Regence

Medical Policy Manual Medicine, Policy No. 91

Quantitative Sensory Testing

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

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.

MEDICAL POLICY CRITERIA

All types of quantitative sensory testing (QST) are considered **investigational**, including but not limited to current perception threshold testing, pressure-specific sensory device testing, vibration perception threshold testing, and thermal threshold testing.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Automated Point-of-Care Nerve Conduction Studies, Medicine, Policy No. 128

BACKGROUND

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.

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, Phalen and Roos sign) to enhance the diagnosis and treatment planning process, and confirm physical findings with quantifiable data. Stimuli used in QST include touch, pain, pressure, vibratory, and thermal (warm and cold) stimuli. All of the systems discussed here have received US Food and Drug Administration 510(k) marketing clearance.

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 (NCS). 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. For example, touch and vibration devices such as the (Vibration Perception Threshold) VPT Meter (Xilas Medical), and the CASE IV Computer Aided Sensory Evaluator (WR Medical Electronics), measure the function of large myelinated A-alpha and A-beta sensory fibers. Thermal stimuli devices are used to evaluate pathology of small myelinated and unmyelinated nerve fibers.

Current perception threshold (CPT) testing involves the quantification of the sensory threshold to transcutaneous electrical stimulation. In CPT 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. The Neurometer® Current Perception Threshold (CPT®; Neurotron, Inc) and the Medi-Dx 7000® (NeuroDiagnostic Associates) are two of these devices.

Pressure-specified sensory devices assess large myelinated sensory nerve function by quantifying the thresholds of pressure detected with light, static, and moving touch. The Nk Pressure-Specified Sensory Device™ (Nk Biotechnical Engineering) consists of one or two blunt probes and sensitive transducers to measure and record the perception thresholds of pressure on the surface of the body in grams per square millimeter. The device has been used to aid in the diagnosis and assessment of nerve function, including diabetic peripheral neuropathy, carpal tunnel syndrome, and other nerve entrapment or compression syndromes, and postoperative assessment of sensory outcomes after liposuction, breast reduction mammaplasty, etc.

Because QST combines the objective physical sensory stimuli with the subjective 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.

EVIDENCE SUMMARY

In any proposed application, it is important to evaluate whether results from QST enhance

patient management and improve net health outcomes (i.e., the clinical utility of QST) either in terms of instituting more prompt or effective therapy, or in the avoidance of more invasive tests, such as NCS. Therefore, the focus of this review is on randomized controlled trials (RCTs) demonstrating clinical utility of QST.

QST has been used in initial diagnostic testing or in the monitoring of patients to assess ongoing sensory deficits. The type of data required to validate QST in these two different settings is different. For example, as an initial diagnostic test, standard measures of diagnostic performance, such as sensitivity; specificity; positive and negative predictive values, as compared to conventional tests such as monofilament testing, pinprick, etc. are needed. Where QST has been proposed as an alternative to NCS, the diagnostic performances of these two tests should be compared. Additionally, where QST is used as a monitoring technique, test/retest reliability is an important outcome, and one which must be associated with defining a clinically significant change in sensory perception.

MULTIPLE TYPES OF QUANTATATIVE SENSORY TESTING

Systematic Reviews and technology Assessments

Marcuzzi (2016) published a SR that evaluated QST's ability to predict health outcomes for patients with acute or chronic low back pain (LBP).[1] The authors included three studies that determined if pressure pain responses, cold pressure testing, conditioned pain modulation, and/or mechanical temporal summation can be associated with acute or chronic LBP outcomes. The authors concluded the few studies found had methodological limitations, risk of bias and that it is unclear if QST can predict health outcomes in people with LBP.

In 2013, the American Academy of Neurology published a technology assessment for QST.[2] They included class II and class III studies, as no class I studies were found identifying the efficacy of QST. The class II and III studies showed QST may identify sensory deficits for diabetic neuropathy, small fiber neuropathies, uremic neuropathies, and demyelinating neuropathy. The authors concluded QST devices could not be compared to each other, reproduction of the results was unclear, and more well-designed studies are needed.

Multiple types of QST were reviewed in a 2013 systematic review (SR) by Grosen and colleagues.[3] Fourteen studies that evaluated the association between QST findings and analgesic response were identified. One study was conducted in healthy volunteers, nine in surgical patients and four in patients with chronic pain. Study findings were not pooled, but were discussed for each patient population. The authors reported that all 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 nine studies found a correlation between QST measurement (electrical, pressure and/or thermal stimulation) and consumption of analgesics. The article did not report whether the correlation was for all or some of the outcomes related to analgesic consumption. The four 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 to make conclusions that QST parameters are predictors of response to analgesic treatment.

Randomized Control Trials

No RCTs were identified published after the SRs.

CURRENT PERCEPTION THRESHOLD TESTING (CPT)

CPT testing 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.

Systematic Reviews

No recent systematic reviews were identified.

Randomized Controlled Trials

No RCTs were identified.

Nonrandomized Studies

Three comparative studies reported on attempts to establish the diagnostic utility of CPT testing.[4-6] Authors concluded that CPT testing and quantification was feasible. However, there was no discussion of how this quantification could be used in the management of the patient.

Uddin (2014) performed CPT testing in 106 patients with mechanical neck disorders (MND) to determine whether the testing could differentiate between three groups of neck pain, with or without musculoskeletal signs or with neurological signs. The predicted probably of abnormal CPT findings in MND with neurological signs had an estimated sensitivity and specificity of 73% and 81%, respectively. Moderate discriminatory accuracy was found for MND with musculoskeletal signs and without musculoskeletal signs. The study did not evaluate the use of CPT testing or the impact of testing on health outcomes.

Ziccardi (2012) evaluated 40 patients presenting with trigeminal nerve injuries involving the lingual branch.[7] 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).

A 2009 study used the Neurometer device in individuals with hand-arm vibration exposure.[8] However, 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 QST. Therefore, it did 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 DEVICE (PSSD) TESTING

Evidence supporting the use of PSSD testing must demonstrate that PSSD testing provides additional information beyond that ordinarily determined during standard evaluation and management of patients with potential nerve compression, disease, or damage. Standard evaluation and management consist of physical examination techniques and may include Semmes-Weinstein monofilament testing and, in some more complex cases, nerve conduction

velocity testing.

While PSSD may be a useful adjunct in neurosensory testing, no RCTs were identified that demonstrate the use of the PSSD resulted in earlier and/or more accurate diagnoses of nerve damage and improved patient outcomes. The literature discussed below is representative of the available evidence on PSSD.

Systematic Reviews

Hubscher (2013) published a SR that 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 suggested low accuracy of QST as a tool for diagnosing patients' level of spinal pain and disability. The authors concluded their study indicated either that pain threshold is a poor marker of central sensitization or that sensitization did not play a major role in patients' reporting of pain and disability.

Suokas (2012) published a SR 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.

Randomized Control Studies

No RCTs were identified pubilshed after the SR.

Nonrandomized Studies

Nath evaluated 30 patients with winged scapula and upper trunk injury and 10 healthy controls.[11] They used the FDA-cleared PSSD by Sensory Management Services to measure the minimum perceived threshold in both arms for detecting 1-point static (1PS) and two-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 EMG testing was performed 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 findings suggested that PSSD was 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.

VIBRATION PERCEPTION THRESHOLD (VPT) TESTING

Systematic Reviews

No SRs were identified.

Randomized Control Trials

No RCTs evaluating clinical utility were identified.

Nonrandomized Studies

A multicenter study funded by a pharmaceutical company compared VPT testing (CASE IV, biothesiometer, C64 graduated tuning fork) with standard NCS in 195 (86% follow-up) subjects with diabetes mellitus.[12] The tests were performed independently by trained technicians; all NCS evaluations were sent to a central reading center. Intra-class 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 indicated that VPT testing could not replace NCS testing but might provide a complementary outcome measure.

A 2010 study 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.[13] The authors reported sensitivities and specificities using standard NCS. For VPT 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. Per the NCS findings, 70 of 100 patients had evidence of neuropathy; sensitivity was 86% and the specificity was 76%. Semmes-Weinstein monofilament testing, which was also done, had a higher sensitivity than VPT 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 VPT testing. The Sensitometer is not available in the United States and it is not known how similar this device is to FDA-cleared VPT testing devices.

THERMAL THRESHOLD TESTING

Current literature on thermal threshold testing consists of observational, small or retrospective comparative studies on the detection of small fiber neuropathy in a variety of clinical conditions (including knee osteoarthritis and diabetic neuropathy). There are no studies that address the clinical utility of this type of testing.

Systematic Review

Moloney (2012) published a SR that examined the literature on the reliability of thermal QST.[14] 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 five 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.

Randomized Control Trials

No RCTs were identified.

Nonrandomized Studies

Vuilleumier (2015) evaluated reliability of QST in a low back pain population; it included thermal QST using an FDA-approved device by Medoc.[15] A total of 89 patients participated in two QST sessions conducted at least seven days apart. The median of three thermal perception trials on the first day was compared with the median on the second day (between-session reliability). Several measures of reliability were reported (i.e., coefficient of variability [CV]), ICC, coefficient of reliability). The reliability of heat pain detection and tolerance at the arm and leg were considered to be acceptable, with between-session CVs ranging from 1.8% to 6.1%. However, cold pain detection at the arm or leg did not have acceptable reliability, with between-session CVs ranging from 44% to 87%.

Devigili (2008) published a retrospective review of 486 patients referred for suspected sensory neuropathy.[16] A total of 150 patients met the entry criteria for the study, which included symptoms suggesting sensory neuropathy and availability of clinical examination (including spontaneous and stimulus-evoked pain), sensory and motor NCS, warm and cooling thresholds assessed by QST, and 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; 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 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). Additional prospective studies are needed to evaluate whether the addition of thermal QST results in improved outcomes over clinical diagnosis alone.

Results from several small non-comparative studies have raised questions about the reliability of QST. For example, one study noted “significant” variability in thermal perception thresholds during a one-hour time in 24 female volunteers.[17]

In another small study, mean QST thresholds for vibration, cold, warmth, and heat pain were no different in 10 patients (with type 2 diabetes and painful neuropathy) than in 15 healthy control subjects.[18] In the same study, QST thresholds were also evaluated in 12 patients with type 2 diabetes and advanced painless neuropathy; these were found to be significantly higher than the control thresholds for all stimuli, suggesting that QST was not able to detect early stages of neuropathy. The study found that the laser Doppler imager flare, a new functional test of dermal vasodilation, showed significant changes in both the painful (mild) and painless (severe) neuropathy patients.

Other examples of non-randomized comparative studies have focused on the use of thermal QST to identify early clinical markers and predictors of neurotoxicity with chemotherapy drugs

and are detailed below. There are no studies of clinical utility of this type of testing; neither has the devices used in these studies received clearance by the FDA for use in the United States.

Attal and colleagues conducted a study to identify early clinical markers and predictors of neurotoxicity with the chemotherapy drug oxaliplatin.[19] Of 67 consecutive patients with mainly colorectal cancer, 48 (72%) were able to be evaluated prospectively before, during, and after 9 cycles of oxaliplatin (n=28) or cisplatin (n=20) treatment. Eighteen of the oxaliplatin patients were reassessed at 12 months. Evaluation with QST included detection/pain thresholds for mechanical, vibration, and cold and heat stimuli. Thermal testing (cold or heat) two weeks after the third cycle identified sustained neurotoxicity during oxaliplatin treatment, while cold-evoked symptoms lasting 4 days or more after the third cycle predicted chronic neuropathy (odds ratio of 22; 95% confidence interval [CI]: 1.5-314.7) and severe neuropathy (odds ratio of 39; 95% CI 1.8-817.8). These results were limited by the small number of patients and large confidence intervals. Additional studies are needed to evaluate the predictive value of abnormal thermal QST and their clinical implications.

Scott (2011) evaluated 23 patients with cancer-induced bone pain before and after treatment with radiotherapy.[20] Patients were evaluated using monofilament tests, pin prick stimulus, and thermal perception testing (Rolltemp device). Pain was tested at the area reported as painful by the patient and a control area. Patients were also assessed with the short-form Brief Pain Inventory, a validated measure of cancer pain. To maximize reproducibility, one researcher conducted all QST measurements. For QST measurements, responses were recorded as increased, reduced, or equivalent sensation as the normal control (rather than measuring actual thresholds). Compared to the pre-radiotherapy values, there was no change in response to warm stimulation in 16 of 23 (70%) of patients. Six patients (26%) had reduced sensation and 1 had increased sensation. There was no change in response to cool stimulation in 15 of 23 (65%) of patients; six (26%) had reduced sensation and two had increased sensation. Among patients who responded to radiotherapy according to other measures, five of the seven patients (71%) who had abnormal response to warm sensation at baseline had reduced sensation (normal) at follow-up. Four of six (67%) patients who had an abnormal response to cool sensation at baseline experienced reduced sensation (normal) at follow-up. The numbers of patients who experienced a change in thermal sensation after radiotherapy are too small to draw conclusions about the accuracy of thermal threshold testing with the Somedic device for predicting response to radiotherapy.

PRACTICE GUIDELINE SUMMARY

No evidence-based clinical practice guidelines were identified that recommended the use of quantitative sensory testing in the diagnosis or management of any indication.

SUMMARY

Investigational

There is not enough research to show that quantitative sensory testing (QST) improves health outcomes for people with any condition. No clinical guidelines based on research recommend QST. Therefore, the use of QST techniques, including current perception threshold testing, pressure-specified sensory device testing, vibration perception threshold testing, or thermal threshold testing, for any condition is considered investigational.

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CODES

Codes	Number	Description
CPT	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
HCPCS	G0255	Current perception threshold/sensory nerve conduction test (sNCT), per limb, any nerve

Date of Origin: *September 2001*