

US Decisions, Inc.

An Independent Review Organization

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Notice of Independent Review Decision

DATE OF REVIEW: June 30, 2008

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Oxycontin 10mg. TID, Oxycontin 20mg TID, Oxycodone APAP 10/325 TID for break through pain

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

M.D., Board Certified in Physical Medicine and Rehabilitation
Subspecialty Board Certified in Pain Management
Subspecialty Board Certified in Electrodiagnostic Medicine
Residency Training PMR and Orthopedic Surgery

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)

Upon independent review the reviewer finds that the requested medication Oxycontin 10mg. TID is medically necessary, that the requested medication Oxycontin 20mg TID is medically necessary, and that the requested medication Oxycodone APAP 10/325 TID for break through pain is medically necessary.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Adverse Determination Letters 6/11/08, 5/22/08, 5/14/08
ODG Guidelines and Treatment Guidelines
Medication Agreement and Instruction 2/22/07

MD 6/3/08, 4/9/08, 2/12/08, 1/30/08, 1/14/08, 12/7/07, 11/9/07, 10/12/07, 8/17/07,
7/25/07, 6/14/07, 5/18/07, 4/2/07, 2/27/07
Procedure Details 7/11/07, 6/1/07, 4/27/07
Psychodiagnostic Assessment 1/30/08
Prescription Copies 5/8/08
Pain Drawings 4/2/07, 2/12/08, 1/30/08, 1/14/08, 12/7/07, 11/9/07, 10/12/07, 8/17/07
VAS Scale Forms 4/2/07, 2/12/08, 1/30/08, 1/14/08, 12/7/07, 11/9/07, 10/12/07
Roland Questionnaire

PATIENT CLINICAL HISTORY [SUMMARY]:

This man sustained a back injury on xx/xx/xx. He underwent a left lumbar laminectomy. He failed to improve with the surgery and with physical therapies. He had no improvement of left back and buttock with a transforaminal ESI at L4/5 and L5/S1 and facet injections. He had a discogram with concordant pain at the L4/5 and L5/S1 levels. He was considered for a spinal stimulator. This procedure is pending a possible decompression procedure such as a nucleoplasty.. His pain drawings are consistent with physical pain. He had no abnormal psychological issues. He is being managed on Oxycontin 20 tid, and 10 mg tid with short acting Oxycodone APAP 10/325 tid for break through pain. This apparently is helping. He has not showed any abnormal behaviors on the pain medications. The request for coverage of the prescriptions by Workers Compensation was denied. One reason provided was the absence of a signed pain medication agreement. A signed one was in the records. The current request is for Oxycontin 10mg. TID, Oxycontin 20mg TID, Oxycodone APAP 10/325 TID for break through pain

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

Upon independent review of the provided medical records and ODG Guidelines, this reviewer finds that the requested medication Oxycontin 10mg. TID is medically necessary, that the requested medication Oxycontin 20mg TID is medically necessary, and that the requested medication Oxycodone APAP 10/325 TID for break through pain is medically necessary.

The ODG is not very supportive of the use of pain medications for chronic pain. Yet it recognizes they can be useful in the treatment of chronic pain.

See the [Pain Chapter](#) for more information and studies. When used only for a time-limited course, opioid analgesics are an option in the management of patients with acute low back problems. The decision to use opioids should be guided by consideration of their potential complications relative to other options. Patients should be warned about potential physical dependence and the danger associated with the use of opioids while operating heavy equipment or driving. The studies found that patients taking opioid analgesics did not return to full activity sooner than patients taking NSAIDs or acetaminophen. In addition, studies found no difference in pain relief between NSAIDs and opioids. Finally, side effects of opioid analgesics were found to be substantial, including the risk for physical dependence. These side effects are an important concern in conditions that can become chronic, such as low back problems. ([Bigos, 1999](#)) For more information, and Criteria for Use of Opioids, see the [Pain Chapter](#).

Opioids for chronic pain:

Recommendations for general conditions:

- Neuropathic pain: Opioids have been suggested for neuropathic pain that has not responded to first-line recommendations ([antidepressants](#), [anticonvulsants](#)). There are no trials of long-term use. There are virtually no studies of opioids for treatment of chronic lumbar root pain with resultant neuropathy. See [Opioids for neuropathic pain](#).
- **Chronic back pain: Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. There is no evidence to recommend one opioid over another. In patients taking opioids for back pain, the prevalence of lifetime substance use disorders has ranged from 36% to 56% (a statistic limited by poor study design). Limited information indicated that up to one-fourth of patients who receive opioids exhibit aberrant medication-taking behavior. ([Martell-Annals, 2007](#)) ([Chou, 2007](#)) There are three studies comparing Tramadol to placebo that have reported pain relief, but this increase did not necessarily improve function. ([Deshpande, 2007](#)) ...**

Chronic pain can have a mixed physiologic etiology of both neuropathic and nociceptive components. In most cases, **analgesic** treatment should begin with acetaminophen, aspirin, and NSAIDs (as suggested by the WHO step-wise algorithm). When these drugs do not satisfactorily reduce pain, opioids for moderate to moderately severe pain may be added to (not substituted for) the less efficacious drugs. A major concern about the use of opioids for chronic pain is that most randomized controlled trials have been limited to a short-term period (≤ 70 days). This leads to a concern about confounding issues such as tolerance, opioid-induced hyperalgesia, long-range adverse effects such as hypogonadism and/or opioid abuse, and the influence of placebo as a variable for treatment effect. ([Ballantyne, 2006](#)) ([Furlan, 2006](#)) Long-term, observational studies have found that treatment with opioids tends to provide improvement in function and minimal risk of addiction, but many of these studies include a high dropout rate (56% in a 2004 meta-analysis). ([Kalso, 2004](#)) There is also no evidence that opioids showed long-term benefit or improvement in function when used as treatment for chronic back pain. ([Martell-Annals, 2007](#)) Current studies suggest that the “upper limit of normal” for opioids prior to evaluation with a pain specialist for the need for possible continuation of treatment, escalation of dose, or possible weaning, is in a range from 120-180 mg morphine equivalents a day. ([Ballantyne, 2006](#)) ([AMDG, 2007](#))

There are several proposed guidelines for the use of opioids for chronic non-malignant pain, but these have not been evaluated in clinical practice, and selection of the patient that will best respond to this treatment modality remains difficult. ([Nicholas, 2006](#)) ([Stein, 2000](#)) One of the most recent of these guidelines is the Agency Medical Director’s Group (AMDG) Guidelines from Washington State. This guideline includes an opioid dosing calculator. ([AMDG, 2007](#))

Outcomes measures: It is now suggested that rather than simply focus on pain severity, improvements in a wide range of outcomes should be evaluated, including measures of functioning, appropriate medication use, and side effects. Measures of pain assessment that allow for evaluation of the efficacy of opioids and whether their use should be maintained include the following: 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. ([Nicholas, 2006](#)) ([Ballantyne, 2006](#)) A recent epidemiologic study found that opioid treatment for chronic non-malignant pain

did not seem to fulfill any of key outcome goals including pain relief, improved quality of life, and/or improved functional capacity. ([Eriksen, 2006](#))

Tolerance and addiction: Opioid tolerance develops with the repeated use of opioids and brings about the need to increase the dose and may lead to sensitization. It is now clear that analgesia may not occur with open-ended escalation of opioids. It has also become apparent that analgesia is not always sustained over time, and that pain may be improved with weaning of opioids. ([Ballantyne, 2006](#)) ([Ballantyne, 2003](#)) See [Substance abuse \(tolerance, dependence, addiction\)](#).

Behavior reinforcement: A major concern in the use of opioids has been that a focus on this treatment without coordination with other modalities, such as [psychosocial or behavioral therapy](#), may simply reinforce pain-related behavior, ultimately undermining rehabilitation that has been targeted at functional restoration. ([Ontario, 2000](#)) It has been shown that pain behavior can be reinforced by the prescribing of opioids, generally on an unintentional basis by the patient. ([Fordyce, 1991](#))

Overall treatment suggestions: Current guidelines suggest the following:

- A trial of opioids as a first step in treatment, and the steps involved are outlined in the [Criteria for Use of Opioids](#). The trial includes an initiation phase that involves selection of the opioid and initial dose. ([VA/DoD, 2003](#))
- There is then a titration phase that includes dose adjustment. At this phase it may be determined that opioids are not achieving the desired outcomes, and they should be discontinued.
- The final stage is the maintenance phase. If pain worsens during this phase the differential to evaluate includes disease progression, increased activity, and/or new or increased pre-existing psychosocial factors that influence pain. In addition, the patient may develop hyperalgesia, tolerance, dependence or actual addiction.

The use of opioids for the treatment of CNMP (chronic nonmalignant pain) remains controversial, and there is no universally accepted consensus on whether, when, and how opioid therapy should be administered. Clinicians who choose to offer chronic opioid therapies must formulate rational and individualized regimens according to strategies...Ideally, treatment endpoints should include functional improvement as verifiable objective signs.”(pages 130-131 Drugs for Pain, Howard Smith MD, Hanley and Belfus. 2003)

The ODG requires a treatment plan and consideration for alternative treatments. This man had epidural and facet injections, and there is consideration of a spinal stimulator and nucleoplasty underway. There is no history of substance abuse and he is using the pain medication with reported benefit. The psychological studies did not show any contraindications for their use. The treating doctors appeared to have followed the criteria for the trial of opioids.

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 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).

(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

Therefore, I concur with the treating physician for the role of these medications in the treatment of this patient.

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 KNOWLEDGBASE
- 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)**