Protocol

Quantitative Sensory Testing

(20139)

Medical Benefit		**Effective Date**: 04/01/12	**Next Review Date**: 01/21
Preauthorization	No	**Review Dates**: 01/07, 03/08, 01/09, 01/10, 01/11, 01/12, 01/13, 01/14, 01/15, 01/16, 01/17, 01/18, 01/19, 01/20	

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	Interventions	Comparators	Outcomes
Individuals: • With conditions linked to nerve damage or disease (e.g., diabetic neuropathy, carpal tunnel syndrome)	Interventions of interest are: • Current perception threshold testing	Comparators of interest are: • Standard clinical evaluation • Other sensory assessment tests	Relevant outcomes include: • Test accuracy • Test validity • Symptoms • Functional outcomes
Individuals: • With conditions linked to nerve damage or disease (e.g., diabetic neuropathy, carpal tunnel syndrome)	Interventions of interest are: • Pressure-specified sensory testing	Comparators of interest are: • Standard clinical evaluation • Other sensory assessment tests	Relevant outcomes include: • Test accuracy • Test validity • Symptoms • Functional outcomes
Individuals: • With conditions linked to nerve damage or disease (e.g., diabetic neuropathy, carpal tunnel syndrome)	Interventions of interest are: • Vibration perception testing	Comparators of interest are: • Standard clinical evaluation • Other sensory assessment tests	Relevant outcomes include: • Test accuracy • Test validity • Symptoms • Functional outcomes
Individuals: • With conditions linked to nerve damage or disease (e.g., diabetic neuropathy, carpal tunnel syndrome)	Interventions of interest are: • Thermal sensory testing	Comparators of interest are: • Standard clinical evaluation • Other sensory assessment tests	Relevant outcomes include: • Test accuracy • Test validity • Symptoms • 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. Types of sensory testing include current perception threshold testing, pressure-specified sensory testing (PSST), vibration perception testing, 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.

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 the effects of the technology on health outcomes.

For individuals who have conditions linked to nerve damage or disease (e.g., diabetic neuropathy, carpal tunnel syndrome) who receive PSST, 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 PSST for diagnosing any condition linked to nerve damage or disease. A systematic review found that PSST had low accuracy for diagnosing spinal conditions. 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 the effects of the technology on health outcomes.

For individuals who have conditions linked to nerve damage or disease (e.g., diabetic neuropathy, carpal tunnel syndrome) who receive vibration perception testing, 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 Food and Drug Administration. Also, there is a lack of direct evidence on the clinical utility of vibration perception testing 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 the effects of the technology on health outcomes.

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. Relevant outcomes are test accuracy and validity, symptoms, and functional outcomes. Two studies identified evaluated the diagnostic accuracy of thermal QST using the same Food and Drug Administration-cleared device. Neither found a high diagnostic accuracy for thermal QST but both studies found the test had potential when used 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 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

NERVE DAMAGE AND DISEASE

Nerve damage and nerve diseases can reduce functional capacity and lead to neuropathic pain.

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, before patients would be diagnosed clinically. 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

QST 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. 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 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. 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 three 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 cooperative. 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.

QST has primarily been applied in patients with conditions associated with nerve damage and neuropathic pain. 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.

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
FDA product code: NTU				
Contact Heat-Evoked Potential Stimulator (Cheps)	Medoc, Advanced Medical Systems	Feb 2005	K041908	Thermal sensory testing

FDA: Food and Drug Administration.

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services 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.

1. Ziccardi VB, Dragoo J, Eliav E, et al. Comparison of current perception threshold electrical testing to clinical sensory testing for lingual nerve injuries. J Oral Maxillofac Surg. Feb 2012;70(2):289-294. PMID 22079068
2. Weber RA, Schuchmann JA, Albers JH, et al. A prospective blinded evaluation of nerve conduction velocity versus Pressure-Specified Sensory Testing in carpal tunnel syndrome. Ann Plast Surg. Sep 2000;45(3):252-257. PMID 10987525
3. Nath RK, Bowen ME, Eichhorn MG. Pressure-specified sensory device versus electrodiagnostic testing in brachial plexus upper trunk injury. J Reconstr Microsurg. May 2010;26(4):235-242. PMID 20143301
4. Hubscher M, Moloney N, Leaver A, et al. Relationship between quantitative sensory testing and pain or disability in people with spinal pain-A systematic review and meta-analysis. Pain. Sep 2013;154(9):1497-1504. PMID 23711482
5. Suokas AK, Walsh DA, McWilliams DF, et al. Quantitative sensory testing in painful osteoarthritis: A systematic review and meta-analysis. Osteoarthritis Cartilage. Jul 11 2012;20(10):1075-1085. PMID 22796624
6. Mythili A, Kumar KD, Subrahmanyam KA, et al. A comparative study of examination scores and quantitative sensory testing in diagnosis of diabetic polyneuropathy. Int J Diabetes Dev Ctries. Jan 2010;30(1):43-48. PMID 20431806

7. Abraham A, Albulaihe H, Alabdali M, et al. Elevated vibration perception thresholds in CIDP patients indicate more severe neuropathy and lower treatment response rates. PLoS One. Nov 2015;10(11):e0139689. PMID 26545096
8. Goel A, Shivaprasad C, Kolly A, et al. Comparison of electrochemical skin conductance and vibration perception threshold measurement in the detection of early diabetic neuropathy. PLoS One. Sep 2017;12(9): e0183973. PMID 28880907
9. Azzopardi K, Gatt A, Chockalingam N, et al. Hidden dangers revealed by misdiagnosed diabetic neuropathy: A comparison of simple clinical tests for the screening of vibration perception threshold at primary care level. Prim Care Diabetes. Apr 2018;12(2):111-115. PMID 29029862
10. Devigili G, Tugnoli V, Penza P, et al. The diagnostic criteria for small fibre neuropathy: from symptoms to neuropathology. Brain. Jul 2008;131(Pt 7):1912-1925. PMID 18524793
11. Lefaucheur JP, Wahab A, Plante-Bordeneuve V, et al. Diagnosis of small fiber neuropathy: A comparative study of five neurophysiological tests. Neurophysiol Clin. Dec 2015;45(6):445-455. PMID 26596193
12. Anand P, Privitera R, Yiangou Y, et al. Trench foot or non-freezing cold injury as a painful vasoneuropathy: clinical and skin biopsy assessments. Front Neurol. Sep 2017;8:514. PMID 28993756
13. Shy ME, Frohman EM, So YT, et al. Quantitative sensory testing: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology. Mar 25 2003;60(6):898-904. PMID 12654951
14. American Academy of Neurology. Quantitative Sensory Testing (reaffirmed 2016). 2003; https://www.aan.com/Guidelines/home/GuidelineDetail/87. Accessed May 18, 2018.
15. Chong PS, Cros DP. Technology literature review: quantitative sensory testing. Muscle Nerve. May 2004; 29(5):734-747. PMID 15116380
16. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for sensory Nerve Conduction Threshold Tests (sNCTs) (160.23). 2004; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?CALId=192&CalName=Prothrombin+Time+(PT)+(Addition+of+ICD-9-CM+V58.83%2C+Encounter+for+therapeutic+drug+monitoring%2C+as+a+covered+indication)&ExpandComments=y&CommentPeriod=0&NCDId=270&ncdver=2&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABABAEAAAA%3D%3D&. Accessed May 18, 2018.