American Association of Sensory Electrodiagnostic Medicine
Consensus
&
Practice Policy Guidelines
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PAIN FIBER NERVE CONDUCTION STUDY (PF-NCS)

NATIONAL LIBRARY OF MEDICINE

AASEM Certified Members are eligible to take part in NLM Registered Clinical Trials. These studies use the pf-NCS to evaluate the various pain interventions and treatment modalities.

MEDICARE

Federal Administrative Law Judges (ALJs) in several Medicare Appeals Decisions have found the pf-NCS to be "reasonable and necessary" and "entitled to payment."

VETERANS ADMINSTRATION

In late 2013 the VA began using the pf-NCS.

Neurophysiology of Pain Fibers

1. A-delta (Fast Pain) Fibers – Neospinalthalamic Pathway (excellent connectivity to the cerebral cortex)
a) Early Warning System for nerve injury (50 times smaller than large motor and large sensory fibers).
b) Allow Exact Injury Localization.
c) Transmit hot, cold, vibration fast (sharp) pain and vital proprioceptive signals (pressure & stretch).
d) Synapse with motor neurons in the spinal cord to cause Withdrawal Reflex.

2. C-Type Slow Pain Fibers – Paleospinalthalamic pathway (poor cortical connectivity)
a) Signal deep aching pain as long as the injury is unresolved (100 times smaller than motor fibers).
b) Very poor localization of the source of pain.

Guyton & Hall Textbook of Medical Physiology, 12th Edition (2011) pg. 585-586:
"The paleospinalthalamic pathway is a much older system and transmits pain mainly from the peripheral slow-chronic type C pain fibers. Localization of pain transmitted by way of the paleospinalthalamic is imprecise. The slow pain tends to become stronger over time. It explains why so many patients have serious difficulty localizing the source of some types of chronic pain."

Note: The type of pain Guyton is talking about is the most common type – radiculopathic pain, and the patient does not have difficulty so much he localize pain to the wrong nerve.

Phases of Pain Fiber Injury

INJURY OCCURS
*** Epicritic Phase: (Acute stage)**
a) A-delta (Fast Pain) fibers fire synapse with motor neurons and before the signals reach the brain muscles contract to move the body away from the cause of damage.
b) OUCH! Brain receives A-delta signals and PATIENT EXACTLY LOCATES INJURY.

If the damage persists, such as nerve entrapment or the damage is unresolved the next phase sets in.
*** Protopathic Phase: (Early Chronic Stage)**
a) A-delta fibers <u>DOWN-REGULATE</u> - Sharp Pain Subsides & Localization Becomes Less Accurate
b) C-Type Fibers <u>UP-REGULATE</u> - Deep Aching Pain Begins & Localization Much Less Accurate
Result:
1. **PATIENT INCORRECTLY LOCALIZES SOURCE OF PAIN**
2. **TREATMENT MISDIRECTED & CHRONICITY**

HOW PF-NCS WORKS

A-delta Down-regulation

Since A-delta fibers always down-regulate after an injury, these fibers require stronger stimulus to cause threshold firing than that required to fire uninjured nerves. By testing all the major nerves in a region the patient acts as his own control. Therefore, independent of race, age, gender and other population variables accuracy approaches 100%, as compared to EMG type analysis where results are compared to population averages on a bell-shaped curve, which at best has 67% accuracy.

Neuroselectivity

The literature supports the view that sensory fibers respond to different frequencies. The C-Type fibers respond to a frequency between 1 Hz to 10 Hz (cycles per second), A-delta fibers respond between 150 Hz and 350 Hz, and A-beta fibers respond between 1500 and 3000 Hz [i] [ii] [iii] The most compelling empirical evidence the A-delta frequency is activating the A-delta fibers is that this frequency causes all the sensations transmitted by the A-delta fibers: pricking, hot, cold, vibration, pressure and itch. Additionally, it has been demonstrated that the A-delta frequency will exclusively cause muscle contraction, whereas the C and A-beta frequencies do not. The physiological argument is that each fiber type is known to accommodate within a certain time range, therefore, a stimulus with a frequency timed to that accommodation cycle would selectively stimulate that particular fiber more than other fiber types.

Peer-Reviewed Accuracy

Internet Journal of Pain, Symptom Control & Palliative Care

Carried out by a team of physicians under the leadership of Randall Cork, MD, PhD, Chairman of the Department of Anesthesiology and Director of Pain Medicine at **Louisiana State University (LSU) Pain Center** this Class I study took three years to complete. The study compared the results of the pf-NCS in chronic and failed low back surgery cases with epidurogram radiographic studies in which there was a high probability of nerve root adhesions. The pf-NCS was found to have 94.6% sensitivity. In 2008 a potentiometer was added to the device so the test is now objective in its detection of threshold.

AASEM Multicenter Study (2012) (www.aasem.org) found evidence that supports that nearly 50% of pain neck and back pain is referred to health nerves, and nearly 15% is referred to the side opposite the pain generating lesion. Obviously the misdirected treatment caused by referred pain results in unnecessary suffering and wasted resources.

Multicenter Retrospective Study (AASEM Online Journal) January 2012, R Cork, M Bezell

"Paradoxical Relationship: A-Delta Function and VAS"

"Conclusions: A-delta sensitivity/function as measured by voltage using the pf-NCS is related to the patient's pain perception. As A-delta sensitivity improves from hypo toward normal sensitivity, pain decreases; as A-delta sensitivity/function deteriorates, pain increases. Females have lower A-delta fiber voltage thresholds than males, and the cervical region exhibits lower A-delta fiber voltage thresholds than the lumbar region, but the A-delta voltage thresholds drop independently of sex and spinal level with treatment. In contrast, the VAS responses are not different based on either sex or spinal level, but VAS drops significantly in concert with the drop in A-delta fiber sensitivity/function. In general, A-delta sensitivity/function measured by A-delta small pain fiber nerve conduction study (pf-NCS) is an excellent objective measure of pain change following treatment, and a practical and painless electrodiagnostic procedure for detecting the side and level of painful radiculopathic pain generators."

CODING & REPORTING

AMA CPT Codes GO255-25, 0110T-25 and 95907 to 95913

Insurers erroneously overlook the second part of the pf-NCS and determined that the subjective first part, where the patient's response is used to find the threshold, is the entire test. They decide the test is either a Quantitative Sensory Test(QST Code 0110T) or a Sensory Nerve Conduction (sNCT perception threshold tests GO255). This alleged confusion results in a denial of coverage. The AASEM recommends that to avoid confusion the non-payable parts of the pf-NCS be reported along with the billable second part (amplitude measurement from the potentiometer – 95907 to 95913).

In January 2013 NCS codes for motor (95903), sensory (95904) and mixed (95905) were replaced with codes representing the number of nerves tested regardless of the type. 1 to 2 nerves is coded 95907, 95908 (3-4), 95909 (5-6), 95910 (7-8), 95911 (9-10), 95912 (11-12) and 95913 (13 or more nerves).

When using GO255 and 0110T follow each with modifier 25 at no charge. On the third line use code 95907 up to 95913 followed by the total charge for the number nerves tested.

Medicare ALJs Agree
The AMA definitions for motor, sensory and mixed test have not changed.
AMA EDX Guidelines (April 2002) page 2:
"Scope of Electrodiagnostic Medicine"
"Electrodiagnostic medicine includes a variety of electrodiagnostic studies, including nerve conduction studies (NCSs) (codes 95900, 95903, and 95904), needle electromyography (EMG) (codes) 95860-95870), neuromuscular junction (NMJ) testing."
Next paragraph:
"Although a common problem, such as tingling and numbness in the hand and arm (which could be due to lesions in the brain, spinal cord, cervical roots, brachial plexus, or nerves in the upper extremities), may be studied in a similar way by many EDX providers, there is no single, universally accepted, specific protocol or set of procedures employed for each diagnostic category." (Underline added for emphasis)

AMA EDX Guidelines page 3 (Verbatim AANEM descriptions) :
A typical NCS has three parts:

a) **"Development of a differential diagnosis . . ."**
   In other words the examiner suspects the patient may have a nerve problem.
b) **"NCSs of a number of nerves, and the muscles they innervate."**
   In other words, the NCS is performed on MOTOR NERVES (AANEM EMG-type NCS).
c) **"Completion of indicated needle EMG studies . . ."**

Note (b): **"and the muscles they innervate."** This shows the description is that of large fiber NCS, which means (c) if a patient has no sign of motor deficit (gross muscle weakness or atrophy) a needle EMG is "NOT INDICATED."

Clearly, the above describes a motor (large fiber) NCS, not a small pain fiber NCS. Insure websites list up to 80 references. Usually the AANEM is listed 4 or more times. The AANEM references describe the above NCS, but no references mentions the Axon-II. Yet, the Axon-II is named as a device that cannot perform both NCS (AANEM description) and needle EMG. However, ALJs have found in several Medicare Appeals that Axon-II small pain fiber NCS is covered, so using it as an example of a device that cannot perform large fiber NCS and EMG is like describing a boat and giving a pickup truck as an example of the vehicle that cannot perform the same functions as a boat. Perhaps the Axon-II is named in two insurer references that cannot be found; a) Other carrier websites and, b) Carrier managers. Is it possible that insurers just add the Axon-II without any legal basis?

OVERUTILIZATION PREVENTION

Overutilization can be avoided by adhering to reasonable indications. The physician must consider the history and circumstances surrounding the onset of symptoms, duration, location and character of the complaint. For example, a twisted knee should not cause one to suspect nerve entrapment. **A Negative pf-NCS Does Not Mean It Was Unnecessary because it is equally important to rule out pathology.**

Indications:
The consensus of pf-NCS certified physicians supports the following list of indications, which conforms to AMA guidelines:
1. Radiating symptoms following trauma.
2. Symptoms resistant to conservative care.
3. Radiation of pain exacerbated by motion or position.
4. Axial symptoms for longer than two months.
5. Symptoms with concomitant weakness.
6. To determine the distribution of sensory dysfunction.
7. To estimate the severity of sensory abnormalities.
8. To determine the progression or rate of recovery.
9. To aid in the prognosis of sensory disorders.
10. Localization of injury prior to peripheral nerve or spinal block therapy.
11. To aid the targeting of large fiber EMG/NCV EDXs.

Maximum Number of Nerves Tested

AMA Guidelines support that **"bilateral testing is often necessary and reasonable for comparison purposes."** The pf-NCS is generally performed bilaterally, since over 50% of patients incorrectly localize the source of their symptoms, and up to 20% localize to the wrong side. Literally, the more nerves and branches tested the higher the degree of accuracy. By using the patient as his own control there is a distinct advantage over comparison with population averages on a bell-shaped curve, which yields about 67% sensitivity. Regardless, it is the consensus that since the pf-NCS is less complex than conventional EDX, and requires less time to perform, it is reasonable to generally limit billing to six nerves per side, since some testing may involve branches of a major peripheral nerve. The rule is that the billing is for the testing of a major nerve, regardless of the number of branches tested.

Presumptive Diagnosis

It is sound medical practice to use a broad enough presumptive diagnosis to allow testing that can detect less likely etiologies. For example, it would be short sighted to make a diagnosis of C6 radiculopathy based on the patient reporting his symptoms of neck pain with some radiation into the right arm to the thumb and index finger. Since 50% of patients incorrectly localizing pain and 15% localizing to the wrong side, there are several other possibilities, such as peripheral entrapment at the wrist or elbow with radiation up to the neck, or another nerve root or cervical plexus entrapment. The possibility even exists that this is referred pain from cardiac disease. Therefore, when nerve involvement is suspected the safest diagnosis is a presumptive diagnosis of cervical or lumbar plexopathy. Once the more common causes, such as cervical or lumbar involvement is ruled out, then it would be appropriate to test for distal peripheral neuropathy. Below is a list of diagnoses and the consensus of the reasonable number of nerves to bill for:

Nerves		
Cervical Plexopathy	**6**	**– Bilateral 12**
Lumbosacral Plexopathy	**6**	**" "**
Carpal Tunnel	**2**	**" 4**
Guyon's Canal	**2**	**" "**
Cubital Tunnel	**2**	**" "**
Ankle Entrapment	**3**	**" 6**
Polyneuropathy	**6**	**" 12**

Repeat pf-NCS Studies

Generally repeating a study is necessary in one of the following clinical situations:

1. A reasonable time passes without symptoms improving.
2. Symptoms change location or worsen.
3. To determine and clarify the prognosis.

It is not generally warranted to test when symptoms have completely resolved. Additionally, repeat testing of all the nerves may not be necessary when often only the abnormal nerve can be tested for comparison with its previous measurement.

BILLING EXAMPLES

Massachusetts General Hospital Pain Handbooks states: **"*In most cases (over 50%) of neck and back pain the diagnosis is unclear.*"** In light of this, a presumptive diagnosis of plexopathy may be the most honest, because one cannot presume that a certain nerve root or peripheral nerve is involved without the pf-NCS. Though others codes may be substituted, it is the consensus that plexopathy allows regional testing to detect hidden lesions, which is one of the main strength of the pf-NCS EDX.

ALL INSURANCE TYPES

CERVICAL PLEXOPATHY

ICD-10 Code – G54.2 - ICD-9: 350.0

LUMBOSCARAL PLEXOPATHY

ICD- 10 Code – G54.1 - ICD-9: 350.1

GENERAL INFORMATION

DIFFERENCE BETWEEN PF-NCS AND EMG-TYPE ELECTRODIAGNOSTIC EXAMS (EDX)

With the use of the pf-NCS to evaluate treatments in the NLM Clinical Trials pf-NCS is established as the Gold Standard for diagnosing pain fiber pathology. It should be noted that EMG-type tests have never been used for such studies. Radiculopathy is the most common nerve disorder causing pain. A 2013 **Mayo Clinic** study "**Why Patients Visit Doctors: Assessing the Most Prevalent Conditions in a Defined American Population"** found in a population of 142,377 that 23.9% of patients visits were for spine pain. Combine this with the fact that over 50% of pain is referred to healthy nerve roots, and it is easy to understand why a 2002 NIH study found 43% of pain patients develop chronic symptoms and over 50% of spinal surgeries end in failure.

Developed during World War II, EMG0type tests have remained basically unchanged since the 1960s, and cannot test the early warning pain nerve fibers. The large fibers EMG-type tests assess must have lost at least 50% of their protective myelin before any change in conduction even begins. By comparison, pf-NCS tests the early warning pain fibers and can detect changes without hours of injury

Medical Literature Review

The following quotes from the literature clearly reflect the limitations of EMG-type tests.

The Spine, 5th Edition, (Saunders 2006) pg. 218:
"Whenever a patient, whose sole complaint is pain (affecting the limbs, neck or back), is referred for an EDX examination* (EMG/NCV)*, there is the expectation that there has been some concomitant damage to large nerve fibers. As is noted later, with chronic lesions this is usually an unrealized hope."

Massachusetts General Hospital Handbook of Pain Management, 2nd Edition (2002) page 382:
"In most cases (over 50%) ***of neck and back pain the anatomical and physiological diagnosis remains unclear."*** page 380 states: ***"History and physical examination have a limited role in the diagnosis of back and neck pain but are important in ruling out serious pathology. The etiology of pain in a significant number of patients with back and neck pain may remain unknown. Nonspecific back or neck pain is a legitimate diagnosis."***

Massachusetts General Hospital Handbook of Pain Management, 2nd Edition (2002) pg. 353:
"Most neuropathic pain syndromes are mediated by small-diameter C fibers, which are not evaluated by these tests (EMG/NCV) ***so their value in the evaluation of neuropathic pain syndromes is limited. It is important to note that the sensory nerve action potentials (SNAP) can be normal in patients with neuropathic pain syndromes of radicular origin, because the causative lesion is proximal to the dorsal nerve root ganglion."***

Physical Medicine & Rehabilitation: State of the Art Reviews Vol.13, No.2, (June 1999): ***EVALUATION OF RADICULOPATHY: HOW USEFUL IS ELECTRODIAGNOSTIC TESTING?***

- ***"In chronic cases, particularly in individuals with predominantly sensory symptoms, it is difficult or impossible to clinically estimate the type or severity of nerve injury."***
- **"Only if there is observable muscle atrophy can one know for certain that motor axon degeneration has occurred."**
- **H wave -** ***"Named after Hoffman, who described it in 1918. However, the only H response that is used with any regularity is in the assessment of the S1 fibers. . . Many would argue that the H reflex is simply a neurophysiologic ankle stretch reflex*** (rubber hammer reflex test) ***and, therefore, does not have added value in the evaluation of radiculopathy."***
- **F wave -** ***". . . named for the location of the wave forms, first found in the foot muscles. . . Despite the theoretical advantage of using the F wave response . . . it is of little practical application in the evaluation of radiculopathy, especially a lesion at a single level. If even a few of the large myelinated motor fibers are preserved, the F latency will remain normal. Severe root damage at multiple levels is necessary to prolong the latency. The abnormalities of F waves do not correlate with either needle examination or clinical findings.***
- Considering the fact that most radiculopathies are associated with little or no motor deficit: ***"Thus, the sensitivities reported in the literature are falsely elevated and tend to lull us into thinking that electrodiagnostic evaluation of radiculopathy is both sensitive and specific."***

Neurology for the Non-Neurologist (Wiener & Goetz), Lippinott (2002) pg. 23:
"EMG and NCV in neck, shoulder and back pain, in the absence of motor deficit, is costly, time consuming and seldom benefits the patient."

Amplitude –Velocity – Latency – Waveform Configuration

ALJs have evaluated the evidence and found that pain fibers have little or no myelin because they are 50 to 100 times smaller than large motor fibers. Therefore, velocity, latency and configuration are of no known diagnostic significance in small fiber testing. However, the increased electrical amplitude that accompanies firing (action potential) verifies changes in threshold to detect pathology.

Failed Formula - EMG & Imaging
EMG cannot detect referred early warning pain and matching symptoms with MRI findings is a formula for failure. The literature supports that referred symptoms misdirect doctors in over 50% of cases.

MRI - Imaging Limitations: The New England Journal of Medicine (July 1994):
"52% of 98 asymptomatic subjects, with no history of injury, were found to have diagnosable bulging discs, herniated discs or both."

Pain Medicine & Management, McGraw Hill (2005) pg: 28
"Pain cannot be imaged."

Answering Erroneous Insurer Statements

1. The Axon-II is a handheld device:
No! It takes 2 hands and one foot to operate and weighs 30lbs to 50lbs depending on the type of computer, printer and cart used.

2. The Axon-II is automated and uses a fixed electrode array:
No! Examiner controls the stimulus output and records all data.

3. The Axon-II uses remote analysis:
No! Analysis and interpretation is performed on cite.

4. The Axon-II is Experimental or Investigational:
The Axon-II is FDA Class II (Safe & Effective).
No insurance company has the authority to classify medical devices. Only the FDA has the authority to classify medical devices.
Title 42: Public Health, Subpart B – Medical Service Coverage Decisions That Relate to Health Care Technology, Authority: Sections 1102, 1862 and 1871 of the Social Security Act as amended (42 U.S.C. 1302 and 1395hh). Source: 60 FR 48423, Sept. 19, 1995 – SS 405.201,
Class-A, Investigational/Experimental Devices:

5. The Axon-II is a non-reimbursable "sNCT psychophysical assessment" described in CMS NCD 160.23 (April 1, 2004), because the Axon-II does not measure velocity/latency or configuration:
No! Several ALJs in Medicare Appeals have found the Axon-II and Neural-Scan tests to be "reasonable and necessary" and "entitled to payment" with amplitude only required and not velocity, latency or configuration responses. Small pain fibers are 50 to 100 times smaller than large fibers that must have lost at least 50% of their protective myelin before large fiber EMG-type test even begin to detect changes in velocity, latency and configuration.

6. The Axon-II is incapable of both NCS and EMG so it is not covered.
This goes against ALJ decisions and wrong. The actual quote from insurer websites: **"Devices incapable of real-time waveform display and analysis and incapable of both NCS and EMG testing will be included in the E/M service. Generally, the NCS is followed by a needle EMG. Devices that cannot conform to these requirements are the Axon-II and Neural-Scan.**
What insurers are doing is describing a device that performs large fiber tests and then saying the Axon-II does not do large fiber tests. This is true, but ALJs have repeatedly found the Axon-II and Neural-Scan only need to measure the amplitude of the action potential to detect threshold. EMG is out of the question

because the Axon-II is looking at pain fibers. This is like describing the attributes of a boat and then saying a pickup truck does not conform to these requirements. Additionally, insurer sites that say this nonsense list the AANEM as the source of such statements and not a single reference names the Axon-II, so the question comes: Who says the Axon-II must perform both NCS and EMG? Insurance company executives?

7. AANEM Position Statement & Memo to Healthcare Policymakers:
Everything in these documents concerning the Axon-II and Neural-Scan is false and grossly misleading. The AANEM, whose members derive about half of their income testing spinal pain, talks about CMS Memorandum CAG-00106R, which is not an NCD, but required to allow input before an NCD is issued. This is clearly explained in a paragraph above the title of such memos. After input CMS deleted Memorandum CAG-00106-R from the final NCD 160.23 and only used CAG-00106-N (N not R), which dealt exclusively with the Neurometer. The term used for the non-reimbursable test is "sNCT" which is trademarked by Neurometer. Several ALJs have found NCD 160.23 supports reimbursement for the Axon-II, Neural-Scan pf-NCS.

AANEM Criticizes Axon-II Analysis
EMG-type tests compare results to population averages, but there is a better, more accurate way of analysis. EMG-type tests hurt, so only a few nerves can be tested and compared with populations averages by race, age and gender, which at best have 67% accuracy on a bell-shaped curve. The Axon-II tests all the major nerves in a region (cervical 9 bilateral [18] and 7 bilateral [14] lumbosacral. The measures are analyzed using a nomogram in which each patient's acts as his own control. He has his own bell-shaped curve. Therefore, accuracy is as close to 100% and independent of age, race and gender.

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[i] Chado H N: ***Current Perception Threshold Evaluation of Sensory Nerve Function in Pain Mgmt.*** **Pain Digest:**5:127-34, 1995.
[ii] Finkel, et al: ***Neuroselective Sensory Electrodiagnostic Evaluation 4% Liposomal Topical Lidocaine, Anesthesiology Analog*****. International Anesthesiology Research Society**, 2002.
[iii] Imoto K., et al: ***Quantitative Analysis of Sensory Function After Lumbar Discectomy Using Current Perception Threshold Testing*****. European Spine Journal.** 16:971-975 DOI 10. 1007/s00586-006-0285-7, 2007.