

Notice of Independent Review Decision

September 22, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Medical Necessity ~ 210 Tablets of Norco (Hydrocodone Bitartrate and Acetaminophen) 7.5/325 MG (3 Month Supply) between 8/18/14 and 10/17/14

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

The physician performing this review is Board Certified, American Board of Physical Medicine & Rehabilitation. The physician is certified in pain management. The physician has a private practice of Physical Medicine & Rehabilitation, Electro Diagnostic Medicine & Pain Management in Texas. The physician is a member of the Texas Medical Association and the Houston Physical Medicine and Rehabilitation Society. The physician is licensed in Texas and Michigan and has been in practice for over 25 years.

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 medical necessity exists for each of the health care services in dispute.

Upon independent review, the physician finds that the previous adverse determination should be ~ Overturned

PATIENT CLINICAL HISTORY [SUMMARY]:

The man sustained the work related injured in xxxx. He had back pain and pain to the right lower extremity. The last MRI apparently was in 2007. It showed degenerative changes from L3-S1. he had back and right lower extremity pain with paresthesias. He was diagnosed with a lumbar radiculopathy, degenerative

The DYLL REVIEW

We take the worry out of Peer Reviews

25 Highland Park Village #100-177 Dallas TX 75205
Phone: 888-950-4333 Fax: 888-9504-4443

spine and a peripheral neuropathy. He had prior ESIs with some transient benefit. He has been on several medications with some limited benefit. He apparently has no evidence of diversion or abuse. The only medication I have been requested to review in the need for the opiates. Texas requires the ODG as the sole reference guide.

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

reports this man found it to help the quality and function of his life. He is not working. There is no described abuse, diversion, etc. Other treatments, as done in this case, have not helped. So my understanding of the ODG is that while it discourages the use of chronic opiates, there are exceptions. This man appears to be one. I therefore override the denial.

The pain section addresses chronic pain, opiate use in general and hydrocodone in specific.

The national trend as reflected in the DWC policies and the ODG is against long term opiate use. This man has been on it for nearly 10 years. While most of the ODG frowns upon it, there are areas where it does consider the use appropriate. This is based upon the sections stating that they should be stopped if there is no overall improvement. This implies that they can be given if there is improvement. There are criteria when to continue these medications. This includes the subsection:

7) When to Continue Opioids

(a) If the patient has returned to work

(b) If the patient has improved functioning and pain.

In the section on chronic pain is written:

Opioids may be recommended as a 2nd or 3rd line treatment option for chronic non-malignant pain, with caution, especially at doses over 100 mg morphine equivalent dosage/day (MED). That appears to be the situation with averaging less than 3 pills a day.

It discusses the maintenance phase and the problems that can occur.

- 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.

Specifically it has a paragraph on the long term use and states that:

d) Document pain and functional improvement and compare to baseline. 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. Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument.

And lastly in the last section on the long term use, it said

The DYLL REVIEW

We take the worry out of Peer Reviews

25 Highland Park Village #100-177 Dallas TX 75205
Phone: 888-950-4333 Fax: 888-9504-4443

2) Strategy for maintenance

(a) Do not attempt to lower the dose if it is working

Opioids	<p>This topic is covered under multiple headings. See more specific entries, as follows: Opioids, criteria for use; Opioids for chronic pain; Opioids for neuropathic pain; Opioids for osteoarthritis; Opioids, cancer pain vs. nonmalignant pain; Opioids, dealing with misuse & addiction; Opioids, dosing; Opioids, indicators for addiction; Opioids, long-acting; Opioids, long-term assessment; Opioids, pain treatment agreement; Opioid provider outreach; Opioids, psychological intervention; Opioids, specific drug list; Opioids, screening for risk of addiction (tests); Opioids, state medical boards guidelines; Detoxification; Substance abuse (tolerance, dependence, addiction); Urine Drug Testing (UDT) in patient-centered clinical situations; Weaning of medications; Implantable drug-delivery systems (IDDSs); Methadone; Buprenorphine; Rapid detox; Testosterone replacement for hypogonadism (related to opioids); Opioid hyperalgesia; Opioid-induced constipation treatment; & Opioids, specific drug list. Opioid drugs are also referred to as opiate analgesics, narcotic analgesics, or schedule C (II -IV) controlled substances. Opioid analgesics are a class of drugs (e.g., morphine, codeine, and methadone) that have a primary indication to relieve symptoms related to pain. Opioid drugs are available in various dosage forms and strengths. They are considered the most powerful class of analgesics that may be used to manage both acute and chronic pain. These medications are generally classified according to potency and duration of dosage duration. ...</p> <p><u>Opioid Classifications: Short-acting/Long-acting opioids:</u> <u>Short-acting opioids</u>: also known as “normal-release” or “immediate-release” opioids are seen as an effective method in controlling both acute and chronic pain. They are often used for intermittent or breakthrough pain. These agents are often combined with other analgesics such as acetaminophen and aspirin. These adjunct agents may limit the upper range of dosing of short-acting agents due to their adverse effects. The duration of action is generally 3-4 hours. Short-acting opioids include codeine, morphine (MSIR, Roxanol®), oxycodone (OxyIR®, Oxyfast®, Oxecta®, Endocodone®), oxycodone with acetaminophen, (Roxicet®, Roxilox®, Percocet®, Tylox®, Endocet®), oxycodone with aspirin (Percodan®), oxycodone with ibuprofen (Combunox®), hydrocodone with acetaminophen (Vicodin®, Lorcet®, Lortab®, Zydone®, Hydrocet®, Norco®), hydromorphone (Dilaudid®, Hydrostat®). (Baumann, 2002)</p>
---------	--

Opioids, criteria for use	<p>CRITERIA FOR USE OF OPIOIDS <u>Therapeutic Trial of Opioids</u> 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</p>
---------------------------	---

The DYLL REVIEW

We take the worry out of Peer Reviews

25 Highland Park Village #100-177 Dallas TX 75205

Phone: 888-950-4333 Fax: 888-9504-4443

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 discomfoting 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:...

3) Initiating Therapy...

5) Recommended Frequency of Visits While in the Trial Phase (first 6 months): ...

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...

(i) If there are repeated violations from the medication contract or any other evidence of abuse, addiction, or possible diversion ...

(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.

The DYLL REVIEW

We take the worry out of Peer Reviews

25 Highland Park Village #100-177 Dallas TX 75205

Phone: 888-950-4333 Fax: 888-9504-4443

	<p>(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.</p> <p>7) When to Continue Opioids</p> <p>(a) If the patient has returned to work</p> <p>(b) If the patient has improved functioning and pain.</p>
Opioids for chronic pain	<p>Not recommended as a first-line treatment for chronic non-malignant pain, and not recommended in patients at high risk for misuse, diversion, or substance abuse. Opioids may be recommended as a 2nd or 3rd line treatment option for chronic non-malignant pain, with caution, especially at doses over 100 mg morphine equivalent dosage/day (MED)....</p> <p>Risk-benefit of use should be carefully weighed for substance abuse and overdose risks, including risk of death, and this information should be provided to the patient as part of informed decision-making...</p> <p><i>Use for specific disease states</i></p> <p>- <i>Neuropathic pain:</i> 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, where opioids are not recommended as a first-line therapy. (McNicol, 2013)</p> <p>- <i>Chronic back pain:</i> Opioids appear to be efficacious but should be limited for short-term pain relief in patients with acute low back pain. 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) (White, 2011) (Franklin, 2009) Failure of activity level 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 indicates that up to one-fourth of patients who receive opioids exhibit aberrant medication-taking behavior...See also the Low Back Chapter for recommendations in acute pain, where opioids are not recommended except for short use for severe cases, not to exceed 2 weeks.</p> <p>...</p> <p><i>Evidence for use:</i> A major concern about the use of opioids for chronic pain is that most randomized-controlled trials are limited to a short-term period (1 to 6 months), with high rates of dropout due to adverse effects and/or lack of efficacy (as high as 60%). Studies usually exclude patients with mental health disease or substance abuse, limiting generalizability. Methodological issues result in limitations, with problems of studies including insufficiently comprehensive outcome assessment, and incomplete inclusion of adverse effects. Results suggest modest pain relief compared to placebo (approximately 30%), but there are no long-term studies to determine if pain relief is maintained. Overall, the safety of long-term use has not been</p>

The DYLL REVIEW

We take the worry out of Peer Reviews

25 Highland Park Village #100-177 Dallas TX 75205

Phone: 888-950-4333 Fax: 888-9504-4443

adequately studied, and some nonrandomized prospective studies suggest opioid treatment may actually retard functional recovery. 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....

Risk factors for progressing to long-term opioid use: It is currently suggested that of the patients that proceed to long-term opioid use (90 days or more), two-thirds continue opioids for years later, creating life-long therapy. Current research involves evaluating what subsets of patients are likely to proceed to long-term use, particularly as (1) the vast majority of patients in randomized-controlled studies abandon opioids after short-term use due to adverse effects and/or lack of efficacy and (2) a small proportion of patients receive the majority of opioids dispensed. Subclasses of individuals who continue with long-term use have been identified as patients who use high daily doses (>120 mg morphine equivalent/day) and/or have a history of opioid misuse. The likelihood of receiving long-term opioids increases with number of pain sites, increased baseline pain, decreased baseline function, number of medical diagnoses, nicotine dependence, psychiatric diagnoses, lower self-reported mental health, fear avoidance beliefs, and lower certainty of return to work in the next six months. The most likely mental health diagnoses are anxiety disorder and post-traumatic stress disorder. It is suggested that long-term opioids are often unknowingly being used to treat the sequelae of both physical and psychological trauma. This is based on theories of endogenous opioid system disruption....

Adverse effects: ...

These include serious fractures, sleep apnea, hyperalgesia, immunosuppression, ...

Risk of overdose:...

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. ...

(Overall treatment suggestions: Current guidelines suggest the following:

- A trial of opioids for chronic pain as a first step in treatment for appropriate conditions that have not responded to other interventions after careful screening and patient informed consent. 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.
- 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 DYLL REVIEW

We take the worry out of Peer Reviews

25 Highland Park Village #100-177 Dallas TX 75205

Phone: 888-950-4333 Fax: 888-9504-4443

Opioids, long-term assessment	<p>(</p> <p>CRITERIA FOR USE OF OPIOIDS</p> <p><u>Long-term Users of Opioids (6-months or more)</u></p> <p>1) Re-assess</p> <p>(a) Has the diagnosis changed?</p> <p>(b) What other medications is the patient taking? Are they effective, producing side effects?</p> <p>(c) What treatments have been attempted since the use of opioids? Have they been effective? For how long?</p> <p>(d) Document pain and <u>functional improvement</u> and compare to baseline. 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. Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument.</p> <p>(e) Document adverse effects: constipation, nausea, vomiting, headache, dyspepsia, pruritus, dizziness, fatigue, dry mouth, sweating, hyperalgesia, sexual dysfunction, and sedation.</p> <p>(f) Does the patient appear to need a psychological consultation? Issues to examine would include motivation, attitude about pain/work, return-to-work, social life including interpersonal and work-related relationships.</p> <p>(g) Is there indication for a screening instrument for abuse/addiction? See Substance Abuse Screening.</p> <p>2) Strategy for maintenance</p> <p>(a) Do not attempt to lower the dose if it is working</p> <p>(b) Supplemental doses of break-through medication may be required for incidental pain, end-of dose pain, and pain that occurs with predictable situations. This can be determined by information that the patient provides from a pain diary or evaluation of additional need for supplemental medication.</p> <p>(c) The standard increase in dose is 25 to 50% for mild pain and 50 to 100% for severe pain (Wisconsin)</p> <p>3) Visit Frequency</p> <p>(a) There is no set visit frequency. This should be adjusted to the patient's need for evaluation</p>
-------------------------------	---

The DYLL REVIEW

We take the worry out of Peer Reviews

25 Highland Park Village #100-177 Dallas TX 75205
Phone: 888-950-4333 Fax: 888-9504-4443

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)