

Case Number:	CM14-0137260		
Date Assigned:	09/05/2014	Date of Injury:	08/13/2001
Decision Date:	10/02/2014	UR Denial Date:	08/12/2014
Priority:	Standard	Application Received:	08/25/2014

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 65-year-old female who reported an industrial injury on 8/13/2001, over 13 years ago, attributed to the performance of her usual and customary job duties. The patient is being treated by pain management. The patient is being treated for the diagnoses of lumbosacral neuritis/radiculopathy; lumbago; post laminectomy syndrome; and chronic pain. The patient complained to pain management of continuing low back and bilateral leg pain. The patient was noted to be using a walker for ambulation. The patient reportedly is cleared for and intrathecal opioid pump. The patient reports increased pain without Prednisone. The use of the Subsys spray (fentanyl) was reported to not be helpful as compared to the previously utilized Actiq. The patient is documented to also receive Celebrex, Cymbalta, Lyrica, Methadone, Nucynta, Prednisone, and Tizanidine. The objective findings on examination included tenderness to palpation over the SI joints; pain to palpation to the lower spine paravertebral muscles with radiation to the bilateral lower extremities; uses a Walker for ambulation. The urine drug screens were appropriate with her drug regimen. The patient was prescribed Subsys 800 mcg spray x30 and Prednisone 5 mg #60.

IMR ISSUES, DECISIONS AND RATIONALES

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

Subsys 800mcg spray x 30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain chapterSubsys (fentanyl sublingual spray)

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

Decision rationale: Subsys 800mcg spray x 30 is not recommended for musculoskeletal pain. Fentanyl is an opioid analgesic with a 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. Subsys is not recommended for 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 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 (70 days). 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 (70 days). 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. 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). There is also no evidence that opioids showed long-term benefit or improvement in function when used as treatment for chronic back pain (ODG, Pain Chapter). There is no clinical documentation with objective findings on examination to support the medical necessity of Fentanyl patches for the treatment of chronic 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 opioids over a prolonged period of time for the cited diagnoses. Therefore, this request is not medically necessary.

Prednisone 5mg x 60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines anti-inflammatory medications Page(s): 67-68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter--medications for chronic pain and NSAIDs; oral corticosteroids

Decision rationale: The patient prescribed Prednisone 5 mg #60 directed to chronic back pain in addition to high dose opioids. The treatment of the patient with prednisone is not demonstrated to be medically necessary over the prescription for NSAIDs. There is no demonstrated chronic inflammatory process. The ACOEM Guidelines do not specifically recommend the prescription of Prednisone for the treatment of chronic pain. There is no demonstrated failure of NSAIDs and no demonstrated chronic inflammatory process. The ODG recommends that Prednisone not be used for the treatment of chronic pain due to efficacy and safety of systemic corticosteroids in chronic pain due to significant side effects. Prednisone is a synthetic corticosteroid drug that is particularly effective as an immunosuppressant, and affects virtually all of the immune system. It is used to treat certain inflammatory diseases and (at higher doses) cancers, but has significant adverse effects. It is usually taken orally but can be delivered by intramuscular injection or intravenous injection. It has a mainly glucocorticoid effect. Prednisone is a prodrug that is converted by the liver into Prednisolone, which is the active drug and also a steroid. Prednisone can be used in autoimmune diseases, inflammatory diseases (such as severe asthma, severe allergies, juvenile dermatomyositis, angioedema episodes, severe urushiol-induced contact dermatitis, systemic lupus erythematosus, ulcerative colitis, rheumatoid arthritis, Still's disease, Bell's palsy, idiopathic thrombocytopenic purpura, Crohn's disease, pemphigus and sarcoidosis), uveitis, various kidney diseases including nephrotic syndrome, mononucleosis Epstein-Barr virus, and to prevent and treat rejection in organ transplantation. Prednisone has also been used in the treatment of migraine headaches and cluster headaches and for severe aphthous ulcer ("Cankersore") outbreaks. It can also be used to treat autoimmune pancreatitis. Prednisone is used as an antitumor drug. Prednisone is very important in the treatment of acute lymphoblastic leukemia, Non-Hodgkin lymphomas, Hodgkin's lymphoma, multiple myeloma, and other tumors in combination with other anticancer drugs. Intravenous application may be employed for cerebral inflammation, as in the periodic attacks caused by multiple sclerosis. Prednisone is also used for the treatment of the Herxheimer reaction which is common during the treatment of syphilis, and to delay the onset of symptoms of Duchenne muscular dystrophy. The mechanism for the delay of symptoms is unknown. Because it suppresses the adrenals, it is also sometimes used in the treatment of congenital adrenal hyperplasia. Dependency Adrenal suppression will occur if prednisone is taken for longer than 7 days. This will cause the body to lose the ability to synthesize natural corticosteroids, resulting in dependence on prednisone. For this reason, prednisone should not be abruptly stopped if taken for more than seven days, and instead, the dosage should be gradually reduced. This weaning process may be over a few days if the course of prednisone was short, but may take weeks or months if the patient had been on long-term treatment. Abrupt withdrawal may lead to an Addisonian crisis. For those on chronic therapy, alternate-day dosing may preserve adrenal function, thereby reducing side-effects.

Glucocorticoids act to feedback inhibit both the hypothalamus (decreasing Corticotropinreleasing hormone [CRH]) and corticotrophs in the anterior pituitary gland (decreasing the amount of Adrenocorticotrophic hormone [ACTH]). For this reason exogenous glucocorticoid analogues down-regulate the body's ability to naturally produce glucocorticoids. This mechanism leads to dependence in a short time and can be very dangerous if medications are withdrawn too quickly. The body must have time to begin synthesis of CRH and ACTH and for the adrenal glands to begin functioning normally again. Side-effects Short-term side-effects, as with all glucocorticoids, include high blood glucose levels, especially in patients who already have diabetes mellitus or are on other medications that increase blood glucose (such as tacrolimus), and mineralocorticoid effects such as fluid retention (it is worth noting, however, that the mineralocorticoid effects of prednisone are very minor; this is why it is not used in the management of adrenal insufficiency unless a more potent mineralocorticoid is administered concomitantly). Additional short-term side-effects include insomnia, euphoria, and, rarely, mania (particularly in those suffering from Bipolar I and II). Long-term side-effects include Cushing's syndrome, truncal weight gain, osteoporosis, glaucoma, type II diabetes mellitus, and depression upon withdrawal. There is no clinical documentation by treating physician to support the prescription of Prednisone 5 mg #60 for the treatment of chronic low back pain. The prescription of Prednisone 5 mg #60 is not considered to be medically necessary.