

Case Number:	CM13-0032858		
Date Assigned:	12/06/2013	Date of Injury:	01/02/1993
Decision Date:	01/21/2014	UR Denial Date:	09/24/2013
Priority:	Standard	Application Received:	10/08/2013

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 Pain Management, has a subspecialty in Disability Evaluation, and is licensed to practice 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 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:

As per medical records provided for review, the patient is a 68-year-old patient who sustained an injury on 01/02/93 while lifting a tanker truck tire according to the nurse case summary. Patient is diagnosed with status post lumbar spine fusion and spinal discopathy. Progress report dated 08/14/13 by [REDACTED] documented that the patient did home exercise and pool therapy and felt decreased low back symptomatology. The patient had some intermittent radiation to the lower extremities. The patient took medications on an as-needed basis. The name, dose, and scheduled use of the medications were not noted in the medical report. On examination of the lumbar spine, there was spasm and tenderness in the paraspinal muscles; sciatic notch was mildly positive; and straight leg raise testing was negative. Treatment plan included prescription for diclofenac XR 100 mg, #90 one tablet by mouth at bedtime with two refills; Tylenol #3, #120 one tablet by mouth every eight hours with two refills for pain relief; and Viagra 100 mg, #15 one by mouth with two refills one hour prior to relations was prescribed for erectile dysfunction. The patient remained permanent and stationary. The patient was diagnosed with status post lumbar spine fusion; and spinal discopathy. The date of the surgery was not documented in the medical reports submitted with this request. This is a request for the medical necessity for Viagra 100mg #15 (two refills); Tylenol #3, #120 (two refills); and diclofenac XR 100mg #90.

IMR ISSUES, DECISIONS AND RATIONALES

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

Viagra 100mg #15 (two refills): Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mode of action of sildenafil, retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/12567500>.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Gempt, J., Rotherl, R.D., Grams, A., Meyer, B., and Ringel, F. (2010). Effect of lumbar spinal stenosis and surgical decompression on erectile function. *Spine (Phila Pa 1976)*, 35(22):E1172-7. doi: 10.1097/B

Decision rationale: The CA MTUS is mute on this topic. In an abstract titled "Effect of lumbar spinal stenosis and surgical decompression on erectile function," published in the *Journal Spine* (2010 Oct 15;35(22):E1172-7.) and PUBMED, the authors evaluated whether and how often patients with lumbar spinal stenosis presenting for surgery have an erectile dysfunction before and after decompressive surgery. So far, there are no reported data on pre- and postoperative erectile function status for patients with lumbar spinal stenosis. The study consisted of a total of 197 male patients with lumbar spinal stenosis who underwent spinal decompression between May 2006 and June 2007 were screened. Patients over 75 years, patients who had previous radical prostatectomy, and patients with psychiatric or other severe concomitant diseases were excluded. Patients with further symptoms for cauda equina syndrome were excluded as well. The erectile function of the remaining 38 patients with a mean age of 63 years was retrospectively rated before and after lumbar spinal decompression using a standardized questionnaire (International Index of Erectile Function-5). Additionally, pre- and postoperative pain, quality of life, and walking distance were assessed. As expected severe preoperative back and leg pain significantly decreased after decompressive surgery. This was associated with a significant increase in the quality of life. The incidence of erectile dysfunction before and after surgery was higher compared to population-based standard data, and surgery was associated with a significant decrease of erectile function at latest follow-up (9.7 months). The study concluded: lumbar spinal stenosis is associated with a neglected prevalence of erectile dysfunction. Surprisingly, it does not improve after decompressive spinal surgery; moreover, a decline was observable. Underlying mechanisms of the postoperative decline remain obscure. Sildenafil (Viagra) is the first oral therapeutic agent for erectile dysfunction. Sildenafil is a selective inhibitor of cGMP-specific phosphodiesterase (PDE-5). Penile erection involves relaxation of the corpus cavernosum, an event mediated by nitric oxide(NO) and cyclic guanosine cyclic monophosphate (cGMP). The biological actions of cGMP are terminated by phosphodiesterase enzymes and phosphodiesterase type 5 (PDE-5) is the major cGMP metabolizing enzyme in this tissue. Sildenafil is relatively safe compared to erection injectables because it does not relax on isolated human corpus cavernosum, and does not cause priapism. Due to the tendency of abuse of sildenafil, its adverse cardiovascular associations with myocardial infraction, ventricular arrhythmia and hypertension need to be alerted. In this case, this patient is status post lumbar spine fusion and spinal discopathy, and this could have caused a decline in his sexual function, therefore the prescription of Viagra 100mg 15 with two refills is medically necessary.

Tylenol #3, #120 (two refills): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Section Opioids Page(s): 92.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Section Codeine Page(s): 35.

Decision rationale: According to CA-MTUS, Tylenol with Codeine (a pure agonist opioids which does not have ceiling effect for their analgesic efficacy nor do they antagonize (reverse) the effects of other pure opioids. Tylenol is recommended as an option for mild to moderate pain, as indicated below. Codeine is a schedule C-II controlled substance. It is similar to morphine. 60 mg of codeine is similar in potency to 600 mg of acetaminophen. It is widely used as a cough suppressant. It is used as a single agent or in combination with acetaminophen (Tylenol® with Codeine) and other products for treatment of mild to moderate pain. Adverse effects included: common effects include central nervous system (CNS) depression and hypotension. Drowsiness and constipation occur in > 10% of cases. Codeine should be used with caution in patients with a history of drug abuse. Tolerance as well as psychological and physical dependence may occur. Abrupt discontinuation after prolonged use may result in withdrawal. Therefore the prescription of Tylenol#3 #120 with two refills is not medically necessary because of abuse potential.

Diclofenac XR 100mg, #90: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Section NSAIDS Page(s): 71.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Section Non-steroidal anti-inflammatory drugs (NSAIDs) Page(s): 71-83.

Decision rationale: The CA-MTUS stated that Diclofenac Sodium (Volteran) is a non-steroidal anti-inflammatory agent are effective, although they can cause gastrointestinal irritation or ulceration or, less commonly, renal or allergic problems. Studies have shown that when nonsteroidal anti-inflammatory drugs (NSAIDs) are used for more than a few weeks, they can retard or impair bone, muscle, and connective tissue healing and perhaps cause hypertension. In addition, MTUS states that there is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough pain. The patient has chronic pain and NSAIDs are a medically reasonable option.