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NOTICE OF INDEPENDENT REVIEW DECISION

DATE OF REVIEW:

Jun/05/2010

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

DETOX PROGRAM 5xWkx2Wks Functional Restoration 80 hrs 97799

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

MD, Board Certified in Physical Medicine and Rehabilitation
Board Certified in Pain Management
Board Certified in Electrodiagnostic Medicine

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)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

OD Guidelines
Adverse Determination Letters, 5/7/10, 5/12/10
Services of Texas 12/31/09, 4/30/10, 5/13/10
2/19/08
M.D. 4/16/10, 4/14/10, 3/30/10, 3/10/10, 9/23/09,
9/10/10, 9/22/09, 9/15/09, 8/10/09, 8/5/10
10/30/09, 8/14/09, 7/24/09, 4/29/10

PATIENT CLINICAL HISTORY SUMMARY

This injured the right ankle with a fall on xx/xx/xx. He apparently had a comminuted plafond fracture and bimalleolar fracture. He underwent surgery that was complicated by wound infection and cellulitis. I saw osteomyelitis was mentioned. The 3/10 note described some additional scapula pain, but apparently no active infection. He has ankle pain and limited motion. He is on hydrocodone taking more than the advised dose. He has been advised to be in a detox program with Suboxone and a functional restoration program.

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

The notes from Dr. states this man has addiction based on 1) intolerable side effects, 2) lack of response to pain medications with dose escalation, 3) hyperalgesia, 4) refractory comorbid psychiatric illness, 5) lack of functional improvement and 6) psychological pathology. Increased pain was described with increased activity in PT and in prior work hardening. Dr. is correct in the role of the psychological support required because Suboxone itself is a habit forming drug. It too leads to dependency. The individual has a period of induction (rather than detoxification) where withdrawal symptoms are created and the Suboxone substitutes for other opiates. The Suboxone is then gradually reduced over weeks or months or continued

as a maintenance drug.

Functional Restoration Programs require evidence of patient motivation to improve. Dr. has written that “the patient has a job to return to but due to his narcotic intake, will not pass the drug screen, which does not allow for his return to work.” In another paragraph he wrote that “He desperately wants to return to work ...without opioid medications.”

Another issue is the question of the psychological comorbidities. The presence was emphasized, yet this can be a negative factor as noted in the ODG.

The deficits in motion are reportedly 5 degrees of inversion and eversion and dorsiflexion compared to the book norm. There is no comparison to his normal left side to know his normal values. The records indicate that the multiple operations and immobilization may have lead to joint and soft tissue tightness that may not be regained and could aggravate the pain.

The ODG does not generally approve a pain program after a failed work hardening program. However, Dr. stated he failed other attempts at treatment and has made the case that he needs detox. Chapter 170 of the Texas Medical Board encourages the use of other treatment options to reduce the use of and need for controlled substances. While there are gaps in the information provided, the reviewer finds that the patient generally meets the criteria for this program. The reviewer finds that medical necessity does exist for DETOX PROGRAM 5xWkx2Wks Functional Restoration 80 hrs 97799.

ODG - Buprenorphin

Recommended for treatment of opiate addiction. Also recommended as an option for chronic pain, especially after detoxification in patients who have a history of opiate addiction (see below for specific recommendations). A schedule-III controlled substance, buprenorphine is a partial agonist at the mu-receptor (the classic morphine receptor) and an antagonist at the kappa-receptor (the receptor that is thought to produce alterations in the perception of pain, including emotional response). In recent years, buprenorphine has been introduced in most European countries as a transdermal formulation ("patch") for the treatment of chronic pain. Proposed advantages in terms of pain control include the following: (1) No analgesic ceiling; (2) A good safety profile (especially in regard to respiratory depression); (3) Decreased abuse potential; (4) Ability to suppress opioid withdrawal; & (5) An apparent antihyperalgesic effect (partially due to the effect at the kappa-receptor). (Kress, 2008) (Heit, 2008) (Johnson, 2005) (Landau, 2007)

Available formulations: Buprenorphine hydrochloride: Buprenex®: Supplied as an injection solution; Subutex®: Supplied as a sublingual tablet in 2 daily dosage strengths (2 mg or 8 mg). Buprenorphine hydrochloride and naloxone hydrochloride: Suboxone®: Also supplied as a sublingual tablet in 2 dosage strengths (2/0.5 mg or 8/2 mg). Developed to have a lower intravenous (IV) misuse potential. When injected IV, naloxone is intended to cause withdrawal effects in individuals who are opiate-dependent, and to prevent the “high-effect” related to opioids such as euphoria. Pharmacokinetics: After sublingual administration the onset of effect occurs in 30 to 60 minutes. Peak blood levels are found at 90 to 100 minutes, followed by a rapid decline until 6 hours, and then a gradual decline over more than 24 hours. (Helm, 2008) (Koppert, 2005)

Indications

Treatment of opiate agonist dependence (FDA Approved indication includes sublingual Subutex® and Suboxone®): Recommended. When used for treatment of opiate dependence, clinicians must be in compliance with the Drug Addiction Treatment Act of 2000. (SAMHSA, 2008) Buprenorphine’s pharmacological and safety profile makes it an attractive treatment for patients addicted to opioids. Buprenorphine’s usefulness stems from its unique pharmacological and safety profile, which encourages treatment adherence and reduces the possibilities for both abuse and overdose. Studies have shown that buprenorphine is more effective than placebo and is equally as effective as moderate doses of methadone in opioid maintenance therapy. Few studies have been reported on the efficacy of buprenorphine for

completely withdrawing patients from opioids. In general, the results of studies of medically assisted withdrawal using opioids (e.g., methadone) have shown poor outcomes. Buprenorphine, however, is known to cause a milder withdrawal syndrome compared to methadone and for this reason may be the better choice if opioid withdrawal therapy is elected. (McNicholas, 2004) (Helm, 2008)

Treatment of chronic pain: Buprenex is an injectable form of buprenorphine which is FDA approved for the treatment of moderate to severe pain. Under study for treatment of pain using a sublingual form. A waiver is not required for the off-label use of sublingual Buprenorphine for the treatment of pain. An "X" should NOT be put before the DEA number. It is recommended that the words, "Chronic Pain Patient" and "Off-Label Use" be written on the prescription. The most common use of Suboxone for the treatment of chronic pain is for individuals who have a history of opioid addiction. When used in this way the provider should strive to make sure the patient is in remission prior to use. The most common research studies in regards to chronic pain treatment are from Europe and are based on transdermal formulations (not available in the US). Research indicates that there are different mechanisms for opioid-induced analgesia and antihyperalgesia. Buprenorphine appears to have a significantly longer half-life of antihyperalgesic effect compared to analgesic effects, which is in contrast to pure mu-receptor agonists (such as morphine). Research is ongoing to determine if this difference will provide improved treatment of pain dominated by central sensitization (i.e. neuropathic pain). (Koppert, 2005) (Hans, 2007) (Heit, 2008) Buprenorphine has been recommended for use in patients with renal impairment as there is no need for adjustment (for example, diabetics or for those on dialysis). (Kress, 2008) It appears to have less of an immunosuppressive effect than morphine and fentanyl. It has also been recommended for elderly patients, particularly those with neuropathic pain. (Pergolizzi, 2005)

Use for pain after long-term use of opiates for chronic pain syndrome: Under study. (Chronic pain syndrome is defined as pain > 6 months duration, alteration of behavior with evidence of depression and/or anxiety, restriction of daily activity, excessive use of medication and medical services, no clear relationship to organic disorders, and non-productive treatment). Early research indicates that with detoxification with buprenorphine from high-dose, pure mu-agonist therapy, patients may show significant decrease in pain, improved functional capacity and improvement in overall sense of well-being. Tolerance was not observed. (Malinoff, 2005)

Functional restoration programs (FRPs)

Recommended for selected patients with low back pain and chronic disabling back pain, although research is still ongoing as to how to most appropriately screen for inclusion in these programs. The evidence base in other conditions is unclear. Functional restoration programs (FRPs), a type of treatment included in the category of interdisciplinary pain programs (see Chronic pain programs), were originally developed by Mayer and Gatchel. FRPs were designed to use a medically directed, interdisciplinary pain management approach geared specifically to patients with chronic disabling occupational musculoskeletal disorders. These programs emphasize the importance of function over the elimination of pain. FRPs incorporate components of exercise progression with disability management and psychosocial intervention. Long-term evidence suggests that the benefit of these programs diminishes over time, but still remains positive when compared to cohorts that did not receive an intensive program. (Bendix, 1998) A Cochrane review suggests that there is strong evidence that intensive multidisciplinary rehabilitation with functional restoration reduces pain and improves function of patients with low back pain. The evidence is contradictory when evaluating the programs in terms of vocational outcomes. (Guzman 2001) It must be noted that all studies used for the Cochrane review excluded individuals with extensive radiculopathy, and several of the studies excluded patients who were receiving a pension, limiting the generalizability of the above results. Studies published after the Cochrane review also indicate that intensive programs show greater effectiveness, in particular in terms of return to work, than less intensive treatment. (Airaksinen, 2006) There appears to be little scientific evidence for the effectiveness of multidisciplinary biopsychosocial rehabilitation compared with other rehabilitation facilities for neck and shoulder pain, as opposed to low

back pain and generalized pain syndromes. (Karjalainen, 2003) Treatment is not suggested for longer than 2 weeks without evidence of demonstrated efficacy as documented by subjective and objective gains. For general information see Chronic pain programs.

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

ACOEM-AMERICA 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)