

Notice of Independent Review Decision

DATE OF REVIEW: OCTOBER 15, 2010

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Supplies & Materials PRV by PHYS (Norco 10/325 #120/30 and Zanaflex 4mg #120/30 with 1 refill)

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

This physician is Board Certified by American Board of Pain Management and Anesthesiology with 40 years of experience.

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)

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

On March 31, 2006, M.D. performed a peer review. He determined that the current complaints are not related to the compensable injury of xx/xx/xx. The patient had pre-existing degenerative back changes and previous surgery. The hardware from the 1997 surgery might be causing the current complaints, but is not related to the xx/xx/xx injury. The acute injury of xx/xx/xx would have reasonably been resolved by now and no further treatment is necessary. The removal of the hardware would not be related to the incident of xx/xx/xx.

On January 21, 2009, a Notice of Independent Review Decision determined that the requested chronic pain management program is not medically necessary as he has completed both work conditioning program in 20 as well as a work hardening program in 2008 with reported significant improvement. The ODG Guidelines do not recommended chronic pain management for injuries greater than 2 years old.

On January 7, 2010, the claimant was evaluated by M.D., a physical medicine and rehabilitation physician. His pain at the time of the appointment was 2-3/10. The pain is in his low back, hips, and SI joint. He has been taking Norco 10/325 and Zanaflex 4 mg. These medications have been helpful for him, however he has had increased pain especially with the colder weather. In January 2009 he underwent an SI joint injection which reportedly helped significantly.

On February 19, 2010, M.D., an orthopedic spine surgeon performed a peer review. He determined that There is a history of prior injuries and/or pre-existing conditions that could impact the patient's current condition. The current diagnosis is failed back syndrome. The claimant appears to have suffered a lumbar sprain/strain as a result of the compensable injury. His current complaints are most probably related to his failed lumbar fusion surgery. No further treatment is necessary. If the failed back syndrome is accepted as part of the compensable injury, then the medications the patient is currently utilizing are reasonable and necessary. The effects of the compensable injury as it related to the lumbar sprain have resolved.

On April 13, 2010, the claimant was re-evaluated by, M.D. He has been taking Norco 10/325 one qid prn and Zanaflex 4 mg po qid for spasms. Overall, his pain his better from the last visit. He has been cleared to use Mobic 7.5 mg po qid per day as an NSAID prn for his symptoms. He underwent an SI injection in January 2010 which helped significantly.

On April 13, 2010, the claimant was re-evaluated by M.D. He has been cleared to lift up to 35 pounds intermittently. He has mild to moderate lumbar paraspinal muscle spasms. He is to continue Norco 10/325, Zanaflex 4 mg and Mobic 7.5 mg.

On August 13, 2010, M.D., a physical medicine and rehabilitation physician, performed a utilization review on the claimant. Rational for Denial: The records

available for review do not provide documentation to indicate that utilization of prescription medications significantly enhances functional activities and/or assists in the ability to perform work activities. Therefore, it is not certified.

On August 20, 2010, M.D., an orthopedic surgeon, performed a utilization review on the claimant Rational for Denial: ODG guidelines indicates Norco is an opioid and not recommend for first line therapy. Zanaflez is a central acting muscle relaxer that is approved for management of spasticity and has unlabeled use for low back pain, the claimant does have spasm on physical examination and this would be supported. Therefore, it is not certified.

PATIENT CLINICAL HISTORY:

On xx/xx/xx, the claimant stated he strained his back pushing a stalled golf car. He had a previous history of a lower back injury resulting in a lumbar fusion surgery in 1997.

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

As reported above the ODG guidelines do not recommend narcotics for first line therapy for chronic pain management. Thus, the Norco 10/325, which is an opioid, is not recommended. The only report here is a pain level of 2-3 on a scale of 1-10 on January 7, 2010, which is minimal and probably related to the reported "failed back syndrome", and not to the compensable injury of a lumbar sprain/strain, which occurred x years ago.

Secondly, he is reported to have mild to moderate lumbar paravertebral muscle spasms. Again, this is probably not related to the compensable injury sustained in. He has been cleared to lift up to 35 pounds intermittently on April 13, 2010, on examination by Dr.. The continued use of Xanaflex (tizanidine), 4 mg. capsules is not innocuous. Relevant side effects of this drug include dry mouth, somnolence, weakness, fatigue, tiredness, and occasionally dizziness.

As stated by the previous reviewers, documentation does not warrant the necessity for the use of Norco 10/325 and Zanaflex 4mg. Therefore, the adverse determination is upheld.

Per the ODG Guidelines: 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. Long-term efficacy is unclear (>16 weeks), and there is also limited evidence for the use of opioids for chronic low back pain. ([Martell-Annals, 2007](#)) 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](#))

- - *Nociceptive pain:* Recommended as the standard of care for treatment of moderate or severe nociceptive pain (defined as pain that is presumed to be maintained by continual injury, with the most common example being pain secondary to cancer).

- *Mechanical and compressive etiologies:* rarely beneficial.

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.

([Washington, 2002](#)) ([Colorado, 2002](#)) ([Ontario, 2000](#)) ([VA/DoD, 2003](#)) ([Maddox-AAPM/APS, 1997](#)) ([Wisconsin, 2004](#)) ([Warfield, 2004](#)) See [Substance abuse \(tolerance, dependence, addiction\)](#). See also [Implantable pumps for narcotics](#). See also Opioids in the [Low Back Chapter](#). See [Criteria for Use of Opioids](#).

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)