

Case Number:	CM13-0058713		
Date Assigned:	07/02/2014	Date of Injury:	11/05/2000
Decision Date:	09/26/2014	UR Denial Date:	10/25/2013
Priority:	Standard	Application Received:	11/27/2013

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 34 year old male who reported an industrial injury to the back on 11/5/2000, almost 14 years ago, attributed to the performance of regular job tasks. The patient subsequently underwent surgical intervention to the lumbar spine. The patient continues to complain of chronic low back pain radiating to the BLEs and reported numbness to the BUEs. The objective findings on examination documented only TTP over the area of the lumbar spine hardware. The patient is being treated for chronic pain. The patient was prescribed Cymbalta 30 mg #90 with 4 refills; Fentanyl 12 mcg/hr patch #10; Nuvigil 250 mg #30 with 3 refills; Norco 10/325 mg #240; Inderal 20 mg #30 with 4 refills.

IMR ISSUES, DECISIONS AND RATIONALES

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

CYMBALTA 30MG #90 WITH 4 REFILLS: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter medications for chronic pain; antidepressants; Duloxetine.

Decision rationale: The prescription of the antidepressant Cymbalta for the treatment of chronic pain is consistent with the recommendations of the Official Disability Guidelines for the treatment of neuropathic pain. The Official Disability Guidelines recommend the use of Cymbalta as a first line treatment for neuropathic pain. There is no documented neuropathic pain documented for this patient. The patient is diagnosed with chronic low back pain. There is no clinical documentation by the provider to support the prescription for Cymbalta 30 mg #90 with 4 refills for the effects of the industrial injury. There was no trial with the recommended tricyclic antidepressants. The patient has not been demonstrated to have functional improvement based on the prescribed significant dose of Cymbalta. There has been no attempt to titrate the patient down or off the Cymbalta. The prescribing provider did not provide a rationale for the use of the Cymbalta for the treatment of chronic pain and the clinical documentation provided did not note depression or neuropathic pain. There was no documentation of any functional improvement attributed to Cymbalta. There was no objective evidence to support the medical necessity of the prescription for Cymbalta. The patient is given a nonspecific diagnosis and has been prescribed Cymbalta for a prolonged period time without demonstrated functional improvement. There is no documented mental status examination and no rationale to support medical necessity. There is no provided nexus to the stated mechanism of injury over 14 years ago for the current symptoms. Cymbalta is an antidepressant in a group of drugs called selective serotonin and norepinephrine reuptake inhibitors (SSNRIs). Cymbalta is used to treat major depression disorder and general anxiety disorder. Cymbalta is used to treat chronic pain disorder called fibromyalgia, treat pain caused by nerve damage in people with diabetes, and to treat chronic muscular skeletal pain including discomfort from osteoarthritis and chronic lower back pain. The California MTUS guidelines state that Cymbalta is FDA approved for anxiety, depression, diabetic neuropathy, and fibromyalgia. This medication is often used off label for neuropathic pain and radiculopathy. Cymbalta is recommended as a first-line option for diabetic neuropathy. The patient does not have a diagnosis of specific neuropathic pain. The patient had no medications for the prior three weeks with no demonstrated significant effect. There is no demonstrated medical necessity for the continued prescription of Cymbalta 30 mg #90 with 4 refills for the treatment of the effects of the cited industrial injury.

FENTANYL 12MEG/HR PATCH 72 HOURS #10: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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 Official Disability Guidelines (ODG) pain chapter opioids American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004) chapter 6 pages 114-116.

Decision rationale: 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 patches 12 mcg/hr #10 for pain is being prescribed as an opioid analgesic for the treatment of chronic back pain. There is 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 patches. 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 knee 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 knee 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. (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 patches for the treatment of chronic knee pain. There is no provided evidence that the patient has received benefit or demonstrated functional improvement with Fentanyl patches. There is no demonstrated medical necessity for the prescribed Opioids over a prolonged period of time for the cited diagnoses.

NUVIGIL 250MG #30 WITH 3 REFILLS: 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 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 Official Disability Guidelines (ODG) pain chapter opioids American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004) chapter 6 pages 114-116.

Decision rationale: The patient has been prescribed Nuvigil 250 mg #30 with 3 refills in order to keep the patient awake while on his other medications. The medication is approved for the treatment of Narcolepsy; obstructive sleep apnea/hypopnea syndrome OSAHS; and shift work sleep disorder. There is no approval to counter the effects of pain management medication with another stimulant medication. The patient does not meet the criteria recommended by evidence based guidelines for this medication and there is no industrial indication for the prescription of this medication. The patient is not diagnosed with Narcolepsy; sleep apnea and does not perform shift work. There is no objective evidence documented that the patient has Narcolepsy, OSAHS, or work shift sleep disorder on an industrial basis or as a nexus to this industrial claim. There is no medical necessity for the use of this medication to counter act the effects of pain management medications. It is not clear that the polypharmacy prescribed to this patient does not account for the excessive daytime sleepiness for which the patient is prescribed yet another medication to stay awake. There is no demonstrated medical necessity for the prescribed Nuvigil 250 mg #30 with 3 refills.

NORCO 10/325MG #240: 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 opioids Page(s): 74-97. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter-opioids.

Decision rationale: The prescription for Hydrocodone-APAP (Norco) 10/325 mg #240 for short acting pain is being prescribed as an opioid analgesic for the treatment of chronic pain to the back for the date of injury 14 years ago. The objective findings on examination do not support the medical necessity for continued opioid analgesics. The patient is being prescribed opioids for mechanical back pain, which is inconsistent with the recommendations of the CA MTUS. There is no objective evidence provided to support the continued prescription of opioid analgesics for the cited diagnoses and effects of the industrial claim. The patient should be titrated down and off the prescribed Hydrocodone. The patient is 14 years s/p DOI with reported continued issues. There is no demonstrated medical necessity for the continuation of opioids for the effects of the industrial injury. The chronic use of Hydrocodone-APAP/Norco 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 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 for the treatment of chronic pain. The current prescription of opioid analgesics is inconsistent with evidence-based guidelines. The prescription of opiates on a continued long-term basis is inconsistent with 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 for the treatment of chronic pain issues. 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 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." There is no clinical documentation by with objective findings on examination to support the medical necessity of Hydrocodone-APAP for this long period of time or to support ongoing functional improvement. There is no provided evidence that the patient has received benefit or demonstrated functional improvement with the prescribed Hydrocodone-APAP. There is no demonstrated medical necessity for the prescribed Opioids. The continued prescription for Norco 10/325 mg #240 is not demonstrated to be medically necessary.

INDERAL 20MG #30 WITH 4 REFILLS: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Disciplinary Guidelines for the general practice of Medicine.

Decision rationale: The prescription for Inderal is not supported by a rationale with objective evidence and a nexus to the cited mechanism of injury. There is no evidence of functional improvement with Inderal for anxiety or hypertension. Inderal is used for treating high blood pressure or atrial fibrillation. It is used in patients with angina to decreased angina frequency and increase exercise tolerance. Inderal used to decrease the risk of heart death in certain patients who have survived heart attacks. It is used to manage certain HTN in diabetes, a heart condition called hypertrophic subaortic stenosis, or certain symptoms of pheochromacytoma. It is used to prevent migraine headaches. It may also be used in other conditions. Inderal is a beta blocker. It works by slowing down the heart and decreasing cardiac output. The California MTUS as do not specifically address this medication. Inderal is prescribed to treat anxiety or performance anxiety. This appears to be directed to the underlying comorbidity for this patient as there is no documented sustained elevated BP due to the reported pain issues that are reportedly controlled with the prescribed medications. Inderal is a nonselective beta-adrenergic receptor blocking agent possessing no other autonomic nervous system activity. It specifically competes with beta-adrenergic receptor agonist agents for available receptor sites. When access to beta-receptor sites is blocked by Inderal, the chronotropic, inotropic, and vasodilator responses to beta-adrenergic stimulation are decreased proportionately. Inderal is used for the treatment of hypertension; angina pectoris; antiarrhythmic effects; treatment of migraine headaches; tremors and anxiety. There is no demonstrated medical necessity for the prescribed Inderal 20 mg #30 with 4 refills.