

Case Number:	CM15-0174575		
Date Assigned:	09/24/2015	Date of Injury:	12/29/2003
Decision Date:	11/19/2015	UR Denial Date:	08/04/2015
Priority:	Standard	Application Received:	09/04/2015

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California

Certification(s)/Specialty: Emergency Medicine

CLINICAL CASE SUMMARY

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

The injured worker is a 47 year old male, who sustained an industrial injury on 12-29-2003. A review of the medical records indicates that the injured worker (IW) is undergoing treatment for cervical myelopathy, lumbar post-laminectomy syndrome, bilateral lower extremity radiculopathy, medication induced gastritis, reactionary depression and anxiety, and right distal fibular fracture. Medical records (03-03-2015 to 07-23-2015) indicate ongoing persistent low back pain with radiating pain into both lower extremities. Pain levels were 7 out of 10 on a visual analog scale (VAS). Records also indicate no changes in activity levels or functioning. Per the treating physician's progress report (PR), the IW has had not returned to work. The physical exam, dated 07-23-2015, reported the IW to be in mild to moderate distress, tenderness to palpation over the posterior cervical musculature bilaterally with increased muscle rigidity, palpable numerous trigger points throughout the left cervical paraspinal musculature, decreased range of motion (ROM) with muscle guarding, decreased motor strength in the left upper extremity, decreased sensation along the lateral arm and forearm in the approximate C5-6 distribution bilaterally, tenderness to palpation over the lumbar posterior musculature bilaterally with increased muscle rigidity, numerous palpable tender trigger points throughout the lumbar paraspinal muscles, decreased ROM in the lumbar spine, decreased motor strength in the lower extremities bilaterally, and diminished sensation in the L5-S1 distribution. There were no changes from previous exam dated 06-25-2015. Relevant treatments have included lumbar laminectomy and fusion surgery, lumbar epidural steroid injections (2011), intrathecal pain pump implantation, physical therapy (PT), work restrictions, and extensive medications

(including: MS Contin, Norco and Soma since 2014, and Ativan since at least 03-2015). It was also reported that the IW requested that the Dilaudid dose be increased in the pain pump to decrease dependence on oral pain medications. This was completed in office. The request for authorization (07-23-2015) shows that the following medications and laboratory tests were requested: MS Contin 15mg #40, Norco 10-325mg #150, Soma 350mg (unspecified quantity), comprehensive metabolic panel (CMP), complete blood count (CBC), testosterone level, retrospective Zofran 8mg, (DOS 07-23-2015), and Ativan 1mg #60. The original utilization review (08-04-2015) non-certified the request for MS Contin 15mg #40; non-certified Norco 10-325mg #150; non-certified Soma 350mg (unspecified quantity); non-certified the CMP; non-certified the CBC; non-certified the testosterone level; non-certified the retrospective request for Zofran 8mg (DOS 07-23-2015); and non-certified Ativan 1mg #60.

IMR ISSUES, DECISIONS AND RATIONALES

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

MS Contin 15mg #40: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

Decision rationale: The request is for the use of a medication in the opioid class. The MTUS guidelines state that for ongoing treatment with a pharmaceutical in this class, certain requirements are necessary. This includes not only adequate pain control, but also functional improvement. Four domains have been proposed for management of patients on opioids. This includes pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug-related behaviors. In this case, there is inadequate documentation of persistent functional improvement seen. As such, the request is not medically necessary. All opioid medications should be titrated down slowly in order to prevent a significant withdrawal syndrome.

Norco 10/325mg #150: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

Decision rationale: The request is for the use of a medication in the opioid class. The MTUS guidelines state that for ongoing treatment with a pharmaceutical in this class, certain requirements are necessary. This includes not only adequate pain control, but also functional improvement. Four domains have been proposed for management of patients on opioids. This includes pain relief, side effects, physical and psychosocial functioning, and the occurrence of

any potentially aberrant drug-related behaviors. In this case, there is inadequate documentation of persistent functional improvement seen. As such, the request is not medically necessary. All opioid medications should be titrated down slowly in order to prevent a significant withdrawal syndrome.

Soma 350mg (unspecified quantity): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

Decision rationale: The request is for the use of a muscle relaxant to aid in pain relief. The MTUS guidelines state that the use of a medication in this class is indicated as a second-line option for short-term treatment of acute exacerbations of low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, which can increase mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain improvement. Efficacy appears to diminish over time, and prolonged use may lead to dependence. (Homik, 2004) Due to inadequate documentation of a recent acute exacerbation and poor effectiveness for chronic long-term use, the request is not medically necessary.

Comprehensive metabolic panel: Upheld

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

MAXIMUS guideline: Decision based on MTUS Low Back Complaints 2004, Section(s): Diagnostic Criteria.

Decision rationale: The request is for blood testing. The ACOEM guidelines state that certain diagnostic tests are appropriate for low back complaints depending on physical exam finding. There is no indication listed for hematologic testing to aid in diagnosis or management of patients with lumbosacral strain or nerve root compression and radiculopathy, sciatica, or spinal stenosis. In this case, the reasoning for the studies is not adequately delineated. As such, the request is not medically necessary.

CBC: Upheld

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

MAXIMUS guideline: Decision based on MTUS Low Back Complaints 2004, Section(s): Diagnostic Criteria.

Decision rationale: The request is for blood testing. The ACOEM guidelines state that certain diagnostic tests are appropriate for low back complaints depending on physical exam finding. There is no indication listed for hematologic testing to aid in diagnosis or management of patients with lumbosacral strain or nerve root compression and radiculopathy, sciatica, or spinal stenosis. In this case, the reasoning for the studies is not adequately delineated. As such, the request is not medically necessary.

Total testosterone level: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Testosterone replacement for hypogonadism (related to opioids).

Decision rationale: The request is for a testosterone blood test. The ODG state the following regarding this topic: Recommended in limited circumstances for patients taking high-dose long-term opioids with documented low testosterone levels. Hypogonadism has been noted in patients receiving intrathecal opioids and long-term high dose opioids. Routine testing of testosterone levels in men taking opioids is not recommended; however, an endocrine evaluation and/or testosterone levels should be considered in men who are taking long term, high dose oral opioids or intrathecal opioids and who exhibit symptoms or signs of hypogonadism, such as gynecomastia. If needed, testosterone replacement should be done by a physician with special knowledge in this field given the potential side effects such as hepatomas. There are multiple delivery mechanisms for testosterone. Hypogonadism secondary to opiates appears to be central, although the exact mechanism has not been determined. The evidence on testosterone levels in long-term opioid users is not randomized or double-blinded, but there are studies that show that there is an increased incidence of hypogonadism in people taking opioids, either intrathecal or oral. There is also a body of literature showing that improvement in strength and other function in those who are testosterone deficient who receive replacement. (Nakazawa, 2006) (Page, 2005) (Rajagopal, 2004) This appears to be more pronounced in patients taking oral opiates than in patients receiving intrathecal opioids, and this difference seems to be related to differences in absorption. Hypogonadism secondary to opiates appears to be central, although the exact mechanism has not been determined. (Abs, 2000) (Roberts, 2002) (Roberts, 2000) The odds of being hypogonadal on long-acting opioids may be 4-5 times higher than the odds on a short-acting equipotent dose. (Rubinstein, 2012) Etiology of decreased sexual function, a symptom of hypogonadism, is confounded by several factors including the following: (1) The role of chronic pain itself on sexual function; (2) The natural occurrence of decreased testosterone that occurs with aging; (3) The documented side effect of decreased sexual function that is common with other medications used to treat pain (SSRIs, tricyclic antidepressants, and certain anti-epilepsy drugs); & (4) The role of comorbid conditions such as diabetes, hypertension, and vascular disease in erectile dysfunction. There is little information in peer-reviewed literature as to how to treat opioid induced androgen deficiency. Long-term safety data of testosterone replacement (overall): Not available. Cardiovascular risk: There have been no large randomized controlled trials to evaluate the cardiovascular risk associated with long-term testosterone use, although

current studies weakly support that there is no association with important cardiovascular effects. (Haddad 2007) Osteoporosis: The extent to which testosterone can prevent and treat osteoporosis remains unclear. (Tracz 2006) (Isidori, 2005) Sexual function: Current trials of testosterone replacement in patients with documented low testosterone levels have shown a moderate non-significant and inconsistent effect of testosterone on erectile function, a large effect on libido, and no significant effect on overall sexual satisfaction. (Bolona, 2007) (Isidori, 2005) The one study (sponsored by the drug company) that has evaluated the use of testosterone replacement in patients with opioid-induced androgen deficiency, measured morning serum free testosterone levels and PSA prior to replacement. This study did not include patients taking antidepressants. (Daniell, 2006) In this case, this test is not indicated. As stated above, routine testing in patients is not indicated. There is inadequate documentation of clinical findings of testosterone deficiency to justify testing. Pending receipt of this information, the request is not medically necessary.

Retro Zofran 8mg #10 DOS 7/23/15: 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, Antiemetics and Ondansetron.

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

Decision rationale: The request is for the use of Zofran. The MTUS and ACOEM guidelines are silent regarding this topic. The ODG guidelines states that this medication is not recommended for nausea and vomiting secondary to chronic opioid use. It is 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) Ondansetron (Zofran): This drug is a serotonin 5-HT₃ receptor antagonist. It is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also FDA-approved for postoperative use. Acute use is FDA-approved for gastroenteritis. In this case, the use of Zofran is not indicated. As stated above, it is not to be used for nausea and vomiting related to chronic opioid use. As such, the request is not medically necessary.

Ativan 1mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Benzodiazepines.

Decision rationale: The request is for the use of a medication in the category of benzodiazepines. It is usually indicated to treat anxiety disorders but has been used short-term as a muscle relaxant. The MTUS guidelines state the following: Not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. (Baillargeon, 2003) (Ashton, 2005) In this case, a medication in this class would not be advised for continued use due to the duration of therapy. As such, the request is not medically necessary. All benzodiazepine medications should be titrated down slowly to prevent an acute withdrawal syndrome.