Final Comments and Responses- Nerve Blocks for Peripheral Neuropathy NEURO-014

Comment

We received patient testimonials.

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.

Comment

For the neurology policy; the peripheral nerve block accompanied by nerve stimulation technique for pain control, I support the recommendation of non-coverage. The technique being proposed is not the same as a nerve stimulation that might be done to help localize a nerve trunk or nerve root for a regional anesthesia procedure for surgery or a selective nerve root or sympathetic nerve block done for pain control. The latter are standard techniques.

Response

Thank you for your comment.

Comment

Two commenters had an issue with the statement "Medical management using systemic medications is clinically indicated for the treatment of these conditions." Specifically that scientific evidence demonstrates the limitations of the statement that; "Medical management using systemic medications is clinically indicated for the treatment of these conditions". To be accurate WPS should modify its statement to indicate that many medical experts, including some quoted by WPS, clearly state that medical management has serious limitation and that "new treatment options" are urgently needed. In Dr. Bril's paper she states "Effective treatments for PDN are available, but many have side effects that limit their usefulness and few studies have sufficient information on treatment effects on function and QOL(Quality of Life)." Additionally by Dr. Bril in which she divided the available treatments into those that caused "Disease modification" and those that gave "symptom control." Dr. Bril could find no treatment that modified "the impaired axons" and stated that "interventions aimed specifically at nerve regeneration may need to be employed." In terms of "symptom control" Dr. Bril stated that "Class I (RCT) comparison studies of different interventions are not available and the mechanisms of pain relief for many interventions are not understood. Pain is not completely relieved in most patients, only a proportion of patients respond to any intervention, and strong evidence for combination treatments is lacking."

Response

There are several medications with FDA approval for use in the treatment of peripheral neuropathy. While systemic medications and topical medications may not completely work for all patients, there is scientific evidence to support these treatments. The studies on nerve regeneration, currently is not enough to change this treatment protocol from investigative/experimental.

Comment

We received an unpublished article that has been submitted to "The Pain Physician" the official journal of the American Academy of Pain Management documenting how 98 patients with five different types of PPN have results that are 50-60% better than those described in the RCTs that justify the use of pregabalin, and cause essentially no side effects. The commenter states that the scientific evidence presented in the article suggests that when properly used, CET has the potential to help millions more Americans who suffer from PPN than does the current "medical management".

Response

Unpublished literature is not considered as evidence for coverage.

Comment

We received several comments from anesthesia groups and billing companies about receiving denials for 64450 when performed as post-operative pain management injections. These blocks are not being performed for peripheral neuropathy or multiple neuropathies. Occasionally the 64450 injection is done for postoperative pain from a foot or knee procedure. Example: TKA blocks performed included an obturator nerve block. We used 338.18 (postoperative pain) and 719.46(for knee pain) or on occasion, we have a Saphenous Block performed for the post-operative pain of a foot procedure. We would report 338.18 and 719.47. However, this diagnosis is on the non-covered diagnosis list and therefore we receive denials. We have additionally seen the denial of this when we bill as 338.18 and 729.5. I suggest to remove the CPT code 64450 from the LCD to stop the constant denials of services that are not related to this LCD. Please reconsider using the LCD: Nerve Blocks for Peripheral Neuropathy as the coverage determination for Post-Operative Pain Nerve Blocks or revise the content to acknowledge those providers that perform blocks for other reasons than to treat peripheral neuropathy.

Response

We have attempted a variety of edits to curtail the widespread overutilization of this particular code without success and found it necessary to stop all automatic payments. While it is unfortunate that legitimate services get denied there is a process described in the LCD that will allow appropriate services with review of the medical records.

Comment

This situation described definitely appears to abuse the system. However, there are instances in diabetic neuropathy where a peripheral region of compression may be treated effectively with a nerve block, guided by ultrasound. I cannot defend multiple injections per foot, multiple times per week, with or without ultrasound. For a similar situation, I have heard that some use ultrasound for myofascial trigger point injections. For the majority of situations, myofascial trigger point injection is not proper use of ultrasound. Deep muscular injections, such as the iliopsoas, or situations where botulinum neurotoxin is used on specific muscles, it can still be a valuable tool. I am sure there are multiple other uses of ultrasound and peripheral injections that are not entirely appropriate. For the sake of the patient, inappropriate injections et cetera should be controlled. It is obviously a complex situation to try to manage the use of a tool that has the potential to be abused through inappropriate use. Hopefully, there can be a way to rein in some of the inappropriate uses of injections, and ultrasound, while preserving the use for situations of true medical necessity, such as those cases I described. That can be a formidable challenge.

Response

This is a difficult situation and we appreciate your understanding. We have included a statement in the utilization guidelines that will allow for a service to be reviewed and allowed on reconsideration if the medical record supports a medically necessary service.

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 redetermination process if the medical record supports a medically necessary service.

Additionally, our intention is not to limit ultrasound guidance for all injections.

Comment

We received a request to use a policy by another contractor because the guidelines include a broader yet reasonable range of diagnosis codes for meeting medical necessity in those cases that require a peripheral injection. It also allows 64450 to be covered when used as an injection that provides post-surgical pain control.

Response

The suggested LCD was reviewed; it includes additional CPT codes for different nerve injections. Currently the overutilization of CPT code 64450 is the issue we are addressing, however we will consider the suggested LCD if it becomes necessary to limit other nerve injections codes.

Comment

As an anesthesiologist trained in regional anesthesia with the "classic" "landmark" and fluoroscopy approaches, ultrasound has been a practice changing addition in the treatment armamentarium. Accuracy, safety, as well as patient comfort, are all greatly improved when the needle can be visualized in the tissues in real time, rather than "fishing around" for the landmarks as a block is being performed. For example, during a stellate ganglion block, the needle tip is actually quite close to the carotid and thyroidal arteries, the brachial plexus, esophagus, and the lung. In the "classic" technique, considerable force is applied to the carotid artery to the patient's hyperextended neck in order to essentially push the carotid artery away from the bony landmark structure near where the needle is to be placed. This force is quite uncomfortable, and at times may be dangerous to patients with carotid artery disease. If one of the arteries would be punctured with the needle, not only is there a high risk of hemorrhage, but also seizure. One is never absolutely positive if they are in the proper fascial layer with needle placement, necessitating a larger volume of local anesthetic injected into the neck adjacent to many very sensitive structures. There is a substantial risk for seizure, pneumothorax, hemorrhage, esophageal perforation with infection, and blockade of other structures (larynx, brachial plexus) with the classic technique. Fluoroscopy offers only minimal benefit, and exposes the patient, physician and staff to radiation. Ultrasound allows accurate placement of the needle directly onto the stellate ganglion, avoiding potentially life-threatening structures, with a lower volume of local anesthetic, and without the discomfort and increased risk of compression of the carotid artery and other structures of the neck. For patient safety and efficacy of the stellate ganglion block, ultrasound is definitely medically necessary. I would not do a stellate ganglion block without ultrasound.

Another example of many for medically necessary use of ultrasound is in the intercostal block, where if the needle is just slightly too deep, the lung is collapsed. If the needle is not placed directly onto the nerve, larger volumes of local anesthetic are required, in hopes of obtaining a neural blockade through diffusion. These large volumes increase the risk of toxicity and seizures. The intercostal artery is also in the region, and prone to be lacerated with the needle tip. Ultrasound allows placement of the needle tip into the specific layer between intercostal muscles, directly onto the nerve, avoiding the intercostal artery and lung pleura, to deliver a very potent block using relatively low volumes of local anesthetic. With the classic technique, only a narrow area of rib is palpable to perform a safe block. In obese patients, that region is further limited. Having seen pneumothorax, hemothorax, and drug induced toxicity from intercostal blocks in teaching situations, the danger of this block cannot be stressed enough. Now that we have a tool that allows an accurate, efficient, and safe injection of the entire intercostal region; treatment of such problems as cancer pain, rib fractures, and postoperative pain can be controlled much more safely and effectively. These are only two of many examples where ultrasound is medically necessary for patient safety and effectiveness of the peripheral nerve block in various neuropathic pain syndromes. Ultrasound guided nerve and joint blocks have definitely improved pt comfort and safety, as well as saving countless lives. Loosing this tool would have devastating effects to patient care.

Response

The Nerve Blocks for Peripheral Neuropathy LCD, restrictions only apply when treating multiple neuropathies or peripheral neuropathies caused by underlying systemic diseases (eg diabetes), the

restriction would not apply to CPT code 64510 Injection, anesthetic agent: stellate or CPT codes 64420, or 64421 injection of anesthetic agent: intercostal.

The LCD will not limit the use of ultrasound for all nerve injections, only when used as a part of this non covered treatment.

Comment

There may be cases where there is a systemic peripheral neuropathy and a compression neuropathy such as carpal tunnel and the commenter was concerned that this would not be allowed according to this policy.

Response

The majority of injection codes for specific nerves have their own CPT codes for example procedure code 20526, Injection, therapeutic (eg, local anesthetic, corticosteroid), carpal tunnel. There is also a sentence in the LCD that states a medically necessary service may be allowed with review of the documentation. If an injection for compression neuropathy for a nerve without a specific code is denied based on this LCD a reconsideration request would be required.

Comment

Multiple comments were received about the possibility of taking the diagnosis codes out of the LCD. The Proposed Draft LCD listed codes that are not payable. These codes originated from the initial data for these services. There does seem to be some confusion about this list of codes and it is suggested that all diagnosis codes be removed from the LCD.

Response

The list of diagnosis codes were removed from the final LCD, when the procedure is used repeatedly for the treatment of peripheral neuropathy related to a systemic disease it is a non-covered service regardless of which diagnosis code is used on the claim.

Comment

One Anesthesiologist was concerned that this LCD would limit treatment of entrapment neuropathy, for example, post hernia ilioinguinal entrapment pain.

Response

This LCD would not apply to this situation. There is a specific CPT code, 64425 Injection, anesthetic agent; ilioinguinal, iliohypogastric nerves that would be used in this situation.

Comment

One commenter explained that this LCD has been around for a while since a company marketed a machine with some sort of electrotherapy and recommended multiple injections into nerves were done two to three times a week along with using their machine which resulted in high utilization of this code.

The problem was 64450 was denying for appropriate diagnosis codes such as tarsal tunnel syndrome and mononeuritis traumatically induced. Even when in appeals they aren't being covered since there are no covered diagnosis codes listed that are considered to be medically necessary. This put the provider in a bind when it comes to treating traumatized nerve or a diagnostic study to determine joint pain versus tarsal tunnel syndrome. It is medically necessary for these indications. We were hoping the policy would be strengthened to limit its use in peripheral neuropathy and allow it when it is appropriate.

Response

The diagnosis code list in the LCD has created some confusion; we have therefore decided to remove all diagnosis codes from the LCD. A particular code on a claim will not guarantee payment. The medical records will need to be reviewed for this service to be allowed.

Comment

One commenter asked why the ultrasound code was included in this policy since ultrasounds can be used for multiple indications.

Response

The additional codes were added to the LCD so that the ultrasound code would also be denied when the nerve injection was denied and likewise it would be allowed if the medical record was reviewed and the nerve injection was allowed.

Comment

One commenter submitted a list of references without copies of the articles for review.

Response

Articles for review must be submitted, we did not research the list that was submitted.

Comment

The following articles and abstract were submitted for review: Bril,V. (2012), Treatments for diabetic Neuropathy, Journal of Peripheral Nervous System, 17:22-27 doi:10.111/j.1529-8027.2012.00391

Chapter 14 <u>Diabetic Somatic Neuropathy</u> from Diabetes: An Old Disease. Zdravko A Kamenov and Latchezar D. Traykov

Odell R., Sorgnard R. <u>Anti- inflammatory Effects of Electronic Signal Treatment</u>, Pain Physicians 2008: 11:981-907 ISSN 1533-3159

Milne, D., Sorgnard, R. Quantum Theory Underpins Electromagnetic Therapies for Pain Management.

Abstract - Bril V¹, England J, Franklin GM, Backonja M, Cohen J, Del Toro D, Feldman E, Iverson DJ, Perkins B, Russell JW, Zochodne D; Evidence-based guideline: Treatment of painful diabetic neuropathy: report of the American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation; American Academy of Neurology; American Association of Neuromuscular and Electrodiagnostic Medicine; American Academy of Physical Medicine and Rehabilitation. 2011.

Response

The studies are not enough to change this treatment protocol from investigative/experimental.

Comment

A Power Point Presentation from New Promise Neuropathy Care Centers was submitted for review. **Response**

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