MEDICAL CONTESTED CASE HEARING NO. 13000
M6-11-35899-01
M6-11-35900-01
M6-11-35901-01

DECISION AND ORDER

These cases are consolidated and decided pursuant to Chapter 410 of the Texas Workers' Compensation Act and Rules of the Division of Workers' Compensation adopted thereunder.

ISSUES

A contested case hearing was scheduled for November 17, 2011, January 12, 2012 and February 23, 2012 but reset to and held on September 12, 2012 to decide the following disputed issues:

In Docket No.:

Is the preponderance of the evidence contrary to the decision of the Independent Review Organization (IRO) that Claimant is not entitled to the prescription MSIR 30 mg po quid #120 for the compensable injury of (Date of Injury)?

In Docket No. :

Is the preponderance of the evidence contrary to the decision of the IRO that Claimant is not entitled to the prescription MS Contin 100 mg po qid #120 for the compensable injury of (Date of Injury)?

In Docket No. :

Is the preponderance of the evidence contrary to the decision of the IRO that Claimant is not entitled to the prescription Soma 350 mg po qid #90 for the compensable injury of (Date of Injury)?

PARTIES PRESENT

Petitioner/Claimant appeared, by telephone, and was assisted by IG, ombudsman. Respondent/Carrier appeared and was represented by NM, adjuster.

BACKGROUND INFORMATION

These cases involve three separate requests for preauthorization of prescription medications that were reviewed by three separate IRO physician reviewers. Claimant sustained a compensable injury to his lumbar spine when he was lifting a 300 pound air conditioning unit on (Date of Injury). Claimant subsequently underwent a microdiscectomy and L5-S1 fusion. Medical records also indicate that Claimant sustained a broken neck when he was 15 years old and again when he was 18 years old. Claimant testified that his job duties installing AC units aggravated

his cervical spine condition and that he needs cervical spine surgery. Claimant has had on-going complaints of pain and he has been prescribed a number of narcotics which he has been taking for many years. Claimant's treating physician has recommended the continued use of MSIR 30 mg, MS Contin 100 mg and Soma 350 mg. This request was denied by the Carrier and submitted to three separate IRO's who upheld the Carrier's denial.

Texas Labor Code Section 408.021 provides that an employee who sustains a compensable injury is entitled to all health care reasonably required by the nature of the injury as and when needed. Health care reasonably required is further defined in Texas Labor Code Section 401.011 (22a) as health care that is clinically appropriate and considered effective for the injured employee's injury and provided in accordance with best practices consistent with evidence-based medicine or, if evidence-based medicine is not available, then generally accepted standards of medical practice recognized in the medical community. Health care under the Texas Workers' Compensation system must be consistent with evidence based medicine if that evidence is available. Evidence-based medicine is further defined in Texas Labor Code Section 401.011 (18a) to be the use of the current best quality scientific and medical evidence formulated from credible scientific studies, including peer-reviewed medical literature and other current scientifically based texts and treatment and practice guidelines in making decisions about the care of individual patients. The Commissioner of the Division of Workers' Compensation is required to adopt treatment guidelines that are evidence-based, scientifically valid, outcome-focused and designed to reduce excessive or inappropriate medical care while safeguarding necessary medical care. Texas Labor Code Section 413.011(e). Medical services consistent with the medical policies and fee guidelines adopted by the commissioner are presumed reasonable in accordance with Texas Labor Code Section 413.017(1).

In accordance with the above statutory guidance, the Division of Workers' Compensation has adopted treatment guidelines by Division Rule 137.100. This rule directs health care providers to provide treatment in accordance with the current edition of the ODG, and such treatment is presumed to be health care reasonably required as defined in the Texas Labor Code. Thus, the focus of any health care dispute starts with the health care set out in the ODG. Also, in accordance with Division Rule 133.308(t), "[a] decision issued by an IRO is not considered an agency decision and neither the Department nor the Division [is] considered [a party] to an appeal. In a Contested Case Hearing (CCH), the party appealing the IRO decision has the burden of overcoming the decision issued by an IRO by a preponderance of evidence-based medical evidence."

Regarding Docket No. :

The IRO reviewer, identified as a medical doctor board certified in anesthesiology and pain management, determined that the request for MSIR 30 mg qid #120 is not supported by the submitted clinical records and upheld the previous denials. The IRO reviewer stated that the

available data indicates that Claimant is receiving paradoxical response to increases in opiate doses without improvement in his pain levels suggesting opiate hyperalgesia. The historical records also suggest compliance issues and that Claimant's medication profile is excessive. The IRO reviewer concluded by stating, based on the totality of the clinical information, the request for MSIR 30 mg qid #120 is not found to be medically necessary or supported under the ODG.

Regarding Docket No.:

The IRO reviewer, identified as a physician board certified in physical medicine and rehabilitation, determined that the ODG pain chapter recommends opioid dosing not to exceed 120 mg oral morphine per day and to discontinue opioids if "persistent pain and lack of improve function despite high doses of opiates of > 120 mg per day." This Claimant has persistent pain despite escalating dosage of opioids with a morphine equivalent dose on MS Contin 100 mg qid, MSIR 30 mg, Percocet 10/325 mg is at a minimum of 490 mg per day to a maximum of 580 mg per day. Also submitted clinical records do not note monitoring for adverse side effects or abhorrent behavior with no notation of urine drug screens despite ever increasing amounts of opioids prescribed.

Regarding Docket No. :

The IRO reviewer, identified as a medical doctor board certified in physical medicine, rehabilitation and pain management, determined that the request for Soma 350 mg po qid #90 was not supported by the submitted clinical information and the current evidence based guidelines. The IRO reviewer noted that the submitted clinical record indicates Claimant has chronic low back pain with subjective reports of radiation into bilateral lower extremities. Claimant has undergone extensive conservative treatment including multiple interventional procedures and he has been managed on oral pain medications. The most recent physical examination provides no objective data of acute or chronic myospasms. The IRO reviewer concluded by stating that, the absence of acute myospasms and noting that the current evidence based guidelines do not support the chronic use of Soma secondary to abuse potential, the request is not medically necessary.

ODG Criteria for use of MSIR (Morphine):

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? 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. (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.

(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 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 dairy 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 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.

(7) When to Continue Opioids

(a) If the patient has returned to work

(b) If the patient has improved functioning and pain

ODG Criteria for use of MS Contin:

Morphine sulfate, Morphine sulfate ER, CR (Avinza®; Kadian®; MS Contin®; Oramorph SR®; generic available, except extended release capsules): Side Effects: See opioid adverse effects. Analgesic dose: Immediate release tablets for acute pain (moderate to severe); Opiate naive patients should begin with 10mg PO every 4 hours as needed. Opioid tolerant patients may need higher starting doses to achieve pain relief (10-30mg every 4 hours as needed). See specific product for full prescribing information. Controlled, extended and sustained release preparations should be reserved for patients with chronic pain, who are in need of continuous treatment. Avinza® - morphine sulfate extended release for once daily dosing. The 60mg, 90mg and 120mg capsules are for opioid tolerant patients only. Kadian® - (extended release capsules) May be dosed once or twice daily. The 100mg and 200mg capsules are intended for opioid tolerant patients only. MS Contin® - (controlled release tablets) Doses should be individually tailored for each patient.

ODG Criteria for use of Soma (Carisoprodol):

Not recommended. This medication is FDA-approved for symptomatic relief of discomfort associated with acute pain in musculoskeletal conditions as an adjunct to rest and physical therapy. (AHFS, 2008) This medication is not indicated for long-term use. Carisoprodol is a commonly prescribed, centrally acting skeletal muscle relaxant whose primary active metabolite is meprobamate (a schedule-IV controlled substance). Carisoprodol is now scheduled in several states but not on a federal level. It has been suggested that the main effect is due to generalized sedation and treatment of anxiety. Abuse has been noted for sedative and relaxant effects. In regular abusers the main concern is the accumulation of meprobamate. Carisoprodol abuse has also been noted in order to augment or alter effects of other drugs. This includes the following: (1) increasing sedation of benzodiazepines or alcohol; (2) use to prevent side effects of cocaine; (3) use with tramadol to produce relaxation and euphoria; (4) as a combination with hydrocodone, an effect that some abusers claim is similar to heroin (referred to as a “Las Vegas Cocktail”); & (5) as a combination with codeine (referred to as “Soma Coma”). (Reeves, 1999) (Reeves, 2001) (Reeves, 2008) (Schears, 2004) (Owens, 2007) There was a 300% increase in numbers of emergency room

> episodes related to carisoprodol from 1994 to 2005. (DHSS, 2005) Intoxication appears to include subdued consciousness, decreased cognitive function, and abnormalities of the eyes, vestibular function, appearance, gait and motor function. Intoxication includes the effects of both carisoprodol and meprobamate, both of which act on different neurotransmitters. (Bramness, 2007) (Bramness, 2004) A withdrawal syndrome has been documented that consists of insomnia, vomiting, tremors, muscle twitching, anxiety, and ataxia when abrupt discontinuation of large doses occurs. This is similar to withdrawal from meprobamate. (Reeves, 2010) (Reeves, 2007) (Reeves, 2004) There is little research in terms of weaning of high dose carisoprodol and there is no standard treatment regimen for patients with known dependence. Most treatment includes treatment for symptomatic complaints of withdrawal. Another option is to switch to phenobarbital to prevent withdrawal with subsequent tapering. A maximum dose of phenobarbital is 500 mg/day and the taper is 30 mg/day with a slower taper in an outpatient setting. Tapering should be individualized for each patient.

Claimant testified that he suffers from constant low back and neck pain, radiating pain and muscle spasms. Claimant testified that he has been taking the prescribed medications for approximately five years and that they are all effective to some extent. Claimant testified that he would be able to reduce his medications if he could undergo spinal surgery as recommended by his treating surgeon. Claimant submitted a medical report from Dr. B dated March 1, 2012. Dr. B notes that the medication program continues to be moderately helpful at improving pain and function. Dr. B fails to address the concerns raised by the IRO's and he did not provide an evidence-based medical opinion regarding the medical necessity of the continued narcotic use by Claimant. Although Claimant testified that he needs to continue to take the prescribed medications for pain and muscle spasms, he failed to offer a medical opinion regarding the requirements in the ODG for the continued use of the narcotics at issue or any other evidence-based medical opinion regarding the medical necessity of these prescriptions for treatment of his compensable injury. The preponderance of the evidence is not contrary to the determinations of the IRO's that these requested prescriptions are not medically necessary for treatment of Claimant's compensable injury of (Date of Injury)**.**

Even though all the evidence presented may not have been discussed in detail, it was considered; the Findings of Fact and Conclusions of Law are based on all of the evidence presented.

FINDINGS OF FACT

1. The parties stipulated to the following facts:

   A. Venue was proper in the (City) Field Office of the Texas Department of Insurance, Division of Workers' Compensation.

B. On (Date of Injury), Claimant was the employee of (Employer), Employer.

C. On (Date of Injury), Employer had workers' compensation insurance coverage with American Home Assurance Company, Carrier.

D. The Claimant sustained a compensable injury on (Date of Injury).

2. Carrier delivered to Claimant a single document stating the true corporate name of Carrier, and the name and street address of Carrier's registered agent, which document was admitted into evidence as Hearing Officer's Exhibit Number 2.

In Docket No.:

3. Claimant does not meet the requirements of the ODG for the prescription MSIR 30 mg po qid #120 and Claimant failed to present evidence-based medicine sufficient to overcome the determination of the IRO.

4. MSIR 30 mg po qid #120 is not health care reasonably required for the Claimant's compensable injury of (Date of Injury).

In Docket No.:

5. Claimant does not meet the requirements of the ODG for the prescription MS Contin 100 mg po qid #120 and Claimant failed to present evidence-based medicine sufficient to overcome the determination of the IRO.

6. MS Contin 100mg po qid #120 is not health care reasonably required for the Claimant's compensable injury of (Date of Injury).

In Docket No.:

7. Claimant does not meet the requirements of the ODG for the prescription Soma 350 mg po qid #90 and Claimant failed to present evidence-based medicine sufficient to overcome the determination of the IRO.

8. Soma 350mg po qid #90 is not health care reasonably required for the Claimant's compensable injury of (Date of Injury).

CONCLUSIONS OF LAW

1. The Texas Department of Insurance, Division of Workers' Compensation, has jurisdiction to hear this case.

2. Venue was proper in the (City) Field Office.

In Docket No.:

> The preponderance of the evidence is not contrary to the decision of the IRO that the prescription MSIR 30 mg po quid #120 is not health care reasonably required for the compensable injury of (Date of Injury).

In Docket No.:

> The preponderance of the evidence is not contrary to the decision of the IRO that the prescription MS Contin 100 mg po qid #120 is not health care reasonable required for the compensable injury of (Date of Injury).

In Docket No.:

> The preponderance of the evidence is not contrary to the decision of the IRO the prescription Soma 350 mg po qid #90 is not health care reasonable required for the compensable injury of (Date of Injury).

DECISION

In Docket No.: Claimant is not entitled to the prescription MSIR 30 mg po quid #120 for the compensable injury of (Date of Injury).

In Docket No.: Claimant is not entitled to the prescription MS Contin 100 mg po qid #120 for the compensable injury of (Date of Injury).

In Docket No.: Claimant is not entitled to the prescription Soma 350 mg po qid #90 for the compensable injury of (Date of Injury).

ORDER

In Docket No., Carrier is not liable for the benefits at issue in this hearing. Claimant remains entitled to medical benefits for the compensable injury in accordance with §408.021.

In Docket No.: Carrier is not liable for the benefits at issue in this hearing. Claimant remains entitled to medical benefits for the compensable injury in accordance with §408.021.

In Docket No.: Carrier is not liable for the benefits at issue in this hearing. Claimant remains entitled to medical benefits for the compensable injury in accordance with §408.021.

The true corporate name of the insurance carrier is **AMERICAN HOME ASSURANCE COMPANY,** and the name and address of its registered agent for service of process is:

CORPORATION SERVICE COMPANY
211 EAST 7TH STREET, SUITE 620
AUSTIN, TX 78701-3218

Signed this 12th day of September, 2012.

Carol A. Fougerat
Hearing Officer