BlueCross BlueShield of Alabama

Name of Policy:
Quantitative Sensory Testing (QST)

Policy #: 066
Category: Medical
Latest Review Date: July 2018
Policy Grade: B

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

Quantitative sensory testing (QST) systems are used for the noninvasive assessment and quantification of sensory nerve function in patients with symptoms of or the potential for neurologic damage or disease. Types of sensory testing include current perception threshold testing, pressure-specified sensory testing, vibration perception testing, and thermal sensory testing. Information on sensory deficits identified using QST has been used in research settings to better understands neuropathic pain. It could potentially be used to diagnose conditions linked to nerve damage and disease, and to improve patient outcomes by impacting management strategies.

Nerve Damage and Disease

Nerve damage and nerve diseases can reduce functional capacity and lead to neuropathic pain.

Treatment

There is a need for tests that can objectively measure sensory thresholds. Moreover, quantitative sensory testing (QST) could aid in the early diagnosis of disease, before patients would be diagnosed clinically. Also, although the criterion standard for evaluation of myelinated, large fibers is electromyography nerve conduction study, there are no criterion standard reference tests to diagnose small fiber dysfunction.

Quantitative Sensory Testing

Quantitative sensory testing (QST) systems measure and quantify the amount of physical stimuli required for sensory perception to occur. As sensory deficits increase, the perception threshold of QST will increase, which may be informative in documenting progression of neurologic damage or disease. QST has not been established for use as a sole tool for diagnosis and management but has been used with standard evaluative and management procedures (e.g., physical and neurologic examination, monofilament testing, pinprick, grip and pinch strength, Tinel sign, and Phalen and Roos test) to enhance the diagnosis and treatment-planning process, and to confirm physical findings with quantifiable data. Stimuli used in QST includes touch, pressure, pain, thermal (warm and cold), or vibratory stimuli.

The criterion for evaluation of myelinated large fibers is the electromyographic nerve conduction study (EMG-NCS). However, the function of smaller myelinated and unmyelinated sensory nerves, which may show pathologic changes before the involvement of the motor nerves, cannot be detected by nerve conduction studies. Small fiber neuropathy has traditionally been a diagnosis of exclusion in patients who have symptoms of distal neuropathy and a negative nerve conduction study.

Depending on the type of stimuli used, QST can assess both small and large fiber dysfunction. Touch and vibration measure the function of large myelinated A-alpha and A-beta sensory fibers. Thermal stimulation devices are used to evaluate pathology of small myelinated and unmyelinated nerve fibers; they can be used to assess heat and cold sensation, as well as thermal pain thresholds. Pressure-specified sensory devices (PSSD) assess large myelinated sensory nerve function by quantifying the thresholds of pressure detected with light, static, and moving touch. Finally, current perception threshold testing involves the quantification of the sensory threshold to transcutaneous electrical stimulation. In current perception threshold

testing, typically three different frequencies are tested: 5 Hz, designed to assess C fibers; 250 Hz, designed to assess A-delta fibers; and 2,000 Hz, designed to assess A-beta fibers. Results are compared with those of a reference population.

Because QST combines the objective physical sensory stimuli with the subject patient response, it is psychophysical in nature and requires patients who are alert, able to follow directions, and cooperative. In addition, to get reliable results, examinations need to be standardized with standardized instructions to the patients, and stimuli must be applied in a consistent manner by trained staff. Psychophysical tests have greater inherent variability, making their results more difficult to standardize and reproduce.

Policy:

Quantitative sensory testing (QST) does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

Current perception threshold (CPT) testing does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

Pressure-specified sensory device (PSSD) testing does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The most recent literature review was updated through May 01, 2018.
Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

Literature searches focus on types of quantitative sensory testing (QST) approved or cleared by the U.S. Food and Drug Administration (FDA). This includes current perception threshold testing, pressure-specified sensory testing (PSST), vibration perception threshold (VPT) testing, and thermal threshold testing.

Quantitative Sensory Testing

Clinical Context and Proposed Clinical Utility

The purpose of QST using current perception threshold testing, PSST, VPT, or thermal sensory testing in patients who have conditions linked to nerve damage or disease (e.g., diabetic neuropathy, carpal tunnel syndrome) is to inform a diagnosis and appropriate treatment.

The question addressed in this evidence review is: In individuals with conditions associated with nerve damage or disease, does QST improve the diagnosis of patients and lead to improved patient management decisions and health outcomes?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest is patients with conditions associated with nerve damage or disease.

Interventions

The relevant intervention of interest is QST using current perception threshold testing, PSST, VPT testing, or thermal sensory testing.

Comparators

The comparators of interest are standard clinical examination, other sensory threshold tests, and, for large fiber dysfunction, EMG-NCS.

Outcomes

The primary outcomes of interest relate to diagnostic accuracy (i.e., test accuracy and validity) and to health outcomes (i.e., symptoms, functional outcomes).

Timing

Diagnostic accuracy is a short-term outcome. Functional outcomes would be measured over the long term, after patients have been diagnosed and treated.

Setting

Patients would be tested in the primary or specialty (e.g., neurology setting).

Current Perception Threshold Testing

Technically Reliable

Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review, and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Limited published evidence is available on diagnostic performance. Several studies have compared current perception threshold testing with other testing methods, but sensitivity and specificity have not been reported. For example, in 2012, Ziccardi et al evaluated 40 patients presenting with trigeminal nerve injuries involving the lingual branch. Patients underwent current perception threshold testing and standard clinical sensory testing. Statistically significant correlations were found between findings of electrical stimulation testing at 250 Hz and the reaction to pinprick testing ($p=0.02$), reaction to heat stimulation ($p=0.01$), and reaction to cold stimulation ($p=0.004$). In addition, significant correlations were found between electrical stimulation at 5 Hz and the reaction to heat stimulation ($p=0.017$), to cold stimulation ($p=0.004$), but not to pinprick testing ($p=0.096$).

In addition, Park et al (2001) compared current perception threshold testing with standard references for thermal sensory testing and von Frey tactile hair stimulation in a randomized, double-blind, placebo-controlled trial with 19 healthy volunteers. All current perception threshold measurements showed a higher degree of variability than thermal sensory testing and von Frey measurements but there is some evidence that similar fiber tracts can be measured, especially C-fiber tract activity at 5 Hz, with current perception threshold, thermal sensory, and von Frey testing methods. This study only included healthy volunteers.

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

No direct evidence from comparative studies evaluating the impact of current perception testing on patient management decisions or health outcomes was identified.

Chain of Evidence
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.
Because the evidence is insufficient to demonstrate test performance for current perception threshold testing, no inferences can be made about clinical utility.

Section Summary: Current Perception Threshold Testing

There is insufficient evidence on the accuracy of current perception threshold testing for diagnosing any condition linked with nerve damage or disease using current perception threshold testing. Several studies have compared current perception threshold testing with other testing methods, but sensitivity and specificity were not reported. No direct evidence was identified for the clinical utility of current perception testing and, since there is insufficient evidence on test performance, a chain of evidence for clinical utility cannot be constructed.

Pressure-Specified Sensory Testing

Technically Reliable

Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review, and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Standard evaluation and management of patients with potential nerve compression, disease, or damage consists of physical examination techniques and may include Semmes-Weinstein monofilament testing and, in more complex cases, nerve conduction velocity (NCV) testing. Several studies have compared performance of PSST devices. For example, a 2000 study by Weber et al (2000) evaluated the sensitivity and specificity of PSST and NCV testing in 79 patients, including 26 healthy controls. The NCV test had a sensitivity of 80% and a specificity of 77%; the PSST had a sensitivity of 91% and a specificity of 82%. The difference between the 2 tests was not statistically significant.

A 2010 study by Nath et al evaluated 30 patients with winged scapula and upper trunk injury and 10 healthy controls. They used the FDA-cleared PSST device by Sensory Management Services to measure the minimum perceived threshold in both arms for detecting 1-point static (1PS) and 2-point static (2PS) stimuli. The authors used a published standard reference threshold value for the dorsal hand first web (DHFW) skin and calculated threshold values for both the DHFW and the deltoid using the upper limit of the 99% normal confidence interval (CI). No published threshold values were available for the deltoid location. PSST was done on both arms of all participants, and electromyography (EMG) testing only on the affected arms of symptomatic patients. Using calculated threshold values, patients with normal EMG results had positive PSST results on 50% (8/16) of 1PS deltoid, 71% (10/14) of 2PS deltoid, 65% (11/17) of 1PS DHFW, and 87% (13/15) of 2PS DHFW tests. Study findings suggested that PSSD is more sensitive than needle EMG in detecting brachial plexus upper trunk injury.

A 2013 systematic review by Hubscher et al evaluated the relation between QST and self-reported pain and disability in patients with spinal pain. Twenty-eight of 40 studies identified used PSST devices. The overall analysis found low or no correlations between pain thresholds,

as assessed by QST and self- reported pain intensity or disability. For example, the pooled estimate of the correlation between pain threshold and pain was -0.15 (95% CI, -0.18 to -0.11) and between pain threshold and disability, it was -0.16 (95% CI, -0.22 to -0.10). The findings suggested that QST provides low accuracy for diagnosing patients' level of spinal pain and disability.

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

No direct evidence from clinical trials identified has demonstrated that use of the PSST resulted in changes in patient management or improved patient outcomes. Suokas et al (2012) published a systematic review of studies evaluating QST for painful osteoarthritis; most studies used pressure testing. Reviewers did not report finding any studies evaluating the impact of QST on health outcomes.

Chain of Evidence
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Indirect evidence on clinical utility rests on clinical validity. Because the evidence is insufficient to demonstrate test performance for PSST, no inferences can be made about clinical utility.

Section Summary: Pressure-Specified Sensory Testing
No studies on the technical performance of PSST were identified. The available evidence on the diagnostic accuracy of PSST for conditions linked with nerve damage or disease is limited, but those studies available report relatively low diagnostic accuracy. There is insufficient direct evidence on the clinical utility of PSST and, because there is insufficient evidence on test performance, an indirect chain of evidence for clinical utility cannot be constructed.

Vibration Perception Testing
Technically Reliable
Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review, and alternative sources exist.

This evidence review focuses on the clinical validity and clinical utility.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

A study from India, Mythili et al (2010) evaluated 100 patients with type 2 diabetes using a VPT device (Sensitometer; Dhansai Lab). The device is not FDA-approved or cleared. The authors reported sensitivities and specificities for the device and standard NCSs. For vibration testing, a positive finding (i.e., presence of neuropathy) was defined as patients reporting no vibration sensation at a voltage of more than 15 volts. According to NCSs, 70 of 100 patients had evidence of neuropathy. Vibration perception thresholds had a sensitivity of 86% and a specificity of 76%. Semmes-Weinstein monofilament testing, which was also done, had a higher sensitivity than vibration testing (98.5%) but a lower specificity (55%). Finally, a diabetic neuropathy symptom score, determined by responses to a patient questionnaire, had a sensitivity of 83% and a specificity of 79%. The authors commented that the simple neurologic examination score appeared to be as accurate as vibration testing. It is not known how similar the Sensitometer device is to FDA-approved vibration threshold testing devices.

In 2015, Abraham et al retrospectively reviewed the charts of 70 patients with chronic inflammatory demyelinating polyneuropathy (CIDP) who were evaluated with a VPT device (Neurothesiometer). Stimulus was applied to the first finger and toe on each side; the voltage was gradually increased and patients were asked to state when they first perceived vibration. The threshold for a normal test result was 5 volts or less in the fingers and 15 volts or less in the toes. Data on the results of neurologic examinations were also reviewed, including testing using semiqualitative vibration testing with a 128-Hz tuning fork. Fifty-five (79%) patients had elevated VPT values. Abnormal neurologic findings were more common in CIDP patients with elevated VPT scores (92.7%) at the toes than those without elevated VPT scores (46.7%; $p<0.001$). Compared with patients with normal VPT values, patients with elevated VPT values were more likely to meet European Federation of Neurological Societies and Peripheral Nerve Society electrophysiologic criteria for CIPD (51% vs 13%, $p=0.01$) and had significantly lower treatment response rates (54% vs 93%, $p=0.03$). The authors did not report the sensitivity or specificity of the device compared with standard diagnostic tests. The Neurothesiometer is not FDA-approved or cleared.

Goel et al (2017) published a cross-sectional study comparing the diagnostic performance of several testing methods to detect early symptoms of diabetic peripheral neuropathy. Five hundred twenty-three patients with type 2 diabetes between the ages of 18 and 65 (mean, 49.4 years) were first assessed with the modified Neuropathy Disability Score as the reference standard; then both feet were tested with electrochemical skin conductance, VPT, and Diabetic Neuropathy Symptom Score. For feet electrochemical skin conductance less than 60 μS, VPT, and Diabetic Neuropathy Symptom Score, the sensitivity was 85%, 72%, and 52%, respectively; specificity was 85%, 90%, and 60%, respectively. There was a significant inverse linear relation between VPT and feet electrochemical skin conductance ($r = -0.45$, $p<0.001$); feet electrochemical skin conductance was determined to be superior to VPT for identifying early signs of diabetic peripheral neuropathy (DPN). The study lacked follow-up data.

Azzopardi et al (2018) published a prospective multicenter cross-sectional study comparing 3 types of vibration screening used to diagnose DPN. The study collected data from 100 patients (age range, 40-80 years) who had type 2 diabetes for at least 10 years. Each participant was assessed with a VibraTip (not registered with FDA), neurothesiometer, and 128-Hz tuning fork in both feet. Vibrations were not perceived by 28.5% of patients when using VibraTip, 21% using a neurothesiometer, and 12% using a tuning fork; a small-to-moderately strong association (Cramer's V, 0.167) was found between the instruments. The study lacked a criterion standard for assessing neuropathy. The authors concluded that multiple methods of assessment would be necessary to avoid a false-negative diagnosis.

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

No direct evidence from clinical trials was identified demonstrating that use of vibration testing resulted in changes in patient management or improved patient outcomes.

Chain of Evidence
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Indirect evidence on clinical utility rests on clinical validity. Because the evidence does not demonstrate the test performance of VPT, no inferences can be made about clinical utility.

Section Summary: Vibration Perception Testing
A few studies have evaluated the diagnostic performance of VPT using devices, not FDA-cleared. In 1 study, a neurologic examination score had similar diagnostic accuracy to vibration testing, and Semmes-Weinstein monofilament testing had a higher sensitivity than VPT but a lower specificity. The other study did not report sensitivity or specificity for VPT but reported that patients with elevated VPT findings were significantly more likely to meet society criteria for CIDP compared with patients with normal VPT results. Another study compared VPT with electrochemical skin conductance and determined that electrochemical skin conductance was superior for early identification of DPN, while a fourth study concluded that multiple methods of assessment were necessary to diagnose DPN. No direct evidence for the clinical utility of VPT was identified and, because there is since there is insufficient evidence about test performance, an indirect chain of evidence on clinical utility cannot be constructed.

Thermal Sensory Testing

Technically Reliable

Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review, and alternative sources exist.

This evidence review focuses on the clinical validity and clinical utility.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

In 2008, Devigili et al published a retrospective review of 486 patients referred for suspected sensory neuropathy. The study used an FDA-approved Medoc, Ltd. thermal perception-testing device. A total of 150 patients met the entry criteria for the study, which included symptoms suggesting sensory neuropathy and availability of 1) clinical examination, including spontaneous and stimulus-evoked pain, 2) a sensory and motor nerve conduction study, 3) warm and cooling thresholds assessed by quantitative sensory testing, and 4) skin biopsy with distal intraepidermal nerve fiber (IENF) density. Based on the combined assessments, neuropathy was ruled out in 26 patients; 124 patients were diagnosed with sensory neuropathy and of these, 67 patients were diagnosed with small nerve fiber neuropathy. Using a cutoff of 7.63 IENF/mm at the distal leg (based on the 5th percentile of controls), 59 patients (88%) were considered to have abnormal IENF (small nerve fiber) density. Only 7.5% of patients had abnormal results for all three examinations (clinical, QST, skin biopsy), 43% of patients had both abnormal skin biopsy and clinical findings, and 37% of patients had both abnormal skin biopsy and QST results. The combination of abnormal clinical and QST results was observed in only 12% of patients. These results indicate that most of the patients evaluated showed an IENF density of less than 7.63 together with either abnormal spontaneous or evoked pain (clinical examination) or abnormal thermal thresholds (QST). The authors of this study recommended a new diagnostic “gold standard” based on the presence of at least two of three abnormal results (clinical, QST, and IENF density).

In 2015, Lefaucheur et al compared 5 tests for diagnosing small fiber neuropathy (SFN), including QST using a Medoc thermal perception testing device. The QST device was used to assess the warm detection threshold and cold detection threshold. Other tests were laser-evoked potential (LEP), sympathetic skin response, electrochemical skin conductance. The study enrolled 87 consecutive patients being evaluated for definite (n=33) or possible (n=54) painful SFN. All 5 tests were conducted in a single session. Findings were compared with those for 174 healthy subjects, matched for age and sex. Results of each test were categorized as normal or abnormal, using findings in healthy subjects as the reference range for normal values. All patients with definite SFN and 70% of those with possible SFN had at least 1 abnormal test. The sensitivity and specificity of each test in the series of 87 patients are shown in Table 1.

Table 1. Sensitivity and Specificity in Lefaucheur et al (N=87)

Test	Sensitivity, %	Specificity, %
Warm detection threshold	44.8	91.4
Cold detection threshold	26.4	97.1
Laser-evoked potential	64.4	87.4
Sympathetic skin response	33.3	77.6
Electrochemical skin conductance	49.4	92.5

LEP was the most sensitive test. However, not all patients were correctly categorized with LEP. Fifteen patients with at least 1 abnormal test had normal LEP tests, but abnormal warm detection threshold or electrochemical skin conductance tests. Findings of the other 2 tests (cold detection threshold, sympathetic skin response) were redundant. As noted by the authors, a limitation of their study was the lack of a definitive criterion standard for SFN with which to compare test findings.

Anand et al (2017) assessed 30 patients with nonfreezing cold injury, or trench foot, described as a peripheral vaso-neuropathy. The author's evaluated use of skin biopsies immunohistochemistry, clinical examination of the feet, including pinprick, as well as QST assessments, and NCSs as diagnostic tools. Abnormal pinprick sensation was reported in 67% of patients. Monofilament perception threshold was abnormal in 63% of patients, 40% for VPT thresholds, and between 67% and 83% for the various thermal thresholds; NCSs showed 23% of subjects had axonal neuropathy. It was noted that performing QST could be difficult for patients with cutaneous hypersensitivity and severe limb pain. No study limitations were reported.

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

No direct evidence from clinical trials was identified demonstrating that use of thermal testing resulted in changes in patient management or improved patient outcomes.

Chain of Evidence
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Indirect evidence on clinical utility rests on clinical validity. Because of limited evidence about test performance for thermal threshold testing, no inferences can be made about clinical utility.

Section Summary: Thermal Sensory Testing

Two studies have evaluated the diagnostic accuracy of thermal QST using the same FDA-cleared device. Neither found a high diagnostic accuracy of thermal QST, but both found the test had potential when used in combination with other tests. The optimal combination of tests is not well-defined. No studies reporting on the clinical utility for thermal sensory testing were identified, and, because there is insufficient evidence on test performance, an indirect chain of evidence on clinical utility cannot be constructed.

Summary of Evidence

For individuals who have conditions linked to nerve damage or disease (e.g., diabetic neuropathy, carpal tunnel syndrome) who receive current perception threshold testing, the evidence includes several studies on technical performance and diagnostic accuracy. Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. The existing evidence does not support the accuracy of current perception threshold testing for diagnosing any condition linked with nerve damage or disease. Studies comparing current perception threshold testing with other testing methods have not reported on sensitivity or specificity. In addition, there is a lack of direct evidence on the clinical utility of current perception testing and, because there is insufficient evidence on test performance, an indirect chain of evidence on clinical utility cannot be constructed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have conditions linked to nerve damage or disease (e.g., diabetic neuropathy, carpal tunnel syndrome) who receive pressure-specified sensory testing (PSST), the evidence includes several studies on diagnostic accuracy. Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. Current evidence does not support the accuracy of PSST for diagnosing any condition linked with nerve damage or disease. A systematic review found that PSST had low accuracy for diagnosing spinal conditions. In addition, there is a lack of direct evidence on the clinical utility of current perception testing and, because there is insufficient evidence on test performance, an indirect chain of evidence on clinical utility cannot be constructed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have conditions linked to nerve damage or disease (e.g., diabetic neuropathy, carpal tunnel syndrome) who receive vibration perception testing, the evidence includes several studies on diagnostic accuracy. Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. A few studies have assessed the diagnostic performance of vibration testing using devices not cleared by the Food and Drug Administration. Also, there is a lack of direct evidence on the clinical utility of vibration perception testing and, in the absence of sufficient evidence on test performance; an indirect chain of evidence on clinical utility cannot be constructed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have conditions linked to nerve damage or disease (e.g., diabetic neuropathy, carpal tunnel syndrome) who receive thermal sensory testing, the evidence includes diagnostic accuracy. Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. Two studies identified evaluated the diagnostic accuracy of thermal QST

using the same Food and Drug Administration- cleared device. Neither found a high diagnostic accuracy for thermal QST, but both studies found the test had potential when used with other tests. The optimal combination of tests is currently unclear. Also, there is a lack of direct evidence on the clinical utility of thermal sensory testing and, because there is insufficient evidence on test performance, an indirect chain of evidence on clinical utility cannot be constructed. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

European Federation of Neurological Societies

In 2010, the European Federation of Neurological Societies (EFNS) updated their guidelines on neuropathic pain assessment. The guideline stated:

> "Quantitative sensory testing (QST) can be used in the clinic along with bedside testing to document the sensory profile. Because abnormalities have often been reported in non-NPs [neuropathic pain] as well, QST cannot be considered sufficient to separate differential diagnoses (GPP) [good practice point, i.e., consensus recommendation]. QST is helpful to quantify the effects of treatments on allodynia and hyperalgesia and may reveal a differential efficacy of treatments on different pain components (Level A)…. The evaluation of pain in response to thermal stimuli is best performed using the computerized thermotest, but the task force does not recommend the systematic measure of thermal stimuli except for pathophysiological research or treatment trials. A simple and sensitive tool to quantify pain induced by thermal stimuli in clinical practice is still lacking."

American Academy of Neurology

A 2003 report (reaffirmed 2016) from the American Academy of Neurology (AAN) concluded that quantitative sensory testing (QST) is probably (level B recommendation) an effective tool for documenting of sensory abnormalities and for documenting changes in sensory thresholds in longitudinal evaluation of patients with diabetic neuropathy. Evidence was weak or insufficient to support the use of QST in patients with other conditions (small fiber sensory neuropathy, pain syndromes, toxic neuropathies, uremic neuropathy, acquired and inherited demyelinating neuropathies, or malingering).

American Association of Neuromuscular & Electrodiagnostic Medicine

The American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) published a technology literature review on QST (light touch, vibration, thermal, pain) in 2004. The review concluded that QST is a reliable psychophysical test of large- and small-fiber sensory modalities but is highly dependent on the full patient cooperation. Abnormalities do not localize dysfunction to the central or peripheral nervous system, and no algorithm can reliably distinguish between psychogenic and organic abnormalities. The AANEM review also indicated that QST has been shown to be reasonably reproducible over a period of days or weeks in normal subjects, but, for individual patients, more studies are needed to determine the maximum allowable difference between 2 QSTs that can be attributed to experimental error.

In 2005, AANEM with AAN and American Academy of Physical Medicine & Rehabilitation developed a formal case definition of distal symmetrical polyneuropathy based on a systematic analysis of peer-reviewed literature supplemented by consensus from an expert panel. QST was not included as part of the final case definition, given that the reproducibility of QST ranged from poor to excellent, and the sensitivities and specificities of QST were found to vary widely among studies. The American Association of Electrodiagnostic Medicine (AAEM) published a technology literature review on quantitative sensory testing (light touch, vibration, thermal, and pain) in 2004. The review concluded that QST is a reliable psychophysical test of large- and small-fiber sensory modalities but is highly dependent on the full cooperation of the patient. Abnormalities do not localize dysfunction to the central or peripheral nervous system, and no algorithm can reliably distinguish between psychogenic and organic abnormalities. The AAEM technology review also indicated that QST has been shown to be reasonably reproducible over a period of days or weeks in normal subjects, but for individual patients, more studies are needed to determine the maximum allowable difference between two QSTs that can be attributed to experimental error.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Key Words:

Neurometer, current perception threshold testing, CPT, nerve conduction study, NCS, Medi-Dx 7000, quantitative sensory testing, sensory testing, pressure-specified sensory devices, PSSD, vibration perception threshold devices, VPT, CASE IV, CASE IV Computer Aided Sensory Evaluator, Thermal Threshold Tester, TTT, Thermal Sensory Analyzer, TSA, Nk Pressure-Specified Sensory Device, Medi-Dx 7000® Current Perception Threshold

Approved by Governing Bodies:

A number of QST devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Examples are listed in Table 2.

Table 2. FDA-Approved Quantitative Sensory Testing Devices

Device	Manufacturer	Date Cleared	510(k)	Indications
FDA product code: LLN				
Neurometer®	Neurotron	Jun 1986	K853608	Current perception threshold testing
NK Pressure-Specified Sensory Device, Model PSSD	NK Biotechnical Engineering	Aug 1994	K934368	Pressure specified sensory testing
AP-4000, Air Pulse Sensory Stimulator	Pentax Precision Instrument	Sep 1997	K964815	Pressure specified sensory testing
Neural-Scan	Neuro-Diagnostic Assoc.	Dec 1997	K964622	Current perception threshold testing
Vibration Perception Threshold (VPT) METER	Xilas Medical	Dec 2003	K030829	Vibration perception testing
FDA product code: NTU				

Contact Heat-Evoked Potential Stimulator (Cheps)	Medoc, Advanced Medical Systems	Feb 2005	K041908	Thermal sensory testing

FDA: Food and Drug Administration.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP contracts: FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

HCPCS:

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

CPT codes:

0106T	Quantitative sensory testing (QST), testing and interpretation per extremity; using touch pressure stimuli to assess large diameter sensation
0107T	Using vibration stimuli to assess large diameter fiber sensation
0108T	Using cooling stimuli to assess small nerve fiber sensation and hyperalgesia
0109T	Using heat-pain stimuli to assess small nerve fiber sensation and hyperalgesia
0110T	Using other stimuli to assess sensation

The following codes should NOT be billed for these procedures:

CPT codes:

95925	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper limbs
95926	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in lower limbs
95927	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in the trunk or head
95937	Neuromuscular junction testing (repetitive stimulation, paired stimuli), each nerve, any one method

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Medical Policy Group, February 2011 **(2):** Key Points, References Updated
Medical Policy Group, September 2011 **(1):** Update to Key Points and References
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Medical Policy Panel, October 2013
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Medical Policy Panel, October 2014
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Medical Policy Panel, June 2017
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