other Indications*

Single studies have published measures of either analytical validity or clinical validity for several of the QST techniques. However, these single studies do not provide enough evidence to draw conclusions about the performance or diagnostic utility of the different types of QST techniques for the indications for which they have been studied. Below are the studies identified that have reported on various QST techniques for indications not addressed in the systematic reviews above.

- Pressure QST:
  - One case-control study comparing pressure QST and convention NCSs in 79 patients with carpal tunnel syndrome and 26 healthy controls.<sup>31</sup>
  - One case-control study evaluating pressure QST in 30 patients with winged scapula and upper trunk injury and 10 healthy controls.<sup>32</sup>
- Vibration QST:
  - One case series comparing vibration threshold testing with standard NCSs in 195 (86% follow-up) subjects with diabetes mellitus.<sup>33</sup>
  - One case series comparing vibration threshold testing (using a non-FDA approved device) with standard NCSs in 100 patients with type II diabetes.<sup>34</sup>
- Thermal QST:
  - One case series evaluating warm and cool thresholds in 89 patients with low back pain.<sup>35</sup>
  - One case series comparing warm and cool thresholds to conventional NCSs and skin biopsy for 124 patients with small fiber neuropathy.<sup>36</sup>

In addition, one small case series evaluated several QST techniques as a potential method of identifying early clinical markers of chemotherapy-induced neurotoxicity in 48 colorectal cancer patients assigned to two different chemotherapy drugs.<sup>37</sup> This was the only study identified using QST for this indication.

*Analytical and Clinical Validity Evidence Summary*

The body of evidence evaluating QST techniques for peripheral neuropathies primarily consists of nonrandomized comparative studies and case series, and systematic reviews of these studies. Primary studies have been published on small, heterogeneous patient populations, evaluating a variety of different QST devices. These studies have reported either device/test performance measures or the diagnostic utility of these devices for a large number of indications. Limitations of the primary studies include flawed study methodology; lack of a control groups; large proportions of patients who did not complete all of the testing and/or were lost to follow-up; lack of comparisons to conventional neurological tools for any given condition; heterogeneity in testing parameters, devices and protocols; and lack of randomization.

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### Clinical Utility

#### *Predicting Response to Analgesic Treatment*

In 2011, Scott et al. published a small case series of 23 cancer patients that compared the ability of thermal QST to other conventional tests, to predict the ability of radiation therapy to reduce cancer-induced bone therapy.<sup>38</sup> However, the numbers of patients who experienced a change in thermal sensation after radiotherapy were too small to draw conclusions about the accuracy of thermal QST for predicting response to radiotherapy.

In 2013, Grosen et al. published the results of a systematic review that evaluated associations between QST findings from several different techniques and analgesic response, including 14 studies (six small RCTs of less than 140 individuals and eight cohort studies).<sup>39</sup> One RCT was conducted in healthy volunteers, nine observational cohort studies on surgical patients, and four studies on chronic pain patients. Study findings were not pooled due to significant heterogeneity. Only six of the nine studies on surgical patients reported a correlation between QST measurement and consumption of analgesics. However, the review did not report whether the correlation was for all, or only some, of the outcomes related to analgesic consumption. Of the four studies on chronic pain patients included in the review, only two studies reported a correlation between QST parameters and one or more analgesic response outcome. The reviewers concluded that the evidence was not sufficiently robust to determine whether QST parameters were predictive of response to analgesic treatment.

#### *Low Back Pain*

In 2016, Marcuzzi et al. published a systematic that evaluated pressure QST's prognostic ability to predict health outcomes for patients with acute or chronic low back pain (LBP), including three studies (out of 6408 references assessed).<sup>40</sup> All three studies included patients with LBP of various etiologies, thereby having heterogeneous patient populations within and between studies. Meta-analysis of pooled results was not possible due to significant heterogeneity between included studies. None of the included studies reported significant associations between the QST measures and LBP outcomes. The studies were determined to have high risk of bias, which may have compromised the validity of their reported results. The reviewers concluded that, "due to the paucity of available studies and the methodological shortcomings identified, it remains unknown whether QST measures are predictive of outcome in LBP."

#### *Post-Operative Pain*

In 2014, Ahmad et al. published a study that addressed how thermal QST might be used in practice to predict post-operative pain, including 124 prospectively recruited patients scheduled for gynecological surgery (abdominal myomectomy or hysterectomy).<sup>41</sup> Preoperative heat and cold pain thresholds correlated significantly with 24-hour morphine consumption, specifically patients with initial thresholds above the median used more morphine (median,  $\geq 19$  mg,  $p=0.004$ ). The authors stated that the findings could be used to stratify patients preoperatively based on their baseline thermal QST scores and to manage patients more or less aggressively, depending on their QST test findings. Since the study did not

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prospectively manage patients and opioid administration was individualized; it is unclear how actual management would have differed if QST scores had been incorporated into the post-surgical management strategy. This study did not report on actual changes in management of these patients.

*Musculoskeletal Disorders*

In 2019, Georgopoulos and colleagues conducted a systematic review and meta-analysis evaluating QST’s capacity to predict outcomes for musculoskeletal pain, disability and negative affect among a range of musculoskeletal disorders.<sup>42</sup> Independent investigators systematically searched the literature through April 2018, identified eligible studies, assessed study quality, extracted data and pooled data. Investigators ultimately included 37 studies for review (32 prospective cohort studies and 5 RCTs) assessing 3,860 patients. Outcomes of interest included pain, disability and negative affect. Meta-analysis indicated that baseline QST predicted musculoskeletal pain (mean  $r = 0.31$ , 95% confidence interval (CI): 0.23-0.38,  $n = 1057$ ) and disability (mean  $r = 0.30$ , 95% CI: 0.19-0.40,  $n = 290$ ). Baseline modalities quantifying central mechanisms such as temporal summation and conditioned pain modulation were associated with follow-up pain (temporal summation: mean  $r = 0.37$ , 95% CI: 0.17-0.54; conditioned pain modulation: mean  $r = 0.36$ , 95% CI: 0.20-0.50), whereas baseline mechanical threshold modalities were predictive of follow-up disability (mean  $r = 0.25$ , 95% CI: 0.03-0.45). Investigators concluded that, across multiple musculoskeletal conditions, baseline QST score was predictive of musculoskeletal pain and disability at follow-up. Study validity was limited by significant heterogeneity across included studies, and disparate findings relative to other meta-analyses conducted to date. Authors called for additional research inside and outside of musculoskeletal disorders to confirm findings, confirm the reliability of specific QST approaches and establish clinically meaningful thresholds in specific pathologies.

*Cancer Pain*

In 2019, Martland and colleagues conducted a systematic review evaluating QST’s assessment of pain in people with cancer.<sup>43</sup> Independent investigators systematically searched the literature through January 2019, identified eligible studies, assessed study quality and extracted data. In total, 18 studies assessing various cancers were included for review. Sample size ranged from 12 to 129. Across all studies, 50% (9/18) reported sensory abnormalities using thermal detection thresholds (cool and warm), 44% (8/18) reported abnormal mechanical detection thresholds using von-Frey filaments and 39% (7/18) found abnormal pinprick thresholds. Abnormal vibration and thermal pain (heat/cold) thresholds were each reported in a third of included studies. Investigators concluded that evidence was insufficient to characterize the phenotype of cancer pain using QST, and called for additional studies to validate individual test parameters from standardized QST protocols.

*Clinical Utility Evidence Summary*

The studies evaluating various QST techniques as tools to measure patient prognosis or effects of pain-reducing therapies consist largely of case series. The evidence for any given indication is insufficient to draw conclusions regarding the potential clinical utility of any of the QST techniques currently being

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evaluated. In addition, no studies were identified that reported that use of any method of QST testing resulted in actual changes in patient management for any indication.

**Sensory Nerve Conduction Threshold (SNCT) Testing**

Analytical and Clinical Validity

Sensory nerve conduction threshold (SNCT) testing has been investigated for a broad range of indications, including detection of peripheral neuropathies, carpal tunnel syndrome, spinal radiculopathy and many others. Single studies have published measures of either analytical or clinical validity for SNCT for these indications. In 2012, ECRI published a report that identified studies evaluating test performance or diagnostic utility of SNCT, listing over 25 indications, from atopic dermatitis to varicose vein surgery.<sup>10</sup>

Single studies that evaluated SNCT for various indications that were identified after the publication of the ECRI review are listed below.

- One case-control study evaluating SNCT in 48 patients with lumbar radiculopathy and 11 healthy controls.<sup>44</sup>
- One small case series of 40 patients with trigeminal nerve injuries.<sup>45</sup>
- One case series of 106 patients with neck pain.<sup>46</sup>

However, these single studies do not provide enough evidence to draw conclusions about test performance or diagnostic utility of SNCT for any indication.

Clinical Utility

No studies were identified reported on any measures of clinical utility, such as improved health outcomes and functional status in patients who underwent SNCT testing compared to those who underwent conventional nerve conduction testing or other tests conventionally used to evaluate or diagnose an indication. In addition, no studies were identified that relied on SNCT to guide patient management for any indication.

**CLINICAL PRACTICE GUIDELINES**

Non-Automated Nerve Conduction Studies

*American Association of Neuromuscular and Electrodagnostic Medicine (AANEM)*

In 2016, the AANEM updated their model policy for needle electromyography and nerve conduction studies, stating the following:<sup>1</sup>

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“Screening testing for polyneuropathy of diabetes or end stage renal disease (ESRD) is **NOT covered**. Testing for the sole purpose of monitoring disease intensity or treatment efficacy in these two conditions is **not covered**.”

In 2015 and 2017, the Professional Practice Committee of the AANEM developed the following recommendations as part of the American Board of Internal Medicine’s (ABIM) Foundation Choosing Wisely® Initiative.<sup>47</sup>

- “Don’t perform nerve conduction studies or electromyography for muscle pain in the absence of other abnormalities on examination or laboratory testing.”

Automated Nerve Conduction Studies

*American Academy of Orthopaedic Surgeons (AAOS)*

In 2016, the AAOS published evidence-based clinical practice guidelines for carpal tunnel syndrome that stated that there was insufficient data on hand-held (automated) nerve conduction study devices to recommend for or against their use.<sup>48</sup> The guideline included one study of moderate quality, but excluded two additional studies due to poor quality.

*American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM)*

In 2016, the AANEM updated their model policy for needle electromyography and nerve conduction studies, stating the following:<sup>1</sup>

“EDX [Electro diagnostic] 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 [conventional] NCSs.”

Quantitative Sensory Testing

*American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM)*

In 2016, the AANEM updated their model policy for needle electromyography and nerve conduction studies, stating the following:<sup>1</sup>

“Psychophysical measurements (electrical, vibratory or thermal perceptions), even though they may involve delivery of a stimulus, are **not covered**.”

*American Academy of Neurology (AAN)*

In 2016, the AAN reaffirmed their 2003 evidence-based guideline on quantitative sensory testing, stating:<sup>49</sup>

“QST results **should not** be the sole criteria used to diagnose pathology. Because malingering

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and other nonorganic factors can influence the test results, QST is not currently useful for the purpose of resolving medicolegal matters. Well-designed studies comparing different QST devices and methodologies are needed and should include patients with abnormalities detected solely by QST.”

Sensory Nerve Conduction Threshold (SNCT) Testing

*American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM)*

In 2016, the AANEM updated their model policy for needle electromyography and nerve conduction studies, stating the following:<sup>1</sup>

“Current Perception Threshold/Sensory Nerve Conduction Threshold Test (sNCT) is **investigational** and **not covered**.”

**POLICY SUMMARY**

Non-Automated Nerve Conduction Studies

There is sufficient evidence that conventional (non-automated) nerve conduction studies are necessary for the diagnosis of peripheral neuropathies. However, the use of these devices for the purposes of screening asymptomatic individuals for peripheral neuropathies, or for monitoring disease intensity or treatment efficacy in peripheral neuropathies, is not supported by current evidence-based clinical practice guidelines. Therefore, non-automated nerve conduction studies may be considered medically necessary and covered for the clinical diagnosis of peripheral nervous system disorders. The use of these devices for the purposes of screening asymptomatic individuals or for monitoring disease intensity or treatment efficacy is considered not medically necessary and not covered.

There is not enough research to know if non-automated nerve conduction improves overall health outcomes for conditions other than peripheral nervous system disorders. No clinical practice guidelines based on research were identified recommending this as a diagnostic tool for other indications. Therefore, the use of non-automated nerve conduction studies for indications other than peripheral nervous system disorders is considered investigational and not covered.

Automated Nerve Conduction Evidence Summary

There is insufficient evidence to show that automated nerve conduction testing devices are valid tools to diagnose peripheral neuropathies. In addition, there is a paucity of evidence on if the use of these devices alters management or improves patient outcomes. Clinical practice guidelines agree that there is insufficient evidence to recommend either for or against the use of automated nerve conduction testing. Therefore, the use of automated nerve conduction testing devices is considered investigational and not covered for any indication.

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Quantitative Threshold Testing

There is insufficient evidence of diagnostic utility for the use of any given type of QST (e.g., pressure, thermal, vibrational) for any indication. In addition, no studies were identified that reported that use of any method of QST testing resulted in actual changes in patient management for any indication. Lastly, current clinical practice guidelines agree that QST should not be used to diagnose or evaluate any condition, due to its subjective nature and other significant limitations. Therefore, the use of quantitative sensory testing is considered investigational and not covered for any indication.

Sensory Nerve Conduction Threshold (SNCT) Testing

There is insufficient evidence to draw conclusions regarding diagnostic utility of SNCT for any indication. In addition, no studies were identified which reported on whether the results of SNCT testing led to changes in patient management or improved patient health outcomes such as functional status. Lastly, current clinical practice guidelines recommend against the use of SNCT testing. Therefore, the use of sensory nerve conduction threshold testing is considered investigational and not covered for any indication.

**INSTRUCTIONS FOR USE**

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days’ notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

**REGULATORY STATUS**

United States Food & Drug Administration (FDA)

Many devices marketed for the investigational nerve studies addressed in this policy have received FDA clearance through the 510(k) clearance process, which does not require data regarding clinical efficacy for approval. Examples of these devices are listed below.

Automated NCS devices with FDA-approval include, but are not limited to:

- NC-stat® (1998) and NC-stat® DPN-Check™ devices (NeuroMetrix, Inc.)
- Virtual Medical Systems VT3000 (Scientific Imaging, Inc.)(2005)



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- XLTEK Neuropath (Excel- Tech Ltd.) (2006) NOTE: this device has been approved for the same indications as the NC-stat® devices.
- Brevio (Neurotron Medical, Inc.)(2007)
- NeuroMetrix ADVANCE™ (NeuroMetrix, Inc.)(2008)

Quantitative sensory testing devices with FDA-approval include, but are not limited to:<sup>7</sup>

- Case IV Computer-Aided Sensory Evaluator (WR Medical Electronics Co.)
- Thermal Sensory Analyzer (TSA)-2001 (Medoc Corp.)
- NK Pressure Specified Sensory Device (NK Biotechnical Engineering Co.)
- TCD Neuropathy Star (JCM Management & Planning Co.)
- VSA-3000 Vibratory Sensory Analyzer (Eare Consulting Service)
- Vibration Perception Threshold (VPT) Meter (Xilas Medical Inc.)

Sensory nerve conduction threshold testing devices with FDA-approval include, but are not limited to:

- Neurometer (Neurotron, Inc.)
- Neural-Scan (formerly known by the name Medi-Dx 7000) (PainDx, Inc.)

#### Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

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