This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

### Populations

- **Individuals:** With conditions linked to nerve damage or disease (e.g., diabetic neuropathy, carpal tunnel syndrome)

### Interventions

- **Interventions of interest are:**
  - Quantitative sensory testing

### Comparators

- **Comparators of interest are:**
  - Standard clinical evaluation
  - Other sensory assessment tests

### Outcomes

- **Relevant outcomes include:**
  - Test accuracy
  - Test validity
  - Other test performance measures
  - Functional outcomes

### 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. 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.

### Summary of Evidence

The evidence for QST in patients who have conditions associated with nerve damage or disease (e.g., diabetic neuropathy, carpal tunnel syndrome) includes several studies on technical accuracy and diagnostic performance. Relevant outcomes are test accuracy and validity, other test performance measures, and functional outcomes. The studies do not adequately address the reproducibility of test results and reference values in normal populations. In addition, there is a lack of evidence on diagnostic accuracy compared with conventional testing; therefore it is not possible to conclude whether the use of QST impacts patient management or improves patient functioning. The evidence is insufficient to determine the effects of the technology on health outcomes.

### Policy

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**.
Background

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

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

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

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 three different frequencies are tested: five 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 in nature and requires patients who are alert, able to follow directions, and cooperative. In addition, to get reliable results, examinations need to include standardized instructions to the patients, and stimuli must be applied in a consistent manner by trained staff. Psychophysical tests have greater inherent variability, making their results more difficult to reproduce.

Regulatory Status

A number of QST devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. They include devices for current perception threshold testing (e.g., Medi-Dx 7000® Current Perception Threshold; Neuro Diagnostic Associates), pressure-specified sensory testing (e.g., NK Pressure-Specified Sensory Device™; NK Biotechnical), vibration testing (e.g., Vibration Perception Threshold meter; Xilas Medical), and thermal testing (e.g., Thermal Sensory Analyzer, TSA and TSA-II; Medoc Corp., Israel).

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.
It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.