



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

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

DATE OF REVIEW: MAY 27, 2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Oxycontin 20 mg, Senokot S 8.6/50 mg, Promethazine 2.5 mg, Topamax 100 mg

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

The reviewer of this case is a physician board certified in Family Medicine and considered to be an expert in their field of specialty, with current experience in the denied treatment and who is currently licensed in the state of Texas.

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)

EMPLOYEE CLINICAL HISTORY [SUMMARY]:

The claimant is a male who was injured on xx/xx/xx when he slipped and fell at work sustaining injury to the lower back. The claimant has since been diagnosed with chronic low back pain, sciatica, nausea and constipation.

Venous Ultrasound of bilateral lower extremity dated 02/09/2015 from showed: Negative exam for deep vein thrombosis.

X-ray of the sacrum and coccyx dated 02/24/2015 from showed: Postsurgical changes lumbar spine with no gross coccygeal or sacral irregularities to suggest fracture. Visualized pelvis is also unremarkable.

X-ray of the lumbar spine dated 02/24/2015 from showed: There are findings of PLIF at L4-5 and residual anterior fixation from the same levels without evidence of gross hardware failure. Nonsurgical levels are relatively unremarkable. There is evidence of



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previous surgical/PLIF at L5-S1 with no anterior hardware and no transpedicular screws at S1 suggestive of removal.

Past surgical history includes a lumbar fusion (03/01/2010), spinal cord stimulator (10/03/2012), Greenfield filter placement, orchiectomy, left knee arthroscopy, left shoulder rotator cuff repair, and umbilical hernia repair.

Prior treatments have included multiple medications including Promethazine 25 mg 1 po BID, Oxycontin 20 mg 1-2 PO BID, Senokot S 8.6-50 mg 1-2 PO BID, Topamax 100 mg 1 PO TID, Pantoprazole Sodium 40 mg 1 PO daily, Wellbutrin 150 mg 1 PO daily, Gabapentin 600 mg TID, Metformin HCL 100 mg 1 BID, Methocarbamol 750 mg QID, Bupropion HCL ER 150 mg XR 24H tablet 1 QD, Duloxetine HCL 30 mg QD, Montelukast Sodium 10 mg 1 HS, Anastrozole 1 mg QD, Tamsulosin HCL 0.4 mg QD, Minocycline HCL 1 BID, Furosemide 40 mg QD, Testosterone Cypionate 200 mg/ML oil inject 1.5 mL every 14 days, Lidocaine 5% Oint apply as needed, and Lyrica.

No documentation of any other conservative treatment attempted for the claimant was provided.

Laboratory test results dated 01/05/2015 showed total testosterone of 57 ng/dL and free testosterone of 11.7 pg/mL.

Laboratory test result dated 03/19/2015 showed positive for opiates and negative for amphetamines, barbiturates, benzodiazepines, cocaine, methadone, and THC.

Recent progress note dated 03/19/2015 by indicates the claimant presented with pain in the lower back and legs. Current pain level of 7, least reported pain since last seen of 5, average pain of 7, and pain level after taking pain medication of 7. The claimant reported not seeing much relief lately after taking medications. On ADLs, the claimant reported he is able to eat, dress and bathe but feels unsteady on his feet and has wife nearby in case of falls. Adverse side effects reported include nausea which he feels may be due to the uncontrolled pain. The claimant uses Senokot 1-2/day BID for constipation. Functional status has declined since last visit as he is no longer able to assist with housekeeping or exercise as he previously did (walking). No evidence of doctor shopping or inappropriate use documented in this visit. Regarding the claimant's medical regimen, he reports excessive weight gain with Lyrica and is on Gabapentin 600 mg TID (which does seem to help) and Topiramate (noted to have less sharp pain and less irritated nerves). It was recommended that the claimant wean the Senna, increase Oxycontin to 30mg BID due to current worsening of pain and decreased function, increase Gabapentin to 800mg TID due to poor control of pain, continue Topiramate as it seems to help with his pain and start Miralax/ wean Senokot.

The exam notes the claimant was in no acute distress. Alert and oriented. Behavior and affect appears to be uncomfortable, frequently shifting position. Cardiovascular: Regular rate and rhythm. No gallops or rubs. No murmur. No pedal edema. Pedal pulses palpable.



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Chest: Respirations even and unlabored. Lungs clear to auscultation. No rhonchi. No crackles. No wheezing. Musculoskeletal: Tenderness of the lumbosacral junction. Shuffling gait. Uses cane.

Prior UR dated 03/04/2015 and 03/31/2015 denied the request for Oxycontin 20 mg, Senokot S 8.6/50 mg, Promethazine 2.5 mg, and Topamax 100 mg. The request for Promethazine was denied because Prometahzine is used in the treatment of acute nausea and vomiting and it is not recommended for use in addition to short-acting or long-acting opioids due to significant adverse effects which include sedation, drug interactions, and respiratory depression. The request for Oxycontin was denied because there is insufficient objective information to show functional improvement with the use of this medication. The request for Senokot was denied because there is insufficient objective information regarding its use for this patient at this time. It would be appropriate to address the cause of constipation which may include opioid medications prior to adding additional treatments. The request for Topamax was denied because it is an antidepressant used in specific types of pain. It is not a 1st line or 2nd line option. There are durg interactions when combined with promethazine and Oxycontin.

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

Oxycontin, which has been prescribed to control the claimant's persistent pain of back and legs, as a long-acting opioid. Claimant has a chronic condition which has persisted since a fall in 2004. The guidelines (ODG & Cochrane Review) indicate that routine long-term opioid therapy is not recommended. Therefore, treatment of claimant with Oxycontin is not appropriate.

Topamax, which has also been prescribed to control the claimant's persistent pain of back and legs, is an anti-epileptic. The guidelines (ODG & BMJ) indicate that treatment of claimant with Topamax is not appropriate.

Senokot, which has been prescribed to the claimant for constipation, is a stimulant laxative. The guidelines (Int J Clin Pract & Am Fam Physician) indicate that treatment of this claimant with Senokot is appropriate due to current constipation issues.

Promethazine, which has been prescribed to the claimant for nausea, is an antipsychotic. The guidelines (ODG) indicate that antiemetics are not recommended for nausea and vomiting secondary to chronic opioid use. Nausea and vomiting is common with use of opioids, but these side effects tend to diminish over days to weeks of continued exposure. Therefore, treatment of claimant with Promethazine is not appropriate based on the available documentation.



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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) – Online Version
Anti-epilepsy drugs (AEDs) for pain**

Topiramate (Topamax®, generic available) has been shown to have variable efficacy, with failure to demonstrate efficacy in neuropathic pain of “central” etiology. It is still considered for use for neuropathic pain when other anticonvulsants fail. Topiramate has recently been investigated as an adjunct treatment for obesity, but the side effect profile limits its use in this regard. (Rosenstock, 2007).



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Opioids, criteria for use

CRITERIA FOR USE OF OPIOIDS

Therapeutic Trial of Opioids

1) Establish a Treatment Plan. The use of opioids should be part of a treatment plan that is tailored to the patient. Questions to ask prior to starting therapy:

(a) Are there reasonable alternatives to treatment, and have these been tried?

(b) Is the patient likely to improve? Examples: Was there improvement on opioid treatment in the acute and subacute phases? Were there trials of other treatment, including non-opioid medications?

(c) Has the patient received a screen for the risk of addiction? Is there likelihood of abuse or an adverse outcome? Specific questions about current use of alcohol, illegal drugs, other prescription drugs, and over-the-counter drugs should be asked. Obtaining a history of personal and/or family substance abuse issues is important. See Substance abuse (tolerance, dependence, addiction). See Opioids, screening for risk of addiction. (Webster, 2008) (Ballyantyne, 2007)

(d) Ask about Red Flags indicating that opioids may not be helpful in the chronic phase:

(1) Little or no relief with opioid therapy in the acute and subacute phases. (2) The patient has been given a diagnosis in one of the particular diagnostic categories that have not been shown to have good success with opioid therapy: conversion disorder; somatization disorder; pain disorder associated with psychological factors (such as anxiety or depression, or a previous history of substance abuse). Patients may misuse opioids prescribed for pain to obtain relief from depressed feelings, anxiety, insomnia, or discomforting memories. There are better treatments for this type of pathology. (Sullivan, 2006) (Sullivan, 2005) (Wilsey, 2008) (Savage, 2008)

(e) 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.

2) Steps to Take Before a Therapeutic Trial of Opioids:

(a) Attempt to determine if the pain is nociceptive or neuropathic. Also attempt to determine if there are underlying contributing psychological issues. Neuropathic pain may require higher doses of opioids, and opioids are not generally recommended as a first-line therapy for some neuropathic pain.

(b) A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics.

(c) Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals.

(d) Baseline pain and functional assessments should be made. Function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale. See Function Measures.

(e) Pain related assessment should include history of pain treatment and effect of pain and function.



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- (f) Assess the likelihood that the patient could be weaned from opioids if there is no improvement in pain and function.
 - (g) The patient should have at least one physical and psychosocial assessment by the treating doctor (and a possible second opinion by a specialist) to assess whether a trial of opioids should occur. When subjective complaints do not correlate with imaging studies and/or physical findings and/or when psychosocial issue concerns exist, a second opinion with a pain specialist and a psychological assessment should be obtained. (Sullivan, 2006) (Sullivan, 2005) (Wilsey, 2008) (Savage, 2008) (Ballyantyne, 2007)
 - (h) The physician and surgeon should discuss the risks and benefits of the use of controlled substances and other treatment modalities with the patient, caregiver or guardian.
 - (i) A written consent or pain agreement for chronic use is not required but may make it easier for the physician and surgeon to document patient education, the treatment plan, and the informed consent. Patient, guardian, and caregiver attitudes about medicines may influence the patient's use of medications for relief from pain. See Guidelines for Pain Treatment Agreement. This should include the consequences of non-adherence.
 - (j) Consider the use of a urine drug screen to assess for the use or the presence of illegal drugs.
- 3) Initiating Therapy
- (a) Intermittent pain: Start with a short-acting opioid trying one medication at a time.
 - (b) Continuous pain: extended-release opioids are recommended. Patients on this modality may require a dose of "rescue" opioids. The need for extra opioid can be a guide to determine the sustained release dose required.
 - (c) Only change 1 drug at a time.
 - (d) Prophylactic treatment of constipation should be initiated.
 - (e) If partial analgesia is not obtained, opioids should be discontinued.
- 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 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



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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

(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



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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

(Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004)

Opioid-induced constipation treatment

Recommended as indicated below. In the section, Opioids, criteria for use, if prescribing opioids has been determined to be appropriate, then ODG recommends, under Initiating Therapy, that Prophylactic treatment of constipation should be initiated. Opioid-induced constipation is a common adverse effect of long-term opioid use because the binding of opioids to peripheral opioid receptors in the gastrointestinal (GI) tract results in absorption of electrolytes, such as chloride, with a subsequent reduction in small intestinal fluid. Activation of enteric opioid receptors also results in abnormal GI motility. Constipation occurs commonly in patients receiving opioids and can be severe enough to cause discontinuation of therapy.

First-line: When prescribing an opioid, and especially if it will be needed for more than a few days, there should be an open discussion with the patient that this medication may be constipating, and the first steps should be identified to correct this. Simple treatments include increasing physical activity, maintaining appropriate hydration by drinking enough water, and advising the patient to follow a proper diet, rich in fiber. These can reduce the



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chance and severity of opioid-induced constipation and constipation in general. In addition, some laxatives may help to stimulate gastric motility. Other over-the-counter medications can help loosen otherwise hard stools, add bulk, and increase water content of the stool.

Second-line: If the first-line treatments do not work, there are other second-line options. About 20% of patients on opioids develop constipation, and some of the traditional constipation medications don't work as well with these patients, because the problem is not from the gastrointestinal tract but from the central nervous system, so treating these patients is different from treating a traditional patient with constipation. An oral formulation of methylnaltrexone (Relistor®) met the primary and key secondary end points in a study that examined its effectiveness in relieving constipation related to opioid use for noncancer-related pain. The effectiveness of oral methylnaltrexone in this study was comparable to that reported in clinical studies of subcutaneous methylnaltrexone in subjects with chronic noncancer-related pain. There was an 80% improvement in response with the 450 mg dose and a 55% improvement with 300 mg. Constipation drug lubiprostone (Amitiza®) shows efficacy and tolerability in treating opioid-induced constipation without affecting patients' analgesic response to the pain medications. Lubiprostone is a locally acting chloride channel activator that has a distinctive mechanism that counteracts the constipation associated with opioids without interfering with the opiates binding to their target receptors. (Bader, 2013) (Gras-Miralles, 2013) See also Tapentadol (Nucynta™), which has improved gastrointestinal tolerability for patients complaining of constipation, nausea, and/or vomiting. The FDA has approved methylnaltrexone bromide (Relistor) subcutaneous injection 12 mg/0.6 mL for the treatment of opioid-induced constipation in patients taking opioids for noncancer pain. (FDA, 2014)

Antiemetics (for opioid nausea)

Not recommended for nausea and vomiting secondary to chronic opioid use.

Recommended for acute use as noted below per FDA-approved indications. Nausea and vomiting is common with use of opioids. These side effects tend to diminish over days to weeks of continued exposure. Studies of opioid adverse effects including nausea and vomiting are limited to short-term duration (less than four weeks) and have limited application to long-term use. If nausea and vomiting remains prolonged, other etiologies of these symptoms should be evaluated for. The differential diagnosis includes gastroparesis (primarily due to diabetes). Current research for treatment of nausea and vomiting as related to opioid use primarily addresses the use of antiemetics in patients with cancer pain or those utilizing opioids for acute/postoperative therapy.

Recommendations based on these studies cannot be extrapolated to chronic non-malignant pain patients. There is no high-quality literature to support any one treatment for opioid-induced nausea in chronic non-malignant pain patients. (Moore 2005)

Promethazine (Phenergan®): This drug is a phenothiazine. It is recommended as a sedative and antiemetic in pre-operative and post-operative situations. Multiple central



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nervous system effects are noted with use including somnolence, confusion and sedation. Tardive dyskinesia is also associated with use. This is characterized by involuntary movements of the tongue, mouth, jaw, and/or face. Choreoathetoid movements of the extremities can also occur. Development appears to be associated with prolonged treatment and in some cases can be irreversible. Anticholinergic effects can occur (dry mouth, dry eyes, urinary retention and ileus).

Ondansetron (Zofran®): This drug is a serotonin 5-HT₃ receptor antagonist. It is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also FDA-approved for postoperative use. Acute use is FDA-approved for gastroenteritis.

See also Nabilone (Cesamet®), for chemotherapy-induced nausea, but not pain.

Opioids (for chronic pain)

Cochrane Database Syst Rev. 2013 Aug 27;8:CD004959

Opioids compared to placebo or other treatments for chronic low-back pain.

Chaparro LE1, Furlan AD, Deshpande A, Mailis-Gagnon A, Atlas S, Turk DC.

Laxatives (for opioid constipation)

Int J Clin Pract. 2007 Jul; 61(7): 1181–1187

Opioid-induced bowel dysfunction: prevalence, pathophysiology and burden

S J Panchal, P Müller-Schwefe, and J I Wurzelmann

In practice, stool softeners such as docusate sodium are commonly administered to patients with Opiate-Induced Bowel Dysfunction; they are also prescribed prophylactically to patients on opioid regimens. Such agents are generally very well tolerated, but seldom achieve relief of opioid-induced constipation when used alone. Therefore, one of the most common regimens prescribed is a stool softener plus a stimulant laxative (e.g. senna).

Laxatives (for opioid constipation)

Am Fam Physician. 2006 Oct 15;74(8):1347-1354

Management of Common Opioid-Induced Adverse Effects

John M. Swegle, Craig Logemann

Monotherapy with stool softeners is considered ineffective, and use of a scheduled stimulant laxative often is required.¹ There are no studies showing superiority of one laxative over another. However, one common approach is the scheduled use of senna with or without a stool softener.

Transcriptionist Initials:

Hp/sj