

INDEPENDENT REVIEWERS OF TEXAS, INC.

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Notice of Independent Review Decision

DATE OF REVIEW: 09/16/11

IRO CASE NO.:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Item in dispute: **(VERY DIFFICULT TO READ)**

07/15/2011 1671438 Zolpidem

07/15/2011 0058203 Diazepam

07/15/2011 0017210 Baclofen

07/02/2011 0071207 Cyclobenzaprine

07/08/2011 0638620 Paroxetine.

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

Texas Board Certified Physical Medicine & Rehabilitation

Texas Board Certified Pain Management

REVIEW OUTCOME

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

Denial Upheld

INFORMATION PROVIDED TO THE IRO FOR REVIEW

1. Clinical notes dated 11/15/10-03/02/11
2. Cover sheet, and working documents.
3. **Official Disability Guidelines**

PATIENT CLINICAL HISTORY (SUMMARY):

The employee is a male who sustained an injury on xx/xx/xx.

The clinical note dated 11/15/10 is an Independent Medical Evaluation (IME), which detailed the employee was involved a motor vehicle accident and injured his neck and low back twelve years ago and underwent two lumbar and one cervical spine surgery for the injuries that he sustained in the accident. The employee was taking Hydrocodone, Baclofen, Ambien, Diazepam, Paxil, and Flexeril at the time. On physical

examination, the employee had decreased range of motion of the lumbar spine and cervical spine. It was noted the employee had been treated with the same medications for the past thirteen years and that they were indicated for continued treatment. The employee reported that he had satisfactory relief for the treatment of his chronic pain syndrome with pain management. The clinical note stated that chronic use of muscle relaxants to include Baclofen and Flexeril was not recommended, and the employee could be weaned off the medications in a matter of weeks. The clinical note also detailed that the use of Paxil and Valium for the employee did not appear to be beneficial per guidelines. It was noted that the employee's continued use of Ambien was concerning and a weaning timeframe recommendation should be given a detoxification expert. Concerns were raised by MD of the sedating qualities of the muscle relaxants and Benzodiazepines the employee had been on and was recommended to continue weaning process.

The clinical note dated 02/15/11 is a letter of intent to endorse RME report recommendations that states the employee would continue to be funded for the medications he was on to allow for a weaning process.

The clinical note dated 03/02/11 states the employee presented with complaints of back and neck pain, rated 8/10. The employee reported that his medications controlled the pain. The treating doctor did not agree with the RME and the carrier's determination to wean the employee off the medications. The note stated that the employee benefitted from the medication regimen that he was on and was given the opportunity to be completely tapered off all his medications; however, the employee did not believe he could tolerate that at that time. It was felt that the employee needed to be treated with the medication regimen he was on, as he felt it was medically reasonable and necessary as a result of his pain related to the injury he sustained in xx.

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

The employee is a male who sustained an injury on xx/xx/xx and has chronic neck and back pain. The employee has been on a medication regimen for the pain and insomnia for many years. **Official Disability Guidelines** do not recommend Diazepam and Paroxetine is not recommended for pain. Zolpidem is only recommended for short-term treatments of insomnia for two to six weeks as well as Cyclobenzaprine recommended for short-term usage. Baclofen is recommended for spasticity and muscle spasms related to muscular sclerosis and spinal cord injuries. The employee has taken Ambien and Flexeril for over at least one year, which is more than the guidelines recommend. The clinical notes provided do not detail that the employee has muscle spasms that are related to spinal cord injuries to warrant the need for Baclofen. Furthermore, the employee was recommended to start the weaning process to discontinue these medications, as they are not needed for long-term use. Therefore, the request is not warranted per evidence-based guidelines. As such, the documentation submitted for review does not support the request to certify at this time.

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

Official Disability Guidelines, Pain Chapter, On-Line Version.

Zolpidem (Ambien®)

Zolpidem is a prescription short-acting nonbenzodiazepine hypnotic, which is approved for the short-term (usually two to six weeks) treatment of insomnia. Proper sleep hygiene is critical to the individual with chronic pain and often is hard to obtain. Various medications may provide short-term benefit. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term. (Feinberg, 2008)

Benzodiazepines

Not recommended for long-term use because long-term efficacy is unproven and there is a risk of psychological and physical dependence or frank addiction. Most guidelines limit use to 4 weeks. Benzodiazepines are a major cause of overdose, particularly as they act synergistically with other drugs such as opioids (mixed overdoses are often a cause of fatalities). Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly (3-14 day). Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. Tolerance to lethal effects does not occur and a maintenance dose may approach a lethal dose as the therapeutic index increases. The best prevention for substance use disorders due to benzodiazepines is careful prescribing.

Baclofen (Lioresal®, generic available): The mechanism of action is blockade of the pre- and post-synaptic GABAB receptors. It is recommended orally for the treatment of spasticity and muscle spasm related to multiple sclerosis and spinal cord injuries. Baclofen has been noted to have benefits for treating lancinating, paroxysmal neuropathic pain (trigeminal neuralgia, non-FDA approved). (ICSI, 2007) Side Effects: Sedation, dizziness, weakness, hypotension, nausea, respiratory depression and constipation. This drug should not be discontinued abruptly (withdrawal includes the risk of hallucinations and seizures). Use with caution in patients with renal and liver impairment. Dosing: Oral: 5 mg three times a day. Upward titration can be made every 3 days up to a maximum dose of 80 mg a day. (See, 2008)

Cyclobenzaprine (Flexeril®)

Recommended as an option, using a short course of therapy. See Medications for subacute & chronic pain for other preferred options. Cyclobenzaprine (Flexeril®) is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. (Browning, 2001) Treatment should be brief. There is also a post-op use. The addition of cyclobenzaprine to other agents is not recommended. (Clinical Pharmacology, 2008) Cyclobenzaprine-treated patients with fibromyalgia were 3 times as likely to report overall improvement and to report moderate reductions in individual symptoms, particularly sleep. (Tofferi, 2004) Note: Cyclobenzaprine is closely related to the tricyclic antidepressants, e.g., amitriptyline. See Antidepressants. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement in LBP and is associated with drowsiness and dizziness. (Kinkade, 2007) Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system (CNS) depressant that is marketed as Flexeril by Ortho McNeil Pharmaceutical. See also Muscle relaxants (for pain), Cyclobenzaprine listing.

Paroxetine (Paxil®, generic available): Also recommended for GAD, SAD, OCD, and PTSD as well as major depressive disorder. Dosing information: dosing is typically 10-60 mg daily. Paroxetine CR (Paxil® CR): Also approved for SAD, major depressive disorder, and premenstrual dysphoric disorder. Sertraline (Zoloft®, generic available): Also approved for PTSD, SAD, OCD, major depressive disorder and premenstrual dysphoric disorder. Dosing information: 50-200 mg once daily.