



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Quantitative Sensory Testing (QST)

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 Nerve Conduction Velocity Studies Including
 Late Response (H-reflex and F-wave)
 Somatosensory Evoked Potentials

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2010 CIGNA

Coverage Policy

CIGNA does not cover ANY quantitative sensory testing (QST) method, including but not limited to the following, because such testing is considered experimental, investigational, or unproven:

- current perception threshold (CPT) testing
- sensory nerve conduction testing (sNCT)
- pressure-specified sensory testing
- vibration perception threshold testing
- voltage-actuated sensory nerve conduction threshold (V-sNCT) testing

General Background

Sensory nerve conduction is typically measured using instrumentation such as the Semmes-Weinstein monofilaments for pressure perception and the 128-Hertz (Hz) Rydel Seiffer graduated tuning fork for vibratory perception. These tests are accurate, reliable, and established methods for aiding in the diagnosing of nerve conduction abnormalities and are recommended by professional societies such as the American Diabetes Association, and the American Association of Electrodiagnostic Medicine (American Diabetes Association, 2010; Brownlee, et al., 2008; England, et al., 2005).

Quantitative sensory testing (QST) has been proposed as a complementary diagnostic and monitoring tool to be used with traditional testing (e.g., Semmes-Weinstein monofilaments, Rydel Seiffert graduated tuning fork) for the detection of sensory nerve abnormalities for conditions such as diabetic neuropathy, carpal tunnel syndrome, multiple sclerosis and vitamin B deficiencies. QST is a psychophysical test used to assess and quantify small and large-fiber sensory nerve function by the use of touch, thermal (i.e., hot and cold), pain, and/or vibratory sensations. Proponents of QST state that conventional testing does not reflect various grades of a disease, and can only detect abnormalities in large myelinated nerve fibers. In contrast, QST, a noninvasive study, is proposed to be able to detect early, subtle changes in small and large sensory nerve fibers. However, the clinical significance of QST has not been demonstrated in clinical trials (Atherton, et al., 2007; Soomekh, 2006; Chong and Cros, 2004; Shy, et al., 2003).

Several limitations of QST have been documented. There is a potential for bias if the patient is cognitively impaired or desires an abnormal result. QST has no localizing value because it is reflective of the integrity of the entire sensory neuraxis from receptors to brain. Abnormal QST values may occur because of peripheral nerve or central nervous system dysfunction. The test may lack objectivity due to patient status (e.g., distraction, boredom, inattention, fatigue, drowsiness), which may be enhanced by the time it takes to complete the test (e.g., one to two hours). The inclusion of the patient's reaction time to a stimulus may distort the actual sensory threshold. Electrode size, site of stimulation, method and rate of change of the stimulation, method of obtaining patient's response, and variations in testing devices make reproducibility of the test results difficult. There is also a lack of standardization for testing procedures and reporting outcomes. Test execution will differ with different examiners. Due to these variables, it is proposed that QST lacks the objectivity of conventional nerve conduction studies (Siemionow, et al., 2006; Chong and Cros, 2004; Freeman, et al. 2003; Shy, et al., 2003).

The various testing methods and devices used for QST to determine sensory abnormalities include:

- Electrical current testing such as current perception threshold (CPT) testing or sensory nerve conduction testing (sNCT) which assesses sensory function. Examples of these devices include the Medi-DX 7000 (Neuro-Diagnostic Associates, Laguna Beach, CA) and the Neurometer[®] CPT or s-NCT (Neurotron, Inc., Baltimore, MD).
- Pressure-specified sensory testing evaluates nerve function by detection of light, static, and moving touch. These devices include the NK Pressure-Specified Sensory Device[™] (PSSD) (NK Biotechnical Engineering Co., Minneapolis, MN).
- Thermal testing is used to assess a distinction between predominantly C fiber and A-delta fiber activity by the application of cold and heat. Examples of thermal devices by Medoc Advanced Medical Systems LTD (Minneapolis, MN) include the Contact Heat-Evoked Potential Stimulator (CHEPS), GSA Genito, TSA-2001 Sensory Analyzer, and the TSA-2001 Sensory Analyzer.
- Vibration perception threshold testing, or vibratory testing, assesses large myelinated nerve fiber dysfunction and measures sensory thresholds. The VSA-3000 Vibratory Sensory Analyzer (Medoc Advanced Medical Systems, Eilat, Israel) and the Bio-thesiometer (Bio-Medical Instruments, Newbury, OH) are examples of these devices.
- Voltage-actuated sensory nerve conduction threshold (V-sNCT) testing is used to evaluate the sensitivity, specificity and predictive value of A-delta fibers to assess localize pain sources. These devices include the Neural-Scan (Neuro-Diagnostic Associates [NDA], Inc., Laguna Beach, CA).

U.S. Food and Drug Administration (FDA)

QST systems and devices are approved by the FDA 510(k) process and are classified either as a Class II device or an unclassified device.

Literature Review

The evidence in the published peer-reviewed scientific literature does not support the clinical utility of QST. Studies evaluating QST for the diagnosis and management of various conditions are primarily in the form of nonrandomized comparative studies and case series with heterogeneous small patient populations and used a variety of different devices. The studies reported the sensitivity and/or specificity of various QST (e.g., current perception threshold, thermal, voltage and/or vibratory testing) for various conditions (e.g., diabetic neuropathy, carpal tunnel syndrome, chronic neuropathic pain). Reported sensitivities ranged from 32%–91% and specificity ranged from 12.5%–100%. Documentation of the reproducibility of the outcomes of the tests is lacking, but ranged from poor to excellent. Most comparative studies have evaluated the outcomes of QST to nerve

conduction studies (NCS) and reported that QST was more sensitive than NCS, that NCS were more sensitive than QST, or that the data from the two tests did not correlate and both tests should be used. QST has not been recommended as a stand alone test. Limitations of the studies include: weak study methodology; inability to verify data; lack of a control group; numbers of patients lost to follow-up; numbers of patients who did not complete all of the testing; lack of comparisons to conventional neurological tools; variations in testing parameters, equipment and protocol; and lack of randomization (Eisenberg, et al., 2006; England, et al., 2005; Gibbons, et al., 2004; Centers for Medicare and Medicaid Services, 2003).

In a multicenter, single-visit, cross-sectional trial, Kincaid et al. (2007) conducted a study to compare the results of vibratory QST and nerve conduction studies (NCS) (EP4 composite score) in 130 type 1 and type 2 diabetics with or without peripheral neuropathy. Patients were assessed for vibratory sensations with the CASE IV system (WR Medical Electronics, Stillwater, Minnesota), a biothesiometer (VPT meter; Xilas Medical, San Antonio, Texas), and the Rydel Seiffer C64 tuning fork. To minimize systematic bias, the order of instrumentation used for each patient was randomized. Technicians were masked to the results of previous testing and patient's clinical histories. Physicians were blinded to the results of the studies when conducting clinical examination. The study was completed by 201 enrollees, and 195 patients underwent all testing except for the C64 tuning fork (n=63). Results of the QST studies were compared to a composite score of peroneal and tibial motor NCS and individual attributes of peroneal, tibial and sural nerve. The correlation between the normal deviant QST and composite score of NCS was low at 0.234 ($p=0.001$). There was a significant correlation between the biothesiometer, the C64 tuning fork and the CASE IV results ($p<0.001$). The correlations between QST and individual attributes of NCS ranged from 0.189 to 0.480 ($p<0.001$), also low, indicating that QST and NCS should not replace each other but be used to complement each other. The study also included a test of the ability to reproduce the outcomes of the studies. Measurements with the intraclass correlation coefficient indicated that the tests had high-to-"excellent" reproducibility.

Brown et al. (2004) conducted a randomized controlled trial to "report the baseline and natural progression of diabetic peripheral neuropathy over 12 months in a large mild-to-moderate neuropathy population" using QST and NCS. The 1428 type 1 or type 2 diabetic patients included in the study, with mild distal symmetrical diabetic peripheral neuropathy (DPN) were randomized to one of three groups: placebo (n=472), zenarestat 600 mg/day (n=481) or zenarestat 1200 mg/day (n=475). The study was discontinued due to an increased serum creatinine in the zenarestat patients. However, data was available to report baseline and 12-month electrophysiologic, sensory and neuropathy outcomes. DPN was confirmed in the patients by NCS and QST. NCS and QST (vibration and cool thermal) were reported at baseline and at one year. In general, nerve conduction declined in all nerves tested, with the decline in sural sensory conduction velocity achieving statistical significance. Compared to baseline, QST outcomes revealed a slight worsening in vibration and cooling thresholds, with the decline in cool thermal sensation being statistically significant ($p=0.0005$). Compared to baseline, NCS results recorded an improvement or lack of progression in both treatment groups at 12 months. The cooling and vibratory QST demonstrated significant worsening at the 12-month visit compared to baseline in the 1200 mg/day group. At 12 months, cool thermal threshold was worse in placebo patients, but a decrease in vibration perception was not statistically significant. The patients treated with zenarestat demonstrated slowing or improvement of neuropathy at 12 months on NCS, compared to significant worsening in all populations, including the placebo group, on the cool thermal testing.

Additional studies, primarily in the form of case series with small patient populations have reported outcomes of QST for multiple conditions. Devigili et al. (2008) conducted a retrospective analysis of 150 patients with sensory neuropathy to compare sensitivity and specificity of clinical examination, QST, and skin biopsy. Assessment of small fiber damage using QST showed a lower diagnostic efficiency than clinical examination and skin biopsy. Kang et al. (2008) conducted a study (n=31) to determine if current perception threshold (CPT) testing would better represent disabilities in carpal tunnel syndrome (CTS) compared to nerve conduction studies (NCS). Based on the outcomes, the authors did not recommend CPT as a monitoring tool or as a screening tool. Atherton et al. (2007) conducted a study (n=41) to evaluate the clinical utility of contact heat-evoked potentials (CHEPS) in patients with small fiber sensory neuropathy. Skin biopsies and flares were advantageous over CHEPs and QST by localizing the pathology within the peripheral nervous system.

QST has also been proposed for use before and after lumbar discectomy (n=33) to analyze sensory nerve dysfunction in the lower-extremities (Imoto, et al., 2007), following greater saphenous vein stripping (n=27 limbs/18 patients) to evaluate postoperative sensory changes (Akagi, et al., 2007), and prior to and following spinal cord stimulation for patients with chronic neuropathic pain (n=13) due to either failed back surgery

syndrome or complex regional pain syndrome (Eisenberg, et al., 2006). Studies have used QST to evaluate sexual dysfunction (n=41) (Gruenwald, et al., 2007), peripheral nerve dysfunction (n=25) (Siemionow, et al., 2006), painful bladder syndrome (n=27) (Fitzgerald, et al., 2005), and radiculopathy (Yamashita, et al., 2002).

Professional Societies/Organizations

American Academy of Neurology (AAN): In a report on QST based on a review of 350 articles, the AAN (Shy, et al., 2003; reaffirmed 2008) concluded that “QST is a potentially useful tool for measuring sensory impairment for clinical and research studies. However, QST results should not be the sole criteria used to diagnose pathology”. The AAN indicated that malingering and other nonorganic factors can affect the outcomes of the test results. They also noted that well-designed studies to compare the various types of QST devices and methodologies are indicated and should include patients with abnormalities detected solely by QST.

In a report on distal symmetric polyneuropathy (England, et al., 2005; reaffirmed 2008), the American Academy of Neurology, the American Association of Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation stated that QST was not recommended as a diagnostic tool because the sensitivities and specificities varied widely among the studies, and the tests have inherent variability. QST is difficult to standardize, and reproducibility of results ranged from poor to excellent.

American Association of Electrodiagnostic Medicine (AAEM): The AAEM (Chong and Cros, 2004) conducted a review of the literature on QST to assess the “methodology, reliability, reproducibility, limitations, and potential clinical applications” of these studies. They concluded the following:

- “QST is a reliable psychophysical test of large- and small-fiber sensory modalities.
- QST tests the integrity of the entire sensory axis from receptors to brain. Abnormalities do not localize dysfunction to the central or peripheral nervous system, or any particular location along the peripheral nervous system.
- QST is highly dependent on the full cooperation of the patient and may be falsely abnormal if the patient is biased toward an abnormal result or is cognitively impaired. No algorithm can reliably distinguish between psychogenic and organic abnormality.
- QST has been shown to be reasonably reproducible over a period of days or weeks in normal subjects. Since longitudinal QST studies of patients in drug trials are usually done over a period of several months to a few years, reproducibility studies on the placebo-controlled group should be included.
- The reproducibility of thermal thresholds may not be as good as that of vibration threshold.
- For individual patients, more studies are needed to determine the maximum allowable difference between two QSTs that can be attributed to experimental error.
- Different commercially available QST instruments have different specifications (thermode size, stimulus characteristics), testing protocols, algorithms, and normal values. Only QST instruments and their corresponding methodologies that have been shown to be reproducible should be used for research and patient care.
- The results of QST can only be interpreted properly if machine calibration and testing protocol are strictly followed.
- The literature does not allow a conclusion to be made regarding whether any QST instrument is better than another”.

European Federation Of Neurological Societies (EFNS): In their 2009 guidelines on the assessment of neuropathic pain, EFNS stated that studies using QST lack blinding, involved a broad spectrum of patients and controls, and only four of 50 new studies were prospective. The variability of methods, results, and patient populations (e.g., diabetic neuropathy, spinal cord injury, radiculopathy) prevented any conclusions from being drawn. The studies primarily involved assessment of small fiber function precluding analysis of small vs. large sensory fiber deficits. Outcomes have suggested that QST may be useful in the early diagnosis of diabetic neuropathy. In their recommendations, EFNS stated that QST may be used to document the sensory profile, but the test “cannot be considered sufficient to separate differential diagnoses”. “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”. They “do 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” (Cruccu, et al., 2010).

Work Loss Data Institute (WLDI): In their guidelines for the diagnosis, evaluation, management and treatment of work-related acute and chronic carpal tunnel syndrome (2008a), acute and chronic lumbar and thoracic back pain (2008b), acute and chronic neck and upper back pain (2008c), and chronic pain (2008d), the WLDI stated that it considered but could not recommend the use of CPT testing.

Summary

Although a number of studies evaluating quantitative sensory testing (QST) have been published, they have generally been poor in quality and design. The diagnostic utility of QST has not been established and its impact on health outcomes is unknown. Threshold standards and quantifiable outcomes have yet to be established and outcomes have varied from setting to setting, from device to device, and from one patient group to another. Studies have been lacking in sample size, randomization, reproducibility of QST results and comparison of QST to conventional testing (e.g., electromyography, nerve conduction studies).

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered:

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

ICD-9-CM Diagnosis Codes	Description
250.60-250.63	Diabetes with neurological manifestations
266.0-266.9	Deficiency of B-complex components
337.20-337.29	Relext sympathetic dystrophy
340	Multiple sclerosis
354.0	Carpal tunnel syndrome
355.71	Causalgia of lower limb
355.9	Mononeuritis of unspecified site
356.0-356.9	Hereditary and idiopathic peripheral neuropathy
724.1	Pain in thoracic spine
724.2	Lumbago
724.4	Thoracic or lumbosacral neuritis or radiculitis, unspecified
724.5	Backache, unspecified
729.2	Neuralgia, neuritis, and radiculitis, unspecified
	All other codes

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	12/15/2007	0268	Quantitative Sensory Testing (QST)

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