

Case Number:	CM14-0132129		
Date Assigned:	08/22/2014	Date of Injury:	11/10/2006
Decision Date:	10/14/2014	UR Denial Date:	07/22/2014
Priority:	Standard	Application Received:	08/18/2014

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert reviewer is Board Certified in Family 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 expert 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. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 38-year-old male patient who reported an industrial injury on 11/10/2006, almost eight (8) years ago, attributed to the performance of his usual and customary job tasks. The patient continues to complain of pain to the lower back, left ankle, abdomen, and right heel. The patient is prescribed Norco 10/325 mg; Subsys 200 mcg/hr spray; oxycodone IR 30 mg; and methadone 10 mg. The objective findings on examination were limited to motor testing limited by pain. The treating diagnoses included post lumbar laminectomy syndrome; low back pain; radiculopathy; sciatica; and chronic pain syndrome. The treatment plan included the addition of methadone 10 mg and a trial of Subsys 200 mcg/hr spray.

IMR ISSUES, DECISIONS AND RATIONALES

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

TRIAL OF SUBSYS 200 MCG/HR #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 300-306, Chronic Pain Treatment Guidelines opioids Page(s): 74-97. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004) chapter 6 pages 114-116; Official Disability Guidelines (ODG) pain chapter opioids; fentanyl sublingual spray

Decision rationale: Subsys 200mcg spray x120 is not recommended for musculoskeletal pain. Fentanyl is an opioid analgesic with potency eighty times that of morphine. Weaker opioids are less likely to produce adverse effects than stronger opioids, such as, fentanyl. Due to significant side effects, the Subsys is not for use in routine musculoskeletal pain. FDA has approved Subsys fentanyl sublingual spray, from Insys Therapeutics, only for breakthrough cancer pain. Breakthrough cancer pain is characterized by sudden, often unpredictable, episodes of intense pain which can peak in severity at three to five minutes despite background pain medication. Subsys is approved in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. The FDA has required a single, shared system risk evaluation and mitigation strategy (REMS) for the whole class of transmucosal immediate-release fentanyl (TIRF) drugs. There has been no attempt to titrate the patient down from the high dose of opioids prescribed even though evidence-based guidelines established that the high dose opioids therapy was not medically necessary for the diagnoses cited. The prescription for Fentanyl spray for pain is being prescribed as an opioid analgesic for the treatment of chronic back pain. There is no objective evidence provided to support the continued prescription of opioid analgesics for chronic back pain based on the objective findings documented. There is no documented functional improvement with the currently prescribed Fentanyl spray. The chronic use of Fentanyl patches is not recommended by the CA MTUS, the ACOEM Guidelines, or the Official Disability Guidelines for the long-term treatment of chronic back pain. The updated chapter of the ACOEM Guidelines and the third edition of the ACOEM Guidelines stated that both function and pain must improve to continue the use of opioids. The patient is being prescribed significantly more than the up to 120 MEDS recommended by evidence-based guidelines for documented intractable pain. The prescription of opiates on a continued long-term basis is inconsistent with the CA MTUS and the Official Disability Guidelines recommendations for the use of opiate medications for the treatment of chronic pain. There is objective evidence that supports the use of opioid analgesics in the treatment of this patient over the use of NSAIDs and OTC analgesics for the treatment of chronic back pain. Evidence-based guidelines necessitate documentation that the patient has signed an appropriate pain contract, functional expectations have been agreed to by the clinician, and the patient, pain medications will be provided by one physician only, and the patient agrees to use only those medications recommended or agreed to by the clinician to support the medical necessity of treatment with opioids. The ACOEM Guidelines updated chapter on chronic pain states, "Opiates for the treatment of mechanical and compressive etiologies: rarely beneficial. Chronic pain can have a mixed physiologic etiology of both neuropathic and nociceptive components. In most cases, analgesic

treatment should begin with acetaminophen, aspirin, and NSAIDs (as suggested by the WHO step-wise algorithm). When these drugs do not satisfactorily reduce pain, opioids for moderate to moderately severe pain may be added to (not substituted for) the less efficacious drugs. A major concern about the use of opioids for chronic pain is that most randomized controlled trials have been limited to a short-term period. 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."

ACOEM guidelines state that opioids appear to be no more effective than safer analgesics for managing most musculoskeletal and eye symptoms; they should be used only if needed for severe pain and only for a short time. The long-term use of opioid medications may be considered in the treatment of chronic musculoskeletal pain, if: The patient has signed an appropriate pain contract; Functional expectations have been agreed to by the clinician and the

patient; Pain medications will be provided by one physician only; The patient agrees to use only those medications recommended or agreed to by the clinician. ACOEM also notes, "Pain medications are typically not useful in the subacute and chronic phases and have been shown to be the most important factor impeding recovery of function."

Evidence-based guidelines recommend: Chronic back pain: 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 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 indicated that up to one-fourth of patients who receive opioids exhibit aberrant medication-taking behavior. The ODG states that chronic pain can have a mixed physiologic etiology of both neuropathic and nociceptive components. In most cases, analgesic treatment should begin with acetaminophen, aspirin, and NSAIDs (as suggested by the WHO step-wise algorithm). When these drugs do not satisfactorily reduce pain, opioids for moderate to moderately severe pain may be added to (not substituted for) the less efficacious drugs. A major concern about the use of opioids for chronic pain is that most randomized controlled trials have been limited to a short-term period. 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. (Ballantyne, 2006) (Furlan, 2006) Long-term, observational studies have found that treatment with opioids tends to provide improvement in function and minimal risk of addiction, but many of these studies include a high dropout rate (56% in a 2004 meta-analysis). (Kalso, 2004) There is also no evidence that opioids showed long-term benefit or improvement in function when used as treatment for chronic back pain. (Martell-Annals, 2007) ODG, Pain Chapter) There is no clinical documentation with objective findings on examination to support the medical necessity of Fentanyl spray for the treatment of chronic neck and back pain. There is no provided evidence that the patient has received benefit or demonstrated functional improvement with Fentanyl spray. There is no demonstrated medical necessity for the prescribed Opioid over a prolonged period of time for the cited diagnoses.