Medical Necessity for NCV and EMG testing

Leon Margolin M.D., Ph.D.

Background

- LCD guidelines
- Understanding AANEM guidelines
- Framework of PM&R (ABPMR position)
- Documentation of organic pathology
- Extension of physical exam
- Reviw of billing patterns
- Expert opinion (AANEM, ABPMR, billing and coding)

Federal Register:
Federal Register Vol. 62, 59047, Supervision of Diagnostic Tests, describes the degree of physician supervision required for diagnostic tests.

CMS Publications:
CMS Publication 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Part 2:
160.23 Sensory Nerve Conduction Threshold Tests (sNCTs)
Program Memorandum Carriers Transmittal B-01-28 Change Request 850, describes tests that may be performed by PTs with ABPTS certification
CMS IOM 100-2. Medicare Benefit Policy Manual Chapter 15 Section 80 Requirements for Diagnostic Tests p. 88-91. 2009.
Transmittal 2663 Change Request 8169 April Update to the CY 2013 Medicare Physician Fee Schedule Database (MPFSDB)

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

CGS Administrators expects healthcare professionals who perform electrodiagnostic (ED) testing will be appropriately trained

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

CGS Administrators expects healthcare professionals who perform electrodiagnostic (ED) testing will be appropriately trained and/or credentialed, either by a formal residency/fellowship program, certification by a nationally recognized organization, or by an accredited post-graduate training course covering anatomy, neurophysiology and forms of electrodiagnostics (including both NCS and EMG) acceptable to this Contractor, in order to provide the proper testing and assessment of the patient's condition, and appropriate safety measures. It would be highly unlikely that this training and/or credentialing is possessed by providers other than Neurologists, or Physical Medicine & Rehabilitation physicians.

The electrodiagnostic evaluation is an extension of the neurologic portion of the physical examination. Both require a detailed knowledge of a patient and his/her disease. Training in the performance of electrodiagnostic procedures in isolation of knowledge about clinical diagnostic and management aspects of neuromuscular diseases, may not be adequate for proper performance of an electrodiagnostic evaluation and correct interpretation of electrodiagnostic test results. Without awareness of the patterns of abnormality expected in different diseases and knowledge that the results of nerve conduction studies (NCS) and electromyography (EMG) may be similar in different diseases, diagnosis solely by EMG-NCS findings may be both inadequate and ultimately be detrimental to the patient.

Guidelines about proper qualifications for qualified health care professionals performing electrodiagnostic evaluations have been developed and published by AANEM (American Association of Neuromuscular and Electrodiagnostic Medicine) and other medical organizations, including the AMA, the American Academy of Neurology, the American Academy of Physical Medicine and Rehabilitation, American Neurological Association, the American Board of Physical Therapy Specialties (ABPTS) in Clinical Electrophysiology, and the Department of Veterans Affairs.

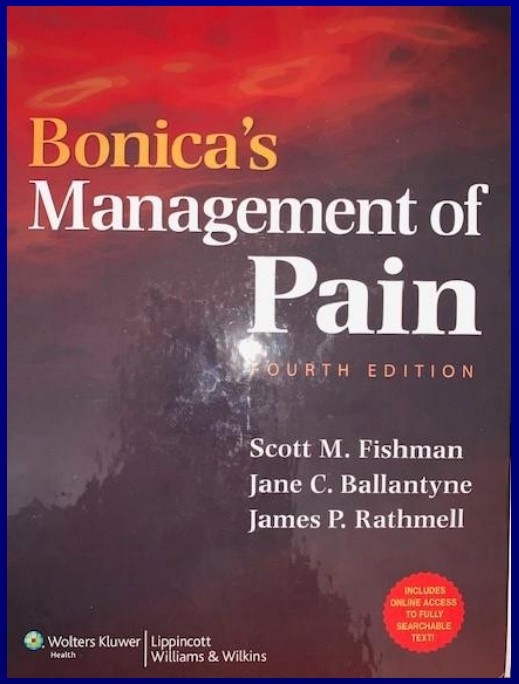
Both EMGs and NCSs are usually required for a clinical diagnosis of peripheral nervous system disorders. Performance of one type of testing does not eliminate the need for the other. The intensity and extent of testing with EMG and NCS are matters of clinical judgment developed after the initial pre-test evaluation, and later modified during the testing procedure.

Decisions to continue, modify or conclude a testing rely on knowledge of anatomy, physiology and neuromuscular diseases. Ongoing real-time assessment of data is required during the clinical diagnostic evaluation and especially during EMG examination.

Nerve conduction studies (NCS) are used to measure action potentials resulting from peripheral nerve stimulation which are recordable over the nerve or from an innervated muscle. With this technique, responses are measured between two sites of stimulation, or between a stimulus and a recording site.

Nerve conduction studies are of two general types: sensory and motor. Either surface or needle electrodes can be used to stimulate the nerve or record the response. Axonal damage or dysfunction

Textbook recommended by ABPMR, FSMB, ABPM



CHAPTER 18 ■ ELECTRODIAGNOSTIC EVALUATION OF ACUTE AND CHRONIC PAIN SYNDROMES

DOUGLAS G. CHANG AND ELAINE S. DATE

INTRODUCTION

Before a clinician can treat pain effectively, the utmost must be done to identify what condition is being treated, and identify what may be causing pain. For this purpose, electrodiagnostic studies are important in the evaluation of acute and chronic pain syndromes. They give valuable, quantitative information on the physiologic health and functioning of nerve and muscle. They help localize injuries, quantify the extent of injury, suggest age of injury, and give valuable prognostic information that can change treatment protocols. They can monitor interval progression. All of this complements the static, anatomic structural information provided by radiological imaging studies. In other words, radiological imaging can identify anatomy that may or may not be the cause of symptoms. Electrodiagnostic studies can quantify symptoms (e.g., show evidence of spinal nerve root compression) but cannot identify the anatomic cause (e.g., infection, tumor, or disk herniation). Together, electrodiagnostic and radiologic studies are extensions of the physical exam and serve to refine the differential diagnosis suggested by a clinical presentation.

Common reasons for ordering electrodiagnostic studies include symptomatic complaints (weakness, pain, numbness and/or tingling in an extremity) and physical examination findings (focal neurological deficits, absent tendon reflexes, strength or sensory losses). Typical clinical scenarios involve radiculopathies, entrapment syndromes, trauma, and metabolic pathology seen in diabetes and alcoholism. Other important scenarios include rheumatologic disease, neuromuscular disease, and various infectious and neoplastic neuropathies. Further details about these conditions can be found in several electrodiagnostic textbooks.[1,2,3,4,5,6]

Practically, electrodiagnostic studies should be thought of when the diagnosis is in doubt, either during the initial patient presentation or as the result of nonresponse to treatment. The studies can evaluate the possibility of additional lesions (e.g., concomitant nerve entrapment syndromes, peripheral neuropathies, and so-called "double crush syndromes"), be used to follow the interval progression of both operative and nonoperative treatments, and provide pre-operative baselines. The objectives of this chapter are to introduce basic principles of electrodiagnosis. Hopefully, this will provide information on when to order electrodiagnostic tests, and help interpret and utilize the resulting electrodiagnostic reports.

TERMINOLOGY

Electrodiagnostic studies involve two components: nerve conduction studies (NCS) and needle electromyography (EMG). Al

Indications	Limbs Studies by Needle EMG 95860-95864, 95867-95870, 95885-95887	Nerve Conduction Studies Total nerves Studied 95907-95913	Neuromuscular junction testing (Repetitive simulation 95937)
Carpal Tunnel unilateral	1	7	N/A
Carpal Tunnal bilateral	2	10	N/A
Radiculopathy	2	7	N/A
Mononeuropathy	2	8	N/A
Polyneuropathy/Mononeuropathy Multiplex	3	10	N/A
Myopathy	2	4	2
Motor Neuropathy (e.g., ALS)	4	6	2
Plexopathy	2	12	N/A
Neuromuscular Junction	2	4	3
Tarsal Tunnel Syndrome (unilateral)	1	8	N/A
Tarsal Tunnel Syndrome (bilateral)	2	11	N/A
Weakness, fatigue, cramps, or twitching (local)	2	7	2

Indications	Limbs Studied by Needle EMD 95860-95864, 95867-95870, 95885-95887	Nerve Conduction Studies Total nerves studied 95907-95913	Neuromuscualr Junction Testing (Repetitive simulation 95937)
Weakness, fatigue, cramps, or twitching(general)	4	8	2
Pain, numbness, or tingling (unilateral)	1	9	N/A
Pain numbness, or tingling (bilateral)	2	12	N/A

C. Electromyography

- Use EMG codes 95860-95864 and 95867-95870 when no nerve conduction studies (95907-95913) are performed on that day.
- Use 95885, 95886, and 95887 for EMG services when nerve conduction studies (95907-95913) are performed on the same day.
- To bill these codes, extremity muscles innervated by three nerves (for example, radial, ulnar, median, tibial, peroneal, femoral, not sub branches) or four spinal levels must be evaluated; a minimum of five muscles must have been studied.

Article Guidance

Article Text:

Coding Guidelines

A. Evaluation and Management (E&M)

- Usually an E&M service is included in the exam performed just prior to and during nerve conduction studies and/or electromyography. If the E&M service is a separate and identifiable service, the medical record must document medical necessity and the CPT code must be bill with a modifier 25.
- A clinical history from the referral source must indicate the need for testing. Such data containing pertinent clinical information must be attainable for review in instances where the need for a test may come under scrutiny. Absolute inclusive or exclusive criteria for performance of a diagnostic test are difficult to enumerate.

B. Nerve Conduction Studies

- The table below provides a reasonable maximum number of studies per diagnostic category necessary for a physician to arrive at a diagnosis in 90% of patients with that final diagnosis.
- The appropriate number of studies to be performed is left to the judgment of the physician performing the evaluation; however, in the small number of cases, which require testing in excess of the numbers listed in the table, the physician should be able to provide supplementary documentation to justify the additional testing.
- In some situations it may be necessary to test an asymptomatic contralateral limb to establish normative values for an individual patient. Documentation must support the medical necessity of the additional test.
- Codes 95907-95913 describe one or more nerve conduction studies. A single conduction test is defined as a sensory conduction test, a motor conduction test with or without an F wave test, or an H-reflex test. Each type of study (sensory, motor with or without F wave, H reflex) for each nerve is counted as a distinct study when determining the number of studies billed.
  Each type of study is counted only once when multiple sites on the same nerve are stimulated and recorded. The number of tests (sensory, motor with or without F wave, H reflex) per nerve should be added to determine the code to be billed.

Nerve conduction codes 95907-95913 had their Physician Supervision of Diagnostic Procedures Indicators adjusted to 7A effective 01/01/2013 (CR 8169). Therefore if authorized by state law Physical Therapists are allowed the technical portion and professional component of the test according to

Verification of the Chronic Pain Diagnosis

- 1. Detailed records compliant with OH state TDDD/HB 93 standard
- 2. Referral provider records (enclosed in the chart)
- 3. Imaging enclosed on the charts
- 4. Prescription Monitoring Program reports (OARRS) obtained on each visit proves narcotic prescriptions (indicated *only* for moderate to severe pain) for most patients by several independent providers prior to coming to our practice

providers and clearly documented on the charts. Most studies are performed for the pain in two or more extremities and most studies have a goal of documenting possible diagnosis of peripheral neuropathy since this is the most common referring diagnosis and evaluation request by the referring doctors in our practice.

According to the enclosed OH Local Coverage Article: Nerve Conduction Studies and Electromyography Coding and Billing (A54158) policy, page 3, Appendix J from 2013 CPT codebook such the diagnoses that our patient have require 12 nerve conduction studies, which is the most common test performed at our office.

COMPREHENSIVE PAIN MANAGEMENT INSTITUTE, LLC
5245 E. Main Street, Columbus, OH; 43213
Ph. 614-557-6075, F. 614-453-8222

The rationale for such testing includes the complexity of our patients as reflected by the diagnoses made by referring and CPMI providers, our individualized treatment programs (including the use of medications for neuropathic pain), and the resultant significant time spent directly one-on-one with patients which allow them to achieve an extraordinary level of function relative to managing their pain, all based on documented medical necessity (medical necessity form is used for each test).

Compliance with AANEM

- 1. Informed consent based on the AANEM guidelines
- 2. Medical necessity form for each test
- 3. Proper history documentation (initial, follow up evaluation, PADT, OARRS, etc.)
- 4. Referral provider information / impact of referral patterns
- 5. Full compliance confirmed by the experts (including the past president of AANEM)

GUIDELINES FOR ETHICAL BEHAVIOR RELATING TO CLINICAL PRACTICE ISSUES IN NEUROMUSCULAR AND ELECTRODIAGNOSTIC MEDICINE

NAOMI A. ABEL MD,[1] EDUARDO A. DE SOUSA MD, FAAN,[2] RAGHAV GOVINDARAJAN MD,[3] MATTHEW P. MAYER MD,[4] and DAVID A. SIMPSON DO, MS[5]

[1] Physical Medicine and Rehabilitation, Department of Neurosurgery & Brain Repair, University of South Florida, Tampa, Florida, USA
[2] Department of Neurology, University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma, USA
[3] Department of Neurology, University of Missouri, Columbia, Missouri, USA
[4] Department of Pediatric Rehabilitation Medicine, University of Missouri–Kansas City, Children's Mercy Kansas City, Kansas City, Missouri, USA
[5] MDA Clinic and ALS Center, Michigan Institute for Neurological Disorders, Farmington Hills, Michigan, USA

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ABSTRACT: The American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) developed guidelines to formalize the ethical standards that neuromuscular and electrodiagnostic (EDx) physicians should observe in their clinical and scientific activities. Neuromuscular and EDx medicine is a subspecialty of medicine that focuses on evaluation, diagnosis, and comprehensive medical management, including rehabilitation of individuals with neuromuscular disorders. Physicians working in this subspecialty focus on disorders of the motor unit, including muscle, neuromuscular junction, axon, plexus, nerve root, anterior horn cell, and the peripheral nerves (motor and sensory). The neuromuscular and EDx physician's goal is to diagnose and treat these conditions to mitigate their impact and improve the patient's quality of life. The guidelines are consistent with the Principles of Medical Ethics adopted by the American Medical Association and represent a revision of previous AANEM guidelines.

Muscle Nerve **52**: 1122–1129, 2015

THE PATIENT–PHYSICIAN RELATIONSHIP IN NEUROMUSCULAR AND ELECTRODIAGNOSTIC MEDICINE

The Patient–Physician Relationship. The relationship between the patient and the physician is a key component to assure that excellent care is provided. The quality of this relationship can impact not only the success of the outcome of the interaction between patient and physician, but also the outcome of the patient's treatment. The physician has a fiduciary duty to first safeguard the interests of the patient. The physician must practice competently, respect patient autonomy and confidentiality, maintain patient safety, and protect the patient's best interests.

Beginning and Ending the Relationship. The physician is free to decide whether to perform an EDx or neuromuscular evaluation on a particular patient. The physician should not decline the evaluation on the basis of the patient's race, color, religion, national origin, gender, disability, age, or other personal characteristics. The physician also should not decline an evaluation on the basis of the patient's known or suspected medical diagnosis. The physician should decline performance of the EDx or neuromuscular evaluation if he or she believes it to be unnecessary or not beneficial to the patient.

If possible, it is best for the EDx physician and the referring physician to concur on who should inform the patient (or designated surrogate) of the results of the EDx or neuromuscular evaluation. The physician should discuss with the patient the reason for the evaluation and the methods to be employed. The physician

Abbreviations: AANEM, American Association of Neuromuscular and Electrodiagnostic Medicine; EDx, electrodiagnostic; EMG, electromyogra-

responsibility for urgent care of the patient until an appropriate referral can be made.

Informed Consent in Clinical Evaluation. The physician must obtain valid verbal or written consent from the patient. When the patient cannot give consent or lacks decisional capacity, a verbal or written consent must be obtained from the patient's appropriate legally authorized representative (LAR), who acts as a surrogate decision-maker. If the LAR is unavailable and the situation is urgent, the physician may proceed without consent. The physician must disclose information that the average person would need to know to make an appropriate medical decision. This information must include the benefits and risks of the proposed tests and should include the costs of the proposed tests if the patient desires this information. If the patient is referred for evaluation of a painful symptom, the physician should explain that the EDx studies are directed toward evaluation of certain measurable peripheral nerve abnormalities, not whether pain is present or absent. The patient must give consent voluntarily. If reasonable explanation fails to elicit a patient's consent to carry out the EDx examination, the physician should not undertake the evaluation. The patient may withdraw a prior consent; if this occurs at any point during testing, the physician should not continue with the examination. Physicians must comply with applicable state and federal laws governing informed consent requirements.

Federal Food and Drug Administration (FDA) and institutional review board (IRB) rules should be followed when conducting experimental or investigational studies of procedures, pharmaceuticals, or medical devices that involve human subjects (see section "Clinical Research").

Patient Communication, Comfort, and Preparation. The physician has a duty to communicate with the patient. The physician should convey relevant information in terms the patient can understand and allow adequate opportunity for the patient to raise questions and discuss

Relationship"). Moreover, suggestions for changes in clinical management should generally be made to the referring physician rather than the patient, unless the referring physician has requested that the physician participate in the direct clinical management of the patient.

Medical Risk to the Physician. Physicians have needs and concerns that are relevant for ethical decision-making in the context of evaluation. At the same time, a physician should provide appropriate, compassionate care to all patients, including patients with infectious and other communicable diseases [e.g., human immunodeficiency virus (HIV) or antibiotic-resistant infections]. A physician should not deny care to a patient solely because of real or perceived medical risk to the physician. Physicians must utilize appropriate universal precautions during the examination of any patient to minimize their own medical risk.

Ethical Considerations and the Management of Neuromuscular Disease. Some neuromuscular disorders are progressive or debilitating and may impact a patient's autonomy or competence. Many neuromuscular disorders have limited treatments, which may lead patients to seek unproven interventions. Others may have effective but costly treatments that their insurance may not cover or which patients may not be able to afford. Still others are known to shorten a patient's life expectancy with the prospect of a challenging final few months of life, leading the patient to seek alternatives for end-of-life care. In addition, genetically diagnosed diseases may include issues that affect relatives and future decision-making and have social implications.

Discussion of Disease Implications. First and foremost, physicians must provide patients with their best diagnostic and management skills. They also have a duty to discuss openly with their patients the implications of their EDx diagnosis and related illnesses. This discussion may require a great deal of sensitivity and compassion on the

Comprehensive Pain Management Institute, LLC

Informed Consent for Nerve Conduction Study and/ or EMG testing

Patient's Name _____ Date _____

I hereby authorize Dr. Leon Margolin or Associates or Assistants of his choice at Comprehensive Pain Management Institute, LLC to perform upon me/the patient named above the following EMG/NCV(s)

Nerve Conduction Study and/ or EMG testing

PLEASE INFORM THE DOCTOR

- IF YOUR HAVE PACEMAKER OR DEEP BRAIN STIMULATOR
- IF YOU ARE OR COULD BE PREGNANT
- IF YOU HAVE TAKEN PLAVIX, COUMADIN, ANY OTHER BLOOD THINNER

Dr. Margolin has fully explained the nature and the purpose of this test and has also informed me of expected benefits and complications (from known and unknown causes), attendant discomforts and risks that may arise.

I have been given the opportunity to ask questions or request testing by an alternative provider, and all my questions have been answered fully and satisfactorily. All my questions about the charges for this test were answered. Dr. Margolin has fully explained to me that medical management including initiation or continuation of narcotic medications does not depend on my consent to this or any other procedure or test.

I was informed that scheduling EMG/NCV on the same day as the office visit may result in a substantial increase in the waiting time and was offered an alternative appointment for EMG/NCV only.

Needle EMG testing was offered and discussed with the patient. I explained that the needle EMG report testing is recommended for diagnosis of radiculopathy and better diagnosis of peripheral neuropathy.

I also explained that only diagnosis of "possible" / "cannot exclude" of the S1 level radiculopathy only, can be done without the needle study.

❑patient agreed ❑ patient refused ❑patient wants to reschedule the needle testing.

Patient's signature Date

Physician's signature Date

Patient Name: **INS:** **DOB:** **Date:**

NCV/EMG Clinical Necessity/Indication form

Right / Left / Bilateral Symptoms or Signs of:

1) Lumbar Radiculopathy

2) Carpal Tunnel Syndrome

3) Cubital Tunnel Syndrome (Ulnar Neuropathy)

4) Cervical Radiculopathy

5) Peripheral Neuropathy

6) Polyneyropathies

7) Myopathies

8) Diabetics with persistent or progressive symptoms

9) Dialysis patients or those considering dialysis.

10) Pain, numbness, paresthesia with or without weakness in the spine and upper or lower extremities

11) Other ❑Hepatitis (HBV, HCV), ❑Rheumatic disease (SLE, RA, Other_____) ❑ on statins
❑ History of Cancer (chemo / radiation therapy) ❑ Wrist numbness or pain

Bernard M. Abrams, MD
10701 Nall Ste 120
Overland Park, KS 66211
816-322-4834
Fax: 816-322-2005
Email: babrams@kc.rr.com

February 17, 2018

To whom it may concern:

Re: review of Electrodiagnostic procedures concerning Leon Margolin, M.D., PhD.

Task: I was asked to review Dr. Margolin's policy and procedures including informed consent, training of personnel in an entity doing business as CPMI.

Qualifications: I am Clinical Professor Emeritus, University of Missouri-Kansas City School of Medicine, Past President of the AANEM (then the AAEE), a six year member of the Board of Directors of the AANEM, Board Certified in EMG by the AANEM, author of numerous textbook chapters on Electrodiagnosis in major pain textbooks and have lectured dozens of times on Clinical Neurophysiology and its use in Pain Medicine.

Disclaimer: I have not requested nor have I been paid for rendering my opinion. I am not a colleague or social friend of Dr. Margolin.

Materials reviewed: Updated CPMI NCV EMG policy, NCV 2012 policy informed consent, Pain Medicine CME, CPMI informed consent and EMG paperwork, Staff education in service sessions, NCV technician certificates, AANEM informed consent policy, 5 outside billing and coding reviews, Ohio LCD Medicare policy and EMG CME and the CMPI NCV/EMG medical indications form.

Conclusions:
1. CPMI's informed consent is appropriate and based on the AANEM informed consent policy.
2. CPMI NCV EMG policy appropriately addresses documenting medical necessity.
3. The CMPI NCV/EMG medical indications form appropriately addresses documenting medical necessity.
4. The policy description of our scope of practice according to Ohio LCD is appropriate.
5. In pain medicine practice it is reasonable to use NCV/EMG to document organic pathology as required for proper narcotic medication/ pain program management.
6. The attached CMEs, outside reviews and staff education are appropriate.

Very truly yours,

Bernard M. Abrams, M.D.

Montefiore
THE UNIVERSITY HOSPITAL FOR
ALBERT EINSTEIN COLLEGE OF MEDICINE

March 27, 2018

To whom it May Concern:

Dr Leon margolin has asked me to review and comment upon the policies and procedures in his practice regarding neuromuscular electrodiagnostic (more commonly referred to as EMG) studies, their role in evaluating patients with chronic pain, and their appropriateness as part of patient care. I have reviewed these policies in detail.

I am a Board-certified physiatrist with more than 40 years of clinical experience, which has included performance of and interpretation of electrodiagnostic testing. I have several publications in this area as part of my Curriculum Vitae. As a clinician who sees many patients with chronic pain associated with motor and/or sensory symptoms in arms and legs, nerve conduction and needle electromyography are invaluable to objectively document the presence or absence of pathology involving the peripheral nervous system, including nerve root compression, plexus lesions, or peripheral neuropathies. In the case of patients with suspected cervical or lumbar disc herniations, these studies are complementary with MRI scans: the latter documents the anatomical location of the problem, while EMG clarifies its severity in terms of muscle denervation. It is entirely appropriate to utilize both of these diagnostic tests when evaluating patients with chronic pain, since they provide objective confirmation of the subjective symptoms of pain. A physician with thorough training in the performance and interpretation of nerve conduction/EMG studies, such as Dr margolin, provides valuable clinical data for such patients. I can attest to his competence in these areas since he did his residency training at Montefiore MedicalCenter, where I have been working for the past 21 years.

Yours truly,

Stanley F. Wainapel MD, MPH, Clinical Director, Department of Physical Medicine and Rehabilitation

Montefiore Medical Center

Unique features of our practice

- MD/PhD (implementations of additional methods, research / guidelines analysis)
- Double board certification (PM&R, Anesthesia Pain) – Most practices have a separate pain (medication /procedures) physician and a separate (PM&R or Neurology) NCV / EMG physician
- Additional certification the American Academy of Addiction Medicine, training / courses by AANEM and Radiology (MRI and X rays reading)
- Lab Director training and certification by CLIA / COLA

Unique features of our practice 2

- More than 30 publications (including a research manuscript), recent original study performed at the practice accepted for presentation at the national meeting, request for 2nd manuscript being processed
- Physician's Recognition Award from the American Medical Association (2008, 2014), Resident / Fellow Award from the American Society of Regional Anesthesia and Pain Medicine
- Two Certificates of Merit of the American College of Physicians, the Medical Society of Pennsylvania Award, the Pfizer Scholars in Pain Management Award , Patient's Choice Award (several years including 2019)
- Most Compassionate Physician Award (several years) and "Top Ten Physicians" Award in Pain Medicine (2014)
- America's Most Honored Professionals Award (2017, 2018, 2019) 1% percent ranking

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Letter of Acceptance: AAFP Poster Presentation for FMX

Входящие x

Lisa Leader ср, 1 мая, 11:43 (1 день на

кому: LEON3087@GMAIL.COM

Hello Leon,

Congratulations! Your poster entitled "Correlation between NARX Score and food addictive behavioral patterns in chronic pain patients." has been accepted for presentation at the Philadelphia. Attached you will find two important documents:

1. Congratulations Letter including information on registration, housing, size of poster display area, and poster set up/dismantling.
2. Terms of Agreement which **must be completed and returned to me by July 31.**

If you have additional questions, please feel free to reach out to me at 800 274-2237 x 6098.

Best Regards,
Lisa Leader

Lisa Leader I CME Program Specialist
Continuing Medical Education Division
American Academy of Family Physicians
11400 Tomahawk Creek Parkway, Leawood, KS 66211
Office: (913) 906-6000, ext 6098
lleader@aafp.org

2 прикрепленных файла

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Unique features of our practice 3

- CPMI a solo practice all procedures performed and billed by the same physician

- Tertiary referral based practice with a high percent of high risk patients (based on the OARRS, PADT, SOAPP-R, COMM, ORT and other tools (i.e. NARX score)

- In compliance with the CDC and SMBO regulations, since inception in 2011, more than 2000 patients were discharged from CPMI (non-adherence with the patient contract / aberrant behavior)

Unique features of our practice 4

- High discharge rate and high demand for evaluation of the high risk patients creates a high turnover and high new evaluations rate
- Many new evaluations require NCV / EMG testing as per guidelines
- As an independent practice (not affiliated with a physician group or hospital or provider network) we get higher rate of referrals for difficult patients (risk assessed with the criteria mentioned above) that other physician groups unable or unwilling to handle

FEDERATION OF STATE MEDICAL BOARDS

Guidelines for the Chronic Use of Opioid Analgesics

Adopted as policy by the Federation of State Medical Boards
April 2017

INTRODUCTION

In April 2015, the Federation of State Medical Boards (FSMB) Chair, J. Daniel Gifford, MD, FACP, appointed the Workgroup on FSMB's *Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain* to review the current science for treating chronic pain with opioid analgesics and to revise the Model Policy as appropriate.

To accomplish this charge, the workgroup conducted a thorough review and analysis of FSMB's existing policy document and other state and federal policies on the prescribing of opioids in the treatment of pain, including the March 2016 *CDC Guideline for Prescribing Opioids for Chronic Pain* (https://www.cdc.gov/drugoverdose/prescribing/guideline.html)

In updating its existing policy, the FSMB sought input from a diverse group of medical and policy stakeholders that ranged from experts in pain medicine and addiction to government officials and other thought leaders. Over the course of the last 12 months, the workgroup met on several occasions to examine and explore the key elements required to ensure FSMB's policy document remains relevant and is sufficiently comprehensive to

FSMB opioid policy requirements

- Documentation of the medical indications for opioid prescriptions / organic pathology
- Increased requirements for the patients on opioids referred by other clinicians / started on high doses of opioids by referring provider (the majority of patients in our practice)

including addiction and overdose. Additionally, untreated depression can interfere with the

The patient evaluation may include information from family members and/or significant others[10-11,31-32]. It is strongly recommended that the state prescription drug monitoring program (PDMP) be consulted prior to initiating opioid therapy and at appropriate intervals thereafter to determine whether the patient is receiving prescriptions from any other clinicians, and the results obtained from the PDMP should be reviewed.

In working with a patient who is taking opioids prescribed by another clinician—particularly a patient on high doses—the evaluation and risk stratification assume even greater importance[9-11]. Therefore, to ensure a smooth transition of care, clinicians are encouraged to collaborate with the primary prescriber.

Caution should be used with the administration of chronic opioids in women of childbearing age, as chronic opioid therapy during pregnancy increases risk of harm to the newborn. Opioids should be administered with caution in breastfeeding women, as some opioids may be transferred to the baby in breast milk. When chronic opioid therapy is used for an elderly patient, clinicians should carefully consider the initial dose, titrating slowly upwards if necessary, using a longer dosing interval, and monitoring more frequently. Patients at risk for sleep disordered breathing are at increased risk for harm with the use of chronic opioid therapy. Clinicians should consider the use of a screening tool for obstructive sleep apnea and refer patients for proper evaluation and treatment when indicated.

The patient evaluation should include most of the following elements:

- Post-traumatic stress disorder (PTSD)
- Medical indication(s) for use of opioids
- Review of the PDMP results
- Obtain consultation with other clinicians when applicable
- Urine, blood or other types of biological samples and diagnostic markers

Development of a Treatment Plan and Goals

The goals of pain treatment include reasonably attainable improvement in pain to decrease suffering and to increase function; improvement in pain-associated symptoms such as sleep disturbance, depression, and anxiety; screening for side effects of treatment; and avoidance of unnecessary or excessive use of medications[2,4]. There should be a balance between monitoring for efficacy and side effects with the use of medications for the shortest duration appropriate.

The treatment plan and goals should be established as early as possible in the treatment process and revisited regularly, so as to provide clear-cut, individualized objectives to guide the choice of therapies[22] for both the clinician and the patient.

The treatment plan may contain information supporting the selection of therapies, both pharmacologic (medications other than opioids to include anti-inflammatories

NCV required for the State of OH compliance

- TDDD license (in addition to regular license) based on the HB 93 law
- SMBO/BoPh requirement for organic pathology documentation
- Requires onsite audits
- OH is in the epicenter of the opioid epidemic / high risk patients

Initial Evaluation
4731-21-02, O.A.C.

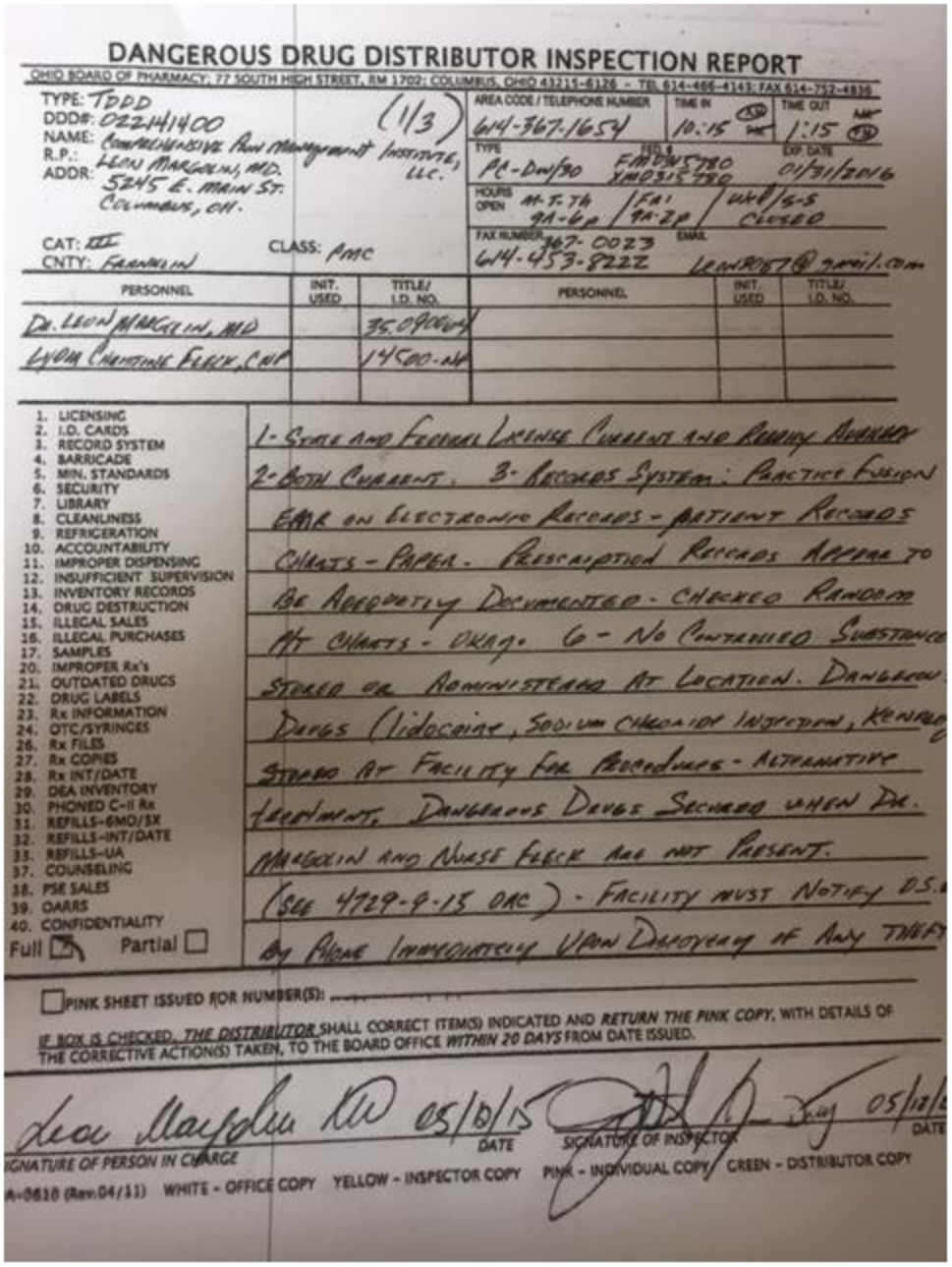
- Patient history, including alcohol & substance abuse
- Assessment of pain impact on function
- Review of previous studies & therapies
- Assessment of coexisting illnesses
- Physical exam

Medical Diagnosis

Document presence of chronic pain

Identify signs, symptoms & causes

- Nature of underlying disease
- Pain mechanism



DANGEROUS DRUG DISTRIBUTOR INSPECTION REPORT

OHIO BOARD OF PHARMACY; 77 SOUTH HIGH STREET, RM 3702; COLUMBUS, OHIO 43215-6126 - TEL 614-466-4143; FAX 614-752-4836

TYPE: TDDD
DDD#: 02241400 (1/3)
NAME: Comprehensive Pain Management Institute, LLC.
R.P.: Leon Margolin, MD.
ADDR: 5245 E. Main St. Columbus, OH.
CAT: III
CNTY: Franklin
CLASS: AMC

AREA CODE / TELEPHONE NUMBER: 614-367-1654
TIME IN: 10:15 AM/PM
TIME OUT: 1:15 AM/PM
TYPE: PC-DW/30
FED. & STATE: FM0345780 XM0345780
EXP. DATE: 01/31/2016
HOURS OPEN: M-T-Th 9A-6P / FA! 9A-2P / W-S CLOSED
FAX NUMBER: 367-0023
EMAIL: 614-453-8222 LEONMD87@gmail.com

PERSONNEL	INIT. USED	TITLE/ I.D. NO.	PERSONNEL	INIT. USED	TITLE/ I.D. NO.
Dr. Leon Margolin, MD		35.09[illegible]			
Lyon Christine Fleck, CNP		14500-NP			

1. LICENSING
2. I.D. CARDS
3. RECORD SYSTEM
4. BARRICADE
5. MIN. STANDARDS
6. SECURITY
7. LIBRARY
8. CLEANLINESS
9. REFRIGERATION
10. ACCOUNTABILITY
11. IMPROPER DISPENSING
12. INSUFFICIENT SUPERVISION
13. INVENTORY RECORDS
14. DRUG DESTRUCTION
15. ILLEGAL SALES
16. ILLEGAL PURCHASES
17. SAMPLES
20. IMPROPER Rx's
21. OUTDATED DRUGS
22. DRUG LABELS
23. Rx INFORMATION
24. OTC/SYRINGES
26. Rx FILES
27. Rx COPIES
28. Rx INT/DATE
29. DEA INVENTORY
30. PHONED C-II Rx
31. REFILLS-6MO/5X
32. REFILLS-INT/DATE
33. REFILLS-UA
37. COUNSELING
38. PSE SALES
39. OARRS
40. CONFIDENTIALITY

Full ☑ Partial ☐

1- State and Federal License Current and Readily Available
2- Both Current. 3- Records System: Practice Fusion EMR on Electronic Records - Patient Records Charts - Paper. Prescription Records Appear to Be Properly Documented - Checked Randomly 4- Charts - Okay. 6- No Controlled Substances Stored or Administered At Location. Dangerous Drugs (Lidocaine, 500 vm Checked for Inspection, Kenalog Stored At Facility for Procedures - Alternative Treatments. Dangerous Drugs Secured when Dr. Margolin and Nurse Fleck are not Present. (See 4729-9-13 OAC) - Facility must Notify D.S. by Phone Immediately Upon Discovery of Any Theft

☐ PINK SHEET ISSUED FOR NUMBER(S): ____

IF BOX IS CHECKED, THE DISTRIBUTOR SHALL CORRECT ITEM(S) INDICATED AND RETURN THE PINK COPY, WITH DETAILS OF THE CORRECTIVE ACTION(S) TAKEN, TO THE BOARD OFFICE WITHIN 20 DAYS FROM DATE ISSUED.

Leon Margolin MD 05/01/15
SIGNATURE OF PERSON IN CHARGE — DATE

[illegible] 05/12/[illegible]
SIGNATURE OF INSPECTOR — DATE

A-0610 (Rev.04/11) WHITE - OFFICE COPY YELLOW - INSPECTOR COPY PINK - INDIVIDUAL COPY GREEN - DISTRIBUTOR COPY

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

COMMUNICATION LOG

PATIENT NAME: STATE of OH TOOD compliance audit memo

DATE/TIME	NOTES
05/12/15	Inspectors reviewed prescription storage area & safes. OARRS policy discussed.
	Inspectors spent about an hour reviewing patient charts. We discussed guidelines for treatment, role of injection for alternative treatments.
	Reviewed treating, prior records, new exams of informed consent & medical records forms, initial & f/u notes, PADT & flow chart forms.
	Need to document pathology discussed. On site NCM, EMG lab & POC testing lab inspected.
	The charts & the policies found compliant and adequately documented.
	Leon Margolin MD

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

COMMUNICATION LOG

PATIENT NAME: Sayers Dan DOB 09/08/42

DATE/TIME	NOTES
05/12/15	This chart has been
	viewed by Inspectors
	during State of OH
	TDDD compliance audit
	Leon Margolin MD

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

COMMUNICATION LOG

PATIENT NAME: Bradshaw Debra 05/01/56

DATE/TIME	NOTES
05/12/15	This chart was reviewed during the state of the board of Pharmacy 100% compliance audit Leon Margolin MD

DANGEROUS DRUG DISTRIBUTOR INSPECTION REPORT

OHIO BOARD OF PHARMACY; 77 SOUTH HIGH STREET, RM 1702; COLUMBUS, OHIO 43215-6126 – TEL 614-466-4143; FAX 614-752-4836

TYPE: PMC Pg 1 of 3
DDD#: 02-2141400
NAME: Comprehensive Pain Management Institute, LLC
R.P.: Leon Margolin, M.D.
ADDR: 1120 Polaris Parkway, Suite 201
Columbus, Ohio 43240
CAT: III CLASS: PMC
CNTY: Delaware

AREA CODE / TELEPHONE NUMBER: 614-557-6075
TIME IN: 1:35 P.M.
TIME OUT:
TYPE: Practitioner ED. #: EXP. DATE: FM0515780 1/31/13
HOURS OPEN: M, T, Th-F 9a-5:30p; Closed Wed
FAX NUMBER: 614-545-0474
EMAIL:

PERSONNEL	INIT. USED	TITLE/ I.D. NO.
Leon Margolin, MD		35.090064

PERSONNEL	INIT. USED	TITLE/ I.D. NO.

1. LICENSING
2. I.D. CARDS
3. RECORD SYSTEM
4. BARRICADE
5. MIN. STANDARDS
6. SECURITY
7. LIBRARY
8. CLEANLINESS
9. REFRIGERATION
10. ACCOUNTABILITY
11. IMPROPER DISPENSING
12. INSUFFICIENT SUPERVISION
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17. SAMPLES
20. IMPROPER Rx's
21. OUTDATED DRUGS
22. DRUG LABELS
23. Rx INFORMATION
24. OTC/SYRINGES
26. Rx FILES
27. Rx COPIES
28. Rx INT/DATE
29. DEA INVENTORY
30. PHONED C-II Rx
31. REFILLS-6MO/5X
32. REFILLS-INT/DATE
33. REFILLS-UA
37. COUNSELING
38. PSE SALES
39. OARRS
40. CONFIDENTIALITY

Full ☒ Partial ☐

1) New PMC license delivered to Dr. Leon Margolin on today's date. Dr. Margolin provided State of Ohio Certificate # 1930626 as articles of organization LLC. Dr. Leon Margolin signed ownership form. attached.

2) I.D. Card - Valid and on person

3) Dr. Margolin uses paper patient charts. Prescriptions records are adequately documented.

6) No controlled substances or dangerous drugs are stored or administered to patients. Dr. Margolin does not give or store drug samples at locations.

☐ PINK SHEET ISSUED FOR NUMBER(S):

IF BOX IS CHECKED, *THE DISTRIBUTOR* SHALL CORRECT ITEM(S) INDICATED AND *RETURN THE PINK COPY*, WITH DETAILS OF THE CORRECTIVE ACTION(S) TAKEN, TO THE BOARD OFFICE *WITHIN 20 DAYS* FROM DATE ISSUED.

Leon Margolin 08/31/11
SIGNATURE OF PERSON IN CHARGE DATE

SIGNATURE OF INSPECTOR 8/31/11
DATE

PHA-0010 (Rev.04/11) WHITE - OFFICE COPY YELLOW - INSPECTOR COPY PINK - INDIVIDUAL COPY GREEN - DISTRIBUTOR COPY

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

COMMUNICATION LOG

PATIENT NAME: HB-93 T088 License Audit memo

DATE/TIME	NOTES
08/31/11	Inspector requested to review radiology charts to document compliance.
	We reviewed & discussed: Patient contract, Consent for Treatment, Initial & follow up evaluation form, PADT form, Prescription forms, Injection reports & consent forms, UDT / urine drug screens with or without EKG needle exams, MRI/EMG report addendum forms.
	I explained the increase in the high risk patient population, the inspector complimented on the correct documentation necessary for proper narcotic prescription & dynamic pain topic discussion as required by the medical and state guidelines to comply with the HB 93 T088 license requirements.
	I explained that all the pts seen by referral only. Previous records for referral for this review.
	Records found compliant and adequately documented (report enclosed)
	Leon Margolin MD

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

dith Ackley
.0-23-1941
ef Dr Shabsigh
Medicare

08/31/11

COMMUNICATION LOG

DATE/TIME	NOTES
	This chart was reviewed and discussed with the inspector during the mandatory 1000 MC license audit by the state OIT (based on the HB 93 law). The chart was found fully compliant. Leon Margolin MD

LEON MARGOLIN, MD PhD
Comprehensive Pain Management Institute

Hubbard, Janene
12-24-1968
Dr Millick
Medicare 08/31/11

COMMUNICATION LOG

DATE/TIME	NOTES
	This chart was viewed and discussed with the Inspector during the mandatory state of OH + Fernandl distributor DMC license audit (based on the recent HB 93 law). The chart found to be in full compliance.
	Leon Margolin MD

Catch 22

- NCV tests required for the TDDD / HB 93 State of OH compliance
- Noncompliance with HB 93 may result in license revocation, $5000 a day fine and even criminal charges
- Despite state mandates, federal agencies raise concerns regarding medical necessity of tests

Ohio – Epicenter of Opioid Epidemic

- 172,000 people died in 2017 in US;
- **Every Day**: 5,800 individuals misuse opioid prescription for the fist time
- **Every Day**: 1,000 individuals treated in the emergency for prescription opioid misuse
- Our practice is in the forefront of the opioid epidemic
- High incidence of high risk patient/ risk of overdose, withdrawal, diversion, aggression
- Proper testing/organic pathology documentation is crucial

McMAHON PUBLISHING

The most-read pain publication in the United States

PAIN MEDICINE NEWS

THE INDEPENDENT MONTHLY NEWSPAPER FOR MANAGING PAIN

PainMedicineNews.com • APRIL 2019 • Volume 17 Number 4

PRIMARY CARE

Rural NPs Drive Growth In Primary Care

The number of nurse practitioners (NPs) in primary care practices grew substantially from 2008 to 2016, from 17.6% and 15.9% in rural and nonrural practices to 25.2% and 23.0%, respectively.

States with full scope of practice laws have the highest percentages of practicing NPs, but growth was fastest in states with reduced and restricted scopes of practice. The research was published in *Health Affairs* (2018;37[6]:908-914).

"NPs now constitute about 25% of primary care providers overall, and as much as 45% of primary care providers in rural areas in full scope of practice states," said Linda H. Aiken, PhD, RN, a professor and the director of the Center for Health Outcomes and Policy Research at the University of Per
Philadelphia.

Opioid Overdose Now Leads to More Deaths Than Motor Vehicle Accidents

Americans are now more likely to die from an accidental opioid overdose than from a motor vehicle accident, according to the annual Odds of Dying report by the National Safety Council (NSC), released in January.

The Odds of Dying report is a reanalysis of the mortality data collected by the National Center for Health Statistics. The NSC, a nonprofit organization focused on lowering the number of preventable deaths, publishes the report "to provide people the information they need to know to make better, safer, more logical decisions," said Ken Kolosh,

Very High Cost of the Epidemic

- More than 500 billion cost nationwide
- Denial of proper testing necessary for organic pathology documentation puts patient at risk
- It is also “save a penny – loose a dollar” approach because of extremely high costs of noncompliance

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Strategy to Combat Opioid Abuse, Misuse, and Overdose

A Framework Based on the Five Point Strategy

Confidential and part of settlement discussions governed by Fed. R. Evid. 408. Nothing in this presentation shall be construed as intending to waive or waiving otherwise applicable attorney-client or work product privileges.

"The five-point HHS strategy to end the opioid crisis, unveiled under President Trump in 2017, uses the best science and evidence to directly address this public health emergency. Now, HHS is expanding the scope and improving the effectiveness of the strategy. The dedicated men and women of HHS will continue to support communities and families across America until, together, we have brought an end to this crisis."

Programs (PDMP) that are accessible by providers (prescribers and pharmacies) across state lines and integrated into the electronic health record.

BETTER PAIN MANAGEMENT

Advance the practice of pain management to enable access to high-quality, evidence-based pain care that reduces the burden of pain for individuals, families, and society while also reducing the inappropriate use of opioids and opioid-related harms.

- Provide prescribers with actionable information on the appropriate use of opioids and other pain treatment modalities, such as the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain, which also ensure patients pain management needs are met.
- Develop evidence-based guidance on appropriate management of acute pain including non-opioid approaches and, when appropriate, short-term opioid management.
- Develop further evidence-based guidance on the management of chronic pain, including non-opioid approaches, pre/peri-operative treatment, and when appropriate, opioid management.
- Develop payment policies and other incentives to encourage best practices for the appropriate prescribing of opioids and the use of a full range of non-opioid pain treatments.
- Develop regulatory strategies, guidance, and policies to promote the appropriate use of opioids, including professional and patient labeling, and packaging at the time of marketing approval and in the post-marketing period.
- Assist states to monitor and support best practices by providers, including through the use of comprehensive prescription drug monitoring programs, other data integration mechanisms across states, and clinical decision support in electronic health records.
- Encourage the use of multidisciplinary team models for the management of pain.

Comprehensive Pain Management

Show all data where the Procedure Code is between 95885,95913
and the Date From is between 1/1/2015, 12/31/2015

Total *

Procedure Code		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total Units
95885	EMG - 1-4 MUSCLES '	5	5	0	1	4	0	2	2	7	14	11	6	57
95886	EMG - 5+ MUSCLES \	9	6	11	8	2	4	1	4	4	52	70	102	273
95907	NCS 1-2	0	0	1	0	0	0	0	0	0	0	0	0	1
95909	NCS 5-6	0	0	3	1	0	9	27	33	17	3	5	0	98
95910	NCS 7-8	0	0	1	0	0	0	0	0	0	0	0	0	1
95911	NCS 9-10	0	1	1	0	1	1	0	0	1	0	0	0	5
95912	NCS 11-12	120	114	107	77	96	76	83	92	59	129	132	164	1,249
95913	NCS 13+	70	84	101	72	84	44	30	26	28	54	9	1	603
	Report Totals:	**204**	**210**	**225**	**159**	**187**	**134**	**143**	**157**	**116**	**252**	**227**	**273**	**2,287**

Printed on: 3/8/2019 1:36:20 PM

Billing patterns 2015

- 57+275=330 needle examinations
- 1+98+1+5+1249+603=1957 NCV
- 330/1957=16.9% of tests with the needle
- The percent of needle examination related to the higher per cent of high risk (including Medicaid HMO patients with poor cooperation)
- NCV even without EMG is valuable and necessary to document organic pathology within the framework of Pain Medicine
- Contemporary documentation / expert opinion support (AANEM, ABPMR, Billing and coding)

2015 Billing continued

- As per CPMI policy and consent (based on AANEM) needle examination provides additional information
- Practice actually gets additional reimbursement for the separate needle code (there is no financial incentive to avoid needle EMG test)
- Dr. Margolin is always on premises during examination

form is used for each test).

Comprehensive Evaluation: A detailed medical necessity form based on the AANEM and OH Local Coverage Article: Nerve Conduction Studies and Electromyography Coding and Billing (A54158) policy definitions of Medical necessity will be filled out prior to each test.

CPMI performs a comprehensive evaluation including detailed history, physical examination and past medical history and prior medical records review.

Frequency of testing: Frequency of testing is defined based on the results of a detailed clinical evaluation. Such evaluation is repeated and documented prior to the decision to repeat the NCV or EMG study. Most common indication in our practice to repetition of the test is chronic moderate to severe pain and or numbness in neck, back and extremities (this documented by the patient in the intake history and by the staff using the SOAP note, VAS, PADT and other tools).

Written Consent: All patients will be offered a written consent for the test (enclosed) based on the ethical guidance of the AANEM (enclosed). Risk and benefits of the test are explained to the patient and documented in the consent form. Based on the level of patient tolerance to the test and the clinical evaluation, patient may undergo separate studies of the upper and lower extremities or a combined study.

Needle Examination: CPMI offered an option of needle examination to every patient but respects patient right to refuse this invasive test (that may include 6-12 needle sticks) as per the ethical guidance of the AANEM. The benefits of the needle examination explained to each patient.

NCV/EMG results incorporated in the treatment plan: All NCV/EMG reports are read by Dr. Margolin. The results are used for the use of medications for neuropathic pain (most common are Gabapentin, Lyrica, compounding medications) and other pain treatment modalities.

In order to avoid prescribing pain medications based on the subjective report of pain alone, the accepted guidelines encourage a thorough evaluation (such as NCV/EMG) and documentation of the underlying pathology (such as peripheral neuropathy or radiculopathy) before prescribing pain medications.

Procedure Code Units by Month

Comprehensive Pain Management

Show all data where the Procedure Code is between 95885,95913
and the Date From is between 1/1/2016, 12/31/2016

Total *

Procedure Code	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total Units
95885 EMG - 1-4 MUSCLES	10	7	15	18	13	9	4	1	2	2	4	17	102
95886 EMG - 5+ MUSCLES V	85	109	54	57	58	50	55	25	74	20	43	53	683
95908 NCS 3-4	0	0	0	0	0	0	0	0	0	0	1	0	1
95909 NCS 5-6	0	0	2	0	2	1	0	0	0	0	0	0	5
95910 NCS 7-8	0	0	0	0	0	0	1	0	0	0	0	0	1
95911 NCS 9-10	0	0	1	0	0	0	0	0	0	0	0	0	1
95912 NCS 11-12	125	154	94	105	96	105	81	43	106	45	92	105	1,151
Report Totals:	**220**	**270**	**166**	**180**	**169**	**165**	**141**	**69**	**182**	**67**	**140**	**175**	**1,944**

Billing patterns 2016

- 102+683=783 needle examinations
- 1+5+1+1+1,151=1,160 NCV
- 785/1,160=**67.2**% of tests with the needle
- The percent of needle EMG testing has increased almost 4 times in 2016 comparison to 2015
- This proves implementation the practice NCV / EMG policy we reviewed in compliance with the AANEM and ABPMR guidelines

Procedure Code Units by Month

Comprehensive Pain Management

Show all data where the Procedure Code is between 95885,95913
and the Date From is between 3/1/2017, 2/28/2018

Procedure Code	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total Units
95885 EMG - 1-4 MUSCLES '	18	0	35	15	15	22	22	21	17	18	26	9	218
95886 EMG - 5+ MUSCLES \	22	0	30	10	17	17	14	11	13	6	17	4	161
95909 NCS 5-6	0	0	0	0	0	1	0	0	0	0	2	2	5
95910 NCS 7-8	0	0	1	1	0	0	1	0	0	0	1	0	4
95912 NCS 11-12	44	1	69	21	33	41	38	31	33	25	46	14	396
Report Totals:	**84**	**1**	**135**	**47**	**65**	**81**	**75**	**63**	**63**	**49**	**92**	**29**	**784**

Billing patterns 2017 - Feb 2018

- 161+218=379 needle examinations
- 5+4+396=405
- 379/ 405 = **95.7**% of tests with the needle
- Almost all electro-diagnostic tests were performed with the needle examination for over 14 months prior to the CID
- Clear indication that practice has no intention to avoid performance of needle examinations

ABPMR analysis

- ABPMR is references in the LCD / National certifying body
- Maintenance of Certification / Research (PIP) project
- All the charts in the CID analyzed by the ABPMR expert panel
- Rigorous statistical analysis applied
- Two full professors (one from the AANEM, one from ABPMR) recommended the project

ABPMR analysis conclusions

- Strong evidence for the medical necessity for NCV / EMG (with or without the needle) for the charts in the sample
- Clear NCV / EMG (with or without the needle) testing impact on the pain reduction and functional improvement
- Full compliance with the LCD / AANEM / ABPMR guidelines
- Study recommended for the third party payers

from the ABPMR
American Board of Physical Medicine and Rehabilitation

Thursday, December 13, 2018

Dr Margolin:

Congratulations! Your Practice Improvement Project (PIP) has been accepted for MOC Part IV credit. Your MOC Homepage will be updated to reflect this acceptance within 2 business days.
Final comments from your reviewer may be available by logging in to your account.

Questions? Please contact our MOC team at moc@abpmr.org or (507) 282-1776, menu option 3.

American Board of Physical Medicine and Rehabilitation
3015 Allegro Park Lane SW
Rochester MN 55902-4139
507-282-1776 / Fax 507-282-9242

---------- Forwarded message ---------
От: **Shelly Walker** <swalker@abpmr.org>
Date: ср, 3 апр. 2019 г. в 15:55
Subject: RE: ABPMR MOC PIP addendum files attached
To: leon3087@gmail.com <leon3087@gmail.com>

Dr Margolin,

Thank you for the submission of your Practice Improvement Project and additional materials you've attached. Well done!

Kind Regards,

Shelly Walker | Maintenance of Certification Manager
American Board of Physical Medicine and Rehabilitation
Ph: 507.282.1776 Ext 1742
swalker@abpmr.org | www.abpmr.org

After review of the NCV studies and the protocols of our practice, ABPMR reported high level of compliance with the LCD and AANEM guidelines

The number of NCV/EMG tests based on the enclosed CPMI NCV/EMG policy and OH local coverage determination (A54158). All patient had a comprehensive evaluation including initial, follow up evaluation forms, PADT forms enclosed and extensive review of OARRS repots, offered a written consent based on the AANEM guidelines with a detailed explanations of the risk and benefits of the tests. NCV are reviewed and incorporated in the treatment plan.

The most commonly tested nerves in the upper extremities were sensory ulnar, median and radial studies, motor median, ulnar, radial and in selected cased Axillary studies with Median and Ulnar F waves. For the low extremities the studies included sensory Sural, Superior Peroneal, Motor studies included Common Peroneal, Tibial nerves and Common Peroneal and Tibial nerve; F waves and H reflex studies selected based on the comprehensive assessment results. The needle examination typically included (UE) Cervical Paraspinals, Deltoid, Biceps, Extensor Carpi Radialis, Triceps, Flexor Carpi Radialis, APB muscle, (LE) Lumbar Paraspinals, Vastus medialis, Extensor Hallucis Longus, Biceps Femoris, Peroneus Longus, Medial Gastrocnemius, the studies selected based on the comprehensive assessment result.

Between 2011-2015 as a result of regulatory changes in the state of Ohio (including HB 93 law), CPMI received a high number of referral/evaluation requests for high risk challenging patient population. Many of these chronic pain patients seen by the CPMI suffer from anxiety and depression, and/or drug seeking behavior and had a poor tolerance of the NCV/EMG testing and poor cooperation with the test, especially with the needle part of the test (EMG), (this part performed with inserting EMG needle in 6-12 sites) and frequently refused by the challenging patient population. All the patients were offered the enclosed written consent based on the enclosed AANEM guidelines.

Dr. Margolin maintains certification by the ABPM&R (that includes NCV and EMG training) in addition to the Pain Medicine certification and has completed a large number of the relevant CMEs (examples attached). CPMI demonstrated a high level of compliance with the AANEM guidelines, OH Local Coverage Determination and state and national guidelines as reflected by the attached CPMI policies and paperwork (i.e. NCV EMG forms, initial follow up evaluation forms and PADT forms).

ABPMR took a position that not performing the NCV tests with or without the needle could put our practice in noncompliance with the state requirements and professional guidelines

What do you want to improve? Look for inefficiencies, annoyances, or safety issues. Consider complex issues, but focus on simple solutions.

Is there a problem that has led you to test the impact of the NCV with or without EMG. Those without testing do worse for example--

Re(Comment): Can you clarify the problem--is it incomplete evaluations that do not include EMG/NCS and poor outcomes prior to your implementation ?
Answer: NCV and EMG testing is an extension of PMR examination (please review medical necessity below), it's important to show the impact of the test on the program outcomes.frequently pain management patients are not fully cooperative with the full test (please see below) and the goal is to test the impart of the NCV with or without EMG.

"Many of these chronic pain patients seen by the CPMI suffer from anxiety and depression, and/or drug seeking behavior and had a poor tolerance of the NCV/EMG testing and poor cooperation with the test, especially with the needle part of the test (EMG), (this part performed with inserting EMG needle in 6-12 sites) and frequently refused by the challenging patient population. All the patients were offered the enclosed (e mailed to Kendell) written consent based on the enclosed AANEM guidelines."

All the patients in the study were referred to us after the opioid medications have been started by the previous provider (typically PCP), under the circumstances we could not wave a necessary test for research purposes to maintain proper Ohio state (TDDD HB 93) compliance. That's why there no controls without NCV/EMG. We did internal controls patients with only NCV, patients who got different degrees of functional improvement and pain reduction. That's the best ethical set up for the study we can create.

ABPMR reported high cost efficiency and cost savings for the third party payers with our protocol

the Pain Medicine certification and has completed a large number of the relevant CMEs (examples attached). CPMI demonstrated a high level of compliance with the AANEM guidelines, OH Local Coverage Determination and state and national guidelines as reflected by the attached CPMI policies and paperwork (i.e. NCV EMG forms, initial follow up evaluation forms and PADT forms).

Cost Efficiency of the Testing: The cost of opioid epidemic is more than 55 billion dollars a year and keeps rising annually. Pain Management programs like our practice that carefully screen and test patient to properly document organic pathology and utilize alternative treatments, careful monitoring and SBIRT approach not only prevent significant morbidity and mortality, but save very significant costs to the healthcare system.
Insufficient testing, can potentially result in either prescribing opioid medications to not appropriate candidates that can potentially overdose or divert medications to other people, or not prescribing

appropriate pain medications to patients who may look for alternatives “on the street” with significant risks or morbidity and mortality. The host of hospitalization including ER, inpatient care, ICU, detoxification and maintenance programs is astronomic and can be reduced by patient screening and testing including NCV/EMG testing and other testing.
Our practice performs the NCV/EMG testing and other testing for a fraction of the cost charged by main hospitals in the area including the Ohio State University clinic.

B) What data (objective measurements) do you have that supports this as a problem?

Review your records or begin tracking how often the issue is occurring and under what conditions.

Montefiore
THE UNIVERSITY HOSPITAL FOR
ALBERT EINSTEIN COLLEGE OF MEDICINE

November 14, 2018

Dear Dr Margolin,

I have reviewed your study on the role of neuromuscular electrodiagnostic testing (including nerve conduction studies and needle electromyography) in the context of your chronic pain practice, found its methodology to be well considered, and its positive impact on clinical outcome provocative and quite compelling. I commend you for making a significant contribution to the specialty area of chronic pain management. These findings would likely be of considerable interest to physiatrists, other specialists treating chronic pain patients, and to the third party payors responsible for authorizing payment for electrodiagnostic testing.

Yours truly,

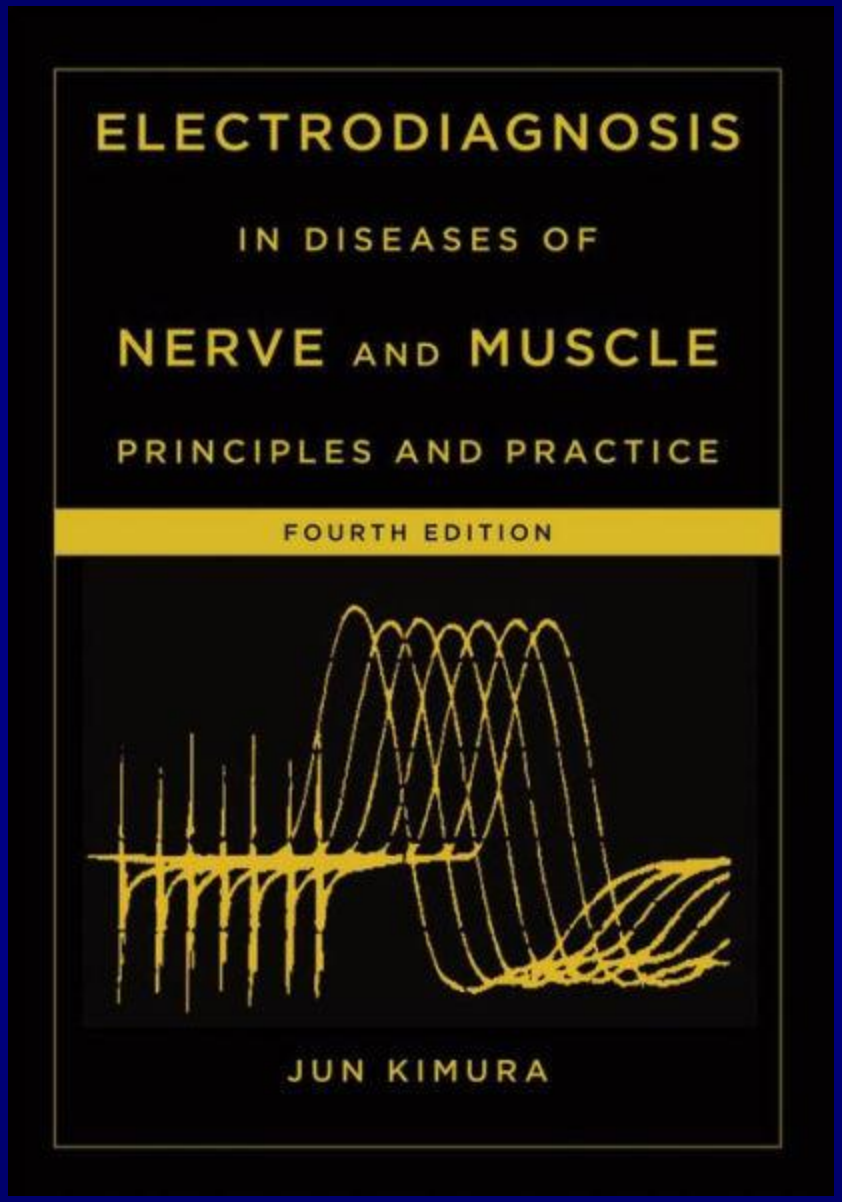
Stanley F.Wainapel MD, MPH, Clinical Director, Department of Rehabilitation Medicine

Montefiore Medical Center

Professor of clinical Rehabilitation Medicine, Albert Einstein college of Medicine

Dr. Jun Kemura

- Jon Kimura got the Distinguished Researcher Award
- by the AANEM (which is the academy mentioned in the LCD) https://old.aanem.org/Membership/Member-Achievement-Awards/Award-Recipients.aspx#FAQLink389
- Author of a major textbook recommended by the AANEM and ABPMR
- Lecturer in the AANEM NCV and EMG courses
- More than 500 publications in the field / 25 professional honorary society membership all around the world



Basics With The Experts

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Jun Kimura, MD
Department of Neurology
University of Iowa Health Care
Iowa City, Iowa

Dr. Kimura received his medical degree from Kyoto University in Japan. He moved to the United States as a Fulbright scholar for residency training in neurology and a fellowship in electrophysiology at the University of Iowa, where he now serves as Professor of Neurology. He also has taught at the University of Manitoba in Canada, Kyoto University in Japan, and Tiantan Hospital in China. Dr. Kimura has more than 500 original publications, including four editions of his book, Electrodiagnosis in Diseases of Nerve and Muscle. Dr. Kimura has received honorary membership from 25 national societies of neurology, neurophysiology, and rehabilitation medicine.

Bassam A. Bass
Neuromuscular Progr
University of South A
Mobile, Alabama

Dr. Bassam completed
fellowship in neuromu
with additional fellows
certified by the America
the American Board of
is a diplomate in the n
Bassam has served on
chair of the Workshop C
Examination Committe
focus on neuromuscula

UNIVERSITY OF IOWA HOSPITALS & CLINICS

University of Iowa Health Care

George B Richerson, MD, PhD
Professor & Head
The Roy J Carver Chair in Neuroscience

Department of Neurology
University of Iowa Health Care
200 Hawkins Drive
Iowa City, IA 52242
319-356-4296 Tel
319-384-7199 Fax
www.uihealthcare.org

December 28, 2018

Leon Margolin MD, PhD
5245 E Main St
Columbus, OH 43213

Dear Dr. Margolin,

Thank you for asking me to review your project on chronic pain management, which is of considerable interest not only to physiatrists but also to other related specialties in general and neurology in particular. I am pleased to evaluate your proposal as a neurologist with special interest in clinical electrophysiology, which I practiced over 50 years.

The project you are undertaking relates to the role of nerve conduction studies (NCS) and needle electromyography (EMG) on clinical assessments of chronic pain patients. I find the study well designed using appropriate methodology to gain a positive impact on clinical practice. I am pleased to learn that the American Board of PM&R has approved this project that was highly evaluated by Dr. Wainapel, an expert in this field. As a neurologist, I too consider the project of considerable value and interest to other specialists and the third party payers.

From my personal experience, I consider NCS as one of the most important tests for evaluation of neuropathy and EMG as an essential tool for clinical study of radiculopathy, two very common conditions where chronic pain management plays an important role. As such these electrodiagnostic methods have demonstrated strong medical necessity on patient care dealing with chronic pain. I wish you continued success in this important endeavor.

Regards,

Jun Kimura, MD
Professor Emeritus
Department of Neurology
University of Iowa
Professor Emeritus