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Quantitative Sensory Testing

Policy Number: 2.01.39 Last Review: 7/2014 Origination: 7/2008 Next Review: 1/2015

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for quantitative sensory testing. This is considered investigational.

When Policy Topic is covered

Not Applicable

When Policy Topic is not covered

Quantitative sensory testing, including but not limited to current perception threshold testing, pressurespecified sensory device testing, vibration perception threshold testing, and thermal threshold testing, is considered **investigational**.

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. Pain conditions evaluated may include diabetic neuropathy and uremic and toxic neuropathies, complex regional pain syndrome, carpal tunnel syndrome, and other nerve entrapment/compression disorders or damage.

Quantitative sensory testing (QST) has been investigated for a broad range of clinical applications, including evaluation of peripheral neuropathies, detection of carpal tunnel syndrome, spinal radiculopathy, evaluation of the effectiveness of peripheral nerve blocks, quantification of hypoesthetic and hyperesthetic conditions, and differentiation of psychogenic from neurologic disorders.

QST systems measure and quantify the amount of physical stimuli required for sensory perception to occur in the patient. 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 in conjunction with standard evaluation and management procedures (e.g., physical and neurologic examination, monofilament testing, pinprick, grip and pinch strength, Tinel's, Phalen and Roos sign) to enhance the diagnosis and treatment-planning process and confirm physical findings with quantifiable data. Stimuli used in QST includes touch, pressure, pain, thermal (warm and cold), or vibratory stimuli.

The gold standard 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 3 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. Psychophysical tests have greater inherent variability, making their results more difficult to standardize and reproduce.

Regulatory Status

Devices cleared for marketing by the FDA through the 510(k) process include:

1987: Thermal Threshold Tester (TTT) (Teca, Inc., Pleasantville, NY)

1992: CASE IV Computer Aided Sensory Evaluator (WR Medical Electronics, Stillwater, MN) (vibration and thermal threshold testing)

1993: Thermal Sensory Analyzer (TSA) (Medoc Corp., Israel)

1994: Nk Pressure-Specified Sensory Device™ (NK Biotechnical Corporation)

1994: Neurometer ® Current Perception Threshold (Neurotron, Inc.)

1994: Pressure-Specified Sensory Device™ (Sensory Management Services LLC, Baltimore, MD)

1997: Medi-Dx 7000® Current Perception Threshold (Neuro Diagnostic Associates)

2003: Vibration Perception Threshold (VPT) meter (Xilas Medical)

Rationale

Literature Review

This policy was originally created in 2001 and was updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period July 2012 through August 27, 2013. Following is a summary of the key literature to date:

Literature is reviewed on the various types of quantitative sensory testing for which there are FDA-approved devices. This includes current perception threshold testing, pressure-specified sensory device testing, vibration perception threshold testing and thermal threshold testing. For each of these, the following questions to the literature were asked:

- What is the technical performance of quantitative sensory testing (QST)? (i.e., test-retest values, interoperator variability)
- What is the diagnostic performance of QST? (i.e., sensitivity and specificity of QST compared to conventional tests, using appropriate reference standards and conducted in appropriate populations)
- Does QST change patient management or improve the net health outcome compared to standard testing?

In addition, systematic reviews and meta-analysis that evaluated studies using more than one type of QST were reviewed.

Systematic reviews: multiple types of QST

A 2013 systematic review by Grosen and colleagues identified 14 studies that evaluated the association between QST findings and analgesic response, (1) One study was conducted in healthy volunteers, 9 in surgical patients and 4 in patients with chronic pain. Study findings were not pooled, but were discussed for each of the patient populations. The authors reported that all of the studies in surgical patients were observational cohort studies, and analgesic response was not a primary outcome in any of the studies. Six of the 9 studies found a correlation between QST measurement (electrical,

pressure and/or thermal stimulation) and consumption of analgesics. The article did not report whether or not the correlation was for all, or only some, of the outcomes related to analgesic consumption. The 4 studies on chronic pain patients were conducted as part of clinical drug trials, and QST was conducted at baseline prior to treatment. Two of the studies found a correlation between QST parameters and at least one analgesic response outcome. The authors concluded that the scientific evidence is not sufficiently robust that QST parameters are predictors of response to analgesic treatment.

Current Perception Threshold Testing

What is the technical performance?

In 1999, the American Association of Electrodiagnostic Medicine (AAEM) published a technology review of the Neurometer® device. (2) Much of the literature compared the results of Neurometer® testing to nerve conduction studies in patients with known disease. In many instances, the results of the Neurometer® testing demonstrated more numerous or pronounced abnormalities compared to nerve conduction studies, a finding that was consistent with the hypothesis that abnormalities of small nerve fibers precede those of large nerve fibers tested in nerve conduction studies. However, this observation could also be related to the fact that use of the Neurometer® involves testing at multiple sites with 3 different frequencies and that any identified abnormality is considered significant. The AAEM assessment's conclusions on the evidence of technical performance of current perception devices include the following:

- Reference values need to be established for well-characterized and representative populations.
- Reproducibility and interoperator variability of the Neurometer® CPT normal values need to be established and expressed statistically in control subjects and patients with specific diseases.

In 2002, Yamashita and colleagues evaluated current perception thresholds using the Neurometer® by comparing findings in 48 patients with lumbar radiculopathy and 11 healthy controls. (3) The authors reported finding significantly higher current perception threshold values in the affected legs of patients with lumbar radiculopathy at 2,000, 250, and 5 Hz frequencies than in the unaffected legs. Current perception threshold values in the affected legs were also significantly higher in control subjects at 2,000 and 250 Hz frequencies but not significantly different at 5 Hz. The authors concluded that current perception threshold testing may be useful in quantifying sensory nerve dysfunction in patients with radiculopathy. However, this study did not establish standardized normal values or evaluate the reproducibility of QST measurements.

What is the diagnostic performance?

Limited published evidence is available. Several studies have compared current perception threshold testing to other testing methods, but sensitivity and specificity have not been reported. For example, in 2012, Ziccardi and colleagues evaluated 40 patients presenting with trigeminal nerve injuries involving the lingual branch. (4) Patients underwent current perception threshold testing, as well as 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), reaction to cold stimulation (p=0.004), but not the reaction to pinprick testing (p=0.096).

In addition, in 2001 Park and colleagues compared current perception threshold testing to standard references for thermal sensory testing and von Frey tactile hair stimulation in a randomized, double-blind, placebo-controlled trial with 19 healthy volunteers. (5) The authors found that all current perception threshold measurements showed a higher degree of variability than thermal sensory testing and von Frey measurements but concluded that there is some evidence that similar fiber tracts may be

measured, especially C-fiber tract activity at 5 Hz, with current perception threshold, thermal sensory, and von Frey testing methods. This study was limited in that only healthy volunteers were included.

Does QST change patient management or improve the net health outcome compared to standard testing?

No comparative studies evaluating the impact of current perception testing on patient management decisions or health outcomes were identified.

A related study, published in 2009, utilized the Neurometer device in individuals with hand-arm vibration exposure. (6) The primary purpose of the study was to evaluate the utility of a staging scale (the Stockholm sensorineural scale), not to determine the accuracy of quantitative sensory testing, so it does not provide additional evidence on the clinical utility of current perception testing as part of the initial evaluation of individuals with possible hand-arm vibration syndrome.

Pressure-Specified Sensory Testing (PSSD)

What is the technical performance?

No published studies were identified.

What is the diagnostic performance?

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 some more complex cases, nerve conduction velocity (NCV) testing. Several studies have compared performance of these tests and PSSD. For example, a 2000 study by Weber and colleagues evaluated the sensitivity and specificity of PSSD and nerve conduction velocity testing in a total of 79 patients including 26 healthy controls. (7) The NCV test had a sensitivity of 80% and a specificity of 77%. The pressure-specified sensory device had a sensitivity of 91% and a specificity of 82%; the difference between the two tests was not significantly different.

A 2010 study by Nath and colleagues evaluated 30 patients with winged scapula and upper trunk injury and 10 healthy controls. (8) They used the U.S. Food and Drug Administration (FDA)-cleared PSSD 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. No published threshold values were available for the deltoid location. PSSD testing was done on both arms of all participants, and electromyographic (EMG) testing only on the affected arms of symptomatic patients. Using calculated threshold values, patients with normal EMG results had positive PSSD 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. The authors stated that the study findings suggest that PSSD is more sensitive than needle EMG in detecting brachial plexus upper trunk injury. These findings should be confirmed in additional studies. In addition, the thresholds used to categorize a PSSD finding as positive for the deltoid should be validated in future reports.

A 2013 systematic review by Hubscher and colleagues evaluated studies on the relationship between QST and self-reported pain and disability in patients with spinal pain. (9) Twenty-eight of 40 studies identified used PSSD. In their overall analysis, the investigators found low or no correlation 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% confidence interval [CI]: -0.18 to -0.11) and between pain threshold and disability was -0.16 (95% CI: -0.22 to -0.10). The findings suggest low accuracy of QST as a tool for diagnosing patients' level of spinal pain and disability.

Does QST change patient management or improve the net health outcome compared to standard testing?

No clinical trials were identified that demonstrated that use of the PSSD resulted in changes in patient management or improved patient outcomes. In 2012, Suokas and colleagues published a systematic review of studies evaluating QST in painful osteoarthritis; the majority of studies used pressure testing. (10) The authors did not report finding any studies that evaluated the impact of QST on health outcomes.

Vibration Testing

What is the technical performance?

A multicenter study funded by a pharmaceutical company compared vibration threshold testing (CASE IV, biothesiometer, C64 graduated tuning fork) with standard nerve conduction studies in 195 (86% follow-up) subjects with diabetes mellitus. (11) The tests were performed independently by trained technicians; all standard nerve conduction evaluations were sent to a central reading center. Intraclass correlation coefficients for the tests ranged from 0.81 to 0.95, indicating excellent to highly reproducible results. Correlation coefficients for the various vibration QST instruments were moderate at -0.55 (CASE IV vs. tuning fork) to 0.61 (CASE IV vs. biothesiometer). In contrast, the correlation coefficient between CASE IV and a composite score for nerve conduction was low (r: 0.24). These results indicate that vibration threshold testing could not replace standard nerve conduction testing but might provide a complementary outcome measure.

What is the diagnostic performance?

In 2010, a study from India evaluated 100 patients with type 2 diabetes using a vibration perception threshold device, the Sensitometer (Dhansai Lab), which is produced in Mumbai and is not FDA-approved. (12) The authors reported sensitivities and specificities compared to standard nerve conduction studies. For vibration testing, a positive finding (i.e., presence of neuropathy) was defined as patient reporting of no vibration sensation at a voltage of more than 15V. According to findings of nerve conduction studies, 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%, and 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. The Sensitometer is not available in the United States, and it is not known how similar this device is to FDA-cleared vibration threshold testing devices.

Does QST change patient management or improve the net health outcome compared to standard testing?

No clinical trials were identified that demonstrated that use of vibration testing resulted in changes in patient management or improved patient outcomes.

Thermal Testing

What is the technical performance?

A 2012 systematic review by Moloney and colleagues examined the literature on the reliability of thermal QST. (13) A total of 21 studies met the review's inclusion criteria, which included using an experimental design, assessing reliability, comparing thermal QST with other methods of assessment and testing at least twice. The investigators used a quality appraisal checklist to evaluate the reliability of the studies that were identified. Only 5 of the 21 studies were considered to be high quality. The

review authors found considerable variation in the reliability of thermal QST; this included the 5 studies considered to be of high quality. The authors also noted several methodologic issues that could be improved in future studies, including better descriptions of raters and their training, blinding and randomization, and better standardization of test protocols.

One of the studies considered to be of high quality in the Moloney systematic review was published in 2010 by Heldestad and colleagues in Sweden. (14) (This study used a device that is not approved by the FDA.) The study included 38 healthy volunteers and found a high level of reproducibility using a Somedic device. Cold and warm perception thresholds and cold and heat pain thresholds were obtained on 3 occasions on 3 days (days 1, 2 and 7) in 29 individuals and on 1 occasion on 3 days in the other 9 individuals. Thermal stimuli were given to the volar surface of the lower arm; a probe was positioned midway between the volar midline and the ulnar border. Cold and warmth perception thresholds were determined by a series of consecutive stimuli delivered at intervals varying between 3 and 5 seconds to avoid subject anticipation or adaptation. Participants were asked to report when they perceived a change in temperature. Cold and heat pain thresholds were determined by consecutive stimuli of each kind delivered at an interval of about 30 seconds; participants were asked to report as soon as the thermal sensation was perceived as painful. The authors found high levels of reproducibility. No statistically significant differences were found in thermal threshold estimates on different days for the same participants and, with the exception of cold testing on day 1, there were no significant differences between the various test sessions of a particular day. There was some effect of test order. Cold and warm thresholds were significantly larger when assessed after thermal pain assessment.

What is the diagnostic performance?

In 2008, Devigili et al. published a retrospective review of 486 patients referred for suspected sensory neuropathy. (15) 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 3 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 2 of 3 abnormal results (clinical, QST, and IENF density).

Does QST change patient management or improve the net health outcome compared to standard testing?

No clinical trials were identified that demonstrated that use of thermal testing resulted in changes in patient management or improved patient outcomes.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

In response to the request for input from physician specialty societies and academic medical centers, input was received from 1 specialty society and 1 academic medical center regarding use of quantitative sensory testing while the policy was under review in 2008. Input from both sources agreed with the policy statement that QST is considered investigational, as adopted in the policy in April 2008.

Summary

There is insufficient evidence that the use of quantitative sensory testing for the noninvasive assessment and quantification of sensory nerve function is as accurate as conventional tests. Questions remain about reference values in normal populations and the reproducibility of test results. In addition, there is a lack of evidence that use of quantitative sensory testing impacts patient management or improves the net health outcome. Therefore, this technology is considered investigational.

Practice Guidelines and Position Statements

In 2010, the European Federation of Neurological Societies (EFNS) updated their guidelines on neuropathic pain assessment. (16) The guideline states the following on QST:

"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). To evaluate mechanical allodynia/hyperalgesia, the task force recommends the use of simple tools such as a brush and at least one high-intensity weighted pinprick or von Frey filament (e.g., 128 mN). 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."

A report from the American Academy of Neurology (AAN) (reaffirmed 2008) concluded that QST is probably (level B recommendation) an effective tool in documenting of sensory abnormalities and in documenting changes in sensory thresholds in longitudinal evaluation of patients with diabetic neuropathy. (17) 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).

The American Association of Electrodiagnostic Medicine (AAEM) published a technology literature review on quantitative sensory testing (light touch, vibration, thermal, and pain) in 2004. (18) 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 2 QSTs that can be attributed to experimental error.

In 2005, the AAEM, in conjunction with the AAN and American Academy of Physical Medicine and Rehabilitation (AAPMR) 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. (19) 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.

Medicare National Coverage

In February 2002, Medicare announced a national noncoverage policy on sensory nerve conduction threshold testing. Requests for reconsideration were submitted by both the makers of the Neurotron® and the Medi-Dx 7000™ devices. On reconsideration, Medicare affirmed its noncoverage policy.

concluding that any use of sensory nerve conduction threshold testing to diagnose sensory neuropathies or radiculopathies is not reasonable and necessary. (20) This decision was reaffirmed effective April 2004. Medicare has not addressed coverage for other types of quantitative sensory testing.

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Billing Coding/Physician Documentation Information

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

**NOTE: This series of codes describes "psychophysical" testing of subjective feelings of sensation to assess endocrine and neurological disorders such as neuropathies. These tests are more complex and standardized than physical examination services. QST is performed in the office or outpatient setting by physicians such as internists, geriatricians, family practitioners, neurologists, and endocrinologists. The codes are "per extremity" so you could receive as many as 4 units per code. Previously these tests would have been coded using 95999 (for other, unlisted neurological or neuromuscular diagnostic procedures). These stimuli are not electrical like those used in current perception threshold testing.

In the past, providers may have used CPT code 95904 (nerve conduction, amplitude and latency/velocity study, each nerve; sensory or mixed) or codes 95925-95927 (code range short-latency somatosensory evoked potential study) for current perception threshold testing. When CPT code 95904 was used, some providers may also have used the modifier–52 (reduced service) to reflect the fact that no latency study was performed. However, the current perception threshold test is not accurately described by either 95904 or 95925-95927. There is a HCPCS code, G0255, which is specific to this test. Another distinction between a nerve conduction test and the current perception threshold test is that the former is performed in a laboratory setting, while the latter is performed in an office setting.

Effective 12/31/12, code 95904 was deleted. Codes 95907-95913 might now be incorrectly reported for these services.

Additional Policy Key Words

Neural-Scan Neural Scan

Policy Implementation/Update Information

7/1/08	New policy; considered investigational.
1/1/09	No policy statement changes.
7/1/09	No policy statement changes.
1/1/10	No policy statement changes.
7/1/10	No policy statement changes.
1/1/11	No policy statement changes.
7/1/11	No policy statement changes.
1/1/12	Policy statement revised to include vibration threshold testing and thermal threshold
	testing as investigational.
7/1/12	No policy statement changes.
1/1/13	No policy statement changes.
7/1/13	No policy statement changes.
1/1/14	No policy statement changes.
7/1/14	No policy statement changes.

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