

Case Number:	CM13-0011959		
Date Assigned:	09/30/2013	Date of Injury:	08/16/2003
Decision Date:	01/03/2014	UR Denial Date:	08/08/2013
Priority:	Standard	Application Received:	08/15/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Internal Medicine, and is licensed to practice in California. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The physician reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This is a male who sustained a work injury on 8/16/2003 when he lifted a tool box in a bent over position which then caused him back pain. The relevant diagnosis includes: lumbar postlaminectomy syndrome, psychogenic pain, and chronic pain. Per progress notes, patient has had medication therapy, physical therapy, and s/p lumbar spine surgery 4 times (disc extrusion at L4-L5 and L5-S1 requiring microdiscectomy and hemilaminectomy from L4-S1 in 2007 and underwent a two stage lumbar fusion surgery from L3-S1). Per documentation patient does get flare ups with pain radiating down left leg with burning sensation in thigh and a constant ache. His range of motion is restricted, he has increased sensitivity to touch and has decreased motor strength. Per notes Oxycontin helps him with pain control but makes him nauseated. Patient did attend the [REDACTED] and did get some functional improvement. Per documentation patient was taken off of oxycontin due to side effects and was placed on buprenorphine and per notes patient states that had better pain control with oxycontin. The relevant issues in this case is whether 60 tablets of Promethazine 25 mg, 90 tablets of Flexeril 10mg, and 180 tablets of Oxycontin 40mg is medically necessary.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

60 tablets of Promethazine 25mg: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints, Chronic Pain Treatment Guidelines Opioids.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Promethazine and Antiemetics.

Decision rationale: My rationale for the above decision on 60 tablets of Promethazine 25mg is not medically appropriate in this specific case is due to the following guidelines of the ODG: Not recommended for nausea and vomiting secondary to chronic opioid use. Recommended for acute use as noted below per FDA-approved indications. Nausea and vomiting is common with use of opioids. These side effects tend to diminish over days to weeks of continued exposure. Studies of opioid adverse effects, including nausea and vomiting, are limited to short-term duration (less than four weeks) and have limited application to long-term use. If nausea and vomiting remains prolonged, other etiologies of these symptoms should be evaluated for the differential diagnosis includes gastroparesis (primarily due to diabetes). Current research for treatment of nausea and vomiting as related to opioid use primarily addresses the use of antiemetics in patients with cancer pain or those utilizing opioids for acute/postoperative therapy. Recommendations based on these studies cannot be extrapolated to chronic non-malignant pain patients. There is no high-quality literature to support any one treatment for opioid-induced nausea in chronic non-malignant pain patients. (Moore 2005) and is not recommended for nausea and vomiting secondary to chronic opioid use. After careful review of the medical records and documentation provided to me Antiemetics are not recommended for nausea due to chronic opioid use. The request for 60 tablets of Promethazine 25mg is not medically necessary and appropriate.

90 tablets of Flexeril 10 mg: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints, Chronic Pain Treatment Guidelines Opioids.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 63-64, 127.

Decision rationale: My rationale for the above decision on 90 tablets of Flexeril 10 is not medically appropriate in this specific case is due to the following guidelines of the MTUS: Chronic Pain Medical Treatment Guidelines Page 63, Muscle relaxants (for pain). The guidelines recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain (LBP). (Chou, 2007) (Mens, 2005) (Van Tulder, 1998) (Van Tulder, 2003) (Van Tulder, 2006) (Schnitzer, 2004) (See, 2008). Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond non-steroidal antiinflammatory drugs (NSAIDs) in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. (Homik, 2004). Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used with caution in patients driving motor vehicles or operating heavy machinery. Drugs with the most limited published evidence in terms of clinical effectiveness include chlorzoxazone, methocarbamol, dantrolene and baclofen. (Chou, 2004) According to a

recent review in American Family Physician, skeletal muscle relaxants are the most widely prescribed drug class for musculoskeletal conditions (18.5% of prescriptions), and the most commonly prescribed antispasmodic agents are carisoprodol, cyclobenzaprine, metaxalone, and methocarbamol, but despite their popularity, skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. (See 2008) Classifications: Muscle relaxants are a broad range of medications that are generally divided into antispasmodics, antispasticity drugs, and drugs with both actions. (See, 2008) (van Tulder, 2006) The Chronic Pain Medical Treatment Guidelines, Page 64, Cyclobenzaprine (Flexeril®®, Amrix®®, Fexmid™, generic available): Recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant with similar effects to tricyclic antidepressants (e.g. amitriptyline). Cyclobenzaprine is more effective than placebo in the management of back pain, although the effect is modest and comes at the price of adverse effects. It has a central mechanism of action, but it is not effective in treating spasticity from cerebral palsy or spinal cord disease. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement. The greatest effect appears to be in the first 4 days of treatment. (Browning, 2001) (Kinkade, 2007) (Toth, 2004) See Cyclobenzaprine. Cyclobenzaprine has been shown to produce a modest benefit in treatment of fibromyalgia. Cyclobenzap

180 tablets of Oxycontin 40mg: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints, Chronic Pain Treatment Guidelines Opioids.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 79,80, 97,127.

Decision rationale: My rationale for the above decision on 180 tablets of Oxycontin 40mg is not medically appropriate in this specific case is due to the following guidelines of the MTUS: Chronic Pain Medical Treatment Guidelines, Page 79: (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 (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. OxyContin® is the brand name of a time-release formula of the analgesic chemical oxycodone, produced by the pharmaceutical company Purdue Pharma. See Opioids. Note: This drug was recently included in a list of 20 medications identified by the FDA's Adverse Event Reporting System, that are under FDA investigation. (FDA, 2008) "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited. Failure to respond to a time- limited