

<b>Case Number:</b>	CM13-0030077		
<b>Date Assigned:</b>	11/27/2013	<b>Date of Injury:</b>	09/20/2005
<b>Decision Date:</b>	03/26/2014	<b>UR Denial Date:</b>	09/11/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/27/2013

### 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 Emergency Medicine, and is licensed to practice in Florida. 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. 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 patient is a 49 year-old with a date of injury of 09/20/05 resulting in ongoing neck and back pain. His occupation is an "order puller." A progress note by [REDACTED], dated 09/16/13, identified subjective complaints of persistent lower back pain radiating into both lower legs and recurring neck pain with constant headaches. Objective findings included midline tenderness of the cervical spine as well as paravertebral muscle tenderness. There was tenderness of the sacroiliac joints and restricted and painful movements of the lumbar spine. Straight leg raising test was positive. He was hypoalgesic in both lower extremities and motor exam showed mild weakness of the lower extremities. Diagnostic studies in the past included MRIs and an EMG. A urine drug screen on 08/15/13 was negative for unprescribed medications and illicit drugs. Diagnoses indicate possible lumbar discogenic and facet pain, bilateral lumbar radicular pain and cervical discogenic pain with bilateral occipital neuralgia. Treatment has included a previous trial of a dorsal column stimulator from 08/05/13 - 09/30/08 reported to significantly his neck pain and headache. The patient had subsequent stimulators that were removed on 10/02/12 and 01/23/13 due to complications of the leads. He has had trigger point injections as recent as 09/13 and oral medications for several years including ibuprofen and Prilosec. The record states that he has had medication induced gastritis. A lumbar fusion was done from L3 through S1. Treatment now recommended is re-insertion of a dorsal column stimulator and continued medication. A Utilization Review determination was rendered on 09/11/13 recommending non-certification of prescribed drugs including MS Contin 100 mg #120, Norco 10/325, Fioricet #120, Topamax 25 mg #30, Acetadryl #30, Prilosec 20 mg as well as one urine drug screen and a trial of a dorsal column stimulator with one battery implant for the neck and back.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**1 prescription of MS Contin 100 mg # 120: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-83.

**Decision rationale:** The patient is on chronic MS Contin. This is classified as an opioid analgesic formulated for controlled-release. The California Medical Treatment Utilization Schedule (MTUS) Guidelines related to on-going treatment of opioids state that there should be documentation and ongoing review of pain relief, functional status, appropriate use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. A recent epidemiologic study found that opioid treatment for chronic non-malignant pain did not seem to fulfill any of the key outcome goals including pain relief, improved quality of life, and/or improved functional capacity (Eriksen 2006). The documentation submitted lacked a number of the elements listed above, including the level of functional improvement afforded by the chronic opioid therapy. The Guidelines also state that with chronic low back pain, opioid therapy "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (> 16 weeks), but also appears limited." Additionally, "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)." The patient has been on opioids well in excess of 16 weeks.

**Norco 10/325 mg: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-83.

**Decision rationale:** The patient is on chronic opioid therapy that includes Norco 10/325. The California Medical Treatment Utilization Schedule (MTUS) Guidelines related to on-going treatment of opioids state that there should be documentation and ongoing review of pain relief, functional status, appropriate use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid state that there should be documentation and ongoing review of pain relief, functional status, appropriate use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. A recent epidemiologic study found that opioid treatment for chronic non-malignant pain did not seem to fulfill any of the key outcome goals including pain relief, improved quality of life, and/or

improved functional capacity (Eriksen 2006). The doc documentation submitted lacked a number of the elements listed above, including the level of functional improvement afforded by the chronic opioid therapy. The Guidelines also state that with chronic low back pain, opioid therapy "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (> 16 weeks), but also appears limited." Additionally, "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)." The patient has been on opioids well in excess of 16 weeks. The patient is also taking MS Contin, another opioid. There is no documentation in the record for the indication for two separate opioids. Likewise, the calculated morphine equivalents of the MS Contin and Norco combined exceed recommended dose limits.

**1 trial dorsal column stimulator with one battery implant for neck and back: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Pain (Chronic)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Spinal Cord Stimulators Page(s): 105-107. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Spinal Cord Stimulators.

**Decision rationale:** A spinal cord stimulator is requested for the cervical spine. The California Medical Treatment Schedule (MTUS) states that stimulators are "Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated." Specifically, the indications are noted to be: - Failed back syndrome (persistent pain in patients who have undergone at least one previous back operation), more helpful for lower extremity than low back pain, although both stand to benefit. The procedure should be employed with more caution in the cervical region than in the thoracic or lumbar. - Complex regional pain Syndrome (CRPS/Reflex sympathetic dystrophy (RSD)). - Post amputation pain. - Post herpetic neuralgia. - Spinal cord injury dysesthesias. - Pain associated with multiple sclerosis. - Peripheral vascular disease. In this case, the patient has a failed low back syndrome. However, the stimulator is requested for cervical therapy for which the patient has not had prior surgery. Likewise, the notation above is that the procedure should be used with more caution in the cervical region. Therefore, the patient does not meet any of the criteria above. The Official Disability Guidelines further state that in failed back syndrome, a stimulator is only indicated if there has been greater than a 50% improvement in pain relief and medication reduction after a temporary trial. There is no documentation as to the quantitative response from previous spinal cord stimulators.

**Fiorcet #120: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Barbiturate-containing analgesic agents (BCAs), Page(s): 23.

**Decision rationale:** Fioricet is a barbiturate-containing analgesic. The California Medical Treatment Utilization Schedule (MTUS) states that these agents are not recommended for chronic pain. It further states: "The potential for drug dependence is high and no evidence exists to show a clinically important enhancement of analgesic efficacy of BCAs due to the barbiturate constituents (McLean, 2000). There is risk of medication overuse as well as rebound headache (Friedman, 1987)."

**Topamax 25 mg #30:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-Epilepsy Drugs Page(s): 16-21.

**Decision rationale:** Topamax (topiramate) is an anti-seizure agent. The California Medical Treatment Utilization Schedule (MTUS) notes that this class of agents is recommended for neuropathic pain, but there are few randomized trials directed at central pain and none for painful radiculopathy. Further, it states: "A recent review has indicated that there is insufficient evidence to recommend for or against antiepileptic drugs for axial low back pain." The Guidelines also state that Topamax specifically has shown variable efficacy, with failure to demonstrate efficacy in neuropathic pain of "central" etiology. It is only considered specifically when other anticonvulsants fail. Due to the lack of supporting data, there is no demonstrated necessity for Topamax in this case.

**Acetadryl #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 (ODG) Pain, Insomnia.

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

**Decision rationale:** Acetadyl is a combination of acetaminophen and an antihistamine used for treatment of insomnia. Pharmacologic therapy for insomnia should include documentation of sleep onset, sleep maintenance, and sleep quality and next-day functioning. Those aspects were not available in the record. Specifically, the Official Disability Guidelines note that: "Sedating antihistamines have been suggested for sleep aids (for example diphenhydramine). Tolerance seems to develop within a few days. Next-day sedation has been noted as well as impaired psychomotor and cognitive function. Side effects include urinary retention, blurred vision, orthostatic hypotension, dizziness, palpitations, increased liver enzymes, drowsiness, dizziness, grogginess and tiredness." In this case, the already achieved short-term benefits and side effects associated with ongoing therapy do not support medical necessity.

**Prilosec 20 mg:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 68-69.

**Decision rationale:** Prilosec, a proton pump inhibitor, is a gastric antacid. It is sometimes used for prophylaxis against the GI side effects of NSAIDs based upon the patient's risk factors. The Medical Treatment Utilization Schedule (MTUS) notes that these risk factors include (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAIDs. The use of non-selective NSAIDs without prophylaxis is considered "okay" in patients with no risk factors and no cardiovascular disease. In this case, the patient was noted to have past medication-induced gastritis. However, the nature and extent of any current gastrointestinal complications have not been specified. Further, there is no documentation of any of the above risk factors. Therefore, the medical record does not document the medical necessity for Prilosec.

**1 urine drug screen:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 94. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Urine Drug Testing.

**Decision rationale:** This patient is on chronic opioid therapy. The Official Disability Guidelines (ODG) state that urine drug testing is recommended as a tool to monitor compliance with prescribed substances. The California Medical treatment Utilization Schedule (MTUS) recommends frequent random urine toxicology screens without specification as to the type. The ODG further suggests that in low-risk patients, yearly screening is appropriate. Also, in contradiction to a previous consideration, it states: "Quantitative urine drug testing is not recommended for verifying compliance without evidence of necessity." Therefore, necessity is met for 1 urine drug screen.