BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 2.01.39 Quantitative Sensory Testing

Effective Policy Date: October 1, 2023

Original Policy Date: September 2012

Related Policies:

None

Quantitative Sensory Testing

Description

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 better understand neuropathic pain. It could be used to diagnose conditions linked to nerve damage and disease, and to improve patient outcomes by impacting management strategies.

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 (eg, 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 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.

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.

OBJECTIVE

The objective of this evidence review is to determine whether quantitative sensory testing improves the net health outcome in individuals with conditions linked to nerve damage or disease.

POLICY STATEMENT

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**.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA 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

Summary of Evidence

For individuals who have conditions linked to nerve damage or disease (eg, 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 (eg, 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 (eg, diabetic neuropathy, carpal tunnel syndrome) who receive vibration perception testing (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 U.S. Food and Drug Administration (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 (eg, 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 quantitative sensory testing (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

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 the 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 2023, the American Diabetes Association published an updated standard for retinopathy, neuropathy, and 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 current routine evaluation or diagnosis of diabetic peripheral neuropathy.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

In 2002, Medicare 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.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2012	New 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.
December 2013	Replace policy	Policy updated with literature review, Policy statement unchanged. References added; other references reordered or removed.
December 2014	Replace policy	Policy updated with literature review. Policy statement unchanged. Reference 16 added.
March 2016	Replace policy	Policy updated with literature review Policy statement unchanged. Reference 14 added.
September 2018	Replace policy	Policy updated with literature review through May 1, 2018; references 9- 11, 13-14, and 16 added. Policy statement unchanged except "not medically necessary, corrected to "investigational, due to FDA 510k process.
September 2019	Replace policy	Policy updated with literature review through April 3, 2019, no references added. Policy statement unchanged.
December 2020	Replace policy	Policy updated with literature review through August 20, 2020; references added. Policy statement unchanged.
September 2021	Replace policy	Policy updated with literature review through April 19, 2021; references added. Policy statement unchanged.
September 2022	Replace policy	Policy updated with literature review through April 27, 2022; background references added. Policy statement unchanged.
September 2023	Replace policy	Policy updated with literature review through April 13, 2023; reference added. Policy statement unchanged.