MEDICAL POLICY

POLICY TITLE	QUANTITATIVE SENSORY TESTING
POLICY NUMBER	MP-2.098

Original Issue Date (Created):	**6/1/2015**
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I. 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**. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

II. PRODUCT VARIATIONS TOP

This policy is only applicable to certain programs and products administered by Capital BlueCross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO - Refer to FEP Medical Policy Manual MP-2.01.39, Quantitative Sensory Testing. The FEP Medical Policy Manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND TOP

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.

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Quantitative Sensory Testing

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 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 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 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.

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.

IV. RATIONALE

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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. The 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. The 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 VPT, the evidence includes several studies on diagnostic accuracy. The 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 theft. 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 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. The 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. 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.

V. DEFINITIONS

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N/A

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are

different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational therefore not covered:

CPT Codes®								
0106T	0107T	0108T	0109T	0110T				

Investigational therefore not covered:

HCPCS Code	Description
G0255	Current perception threshold/sensory nerve conduction test, (SNCT) per limb, any nerve

IX. REFERENCES

TOP

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*
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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*
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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*
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12. *Anand P, Privitera R, Yiangou Y, et al. Trench foot or non-freezing cold injury as a painful vaso-neuropathy: 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 July 8. 2020.*

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 July 8, 2020*
20. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 2.01.39, Quantitative Sensory Testing. July 2019.*

X. POLICY HISTORY

TOP

MP- 2.098	**CAC 1/27/15 New policy created however content was previously addressed in MP-2.063** Electromyography, Nerve Conduction Velocity Studies, and Quantitative Sensory Testing. No changes to the policy statement. References and rationale updated. FEP variation added. Policy coded.
	11/2/15 Administrative change. LCD number changed from L32239 to L34996 due to Novitas update to ICD-10.
	CAC 1/26/16 Consensus review. No change to policy statements. References and rationale updated. Added L35094 to reference list. Deleted L34996 from references. Coding reviewed**.**
	Administrative Update 11/10/16 Variation reformatting
	CAC 1/31/17 Consensus review. Policy statement unchanged. Rationale and Reference sections updated. Coding reviewed.
	12/13/17 Consensus review. No change to the policy statement. Background, rationale, and references updated**.**
	10/10/18 Consensus review. No change to policy statements. References updated. Rationale condensed.
	8/2/19 Consensus review. No change to policy statements. Background and summary of evidence reviewed. References updated.
	7/8/20: Consensus review. No change to policy statement. Table reformatted. References updates.

Top