



**MEDICAL EVALUATORS  
OF T E X A S ASO,LLC.**

2211 West 34<sup>th</sup> St. • Houston, TX 77018  
800-845-8982 FAX: 713-583-5943

**Notice of Independent Review Decision**

02/04/2015 AMENDED- Changes marked by underline below

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**DATE OF ORIGINAL REVIEW: 02/04/2015**

**DATE OF AMENDED REVIEW: 02/04/2015**

**IRO CASE #:**

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

Lyrica 100mg #90 with 2 RF, Ibuprofen 600 mg #30 with 2 RF, and Hydrocodone-Acetaminophen 5/325 mg #90 with 2 RF.

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

This case was reviewed by a physician who holds a board certification in Physical Medicine and Rehabilitation and is currently licensed and practicing in the state of Texas.

**REVIEW OUTCOME**

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

**Upheld** (Agree)

**EMPLOYEE CLINICAL HISTORY [SUMMARY]:**

The patient is a male who sustained a right ankle/ foot injury on xx/xx/xx when he stepped on a platform. Medications history included Lyrica, Ambien, Diazepam, Ibuprofen, and Hydrocodone-Acetaminophen. Prior surgeries includes knee and gastric bypass surgeries.

The patient was seen on 03/20/2014 for follow up on his medications. Musculoskeletal examination of the right ankle revealed no swelling, edema or erythema of surrounding tissues, no instability and normal range of motion, and no crepitation. Palpation revealed moderate and generalized tenderness. He was diagnosed with ankle and foot pain and insomnia, organic persistent and was prescribed Ibuprofen, Lyrica, Hydrocodone, and Ambien.

On 06/20/2014, the patient showed up for a refill for Hydrocodone, Ambien, Lyrica, Diazepam, and Ibuprofen. The patient stated that these medications help his pain in a great



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way and that it hurts all the time when he skip few doses. Physical examination was unremarkable except for mild swelling, and tenderness right ankle/ foot. He was diagnosed with ankle and foot pain; dystrophy, reflex sympathetic lower limb; insomnia, organic persistent; and depressive disorder, not elsewhere classified. He was prescribed a refill for Nexium, Lyrica, Ambien, Diazepam, Ibuprofen, and Hydrocodone-Acetaminophen.

On 09/22/2014, the patient was seen for follow up and refill of his medications. Musculoskeletal examination revealed mild tenderness to palpation over the right ankle, and good ROM of the right ankle. He was diagnosed with ankle and foot pain, episodic mood disorder, and insomnia and was prescribed a refill for Lyrica, Ambien, and Hydrocodone-Acetaminophen.

On 12/18/2014, the patient presented for a refill on his medication. Musculoskeletal examination revealed tenderness to palpation over the right ankle. He was diagnosed with ankle and foot pain, anxiety, and insomnia and was prescribed Nexium and refill for Lyrica, Ambien, Diazepam, Ibuprofen, and Hydrocodone-Acetaminophen.

On 01/06/2015, the patient presented for the doctor to fill paperwork required for insurance regarding his medications. Physical examination revealed the right ankle to have mild swelling and causing pain with motion. The patient was diagnosed with ankle and foot pain, dystrophy; reflex sympathetic lower limb, and episodic mood disorder and was recommended Hydrocodone-Acetaminophen.

On 01/27/2015, the patient presented to review paperwork. Examination of the right ankle revealed moderate tenderness to palpation, boggy swelling, and hypersensitivity was noted. He was diagnosed with dystrophy, reflex sympathetic lower limb.

Peer review from NMR dated 01/15/2015 denied the request for lyrica because there is insufficient objective evidence regarding continuing neuropathic condition, the request for Ibuprofen because the current ODG guidelines does not support the chronic use of prescription NSAIDs as there is limited evidence regarding their efficacy as compared to standard OTC medications for pain such as Tylenol, and the request for Hydrocodone-Acetaminophen based on that the patient has been utilizing this medication over an extended period of time, and per ODG guidelines, the use of a short acting narcotic such as Norco can be considered an option in the treatment of moderate to severe musculoskeletal pain, and because the benefits obtained from short acting narcotics diminishes over time.



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

Medical Records reflect a claimant with a diagnosis of ankle and foot pain, dystrophy; reflex sympathetic lower limb, and episodic mood disorder. Most recent physical examination revealed the right ankle to have mild swelling and causing pain with motion. The claimant is being managed with these medications.

Regarding the request for Lyrica, ODG supports this type of medication for the treatment of neuropathic pain. The recent progress reports indicate this patient has right ankle tenderness, mild swelling and pain with motion. There is an absence in documentation indicating neuropathic pain to support the ongoing use of this medication. Therefore, prescription for Lyrica is not supported.

Regarding the request for Ibuprofen, ODG does not support the long-term use of NSAIDS and there are no extenuating circumstances to support the ongoing use of this medication. According to the medical records provided for review, a progress report dated 03/20/2014 indicates he was taking this medication from 03/27/2013 to 07/02/2013 and then discontinued. He was prescribed this medication again on 06/20/2014. The records do not have evidence to support that the patient was having any pain relief and objective functional improvement with the use of this medication. Therefore, the request for Ibuprofen is not supported.

Regarding the request for Hydrocodone –acetaminophen, the long-term use of an opioid is not supported, particularly if there is no documentation of functional improvement and/or quantification and duration of improvement. According to the medical records provided for review, a progress report dated 03/20/2014 indicates he was started on this medication on 12/20/2013. The records do not have evidence to support that the patient was having any pain relief and objective functional improvement with the use of this medication. Therefore, the ongoing use of this medication is not supported.

In summary, the ongoing use of the requested medications are not medically necessary and appropriate due to lack of documentation of efficacy from prior use of these medications.



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**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)

**ODG – Pain (Chronic)**

**Anti-epilepsy drugs (AEDs) for pain**

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. (Wiffen-Cochrane, 2013) 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



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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 increasing daily doses 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) Significant negative cognitive side effects were documented in healthy volunteers at 600 mg per day in one study. (Salinsky, 2010) 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 limited 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.

### **ODG – Pain (Chronic)**

#### **NSAIDs (non-steroidal anti-inflammatory drugs)**

pecific recommendations:

**Osteoarthritis (including knee and hip):** Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with



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all NSAIDs and is a class effect (with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. (Chen, 2008) (Laine, 2008)

Back Pain - Acute low back pain & acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting to negative evidence that NSAIDs are more effective than acetaminophen for acute LBP. (van Tulder, 2006) (Hancock, 2007) For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. (Roelofs-Cochrane, 2008) The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician. (Hancock, 2007)

Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another. (Roelofs-Cochrane, 2008) See also Anti-inflammatory medications.

Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough pain and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in patients with neuropathic pain. (Namaka, 2004) (Gore, 2006)

See NSAIDs, GI symptoms & cardiovascular risk; NSAIDs, hypertension and renal function; & Medications for acute pain (analgesics). Besides the above well-documented side effects of NSAIDs, there are other less well-known effects of NSAIDs, and the use of NSAIDs has been shown to possibly delay and hamper healing in all the soft tissues, including muscles, ligaments, tendons, and cartilage. (Maroon, 2006) The risks of NSAIDs in older patients, which include increased cardiovascular risk and gastrointestinal toxicity, may outweigh the benefits of these medications. (AGS, 2009)

## **ODG – Pain (Chronic)**

### **Opioids, criteria for use**

4) On-Going Management. Actions Should Include:

- (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy.
- (b) The lowest possible dose should be prescribed to improve pain and function.
- (c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after



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- taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000)
- (d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management.
- (e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control. (Webster, 2008)
- (f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion).
- (g) Continuing review of overall situation with regard to nonopioid means of pain control.
- (h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse. (Sullivan, 2006) (Sullivan, 2005) (Wilsey, 2008) (Savage, 2008) (Ballyantyne, 2007)
- 5) Recommended Frequency of Visits While in the Trial Phase (first 6 months):
- (a) Every 2 weeks for the first 2 to 4 months
- (b) Then at approximate 1 ½ to 2-month intervals
- Note: According to the California Medical Board Guidelines for Prescribing Controlled Substances for Pain, patients with pain who are managed with controlled substances should be seen monthly, quarterly, or semiannually as required by the standard of care. (California, 1994)
- 6) When to Discontinue Opioids: See Opioid hyperalgesia. Also see Weaning of Medications. Prior to discontinuing, it should be determined that the patient has not had treatment failure due to causes that can be corrected such as under-dosing or inappropriate dosing schedule. Weaning should occur under direct ongoing medical supervision as a slow taper except for the below mentioned possible indications for immediate discontinuation. The patient should not be abandoned.
- (a) If there is no overall improvement in function, unless there are extenuating circumstances
- (b) Continuing pain with the evidence of intolerable adverse effects; lack of significant benefit (persistent pain and lack of improved function despite high doses of opiates- e.g. > 120 mg/day morphine equivalents)
- (c) Decrease in functioning



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- (d) Resolution of pain
  - (e) If serious non-adherence is occurring
  - (f) The patient requests discontinuing
  - (g) Immediate discontinuation has been suggested for: evidence of illegal activity including diversion, prescription forgery, or stealing; the patient is involved in a motor vehicle accident and/or arrest related to opioids, illicit drugs and/or alcohol; intentional suicide attempt; aggressive or threatening behavior in the clinic. It is suggested that a patient be given a 30-day supply of medications (to facilitate finding other treatment) or be started on a slow weaning schedule if a decision is made by the physician to terminate prescribing of opioids/controlled substances.
  - (h) Many physicians will allow one “slip” from a medication contract without immediate termination of opioids/controlled substances, with the consequences being a re-discussion of the clinic policy on controlled substances, including the consequences of repeat violations.
  - (i) If there are repeated violations from the medication contract or any other evidence of abuse, addiction, or possible diversion it has been suggested that a patient show evidence of a consult with a physician that is trained in addiction to assess the ongoing situation and recommend possible detoxification. (Weaver, 2002)
  - (j) When the patient is requesting opioid medications for their pain and inconsistencies are identified in the history, presentation, behaviors or physical findings, physicians and surgeons who make a clinical decision to withhold opioid medications should document the basis for their decision.
  - (k) Routine long-term opioid therapy is not recommended, and ODG recommends consideration of a one-month limit on opioids for new chronic non-malignant pain patients in most cases, as there is little research to support use. The research available does not support overall general effectiveness and indicates numerous adverse effects with long-term use. The latter includes the risk of ongoing psychological dependence with difficulty weaning. See Opioids for chronic pain.
- 7) When to Continue Opioids
- (a) If the patient has returned to work
  - (b) If the patient has improved functioning and pain