

# True Decisions Inc.

An Independent Review Organization  
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Notice of Independent Review Decision

**DATE OF REVIEW:** June 7, 2008

**IRO CASE #:**

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

Were the office visits 9/10/07 and 10/8/07 medically necessary?

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

Board Certified in Physical Medicine and Rehabilitation  
Subspecialty Board Certified in Pain Management

**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)

**PATIENT CLINICAL HISTORY [SUMMARY]:**

There are some conflicting information in the material provided by Dr. and Dr.. This is a xx year old who was severely assaulted on x/xx or x/xx. His injuries were severe and he sustained back and head injuries. The latter left him deaf. He had ongoing low back pain. Dr. first saw him on 5/31/07 for the back pain. The notes describe the request for translaminar epidural injections, but these were denied. There was no description of the MRI or a report. Dr. did comment on an appeal letter of the presence of normal aging changes in the back. The man had left thigh tingling that slowly improved with Lyrica. Dr. descresd some left lower extremity weakness, especially in the toe and foot. His patient described his back locking up. The Reviewer could not determine from the record why or when the PEG was inserted. Presumably, this is not related to the injury.

During this time frame, the man was treated with Lyrica, Ultram, Soma and Cymbalta. He was initially followed monthly and then the intervals between visits increase.

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

**The medications described need supervision. The medical visits are justified as the physician was managing the medications closely.**

Lyrica is an antiepileptic agent that is approved for diabetic neuropathy and is effective for off label use in the treatment of neuropathic pain. It is a controlled substance.

Cymbalta is an antidepressant approved for diabetic neuropathy but also used off label in the control of neuropathic pain. As for most if not all antidepressants, the FDA has a black box warning.

Ultram is tramadol. It is not officially considered an opiate in the United States, but is in some other countries. There are people addicted to this medication.

Soma or carisoprodol, is a muscle relaxer. A recent report in Spine in 2008 (unfortunately the Reviewer can not specifically cite it now) reports some people have back pain relief with muscle relaxers. Carisoprodol is not legally a controlled substance by the DEA, but some states, Texas excluded), consider it a controlled substance. It is related to meprobamate. As such it needs to be monitored.

Therefore, this man is on several medications requiring frequent monitoring. The Reviewer does not find a reason for not monitoring this man in the September and October visits.

**Antidepressants**

Acute low back pain: Not routinely recommended.

Chronic low back pain: Tricyclic antidepressants can produce moderate symptom reduction for patients with chronic low back pain. The effect on function has not been determined. SSRIs do not appear to be beneficial. SNRIs have not been evaluated. ([Schnitzer, 2004](#)) ([Staiger-Spine, 2003](#)) ([Airaksinen, 2006](#)) ([Chou, 2007](#)) ([Perrot, 2006](#))

Radiculopathy: There are no medications that have been shown to be efficacious for treatment of lumbosacral radiculopathy. ([Dworkin, 2007](#))

(Note: This recommendation in chronic back pain is different from the 1994 AHCPR Low Back Guideline, which concluded "Recommend Against" for Antidepressants.) ([Bigos, 1999](#)) For more detail and

references, see the Chronic Pain Chapter: [Antidepressants for chronic pain](#); See also the [Stress & Mental Chapter](#) for Antidepressants (as a treatment for depression).

#### Duloxetine (Cymbalta®)

Recommended as an option in first-line treatment of neuropathic pain. Duloxetine (Cymbalta®) is a norepinephrine and serotonin reuptake inhibitor antidepressant (SNRIs). It has FDA approval for treatment of depression, generalized anxiety disorder, and for the treatment of pain related to diabetic neuropathy, with effect found to be significant by the end of week 1 (effect measured as a 30% reduction in baseline pain). The starting dose is 20-60 mg/day, and no advantage has been found by increasing the dose to twice a day, except in fibromyalgia. The medication has been found to be effective for treating fibromyalgia in women with and without depression, 60 mg once or twice daily. ([Arnold, 2005](#)) The most frequent side effects include nausea, dizziness and fatigue. GI symptoms are more common early in treatment. The side effect profile of Duloxetine is thought to be less bothersome to patients than that of tricyclic antidepressants. Note: On October 17, 2005, Eli Lilly and the U.S. Food and Drug Administration (FDA) notified healthcare professionals of revision to the PRECAUTIONS/Hepatotoxicity section of the prescribing information for Cymbalta. Postmarketing reports of hepatic injury (including hepatitis and cholestatic jaundice) suggest that patients with preexisting liver disease who take duloxetine may have an increased risk for further liver damage. The new labeling extends the Precaution against using Cymbalta in patients with substantial alcohol use to include those patients with chronic liver disease. It is recommended that Cymbalta not be administered to patients with hepatic insufficiency. See the [Stress Chapter](#) for more information and references. See [Antidepressants for chronic pain](#) for general guidelines, as well as specific [Duloxetine](#) listing for more information and references.

#### Pregabalin (Lyrica®)

Pregabalin (Lyrica®) 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. See [Anti-epilepsy drugs](#) (AEDs) for general guidelines, as well as specific [Pregabalin](#) listing for more information and references

**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](#))

#### 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](#).

Carisoprodol (Soma®)

Not recommended over [cyclobenzaprine](#), another skeletal muscle relaxant. Carisoprodol is effective in acute LBP but **has abuse and dependency potential. Carisoprodol is metabolized to meprobamate**, an anxiolytic. There is a school of thought that its main effect is due to generalized sedation. Withdrawal symptoms may occur with abrupt discontinuation. Soma has been noted to be a street drug of abuse and is often combined with acetaminophen and codeine, a combination labeled as “Soma-Coma”. For more information and references, see [Muscle relaxants](#).

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](#).

Tramadol (Ultram®)

Tramadol is a centrally acting synthetic opioid analgesic and it is not recommended as a first-line oral analgesic. For more information and references, see [Opioids](#). See also [Diabetic neuropathy; Opioids for neuropathic pain](#); & [Medications for acute pain](#) (analgesics).

### **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 KNOWLEDGBASE**
- 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)**