| 2.01.39 | Quantitative Sensory Testing | | |
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| **Section:** | 2.0 Medicine | **Page:** | Page 1 of 19 |

## Policy Statement

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

**NOTE**: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

## Policy Guidelines

### Coding

The following CPT codes are specific to quantitative sensory testing:

- **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

NOTE: This series of codes describes "psychophysical" testing of subjective feelings of sensation to assess endocrine and neurologic disorders such as neuropathies. These tests are more complex and standardized than physical examination services. Quantitative sensory testing (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 one 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.

The following HCPCS code is specific to this test:

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

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. Codes 95907-95913 might be incorrectly reported for 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. Types of sensory testing include current perception threshold testing, pressure-specified sensory testing , vibration perception testing (VPT), and thermal sensory testing. Information on sensory deficits identified using QST has been used in research settings to understand neuropathic pain better. It could be used to diagnose conditions linked to nerve damage and disease, and to improve patient outcomes by impacting management strategies.

## Related Policies

- N/A

## Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## Regulatory Status

A number of QST devices have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process. Examples are listed in Table 1.

**Table 1. 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 |
| Pain Vision, Model PS-2100 | Osachi Co., LTD | Jan 2009 | K072882 | Current perception threshold testing |
| FDA product code: NTU | | | | |
| Contact Heat-Evoked Potential Stimulator (Cheps) | Medoc, Advanced Medical Systems | Feb 2005 | K041908 | Thermal sensory testing |
| Modified Contact-Heat Evoked Potential Stimulator (Cheps) | Medoc, Advanced Medical Systems | Jun 2005 | K051448 | Thermal sensory testing |
| Pathway - Ats/Cheps | Medoc, Advanced Medical Systems | Jan 2006 | K052357 | Thermal sensory testing |

FDA: U.S. Food and Drug Administration.

## Rationale

**Background**

**Nerve Damage and Disease**

Nerve damage and nerve diseases can reduce functional capacity and lead to neuropathic pain. There are also racial and ethnic disparities due to biological factors as well as social and environmental contributors in diseases that can lead to neuropathic pain.[1,] For example, incidence of neuropathy due to diabetic microvascular complications is higher in minority populations compared to non-Hispanic Whites.[2,]

### 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.. 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 test 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 the progression of neurologic damage or disease. Currently, 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 include touch, pressure, pain, thermal (warm and cold), or vibratory stimuli.

The criterion standard for evaluation of myelinated, large fibers is the electromyography nerve conduction study. 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 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 frequencies are tested: 5 Hz, designed to assess C fibers; 250 Hz, designed to assess A delta fibers; and 2000 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 and requires patients who are alert, able to follow directions, and co-operative. Also, to get reliable results, examinations need to include standardized instructions to the patients, and stimuli must be applied consistently by trained staff. Psychophysical tests have greater inherent variability, making their results more difficult to reproduce.

Primarily, QST has been applied in patients with conditions associated with nerve damage and neuropathic pain. A retrospective analysis of a prospective database maintained by the German Research Network on Neuropathic Pain by Forstenpointner et al (2021) compared QST profiles between patients with painful neuropathic conditions (n=332), patients with neuropathic conditions who did not report pain (n=111), and healthy controls (n=112). After extensive QST testing, including thermal, mechanical/vibration, and pain sensitivity, the researchers found similar QST profiles between patients who reported pain and patients who did not report pain, which raises concern about the role of QST in general in decision-making for neuropathic conditions.[3,]There have also been preliminary investigations to identify sensory deficits associated with conditions such as autism spectrum disorder, Tourette syndrome, restless legs syndrome, musculoskeletal pain, and response to opioid treatment.

## Literature Review

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 , vibration perception threshold (VPT) testing, and thermal threshold testing.

### Current Perception Threshold Testing

### Clinical Context and Test Purpose

The purpose of current perception threshold testing is to provide a diagnostic option and a treatment that is an alternative to or an improvement on existing tests, such as standard clinical evaluation and other sensory assessment tests, in patients with conditions linked to nerve damage or disease (e.g., diabetic neuropathy, carpal tunnel syndrome).

The question addressed in this evidence review is: Does current perception threshold testing improve the net health outcome in patients with conditions linked to nerve damage or disease?

The following PICO was used to select literature to inform this review.

#### *Populations*

The relevant population of interest is individuals with conditions linked to nerve damage or disease (e.g., diabetic neuropathy, carpal tunnel syndrome).

#### *Interventions*

The test being considered is current perception threshold 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. Information on sensory deficits identified using QST has been used in research settings to understand neuropathic pain better. It could be used to diagnose conditions linked to nerve damage and disease, and to improve patient outcomes by impacting management strategies.

#### *Comparators*

Comparators of interest include standard clinical evaluation and other sensory assessment tests.

#### *Outcomes*

The general outcomes of interest are test accuracy, test validity, symptoms, and functional outcomes.

### Study Selection Criteria

Below are selection criteria for studies to assess whether a test is clinically valid.

- The study population represents the population of interest. Eligibility and selection are described.
- The test is compared with a credible reference standard.

- If the test is intended to replace or be an adjunct to an existing test; it should also be compared with that test.
- Studies should report sensitivity, specificity, and predictive values. Studies that completely report true- and false-positive results are ideal. Studies reporting other measures (e.g., receiver operating characteristic [ROC], area under receiver operating characteristic [AUROC]), c-statistic, likelihood ratios) may be included but are less informative.
- Studies should also report reclassification of diagnostic or risk category.

**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).

**Review of Evidence**
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, Ziccardi et al (2012) evaluated 40 patients presenting with trigeminal nerve injuries involving the lingual branch.[4,] 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=.02), reaction to heat stimulation (p=.01), and reaction to cold stimulation (p=.004). Also, significant correlations were found between electrical stimulation at 5 Hz and the reaction to heat stimulation (p=.017), to cold stimulation (p=.004), but not to pinprick testing (p=.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.[5,] All current perception threshold measurements showed a higher degree of variability than thermal sensory testing and von Frey measurements but there was 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 (RCTs).

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 to 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

### Clinical Context and Test Purpose

The purpose of pressure-specified sensory testing is to provide a diagnostic option that is an alternative to or an improvement on existing tests, such as standard clinical evaluation and other sensory assessment tests, in patients with conditions linked to nerve damage or disease (e.g., diabetic neuropathy, carpal tunnel syndrome).

The question addressed in this evidence review is: Does pressure-specified sensory testing improve the net health outcome in patients with conditions linked to nerve damage or disease?

The following PICO was used to select literature to inform this review.

#### *Populations*

The relevant population of interest is individuals with conditions linked to nerve damage or disease (e.g., diabetic neuropathy, carpal tunnel syndrome).

#### *Interventions*

The test being considered is pressure-specified sensory testing.

#### *Comparators*

Comparators of interest include standard clinical evaluation and other sensory assessment tests.

#### *Outcomes*

The general outcomes of interest are test accuracy, test validity, symptoms, and functional outcomes.

### Study Selection Criteria

Below are selection criteria for studies to assess whether a test is clinically valid.

- The study population represents the population of interest. Eligibility and selection are described.
- The test is compared with a credible reference standard.
- If the test is intended to replace or be an adjunct to an existing test; it should also be compared with that test.
- Studies should report sensitivity, specificity, and predictive values. Studies that completely report true- and false-positive results are ideal. Studies reporting other measures (e.g., ROC, AUROC, c-statistic, likelihood ratios) may be included but are less informative.
- Studies should also report reclassification of diagnostic or risk category.

### 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).

### Review of Evidence

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 testing. Several studies have compared the performance of pressure-specified sensory testing devices. For example, a study by Weber et al (2000) evaluated the sensitivity and specificity of pressure-specified sensory testing and nerve conduction velocity testing in 79 patients, including 26 healthy controls.[6,] The nerve conduction velocity test had a sensitivity of 80% and a specificity of

77%; the pressure-specified sensory testing had a sensitivity of 91% and a specificity of 82%. The difference between the 2 tests was not statistically significant.

A study by Nath et al (2010) evaluated 30 patients with winged scapula and upper trunk injury and 10 healthy controls.[7] They used the pressure-specified sensory testing device by Sensory Management Services cleared by the FDA to measure the minimum perceived threshold in both arms for detecting 1-point static and 2-point static stimuli. The authors used a published standard reference threshold value for the dorsal hand first web skin and calculated threshold values for both the dorsal hand first web and the deltoid using the upper limit of the 99% normal confidence interval (CI). No published threshold values were available for the deltoid location. Pressure-specified sensory testing was done on both arms of all participants, and electromyography testing only on the affected arms of symptomatic patients. Using calculated threshold values, patients with normal electromyography results had positive pressure-specified sensory testing results on 50% (8/16) of 1-point static deltoid, 71% (10/14) of 2-point static deltoid, 65% (11/17) of 1-point static dorsal hand first web , and 87% (13/15) of 2-point static dorsal hand first web tests. Study findings suggested that pressure-specified sensory testing is more sensitive than needle electromyography in detecting brachial plexus upper trunk injury.

A systematic review by Hubscher et al (2013) evaluated the relationship between QST and self-reported pain and disability in patients with spinal pain.[8] Twenty-eight of 40 studies identified used pressure-specified sensory testing 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 -0.16 (95% CI , -0.22 to -0.10) between pain threshold and disability. 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 RCTs.

No direct evidence from clinical trials identified has demonstrated that use of the pressure-specified sensory testing 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.[9] 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.

Because the evidence is insufficient to demonstrate test performance for pressure-specified sensory testing , no inferences can be made about clinical utility.

### Section Summary: Pressure-Specified Sensory Testing

The available evidence on the diagnostic accuracy of pressure-specified sensory testing for conditions linked with nerve damage or disease is limited, but available studies have reported relatively low diagnostic accuracy. There is insufficient direct evidence on the clinical utility of pressure-specified sensory testing and, because there is insufficient evidence on test performance, an indirect chain of evidence for clinical utility cannot be constructed.

### Vibration Perception Testing

### Clinical Context and Test Purpose

The purpose of VPT is to provide a diagnostic option that is an alternative to or an improvement on existing tests, such as standard clinical evaluation and other sensory assessment tests, in patients with conditions linked to nerve damage or disease (e.g., diabetic neuropathy, carpal tunnel syndrome).

The question addressed in this evidence review is: Does VPT improve the net health outcome in patients with conditions linked to nerve damage or disease?

The following PICO was used to select literature to inform this review.

#### *Populations*

The relevant population of interest is individuals with conditions linked to nerve damage or disease (e.g., diabetic neuropathy, carpal tunnel syndrome).

#### *Interventions*

The test being considered is VPT.

#### *Comparators*

Comparators of interest include standard clinical evaluation and other sensory assessment tests.

#### *Outcomes*

The general outcomes of interest are test accuracy, test validity, symptoms, and functional outcomes.

### Study Selection Criteria

Below are selection criteria for studies to assess whether a test is clinically valid.

- The study population represents the population of interest. Eligibility and selection are described.
- The test is compared with a credible reference standard.
- If the test is intended to replace or be an adjunct to an existing test; it should also be compared with that test.
- Studies should report sensitivity, specificity, and predictive values. Studies that completely report true- and false-positive results are ideal. Studies reporting other measures (e.g., ROC, AUROC, c-statistic, likelihood ratios) may be included but are less informative.
- Studies should also report reclassification of diagnostic or risk category.

### 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).

### Review of Evidence

A study from India, Mythili et al (2010),evaluated 100 patients with type 2 diabetes using a VPT device (Sensitometer; Dhansai Lab).[10,] The device is not FDA approved or cleared. The authors reported on sensitivities and specificities for the device and standard nerve conduction study (NCS). For vibration testing, a positive finding (i.e., the presence of neuropathy) was defined as patients reporting no vibration sensation at more than 15 volts. According to NCS , 70 of 100 patients had evidence of neuropathy. The VPT 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 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 noted 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.

Abraham et al (2015) retrospectively reviewed the charts of 70 patients with chronic inflammatory demyelinating polyneuropathy (CIDP) who were evaluated with a VPT device (Neurothesiometer).[11,] The 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<.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 CIDP (51% vs 13%, p=.01) and had significantly lower treatment response rates (54% vs 93%, p=.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 (DPN).[12,] Five hundred twenty-three patients with type 2 diabetes between the ages of 18 and 65 years (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<.001); feet electrochemical skin conductance was determined to be superior to VPT for identifying early signs of 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.[13,] 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 the 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.

Papanas et al (2019) assessed the performance of VibraTip against 2 thresholds of the Neuropathy Disability Score for diagnosing distal symmetrical polyneuropathy (DSPN) in 100 consecutive patients with type 2 diabetes.[14,] The mean age was 62.3 years and the mean duration of illness was 12.6 years; 54 subjects were men. Two protocols were used to assess vibration perception: A) 1 foot site at the pulp of the hallux and B) 3 foot sites at the pulp of the hallux and first and third metatarsal head. Neuropathy Disability Score thresholds of ≥ 3 and ≥ 6 were used to establish the diagnosis of DSPN. Compared to the Neuropathy Disability Score ≥ 3 threshold, VibraTip demonstrated a sensitivity, negative predictive value , specificity, and positive predictive value of 91.3%, 92%, 85.2%, and 84% with protocol A; with protocol B, the sensitivity, negative predictive value , specificity, and positive predictive value were 95.6%, 96.1%, 90.7%, and 89.8%. Compared to the Neuropathy Disability Score ≥ 6 threshold, VibraTip demonstrated a sensitivity, negative predictive value , specificity, and positive predictive value of 100%, 100%, 95.2%, and 92.7% with protocol A; with protocol B, the sensitivity, negative predictive value , specificity, and positive predictive value were 100%, 100%, 96.8%, and 95%. The authors conclude that there appears to be no need to explore sites beyond the hallux, and that the device may be especially useful for the exclusion of DSPN. The study is limited by the lack of healthy controls and the use of an outdated version of the Neuropathy Disability Score.

A prospective nonrandomized cohort study by Ferdousi et al (2020) compared several strategies for evaluating DPN severity.[15,] A total of 143 patients with diabetes and 30 controls underwent QST with VPT and thermal perception testing, nerve conduction studies, and a measure of corneal nerve loss (corneal confocal microscopy). Compared to controls, VPT was significantly higher in patients with no neuropathy (p=.02), mild neuropathy (p<.0001), and moderate-severe neuropathy (p<.0001), with a sensitivity of 55% and specificity of 90%. VPT findings worsened with worsening neuropathy severity. Thermal testing, nerve conduction testing, and corneal confocal microscopy were also significantly different between patients with DPN and controls (all p<.05). All other testing methods had lower specificity than VPT, but all had higher sensitivity than VPT with the exception of warm perception threshold. The study may have been limited by using Neuropathy Disability Scores to quantify DPN severity, which may explain the abnormal findings among patients categorized as having no neuropathy.

**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 RCTs.

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.

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 that are 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 electro-chemical skin conductance and determined that electrochemical skin conductance was superior for early identification of DPN, a fourth study concluded that multiple methods of assessment were necessary to diagnose DPN , and another study found that VPT findings increased with increasing DPN severity. Another study concluded that VPT may be useful for ruling out a diagnosis of DSPN. No direct evidence for the clinical utility of VPT was identified and, because there is insufficient evidence about test performance, an indirect chain of evidence on clinical utility cannot be constructed.

**Thermal Sensory Testing**
**Clinical Context and Test Purpose**
The purpose of thermal sensory testing is to provide a diagnostic option that is an alternative to or an improvement on existing tests, such as standard clinical evaluation and other sensory

assessment tests, in patients with conditions linked to nerve damage or disease (e.g., diabetic neuropathy, carpal tunnel syndrome).

The question addressed in this evidence review is: Does thermal sensory testing improve the net health outcome in patients with conditions linked to nerve damage or disease?

The following PICO was used to select literature to inform this review.

***Populations***

The relevant population of interest is individuals with conditions linked to nerve damage or disease (e.g., diabetic neuropathy, carpal tunnel syndrome).

***Interventions***

The test being considered is thermal sensory testing.

***Comparators***

Comparators of interest include standard clinical evaluation and other sensory assessment tests.

***Outcomes***

The general outcomes of interest are test accuracy, test validity, symptoms, and functional outcomes.

**Study Selection Criteria**

Below are selection criteria for studies to assess whether a test is clinically valid.

- The study population represents the population of interest. Eligibility and selection are described.
- The test is compared with a credible reference standard.
- If the test is intended to replace or be an adjunct to an existing test; it should also be compared with that test.
- Studies should report sensitivity, specificity, and predictive values. Studies that completely report true- and false-positive results are ideal. Studies reporting other measures (e.g., ROC, AUROC, c-statistic, likelihood ratios) may be included but are less informative.
- Studies should also report reclassification of diagnostic or risk category.

**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).

**Review of Evidence**

Devigili et al (2008) assessed 150 patients referred for suspected sensory neuropathy and tested with a Medoc thermal perception testing device.[16] Patients underwent (1) clinical examination, (2) a sensory and motor NCS, (3) warm and cooling thresholds assessed by QST, and (4) skin biopsy with distal intraepidermal nerve fiber 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 intraepidermal nerve fiber per millimeter at the distal leg (based on the 5th percentile of controls), 59 (88%) patients were considered to have abnormal intraepidermal nerve fiber (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 indicated that most patients evaluated showed an intraepidermal nerve fiber density of less than 7.63 together with either abnormal spontaneous or evoked pain (clinical examination) or abnormal thermal thresholds (QST). Study authors recommended a new diagnostic criterion standard based on the presence of at least 2 of 3 abnormal results (clinical, QST, intraepidermal nerve fiber density).

Lefaucheur et al (2015) compared 5 tests for diagnosing small fiber neuropathy , including QST using a Medoc thermal perception testing device.[17] The QST device was used to assess the warm detection threshold and cold detection threshold. Other tests were laser-evoked potential, sympathetic skin response, and electrochemical skin conductance. The study enrolled 87 consecutive patients being evaluated for definite (n=33) or possible (n=54) painful small fiber neuropathy. 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 small fiber neuropathy and 70% of those with possible small fiber neuropathy had at least 1 abnormal test. The sensitivity and specificity of each test in the series of 87 patients are shown in Table 2.

**Table 2. Sensitivity and Specificity (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 |

Adapted from Lefaucheur et al (2015).[17]

Laser-evoked potential was the most sensitive test.[17] However, not all patients were correctly categorized with laser-evoked potential. Fifteen patients with at least 1 abnormal test had normal laser-evoked potential 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, their study lacked a definitive criterion standard for small fiber neuropathy 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.[18]The authors evaluated use of skin biopsies immune-histochemistry, clinical examination of the feet, including pinprick, as well as QST assessments, and NCS 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; NCS assessments 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.

A retrospective study by Fabry et al (2020) in 245 patients with small fiber neuropathy symptoms compared several methods of evaluating small fibers: skin biopsy to determine intra-epidermal nerve fiber density, thermal sensory testing using QST (Thermotest device), quantitative sweat measurement, laser-evoked potentials, electrochemical skin conductance measurement, and autonomic cardiovascular tests.[19] Thermal sensory testing findings were not statistically different between patients who ultimately received a diagnosis of no small fiber neuropathy and those who received a diagnosis of definite small fiber neuropathy. The sensitivity, specificity, positive predictive value, and negative predictive value of thermal sensory testing were 72%, 39%, 57%, and 55%, respectively. All other testing methods had higher specificity (69% to 96%) but lower sensitivity (15% to 66%) compared to thermal sensory testing. The authors concluded that the best diagnostic strategy was a combination of skin biopsy, thermal sensory testing, laser-evoked potentials, and electrochemical skin conductance measurement (sensitivity, 92%; specificity, 88%; positive predictive value, 90%; negative predictive value, 91%).

**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 RCTs.

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.

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. An additional study using a different device also supports the potential of thermal QST 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 to nerve damage or disease. Studies comparing current perception threshold testing with other testing methods have not reported on sensitivity or specificity. Also, 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 that the technology results in an improvement in the net health outcome.

For individuals who have conditions linked to nerve damage or disease (e.g., diabetic neuropathy, carpal tunnel syndrome) who receive pressure-specified sensory testing , 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 diagnostic accuracy of pressure-specified sensory testing for diagnosing any condition linked to nerve damage or disease. A systematic review found that pressure-specified sensory testing had low accuracy for diagnosing spinal conditions. Also, there is a lack of direct evidence on the clinical utility of pressure-specified 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 that the technology results in an improvement in the net health outcome.

For individuals who have conditions linked to nerve damage or disease (e.g., diabetic neuropathy, carpal tunnel syndrome) who receive VPT, 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 FDA. Also, there is a lack of direct evidence on the clinical utility of VPT 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 that the technology results in an improvement in the net health outcome.

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 studies. Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. Two studies identified evaluated the diagnostic accuracy of thermal QST using the same FDA -cleared device. Neither found a high diagnostic accuracy for thermal QST but both studies found the test had potential when used with other tests. An additional study using a different device also supports the potential of thermal QST in combination 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 that the technology results in an improvement in the net health outcome.

## Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

### Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to the requests from physician specialty societies and academic medical centers, input was received from 1 specialty society and 1 academic medical center while the policy was under review in 2008. Input from both sources agreed with the policy statement that quantitative sensory testing is considered investigational.

### Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### American Academy of Neurology

The American Academy of Neurology (2003; reaffirmed 2022 ) concluded that quantitative sensory testing (QST) is probably (level B recommendation) an effective tool for documenting of sensory abnormalities and changes in sensory thresholds in longitudinal evaluation of patients with diabetic neuropathy.[20,21,] 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

In 2004, the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) published a technology literature review on QST (light touch, vibration, thermal, pain).[22,] 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 had 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 quantitative sensory tests that can be attributed to experimental error.

In 2005, the AANEM with American Academy of Neurology 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.[23,] 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 varied widely among studies.

### American Diabetes Association

In 2021, the American Diabetes Association published an updated standard for microvascular complications and foot care.[24,] Although temperature and vibration testing are recommended as part of the evaluation of small fiber and large fiber function, respectively, the specific screening tests for diabetic peripheral neuropathy that are described in the standard are manual/clinical rather than quantitative. Therefore, QST does not appear to have a role in the routine evaluation or diagnosis of diabetic peripheral neuropathy.

### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Medicare National Coverage

Medicare (2002) announced a national noncoverage policy on sensory nerve conduction threshold testing. Medicare reconsidered its policy, but affirmed it, concluding that any use of sensory nerve conduction threshold testing to diagnose sensory neuropathies or radiculopathies is not reasonable and necessary. This decision was reaffirmed in 2004.[25,] Medicare has not addressed coverage for other types of QST.

### Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 3.

**Table 3. Summary of Key Trials**

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|---|---|---|---|
| *Ongoing* | | | |
| NCT04393363 | Early Detection of Neuropathy and Cognitive Impairment Following Treatment for Haematological Malignancies (NOVIT1) | 20 | Dec 2030 |
| *Unpublished* | | | |
| NCT04078516 | Perception Threshold Tracking(PTT): A Novel Method for Early Detection and Grading of Diabetic Peripheral Neuropathy | 80 | Aug 2021 |
| NCT03909464 | Exploration Of The Sensitivity And Specificity Of The Pressure-Specified Sensory Device™ (PSSD) For Chemotherapy-Induced Peripheral Neuropathy | 26 | Nov 2019 |

NCT: national clinical trial.

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## Documentation for Clinical Review

- No records required

## Coding

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

| Type | Code | 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 |

## Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

| Effective Date | Action |
|---|---|
| 12/07/2006 | Adopted BCBSA policy |

| Effective Date | Action |
|---|---|
| 10/01/2010 | Policy revision without position change |
| 06/30/2015 | Coding update |
| 09/30/2015 | Policy revision with position change |
| 04/01/2016 | Policy revision without position change |
| 08/01/2017 | Policy revision without position change |
| 08/01/2018 | Policy revision without position change |
| 08/01/2019 | Policy revision without position change |
| 08/01/2020 | Annual review. No change to policy statement. |
| 12/01/2020 | No change to policy statement. Literature review updated. |
| 08/01/2021 | Annual review. No change to policy statement. Policy guidelines and literature review updated. |
| 08/01/2022 | Annual review. No change to policy statement. Literature review updated. |

## Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) 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 the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*

## Appendix A

| POLICY STATEMENT | |
|---|---|
| BEFORE | AFTER<br>Blue font: Verbiage Changes/Additions |
| **Quantitative Sensory Testing 2.01.39**<br><br>**Policy Statement:**<br>Quantitative sensory testing, including but not limited to current perception threshold testing, pressure-specified sensory device testing, vibration perception threshold testing, and thermal threshold testing, is considered **investigational**. | **Quantitative Sensory Testing 2.01.39**<br><br>**Policy Statement:**<br>I. Quantitative sensory testing, including but not limited to current perception threshold testing, pressure-specified sensory device testing, vibration perception threshold testing, and thermal threshold testing, is considered **investigational**. |