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NOTICE OF INDEPENDENT REVIEW DECISION

DATE OF REVIEW:

Jul/15/2009

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Darvocet N-100mg #120 for 30 days

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

MD, 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)

PATIENT CLINICAL HISTORY SUMMARY

This man was injured in xx/xxxx. He was in a chronic pain program in 1997. He failed to improve with RF rhizotomies and other treatments. He reportedly did not receive any relief with on hydrocodone, Lidoderm, Zolofl or Neurontin. He was on Darvocet for pain for several years. One note in the records stated that the use of Darvocet was to avoid the preauthorization issues for hydrocodone. Prior reviews by Dr. noted his nondermatomal leg pain, pain behaviors, symptom magnification and inconsistent medical findings. She advised in 2003 that he be weaned from the Darvocet that was reportedly used in lieu of hydrocodone.

In a separate peer review in November 2008, Dr. found no structural abnormalities in his review. He wrote that "the continue use of medications is not indicated...The claimant should be weaned off gradually from the above medications." Dr. discussed the refills and goals of Darvocet on 1/11/09. She agreed to the refill of the Darvocet with the plans to wean him from it. She wrote that "the Darvocet is intended to replace hydrocodonine (sic) with expected wean of this medication as well." She approved it with no refills and wrote "that the patient should be weaning his dose over time. The goal is wean from all meds ...based on the peer review years ago."

The 3/31/09 progress note from Dr. describes this man as having no pain while on Darvocet, but 10/10 without it. However, function is described in the records as “fair” and comfort level is noted as “poor.” Miss wrote that Dr. told her that he was unsuccessful in weaning this man from Darvocet. He had reached some of his goals of pain relief and improved physical and psychosocial function. His current dose of Darvocet is 4 a day. TNS helps, but he had no benefit with therapy. He has not had psychological assessment since the pain program in 1997.

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

The ODG does recognize a role for the use of controlled substances (opiates) in the management of chronic pain. In essence, the guidelines allow the medication if there is effective relief and improved function. That is not clear from the records provided in this case. The patient’s function is described in the records as “fair” and comfort level is noted as “poor.” There are no details in the records describing any specifics about this patient’s improved function.

In addition, the ODG states this medication has dangerous risks. The ODG states that: “On 1/30/09 an FDA advisory panel narrowly voted to recommend that propoxyphene should be pulled from the market. The committee stated that the evidence of efficacy for propoxyphene was marginally better than placebo and never greater than acetaminophen. The agency had collected reports of more than 1,400 deaths in people who had taken the drug since 1957, though experts stressed the figure does not prove the drug was the cause of death in all cases, but they concluded that the drug showed little benefit and lots of risk. (FDA, 2009)”

Combining the risks and the lack of effective functional gains, along with the prior discussions for weaning, the reviewer cannot find medical necessity for the ongoing use of propoxyphene in this patient. The reviewer finds that medical necessity does not exist for Darvocet N-100mg #120 for 30 days.

Propoxyphene (Darvon®)

Recommended as an option for mild to moderate pain, as indicated below. The most common brand names are Darvon® (propoxyphene hydrochloride), Darvon-N® (propoxyphene napsylate) or in combination with acetaminophen as Darvocet®. Generic available. Propoxyphene is structurally related to methadone. This is a synthetic opiate agonist that is ½ to 1/3 as potent as codeine. High doses are limited due to adverse effects including toxic psychosis. It is FDA approved for mild to moderate pain

Dosage: Neither of these medications is recommended for the elderly. Dosage should be reduced for patients with hepatic or renal impairment. Propoxyphene hydrochloride: The standard adult dose is 65 mg every 3-4 hours. The maximum dose should not exceed 390 mg/day. Propoxyphene napsylate: The standard adult dose is 100 mg every 4 hours with a maximum dose of 600 mg/day

Side effects: sedation, nausea & vomiting and dizziness. Overuse can cause drug-rebound headache. Dependence can occur as well as mild withdrawal. FDA warnings: Do not prescribe to patients that are suicidal or addiction-prone. Prescribe with caution in patients taking tranquilizers or antidepressants, and in patients who use alcohol in excess. A major cause of drug-related deaths is secondary to propoxyphene alone or in combination with other CNS depressants. Other warnings: Use this drug with caution for patients that are dependent on opioids. Propoxyphene will not support morphine dependence. Sudden substitution may produce acute withdrawal. Note: On 1/30/09 an FDA advisory panel narrowly voted to recommend that propoxyphene should be pulled from the market. The committee stated that the evidence of efficacy for propoxyphene was marginally better than placebo and never greater than acetaminophen. The agency had collected reports of more than 1,400 deaths in people who had taken the drug since 1957, though experts stressed the figure does not prove the drug was the cause of death in all cases, but they concluded that the drug showed little benefit and lots of risk. (FDA, 2009)

Overdose: Adverse effects include coma and respiratory depression as well as circulatory collapse. Complications such as irreversible brain damage and death may occur within one

hour. These rapid, serious complications of overdose are due, in part, to the difficulty of reversal with naloxone (due to high tissue concentration and long half-life of metabolites). (Clinical Pharmacology, 2008) (Micromedix, 2008) (Lexi-Comp, 2008) (AHFS Drug Information, 2008) See also Opioids for general guidelines, as well as specific listing of Propoxyphene hydrochloride (Darvon®), Propoxyphene napsylate (Darvon-N®), Propoxyphene/Apap (Darvocet-N) for more information and references.

Opioids, specific drug list

Propoxyphene hydrochloride (Darvon®; generic available), Propoxyphene napsylate (Darvon-N®), Propoxyphene/Apap (Darvocet-N; generic available): Side Effects: See propoxyphene and acetaminophen. Analgesic dose: Propoxyphene Hcl is available in 65 mg capsule and the dose is 65mg every 3 to 4 hours as needed. Maximum daily dose is 390mg. Propoxyphene napsylate is available in 100mg tablets which are to be given 100mg every 4 hours as needed (Maximum daily dose is 600mg). Propoxyphene-N/Apap is available as 50mg/650mg and 100mg/650mg. 50mg/650mg: 1 or 2 tablets PO every 4 hours as needed for pain. 100mg/650mg: 1 PO every 4 to 6 hours as needed for pain. Max daily doses should not exceed that of propoxyphene (600mg) and acetaminophen (4000mg). (Clinical Pharmacology, 2008) Note: On 1/30/09 an FDA advisory panel narrowly voted to recommend that propoxyphene should be pulled from the market. The committee stated that the evidence of efficacy for propoxyphene was marginally better than placebo and never greater than acetaminophen. The agency had collected reports of more than 1,400 deaths in people who had taken the drug since 1957, though experts stressed the figure does not prove the drug was the cause of death in all cases, but they concluded that the drug showed little benefit and lots of risk. (FDA, 2009)

Opioids, long-term assessment

CRITERIA FOR USE OF OPIOID

Long-term Users of Opioids (6-months or more)

1) Re-assess

(a) Has the diagnosis changed?

(b) What other medications is the patient taking? Are they effective, producing side effects

(c) What treatments have been attempted since the use of opioids? Have they been effective? For how long

(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

(e) Document adverse effects: constipation, nausea, vomiting, headache, dyspepsia, pruritis, dizziness, fatigue, dry mouth, sweating, hyperalgesia, sexual dysfunction, and sedation

(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

(g) Is there indication for a screening instrument for abuse/addiction. See Substance Abuse Screening

2) Strategy for maintenance

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

(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

(c) The standard increase in dose is 25 to 50% for mild pain and 50 to 100% for severe pain (Wisconsin)

3) Visit Frequency

(a) There is no set visit frequency. This should be adjusted to the patient's need for evaluation of adverse effects, pain status, and appropriate use of medication, with recommended duration between visits from 1 to 6 months.

Opioids, criteria for use

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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 circumstance
- (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 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

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 ERVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)

OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)