



Specialty Independent Review Organization

**DATE OF REVIEW:** 6/29/2009

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE**

The items in dispute are the retrospective medical necessity of medications: Lidoderm, Lyrica, Carisoprodol, Hydrocodone, and Hydrocodone/Acetaminophen.

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

The reviewer is a Medical Doctor who is board certified in Physical Medicine and Rehabilitation. The reviewer has greater than 10 years of experience in this field.

**REVIEW OUTCOME**

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

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

The reviewer agrees with the previous adverse determination regarding the retrospective medical necessity of Carisoprodol/SOMA and Hydrocodone. However, the reviewer disagrees with the previous adverse determination regarding the retrospective medical necessity of Lidoderm, Lyrica, and Hydrocodone/Acetaminophen.

**INFORMATION PROVIDED TO THE IRO FOR REVIEW**

Records were received and reviewed from the following parties: and Dr.

These records consist of the following (duplicate records are only listed from one source): Records reviewed from: notes – 6/5/06 & 6/15/06; Dr. patient history – 8/7/06, Evaluation – 7/10/06-1/31/07; Surgery Center Operative Report – 9/26/06 & 12/19/06; Dr. ESI report – 9/26/06 & 12/19/06; DWC69 – 11/7/06, 3/20/07, & 7/3/07; Dr. Designated Doctor Evaluation – 11/7/06, 3/20/07, & 7/3/07; Dr. letter – 3/6/07 & 4/24/07; Dr. letter – 7/11/07; Dr. report – 7/30/07; Dr. clinic note – 6/14/07-6/28/07; Dr. report – 11/20/07; Dr. clinic note – 4/22/08; Explanation of

Review – 2/27/09-4/17/09, Nurse’s Chronological List of Submitted Records – 4/3/08; Dr. letter – 10/3/08.

Dr. handwritten daily notes from 2/19/7 to 6/9/09 and handwritten progress note of 10/26/02.

A copy of the ODG was not provided by the Carrier or URA for this review.

**PATIENT CLINICAL HISTORY [SUMMARY]:** The patient was injured in a lifting incident at work. She has left sided radicular symptoms with lumbar DDD at L5/S1. An EMG/NCS was normal. An ESI was temporarily beneficial.

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

The Lidoderm patch is approved and is supported by the ODG: *Indications: Neuropathic pain:* Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI antidepressants or an AED such as gabapentin or Lyrica). Topical lidocaine, in the formulation of a dermal patch (Lidoderm<sup>®</sup>) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. In February 2007 the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical lidocaine. Those at particular risk were individuals that applied large amounts of this substance over large areas, left the products on for long periods of time, or used the agent with occlusive dressings. Systemic exposure was highly variable among patients. Only FDA-approved products are currently recommended. *Non-neuropathic pain:* Not recommended. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo.

Lyrica is an anticonvulsant medication. This medication is approved and supported for neuropathic pain by the ODG: Recommended for neuropathic pain (pain due to nerve damage), but not for acute nociceptive pain (including somatic pain). 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. *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. 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. Preconception counseling is recommended for anticonvulsants (due to reductions in the efficacy of birth control pills). Manufacturers of antiepileptic drugs will need to add a warning to their labeling indicating that use of the drugs increases risk for suicidal thoughts and behaviors, according to an FDA Alert issued December 16.

*Specifically studied disease states:* (also see below for specific drugs)

*Acute pain:* Not indicated due to lack of evidence.

*Chronic non-specific axial low back pain:* A recent review has indicated that there is insufficient evidence to recommend for or against antiepileptic drugs for axial low back pain. There is one randomized controlled study that has investigated topiramate for chronic low back pain. This study specifically stated that there were no other studies to evaluate the use of this medication for this condition. Patients in this study were excluded if they were taking opioids. No patient had undergone back surgery. In terms of the Oswestry low back pain questionnaire scale, the differences in the placebo group and treatment group were significant, although the mean score in both groups remained  $\geq 34$ . Reduction in pain rating index appeared to be correlated with weight reduction. The authors felt additional research was required to see if the results could be replicated and how long-lasting benefits were. There are no other articles available that evaluate the use of other anti-epilepsy drugs in the treatment of chronic non-specific, non-neuropathic axial low back pain.

*Treatment of pain associated with osteoarthritis of the hip:* Not indicated

*Spinal cord injury:* Gabapentin is recommended for chronic neuropathic pain.

*CRPS:* Gabapentin has been recommended

*Fibromyalgia:* Gabapentin and pregabalin have been found to be safe and efficacious to treat pain and other symptoms. Pregabalin is FDA approved for fibromyalgia.

*Lumbar spinal stenosis:* Gabapentin produced statistically significant improvement in walking distance, decrease in pain with movement and sensory deficit in a pilot study.

*Myofascial pain:* Not recommended. There is a lack of evidence to demonstrate that AEDs significantly reduce the level of myofascial or acute musculoskeletal pain, or other sources of somatic pain. *Postop pain:* AEDs may also be an option for postoperative pain, resulting in decreased opioid consumption.

***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. 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. 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.

The patient is on acetaminophen, an analgesic medication. This medication is approved and supported by the ODG: Recommended for early use only. Acetaminophen (safest), or NSAIDs (aspirin, ibuprofen). There is fair to good evidence that NSAIDs are effective for reducing pain in patients with acute low back problems, and there is evidence that acetaminophen is comparable in efficacy to NSAIDs for treating back problems and with fewer side effects. Common oral medications such as acetaminophen and NSAIDs are associated with a number needed to treat of 2 to 3 for 50% pain improvement during 4 to 6 hours. A 2008 Cochrane review found that NSAIDs are not more effective than acetaminophen for acute low-back pain, but acetaminophen had fewer side effects, which support recommending NSAIDs as a treatment option after acetaminophen.) There should be caution about daily doses of acetaminophen and liver disease if over 4,000 mg per day or in combination with other NSAIDs. See also NSAIDs (non-steroidal anti-inflammatory drugs) in the Pain Chapter.

The patient is also taking SOMA/Carisoprodol. This medication is supported by the ODG for acute cases of pain. In this case however, she has been on this medication for chronic pain which is not supported by the ODG: 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. 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. 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. For more information, see the Pain Chapter: Muscle relaxants.

Also, the patient has been prescribed hydrocodone. Hydrocodone is a narcotic or opioid compound and is supported by the ODG for acute cases of pain. In this case she has been on this medication for chronic pain which is not supported by the ODG: 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. Recent studies document a 423% increase in expenditures for opioids for back pain, without demonstrated improvements in patient outcomes or disability rates. With opioid therapy for nonspecific low back pain compared with no opioids, the odds of chronic work loss were six times greater for claimants with schedule II ("strong") opioids; were 11-14 times greater for claimants with opioid prescriptions of any type during a period of  $\geq 90$  days; and 3 years after injury, costs of claimants with schedule II opioids averaged \$19,453 higher than costs of claimants in the no opioids group. For more information, and Criteria for Use of Opioids, see the Pain Chapter.

**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 FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**