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Notice of Independent Review Decision

MEDICAL RECORD REVIEW:

DATE OF REVIEW: 07/27/2010

IRO CASE #:

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

This case was reviewed by a Pain Management (Board Certified) Doctor, Licensed in Texas and Board Certified. The reviewer has signed a certification statement stating that no known conflicts of interest exist between the reviewer and the injured employee, the injured employee's employer, the injured employee's insurance carrier, the utilization review agent (URA), any of the treating doctors or other health care providers who provided care to the injured employee, or the URA or insurance carrier health care providers who reviewed the case for a decision regarding medical necessity before referral to the IRO. In addition, the reviewer has certified that the review was performed without bias for or against any party to the dispute.

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Coverage of prescribed medication: Percocet #90, Duragesic #10, Provigil #90, and Ambien #30

REVIEW OUTCOME

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

Upheld (Agree)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- o Submitted medical records were reviewed in their entirety.
- o Treatment guidelines were provided to the IRO.
- o June 30, 2010 and July 1, 2010 peer review reports from Solutions
- o June 30, 2010, July 1, 2010, and July 2, 2010 letters from
- o February 9, 2007 Required Medical Examination report by, M.D.
- o Undated form Workers' Compensation Utilization Review Request from
- o February 6, 2008 through July 2, 2010 medical records from, M.D.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male who sustained an industrial injury on xx/xx/xx when he reportedly lifted a piece of steel.

A Required Medical Examination report, dated February 9, 2007, outlines the history and notes that the patient had bilateral decompressive laminectomy at L4-5 on December 16, 2000. Imaging in October 2001 revealed a small inferiorly extruded disc herniation at L4-5 and a minimal central disc protrusion at L5-S1. He underwent a spinal cord stimulator trial in September 2002. The plan was for permanent spinal cord stimulator implantation. It appears that he did not get clearance by the psychologist and was unable to get off narcotics. In April 2004, it was noted that he was on Duragesic patches, Gabitril, and Provigil. Multiple disc bulges were demonstrated in a May 2004 lumbar MRI. The patient continued to get medication refills through 2005 and 2006. As of the Required Medical Examination, current medications were Duragesic patches every 3 days, Vicodin ES 2 to 3 times per day, and Provigil 3 times per day. He stated that with the help of medications, he is able to work full duty as a. Without the medications the pain is severe, rated 9/10. With medications, the pain goes down to 5-6/10 and he is able to function reasonably well and work. Provigil helps him to stay awake and without it he tends to fall asleep during the day. The RME physician provided an opinion that the patient suffers from intractable failed back syndrome. He had extensive anesthesiological interventions in the past 6 years which did not result in substantial and lasting improvement. He opined that the patient needs only maintenance care with medications that will enable him to work and function. It appeared that his current drug regimen including Duragesic patch, Vicodin, and Provigil achieve these goals and enable the patient to be functional and work full duty. The physician did not recommend changing the current drug regimen.

April 30, 2008 records noted insomnia secondary to pain syndrome. Ambien was prescribed. Records from July 2008 reflect that Duragesic and Percocet were given. On July 18, 2008, he did not reports side effects from his medications. The medications provided relief described as 5. In December 2009, it was noted that the patient is working full time and continues with

medications.

On February 22, 2010, the patient described symptomatic relief of 7 with medications. He continued working full time. It was noted that the medications are working well. His activity level was deemed stable. As of April 28, 2010, he continued working full time and did not reports side effects from medications. The records include a June 17, 2010 prescription for Provigil and Ambien.

A June 30, 2010 peer review report provided an opinion that Duragesic, Provigil and Percocet are all reasonable and consistent with the ODG guidelines. The physician opined that Ambien is for short-term use only and is not recommended for long-term use as it is being used in this patient. It was noted that the patient has chronic, intractable pain, and has drowsiness from pain medication, but paradoxical insomnia. Although 3 of the 4 drugs were agreed upon, the request was denied as there was no complete agreement on all 4 drugs.

The request was again reviewed on July 1, 2010 and an opinion was provided that Percocet #90, Duragesic #10, Provigil #90, and Ambien #30 were not medically necessary. The peer review report notes that the information regarding random urine drug screens, documentation of improvement in pain, and documentation of improvement in functional state were not provided. It was recommended that the Duragesic and Percocet be weaned and not abruptly stopped. Verbal communication reportedly revealed that urine drug screens were performed, but none were provided for the review. Without the information, the peer review physician stated that the medical necessity could not be established.

The records include a July 2, 2010 report which indicates that the patient describes low back pain, leg pain, and knee pain which has been managed by the office since 2002. There is still notable left leg numbness, and activity such as sitting and bending aggravate the pain while it is improved with his current medication regimen. In the past, his average pain level was 9/10. Currently, his average pain level was 6/10. His current medication regimen includes Duragesic patches 100 mcg every 3 days which provides 30-40% relief and Percocet 10/325 3 times per day for breakthrough pain which provides 30% relief, but only lasts 3-4 hours per pill. Ambien 10 mg is provided for insomnia related to chronic pain syndrome, while Provigil 200 mg helps with excessive daytime sleepiness secondary to insomnia, chronic pain syndrome, and medication side effects related to chronic narcotic consumption. In the past, the patient has had unsuccessful lumbar surgery, failed spinal cord stimulator procedure, multiple failed spinal injections, and physical therapy.

Examination findings include decreased lumbar range of motion, tenderness to palpation, no focal deficits, and ambulation without an assistive device. A request is made for continuation of the current medication regimen as this regimen allows him to maintain a functionally independent lifestyle that ultimately results in the best possible quality of life for him and his family. The physician stated that to discontinue his medications and wean him would destroy what is currently a stable foundation.

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

The Required Medical Examination on February 9, 2007 produced an opinion that the patient's medications were appropriate, including Duragesic patch, Vicodin, and Provigil. Vicodin was later replaced with Percocet and the patient has been stable on these medications for an extended period of time. The first peer review physician felt that it was appropriate for the patient to have access to each of the medications with the exception of Ambien. The records establish that the patient is stable on medication with minimal side effects, with the exception of sleepiness, and these medications allow the patient to continue functioning and working full duty. I agree that it is reasonable for the patient to be maintained on Duragesic patches, Percocet, and Provigil. However, the guidelines indicate that the Ambien is approved for short-term treatment of insomnia, usually 2 to 6 weeks. The patient has been on Ambien for an extended period of time. The records do not establish that an attempt has been made at nonpharmacological methods, including proper sleep hygiene. Given that Ambien is only appropriate for short-term use, my recommendation is to uphold the previous decision to non-certify the request for Percocet #90, Duragesic #10, Provigil #90, and Ambien #30.

The recommendation does not imply an abrupt cessation or constitute a medical order for treatment or discontinuance of treatment for this patient. Any medical order must be considered by the treating physician in accordance with the appropriate standard of care protocol to avoid any adverse consequences which may occur with changes in the treatment regimen.

The IRO's decision is consistent with the following guidelines:

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

ODG Pain Chapter:

Modafinil (Provigil)

Not recommended solely to counteract sedation effects of narcotics until after first considering reducing excessive narcotic prescribing. Use with caution as indicated below. Indications: Provigil is indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea, and shift work sleep disorder. Patients should have a complete evaluation with a diagnosis made in accordance with the International Classification of Sleep Disorders or DSM diagnostic classification. Adverse effects: This drug has been known to be misused and/or abused, particularly by patients that have a history of drug or stimulant abuse. Common adverse effects include headache, nausea, nervousness, rhinitis, diarrhea, back pain, anxiety, insomnia, dizziness, and dyspepsia. Dose: The standard dose for these conditions is 200 mg a day. The dose should be reduced to ½ for patients with severe hepatic impairment. (Clinical Pharmacology, 2008) (Micromedix, 2008) (Lexi-Comp, 2008) (AHFS Drug Information, 2008) Modafinil is increasingly being used as a cognitive enhancer. Although initially launched as distinct from stimulants that increase extracellular dopamine by targeting dopamine transporters, recent preclinical studies suggest otherwise. There is need for heightened awareness for potential abuse of and dependence on modafinil. (Kumar, 2008) (Volkow-JAMA, 2009)

ODG Pain Chapter:

Zolpidem (Ambien)

Zolpidem is a prescription short-acting nonbenzodiazepine hypnotic, which is approved for the short-term (usually two to six weeks) treatment of insomnia. Proper sleep hygiene is critical to the individual with chronic pain and often is hard to obtain. Various medications may provide short-term benefit. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term. (Feinberg, 2008)

ODG Pain Chapter:

Opioids, specific drug list

Oxycodone/acetaminophen (Percocet; generic available): Side Effects: See opioid side effects and acetaminophen. Analgesic dose: Dosage based on oxycodone content and should be administered every 4 to 6 hours as needed for pain. Initially 2.5 to 5 mg PO every 4 to 6 hours prn. Note: Maximum daily dose is based on acetaminophen content (Maximum 4000mg/day). For more severe pain the dose (based on oxycodone) is 10-30mg every 4 to 6 hours prn pain. Dose should be reduced in patients with severe liver disease.

Fentanyl transdermal (Duragesic; generic available): Indicated for management of persistent chronic pain, which is moderate to severe requiring continuous, around-the-clock opioid therapy. The pain cannot be managed by other means (e.g., NSAIDS). Note: Duragesic should only be used in patients who are currently on opioid therapy for which tolerance has developed. The patches should be applied to INTACT skin only. Side Effects: See opioid adverse effects. Analgesic dose: The previous opioid therapy for which tolerance has occurred should be at least equivalent to fentanyl 25mcg/h. Patches are worn for a 72 hour period. (Product information, Purdue Pharma)