

Final Comments and Response

LCD Title

Nerve Blocks for Peripheral Neuropathy

Contractor's Determination Number

NEURO-811

LCD Database ID Number

L32899

Comments

Presentation at the Open LCD Meeting from a physician who manages four clinics that specialize in the treatment of peripheral neuropathy who was deeply concerned with this proposed draft LCD, which would disallow all nerve blocks for peripheral neuropathy.

In the presentation he stated that his clinics have treated thousands of patients with severe peripheral neuropathy. Every one of these patients have previously been seen by their primary care physicians and told that nothing could be done to improve their disease status. In addition, most of his patients have been seen by neurologists. They were placed on oral medications but a high percentage of the patients were not able to tolerate the side effects.

He reported over 90% of the patients reported that the treatment results in significant and long lasting improvements in their neuropathy symptoms which result in significant improvements in their quality of life and ability to engage in activities of daily living.

He states he has documented on average a greater than 50% improvement in the following symptoms of peripheral neuropathy: pain burning, numbness, prickling, tingling, and balance. Most patients are able to reduce or eliminate medications including narcotics that were used for treating the symptoms.

He states the current broadly accepted treatment for peripheral neuropathy is woefully inadequate.

He included two peer reviewed articles;

Cernak C, Marriot E, et al. Electrical current and local anesthetic combination successfully treats pain associated with diabetic neuropathy: *Practical Pain Management*; April 2012 online at: <http://www.practicalpainmanagement.com/issue/1203>

Odell RH, Sorgnard R, New technique combines electrical and local anesthetic for pain management: *Practical Pain Management*; June 2011: online at <http://www.practicalpainmanagement.com/issue/1106>

Response

The literature that was submitted during the comment period was reviewed and it was not found sufficient to allow coverage of this method of treatment. These references are included in the Sources of Information and Basis for Decision section of the LCD.

IOM 100-08 Chapter 13 section:

13.7.1 - Evidence Supporting LCDs

(Rev. 71, 04-09-04)

Contractor LCDs shall be based on the strongest evidence available. The extent and quality of supporting evidence is key to defending challenges to LCDs. The initial action in gathering evidence to support LCDs shall always be a search of published scientific literature for any

available evidence pertaining to the item/service in question. In order of preference, LCDs should be based on:

Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and

General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:

- o Scientific data or research studies published in peer-reviewed medical journals;*
- o Consensus of expert medical opinion (i.e., recognized authorities in the field); or*
- o Medical opinion derived from consultations with medical associations or other health care experts.*

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

Comment

I looked over the two publications mentioned in Neuro-811 about the use of combined electrical stimulation and peripheral nerve blocks for the treatment of pain and/ or peripheral neuropathy that appeared in the online journal “practical pain management”. Based on my review of those two papers I think the techniques are “on the fringe” and do not currently have good supporting data otherwise. I encourage a non-coverage opinion be adopted for these techniques at the current state of the art. I also asked the American Association of Neuromuscular and Electrodiagnostic Medicine to look over these papers. The task will be assigned to a committee. A report will likely not be available until the spring of 2013 at the earliest.

Response

Thank you for your comments.

Comments

We received one comment from a neurosurgeon who for the last two and one-half years has been using a combination of electro-analgesic therapy with peripheral nerve blocks (CEB) to treat patients with peripheral neuropathy he states he was made aware on September 6, 2012 that the WPS has issued a LCD for Nerve Blocks for Peripheral Neuropathy (DL32899) which states that “The use of nerve blocks or injections for the treatment of multiple neuropathies or peripheral neuropathies caused by underlying disease is not considered medically necessary. Medical management using systemic medications is clinically indicated for the treatment of these conditions.”

He objects to this determination on both scientific and ethical grounds.

Quoted below.

1.) Scientific Grounds.

DL 32899 uses four sources of information for the basis of its decision. One, by Chaudhry et al was written in 2006 and contains no information pertaining to the use of CEBs which were first described in December of 2008. One by Brill, et al describes “Evidence-based guideline: Treatment of painful diabetic neuropathy (PDN)” by considering a systematic literature search from 1960 to August 2008. It concludes that pregabalin, at a dose of 300 to 600 mg/d was

effective and that twelve other drugs and treatments were “probably effective and should be considered for treatment of PDN” At low doses pregabalin (300mg/d) reduced pain by 11-13% as compared to placebo while at large doses (600mg/d) pregabalin had a 50% reduction in pain. While Brill, et al do not address the side effects of pregabalin the drug insert for pregabalin does. At 300mg/d pregabalin has 23% chance of producing dizziness and a 13% chance of producing somnolence. At 600 mg/d patients have 29% chance of experiencing dizziness and a 16% chance of experiencing somnolence. Thus the drug that Brill et al “offer for relief of PDN” has at best a 50% chance of helping patients with PDN and at least 29% chance of harming them. In addition, Brill et al also point out that “Based on a Class I study, electrical stimulation is probably effective in lessening the pain of PDN and improving (quality of life.) (It should be noted that the physics involved in these earlier types of “electrical stimulation” is to the physics involved in CEB as the pictures obtained from plain x-rays are to the images obtained from MRIs. The new parameters of “electrical stimulation” used in CEB are far different and more effective than those used in standard “percutaneous electrical stimulation.” While Brill’s study does not include work done after August of 2008, two other studies that you use as your Basis for Decision” come from 2011 and 2012 and as such represent more recent work than that considered by Chaudhry, et al or Brill.

The 2011 article that you reference by Odell and Sorgnard describes how a “New Technique Combines Electrical Currents and Local Anesthetic for Pain Relief” and results in significant pain reduction in patients with peripheral neuropathies who received up to 20 treatments. The physiologic basis for this technique was described by them in December of 2008 in an article entitled “Anti-inflammatory Effects of Electronic Signal Treatment (EST). (See enclosed) Although DL32899 did not reference this article it remains one of the most important articles published in the twenty first century regarding the treatment of pain. The article describes how electronic signals work at a sub cellular and molecular level to promote healing. Using physics rather than pharmacology to help patients without any of the side effects associated with drugs represents a major paradigm shift in treating disease.

The 2012 article, that you reference, by Cernak, et al “Electric current and Local Anesthetic combination Successfully Treats Pain Associated with Diabetic Neuropathy” describes how sixty seven percent of these patients had at least a 30% reduction in their pain and 91 % had improvement in how they functioned. Twenty-three percent need a second treatment to remain pain free. The editor of PRACTICAL PAIN MANAGEMENT states that the “Results were Outstanding.” -Of the four articles used by WPS in establishing DL 32899, one (Chaudhry, et al) is out of date and offers no useful information regarding the effectiveness of EST. One (Brill, et al) does not describe the side effects associated with “using systemic medications” but does admit that Percutaneous electrical stimulation should be considered for the treatment of PDN. Additionally, using new ways of delivering “Percutaneous electrical stimulation” not known before August, 2008 when Brill, et al’s systemic review stopped, one article (Odell and Sorgnard describe an exciting and effective way to use “electrical stimulation” to treat PDN without any side effects and one (Cernak, et al) documents outstanding results by using EST to treat PDN.

Therefore, why can WPS claim to base LCD (DL 32899) on scientific grounds when three of its four cited articles support the use of percutaneous electrical stimulation and one was written before the effectiveness of “percutaneous electrical stimulation” established?

2.) Ethical Grounds: Hippocrates established the ethical basis for the Art of Medicine by stating “As to disease make a habit of two things – to help or at least to do no harm.” Medical therapy has about a 50% chance of helping patients with PDN and at least a 29% chance of harming them. The “percutaneous electrical stimulation” used in CEBs has 67-80% chance of helping

patients and a 0% chance of harming them. Therefore, why is it ethical to force patients to use a treatment that has at best 50% chance of helping and at least a 29% chance of harming them while at the same time denying them access to a treatment that has a 67-80% of helping them and no chance of harming them?

In addition we received a comment from an interventional pain physician who is a colleague of the neurosurgeon quoted above who wrote in support of this treatment and concurred with the objections on scientific grounds.

Response

1. At the time of writing the draft LCD for our other Jurisdictions we were unable to find any published literature to support the number of peripheral nerve injections being used for the diagnosis codes that we were seeing on utilization data. This LCD is restricting peripheral nerve injections and does not address percutaneous electrical stimulation.

The literature that was submitted during the comment period for this LCD in our other Jurisdictions was reviewed and it was not found sufficient to allow coverage of this method of treatment. The references were included in Sources of Information and Basis for Decision section of this Draft LCD.

Odell RH, Sorgnard R, New technique combines electrical and local anesthetic for pain management: *Practical Pain Management*; June 2011: online at <http://www.practicalpainmanagement.com/issue/1106>

Cernak C, Marriot E, et al. Electrical current and local anesthetic combination successfully treats pain associated with diabetic neuropathy: *Practical Pain Management*; April 2012 online at: <http://www.practicalpainmanagement.com/issue/1203>

The article by Cernak describes an advance in electromagnetic treatment. HCPCS code G0295, Electromagnetic therapy, to one or more areas, for wound care other than described in G0329 **or for other uses**, is not covered by Medicare. Code G0295 has an N status on the Medicare Fee Schedule Data Base.

2. No evidence was included to support the claim that there is no chance of harming a patient especially when the percutaneous electrical stimulation is augmented with injections to the feet and lower legs multiple times per day several days per week over many weeks. In this case it was aberrant data and investigations involving the OIG and FBI that prompted the writing of this LCD.

Comment

We received several comments from providers stating that this therapy has helped some of their patients and a physician who has undergone this therapy with significant benefit to quality of life.

Response

Local Coverage Decisions must be based on the strongest scientific evidence available; we are unable to use patient or provider testimonials as evidence for coverage.

Comments

We received copies of two articles for review.

Cernak C, Marriot E, et al. Electrical current and local anesthetic combination successfully treats pain associated with diabetic neuropathy: *Practical Pain Management*; April 2012 online at: <http://www.practicalpainmanagement.com/issue/1203>

Odell RH, Sorgnard R, New technique combines electrical and local anesthetic for pain management: *Practical Pain Management*; June 2011: online at <http://www.practicalpainmanagement.com/issue/1106>

Response

The two articles above have been submitted by several people who are providing this treatment. The articles were reviewed and are included as references in the LCD.

Comment

Several comments were received regarding whether or not this service is ever paid, since it says not applicable under the ICD-9 Codes that Support Medical Necessity section of the policy. The concern was this gives the impression that no diagnosis codes are covered. Additionally several physicians were concerned that we would deny appropriate claims with ICD-9 code 355.8-mononeuritis of lower limbs.

Response

The diagnosis codes in this LCD were chosen based on data showing overutilization. To allow reimbursement for medically necessary injections that were denied based on this LCD the following statements were included in the utilization guidelines section of the LCD:

Utilization Guidelines

Treatment protocols utilizing multiple injections per day on multiple days per week for the treatment of multiple neuropathies or peripheral neuropathies caused by underlying systemic diseases are not considered medically necessary.

A peripheral nerve injection may be allowed during the reconsideration process if the medical record supports a medically necessary service.