

IRO REVIEWER REPORT TEMPLATE -WC

INDEPENDENT REVIEWERS OF TEXAS, INC.

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Notice of Independent Review Decision

[Date notice sent to all parties]:

07/22/2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: Morphine ER 60mg; MSIR 30mg

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

Board Certified Anesthesiology

REVIEW OUTCOME:

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

Partially Overturned (Agree in part/Disagree in part)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

Urine drug screen report dated 03/17/11

Clinical report dated 02/01/07

Clinical report dated 05/14/08

Clinical report dated 08/06/08

Clinical report dated 04/15/09

Clinical report dated 10/26/09

Clinical report dated 11/16/09

Clinical report dated 04/26/10

Clinical report dated 10/05/10

Clinical report dated 04/05/11

Clinical report dated 09/14/11

Clinical report dated 05/04/12
Clinical report dated 09/10/12
Clinical report dated 01/15/13
Clinical report dated 05/13/13
Clinical report dated 11/19/13
Clinical report dated 03/18/14
Clinical report dated 05/20/14
Prior utilization review reports dated 05/22/14 & 06/06/14

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male who has been followed for complaints of chronic low back pain status post lumbar laminectomy. The patient was assessed with failed back surgery syndrome and chronic radicular pain syndrome. The patient has been provided narcotic medications for an extended period of time. Previous narcotics have included Roxycodone through 2013. The patient was switched to MS Contin 60mg every 8 hours and MSIR 30mg 4 times daily as of May of 2013. As of 11/19/13, the patient was no longer working as the work site had sold the business he was working at previously at 40 hours per week. Per the 11/19/13 clinical report, the patient did report decreased pain with medications with improvement of function. Follow up on 03/18/14 reported varying pain scores from 4-7/10 on the VAS. The patient was working part time and was able to tolerate medications appropriately. The patient felt he obtained approximately 30% improvement with the use of medications with pain scores reduced from 7 to 4/10 on the VAS. The patient felt that he was able to function better with medications. No changes in the frequency of MS Contin or MSIR were noted at this evaluation. Follow up on 05/20/14 noted no change in the patient's pain scores. The patient continued to report improved function with the ability to work part time. Physical examination at this evaluation noted a continuing positive straight leg raise to the right at 30 degrees.

The requested Morphine ER 60mg and MSIR 30mg were denied by utilization review on 05/22/14 as there was no documentation of significant positive objective findings to account for the patient's continuing pain condition. There was also no specific documentation regarding the patient's coping mechanisms to support chronic use of narcotic agents.

The request was again denied by utilization review on 06/06/14 as there was no documentation regarding recent urinary drug screens.

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

The patient has been followed for an ongoing chronic pain condition consistent with post-laminectomy syndrome. The patient has had a long history of narcotics use since 2009. The home exercise program was recently switched to MSIR and MS

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Contin in 2013. The amount of medication being provided to the patient exceeds the maximum amount of narcotics recommended for daily intake by guidelines set at 100mg MED. The patient's current intake of narcotics is well above 200mg MED. The patient does report improvement of pain scores from 7 to 4/10 on the VAS. The patient was noted to be available to work part time with the use of the provided medications. Although there are no updated urinary drug screen findings for this patient, there is also no indication of any substantial medication abnormalities or suspicions for diversion documented in the clinical record. Per guidelines, the ongoing use of narcotic medications can be considered for patients with severe musculoskeletal pain with ongoing assessments regarding the efficacy of these medications in terms of pain reduction and functional improvement. As the patient does report decreased pain and is able to work part time, this reviewer would not recommend discontinuation of narcotic medications at this point in time. However, medications are exceeding the maximum amount of narcotics to be provided to a patient in 1 day at greater than 120mg MED per day. Furthermore, the requests are non-specific in regards to quantity, frequency, or duration. As such, it is this reviewer's opinion that ongoing use of Morphine ER 60mg and MSIR 30mg is medically necessary; however, this reviewer does recommend that these requests be modified for a quantity of 60 Morphine ER and 60 MSIR in order to facilitate a weaning period down to 120mg MED as prescribed by the physician. It is expected that the physician would titrate the patient down to acceptable narcotic intake levels appropriately and per guideline recommendations.

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

MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

Official Disability Guidelines, Online Version, Pain Chapter

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) Is there likelihood of abuse or an adverse outcome? See Substance abuse (tolerance, dependence, addiction).
- (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 had a psychological evaluation and has been given a diagnosis of somatoform disorder. (3) 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).
- (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

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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.

(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 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.

(f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion).

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(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.

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

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

Opioids, dosing

Recommend that dosing not exceed 100 mg MED (morphine equivalents dosage/day), while there should be increased caution for dosing over 50 MED.