

P&S Network, Inc.

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DATE OF REVIEW: October 2, 2008

IRO CASE #:

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

This case was reviewed by a Pain Management doctor, Licensed in Texas and Board Certified. The reviewer has signed a certification statement stating that no known conflicts of interest exist between the reviewer and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent (URA), any of the treating doctors or other health care providers who provided care to the injured employee, or the URA or insurance carrier health care providers who reviewed the case for a decision regarding medical necessity before referral to the IRO. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Medication Lyrica 75 mg times one month-then increase to t.i.d. if symptoms don't improve #90 times two refills
Medication Tizanidine 4 mg q.i.d. #120 times two refills
Medication Darvocet N-100 #60 times two refills

REVIEW OUTCOME

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

Overtured (Disagree)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- o Submitted medical records were reviewed in their entirety.
- o Treatment guidelines were provided to the IRO.
- o August 11, 2004 peer review report from, Inc.
- o July 26, 2004 peer review report by, M.D.
- o October 17, 2001 peer review report by, M.D.
- o May 11, 2000 through June 16, 2004 records from doctor,
- o May 11, 2004 laboratory results from
- o July 8, 2002 CT of the lumbar spine and myelogram report by, M.D.
- o July 15, 1997 bone scan report by, M.D.
- o July 15, 1997 hip MRI report by, M.D.
- o June 3, 1997 physical therapy report by, P.T.
- o May 19, 1997 lumbar spine CT report by, M.D.
- o May 14, 1997 electrodiagnostic report by, M.D.
- o May 6, 1997 lumbar spine MRI report by, M.D.
- o May 9, 1997 and May 14, 1997 letters by M.D.
- o September 18, 2008 carrier submission letter from the Law Offices of
- o June 28, 2001 through April 10, 2008 adjuster individual patient activity from an unknown source
- o May 11, 2005 report by, M.D.
- o April 25, 2005 chronic pain program interpreted report by, Ph.D.
- o May 1, 1997 through July 16, 1997 of records from, M.D.
- o November 5, 2002 designated doctor report by, M.D.
- o May 8, 2001 functional capacity evaluation report from
- o May 17, 2007 and September 4, 2008 reports from Orthopedic and Joint Replacement
- o October 15, 1999 and March 22, 2000 records by, M.D.
- o March 13, 2002 through February 6, 2004 records from, M.S.
- o October 11, 1999 through November 22, 1999 reports from the Neurology Center
- o October 6, 2003 chart note from, M.D.

- o May 15, 2002 through November 14, 2003 records from, M.D.
- o November 1, 2004 report from Behavioral Medicine Consultants
- o June 5, 2003 through June 10, 2008 records from, M.D.
- o July 19, 2002 chart note from, M.D.
- o April 19, 2000 report from, M.D.
- o September 9, 1997 report from, M.D.
- o November 11, 1997 through June 27 2000 records from Orthopedic Hospital
- o October 2, 1997 through May 21, 2001 records from, M.D.
- o June 28, 2001 through December 13, 2001 records from, M.D.
- o October 14, 1997 stress echocardiogram report by, M.D.
- o January 13, 1998 report by, M.D.
- o February 25, 1998 records from, M.D.

PATIENT CLINICAL HISTORY [SUMMARY]:

According to the medical records, the patient sustained an industrial injury on xx/xx/xx. According to a peer review summary denial, the patient injured his low back when pulling on a bolt while working. He had implantation of a spinal cord stimulator in June 2000. He currently complains of chronic low back pain with radicular symptoms to the left hip, left leg, both posteriorly and laterally with numbness and tingling in the left leg. He states that it radiates to the mid-thoracic paraspinal region. He also reports occasional right hip pain. A non-certification was rendered for the above-captioned medications as the reviewer commented that there is insufficient information indicating informed consent regarding the medication has been obtained from the patient, a thoroughly detailed patient diary of pain and function associated with medications, and a thoroughly detailed written medication related treatment plan. In addition, several other items were mentioned that need to be adequately and thoroughly addressed as part of an appropriate/ongoing medication management for the patient.

The case was again reviewed and another non-certification rendered. The reviewer commented that the patient is a xx-year-old male who injured his low back in xxxx. The patient has been prescribed Lyrica, Tizanidine, and Darvocet. A note from June 10, 2008 indicates that the patient continues to have low back pain which radiates into his left hip and left leg posteriorly and laterally. On examination, his paraspinal muscles are tight and he is tender to palpation. Straight leg raise elicits low back pain and posterior thigh pain on the right side at 45° and on the left at 30. Lateral flexion elicits low back pain across the midline. Neurologically, motor strength is graded as 5/5. There is hypoesthesia in the left leg from L4 through S1. Vibration is decreased in the left first toe. Reflexes are absent at the wrist, triceps, bilateral knees, and bilateral ankles. He was diagnosed with low back pain status post anterior and posterior fusion with instrumentation of March 1999, low back pain with removal of symptomatic hardware, spinal cord stimulator implantation in October 2000 with revision in March 2004, musculoskeletal spasm of the cervical, thoracic, and lumbosacral spine, dysesthesia in the legs, anxiety and depression, possible disc herniation of the cervical spine, and left rotator cuff tear. The patient was discontinued on Topamax. In an appeal for the denial of these medications, the physician reported that Lyrica is being prescribed for his nerve damage, dysesthesia, and pain. He has been prescribed Tizanidine for muscle spasms and Darvocet for pain. The peer-review physician stated that the use of Lyrica represents an off-label use of this medication. The reviewer states that most private insurance plans require that the patient undergo a trial of gabapentin (Neurontin) and if the patient fails a trial of gabapentin then a trial of Lyrica is warranted with improvement. The peer review report states that the request for tizanidine would be considered appropriate. The medication Darvocet would be considered appropriate for breakthrough pain. Despite these statements, a non-certification was provided for Darvocet and tizanidine as well.

The patient underwent an Independent Medical Examination on September 4, 2008. The patient was examined and the physician stated that the current diagnosis is chronic low back pain, mainly due to sacroiliitis which is stable. The physician opined that it is inconceivable that the sacroiliitis has continued for 11 years. He stated that the treatment has gone on for too long, which is mainly medications, and it has become unreasonable. Office visit should be limited to every six months or annually. He recommended over-the-counter medication such as Motrin if there is no medical contraindication or prescription strength if it is not adequate. He stated that tizanidine for muscle spasms could be substituted with a generic. Darvocet may be used when necessary. Lyrica could be substituted with over-the-counter medication as described above.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION.

According to the Official Disability Guidelines, opioids for chronic back pain appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. The patient appears to be stable on Darvocet and has responded well. He has been seeing the treating physician for several years and the periodic reports reflect that this medication has been dispensed on a long-term basis. The records do not reflect an obvious increase in dosage or frequency of the prescription. This medication is appropriate for breakthrough pain.

According to the Official Disability Guidelines, Anti-epilepsy drugs (AEDs) are also referred to as anti-convulsants. These medications are recommended for neuropathic pain (pain due to nerve damage), but not for acute nociceptive pain (including somatic pain). The patient has been diagnosed with dysesthesia pain in the legs with recent physical examination demonstrating

hypoesthesia of the left leg in the L4-S1 dermatomes. Vibration is decreased in the left first toe. He has apparent failed back syndrome with spinal cord stimulator implantation in 2000 and revision in 2004. Given this information, it is reasonable for the patient to have access to Lyrica.

According to the Official Disability Guidelines, muscle relaxants are recommended as an option in acute cases of moderate to severe LBP. The June 10, 2008 report from the treating doctor states that the patient has musculoskeletal spasm of the cervical, thoracic, and lumbosacral spine. Although this is a chronic pain patient, the patient has musculoskeletal spasm and intermittent acute episodes for which a muscle relaxant such as Tizanidine is appropriate.

Therefore, my recommendation is to overturn the decision to non-certify the request for "Medication Lyrica 75 mg times one month-then increase to t.i.d. if symptoms don't improve #90 times two refills; Medication Tizanidine 4 mg q.i.d. #120 times two refills; and Medication Darvocet N-100 #60 times two refills."

The IRO's decision is consistent with the following guidelines:

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN
- INTERQUAL CRITERIA
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
- MILLIMAN CARE GUIDELINES
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
- TEXAS TACADA GUIDELINES
- TMF SCREENING CRITERIA MANUAL
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME

Official Disability Guidelines (2008)/Low Back Chapter:

Muscle relaxants

Recommended as an option in acute cases of moderate to severe LBP. OK for acute spasms. A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain concludes that available evidence supports the effectiveness of muscle relaxants in acute LBP. (Schnitzer, 2004) (Airaksinen, 2006) Muscle relaxants are commonly used for the treatment of low back problems. Pharmacologically, these are usually benzodiazepines, other sedative medications, or antihistamine derivatives. The therapeutic objective of muscle relaxants is to reduce low back pain by relieving muscle spasm. However, the concept of skeletal muscle spasm is not universally accepted as a cause of symptoms, and the most commonly

used muscle relaxants have no peripheral effect on muscle spasm. Muscle relaxants are an option in the treatment of patients with acute low back problems. While probably more effective than placebo, muscle relaxants have not been shown to be more effective than NSAIDs. No additional benefit is gained by using muscle relaxants in combination with NSAIDs over using NSAIDs alone. Muscle relaxants have potential side effects, including drowsiness in up to 30 percent of patients. When considering the optional use of muscle relaxants, the clinician should balance the potential for drowsiness against a patient's intolerance of other agents. (VanTulder, 2000) (Bigos, 1999) Muscle relaxants are effective in acute LBP. Cyclobenzaprine is associated with a number needed to treat of 3 after two weeks for symptom improvement and is associated with drowsiness and dizziness. Carisoprodol is also effective but has abuse and dependency potential. Metaxalone and low-dose cyclobenzaprine have fewer adverse effects. (Kinkade, 2007) For more information, see the Pain Chapter: Muscle relaxants.

Official Disability Guidelines (2008)/Low Back Chapter:

Opioids

Not generally recommended except for short use for severe cases, not to exceed 2 weeks. See the Pain Chapter for more information and studies. When used only for a time-limited course, opioid analgesics are an option in the management of patients with acute low back problems. The decision to use opioids should be guided by consideration of their potential complications relative to other options. Patients should be warned about potential physical dependence and the danger associated with the use of opioids while operating heavy equipment or driving. The studies found that patients taking opioid analgesics did not return to full activity sooner than patients taking NSAIDs or acetaminophen. In addition, studies found no difference in pain relief between NSAIDs and opioids. Finally, side effects of opioid analgesics were found to be substantial, including the risk for physical dependence. These side effects are an important concern in conditions that can become chronic, such as low back problems. (Bigos, 1999) For more information, and Criteria for Use of Opioids, see the Pain Chapter.

Official Disability Guidelines (2008)/Pain Chapter:

Opioids for chronic pain

Recommendations for general conditions:

- Neuropathic pain: Opioids have been suggested for neuropathic pain that has not responded to first-line recommendations (antidepressants, anticonvulsants). There are no trials of long-term use. There are virtually no studies of opioids for treatment of chronic lumbar root pain with resultant neuropathy. See Opioids for neuropathic pain.
- Chronic back pain: Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. There is no evidence to recommend one opioid over another. In patients taking opioids for back pain, the prevalence of lifetime substance use disorders has ranged from 36% to 56% (a statistic limited by poor study design). Limited information indicated that up to one-fourth of patients who receive opioids exhibit aberrant medication-taking behavior. (Martell-Annals, 2007) (Chou, 2007) There are three studies comparing Tramadol to placebo that have reported pain relief, but this increase did not necessarily improve function. (Deshpande, 2007)
- Headaches: not recommended, in particular, due to the risk of medication overuse headache. (Lake, 2008) (Olesen, 2006) See Medication overuse headache.
- Osteoarthritis: Not recommended as a first-line therapy. Recommended on a trial basis for short-term use after there has been evidence of failure of first-line medication options such as acetaminophen or NSAIDs when there is evidence of moderate to severe pain. Also recommended for a trial if there is evidence of contraindications for use of first-line medications. Under study for long-term use there is a lack of evidence to allow for a treatment recommendation. If used on a long-term basis, the criteria for use of opioids should be followed. See Opioids for osteoarthritis for citations.
- Nociceptive pain: Recommended as the standard of care for treatment of moderate or severe nociceptive pain (defined as pain that is presumed to be maintained by continual injury, with the most common example being pain secondary to cancer).
- Mechanical and compressive etiologies: rarely beneficial.

Chronic pain can have a mixed physiologic etiology of both neuropathic and nociceptive components. In most cases, analgesic treatment should begin with acetaminophen, aspirin, and NSAIDs (as suggested by the WHO step-wise algorithm). When these drugs do not satisfactorily reduce pain, opioids for moderate to moderately severe pain may be added to (not substituted for) the less efficacious drugs. A major concern about the use of opioids for chronic pain is that most randomized controlled trials have been limited to a short-term period (?70 days). This leads to a concern about confounding issues such as tolerance, opioid-induced hyperalgesia, long-range adverse effects such as hypogonadism and/or opioid abuse, and the influence of placebo as a variable for treatment effect. (Ballantyne, 2006) (Furlan, 2006) Long-term, observational studies have found that treatment with opioids tends to provide improvement in function and minimal risk of addiction, but many of these studies include a high dropout rate (56% in a 2004 meta-analysis). (Kalso, 2004) There is also no evidence that opioids showed long-term benefit or improvement in function when used as treatment for chronic back pain. (Martell-Annals, 2007) Current studies suggest that the "upper limit of normal" for opioids prior to evaluation with a pain specialist for the need for possible continuation of treatment, escalation of dose, or possible weaning, is in a range from 120-180 mg morphine equivalents a day. (Ballantyne, 2006) (AMDG, 2007)

There are several proposed guidelines for the use of opioids for chronic non-malignant pain, but these have not been evaluated in clinical practice, and selection of the patient that will best respond to this treatment modality remains difficult. (Nicholas, 2006) (Stein, 2000) One of the most recent of these guidelines is the Agency Medical Director's Group (AMDG) Guidelines from Washington State. This guideline includes an opioid dosing calculator. (AMDG, 2007)

Outcomes measures: It is now suggested that rather than simply focus on pain severity, improvements in a wide range of

outcomes should be evaluated, including measures of functioning, appropriate medication use, and side effects. Measures of pain assessment that allow for evaluation of the efficacy of opioids and whether their use should be maintained include the following: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. (Nicholas, 2006) (Ballantyne, 2006) A recent epidemiologic study found that opioid treatment for chronic non-malignant pain did not seem to fulfill any of key outcome goals including pain relief, improved quality of life, and/or improved functional capacity. (Eriksen, 2006)

Tolerance and addiction: Opioid tolerance develops with the repeated use of opioids and brings about the need to increase the dose and may lead to sensitization. It is now clear that analgesia may not occur with open-ended escalation of opioids. It has also become apparent that analgesia is not always sustained over time, and that pain may be improved with weaning of opioids. (Ballantyne, 2006) (Ballantyne, 2003) See Substance abuse (tolerance, dependence, addiction).

Behavior reinforcement: A major concern in the use of opioids has been that a focus on this treatment without coordination with other modalities, such as psychosocial or behavioral therapy, may simply reinforce pain-related behavior, ultimately undermining rehabilitation that has been targeted at functional restoration. (Ontario, 2000) It has been shown that pain behavior can be reinforced by the prescribing of opioids, generally on an unintentional basis by the patient. (Fordyce, 1991)

Overall treatment suggestions: Current guidelines suggest the following:

- A trial of opioids as a first step in treatment, and the steps involved are outlined in the Criteria for Use of Opioids. The trial includes an initiation phase that involves selection of the opioid and initial dose. (VA/DoD, 2003)
- There is then a titration phase that includes dose adjustment. At this phase it may be determined that opioids are not achieving the desired outcomes, and they should be discontinued.
- The final stage is the maintenance phase. If pain worsens during this phase the differential to evaluate includes disease progression, increased activity, and/or new or increased pre-existing psychosocial factors that influence pain. In addition, the patient may develop hyperalgesia, tolerance, dependence or actual addiction. (Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004) See Substance abuse (tolerance, dependence, addiction). See also Implantable pumps for narcotics. See also Opioids in the Low Back Chapter. See Criteria for Use of Opioids.

Official Disability Guidelines (2008)/Pain Chapter:

Anti-epilepsy drugs (AEDs) for pain

Anti-epilepsy drugs (AEDs) are also referred to as anti-convulsants.

Recommended for neuropathic pain (pain due to nerve damage), but not for acute nociceptive pain (including somatic pain).

(Gilron, 2006) (Wolfe, 2004) (Washington, 2005) (ICSI, 2005) (Wiffen-Cochrane, 2005) (Attal, 2006) (Wiffen-Cochrane, 2007) (Gilron, 2007) (ICSI, 2007) (Finnerup, 2007) There is a lack of expert consensus on the treatment of neuropathic pain in general due to heterogeneous etiologies, symptoms, physical signs and mechanisms. Most randomized controlled trials (RCTs) for the use of this class of medication for neuropathic pain have been directed at postherpetic neuralgia and painful polyneuropathy (with diabetic polyneuropathy being the most common example). There are few RCTs directed at central pain and none for painful radiculopathy. (Attal, 2006) The choice of specific agents reviewed below will depend on the balance between effectiveness and adverse reactions. See also specific drug listings below: Gabapentin (Neurontin®); Pregabalin (Lyrica®); Lamotrigine (Lamictal®); Carbamazepine (Tegretol®); Oxcarbazepine (Trileptal®); Phenytoin (Dilantin®); Topiramate (Topamax®); Levetiracetam (Keppra®); Zonisamide (Zonegran®); & Tiagabine (Gabitril®)

Outcomes: A "good" response to the use of AEDs has been defined as a 50% reduction in pain and a "moderate" response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the "trigger" for the following: (1) a switch to a different first-line agent (TCA, SNRI or AED are considered first-line treatment); or (2) combination therapy if treatment with a single drug agent fails. (Eisenberg, 2007) (Jensen, 2006) After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. AEDs are associated with teratogenicity, so they must be used with caution in woman of childbearing age.

Pregabalin (Lyrica®, no generic available) has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. This medication is designated as a Schedule V controlled substance because of its causal relationship with euphoria. (Blommel, 2007) This medication also has an anti-anxiety effect. Pregabalin is being considered by the FDA as treatment for generalized anxiety disorder and social anxiety disorder. In June 2007 the FDA announced the approval of pregabalin as the first approved treatment for fibromyalgia. (ICSI, 2007) (Tassone, 2007) (Knotkova, 2007) (Eisenberg, 2007) (Crofford, 2005) (Stacey, 2008) Dose adjustment is necessary in patients with renal insufficiency. The antiepileptic agents gabapentin and pregabalin have attained widespread usage in the treatment of painful diabetic peripheral neuropathy (DPN). This pooled analysis of 7 randomized controlled trials comparing different doses and frequencies of pregabalin for painful DPN concluded that pregabalin at doses of 150, 300, and 600 mg daily is associated with dose-related relief of pain and reduction in sleep interference in patients with painful DPN. (Freeman, 2008)

Side-Effect Profile: Pregabalin has been associated with many side effects including edema, CNS depression, weight gain, and blurred vision. Somnolence and dizziness have been reported to be the most common side effects related to tolerability. (Tassone, 2007) (Attal, 2006) It has been suggested that this drug be avoided if the patient has a problem with weight gain.

(Jensen, 2006)

Dosing Information:

Diabetic neuropathy - Begin with 50 mg 3 times a day; may be increased in one week based on tolerability and effect to a maximum of 300 mg/day. (Doses up to 600 mg/day were evaluated with no additional benefit and increase in side effects.)

Postherpetic neuralgia - Begin with 50 mg three times a day for one week; may be increased to 100 mg three times a day after one week based on tolerability and effect. Dose may be increased as tolerated after two to four weeks up to 300 mg twice daily (maximum dose 600 mg/day). (ICSI, 2007)

Trial period: There is no established trial period, but the onset of action is thought to be less than 1 week. (Attal, 2006)

Weaning: Do not discontinue pregabalin abruptly and weaning should occur over a one-week period. Withdrawal effects have been reported after abrupt discontinuation.