

<b>Case Number:</b>	CM14-0139111		
<b>Date Assigned:</b>	09/19/2014	<b>Date of Injury:</b>	12/23/2013
<b>Decision Date:</b>	10/17/2014	<b>UR Denial Date:</b>	08/20/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/27/2014

### 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 Occupational 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 44-year-old male with a date of injury of 1/23/13. The mechanism of injury occurred when he was walking backward pulling a cart and the cart caught on his foot and caused him to fall backward on his tailbone. He had pain in his back, right hip and right knee. He has had prior injury to his lower back in 1995 and 2010. On 8/5/14, he complained of frequent episodes of falling. He had marked antalgic gait and was ambulating heavily on a cane. On exam there was tenderness and spasm of the paralumbar area, 4/5 motor strength in the lower extremity muscle groups, right more than the left, inability to walk on heels and tiptoes, and limited and painful range of motion. The provider is requesting authorization for lumbar decompression and fusion. The diagnostic impression is right knee degenerative joint disease, right knee contracture; right hip pain, acute/chronic low back pain, and right lower extremity radiculitis. Treatment to date: Lumbar laminectomies x2 on 1995 and 2011, physical therapy, EMG/NCV of lower extremities, MRI 3/26/14, ESI on 6/4/14, medication management. A UR decision dated 8/20/14 denied the requests for Diclofenac XR 100mg, Omeprazole 20mg, and Tramadol XR 150mg. The Diclofenac XR was denied because although it was noted that medications provide subjective increase in functional ability and pain relief, there was no evidence of objective functional improvement that supports the subjectively noted benefit. In addition, this medication is not supported by the ODG drug formulary and there is no documentation of failed trials of approved drugs in this class of NSAIDs. The Omeprazole was denied because with the non-certification of the Diclofenac XR, which is an NSAID, and without gastrointestinal complaints noted, Omeprazole is not supported by guidelines. The Tramadol XR was denied because there was no evidence of objective functional improvement that supports the subjectively noted benefit from the medication. In addition, there was no CA MTUS opioid mandated documentation such as

current urine drug tests, risk assessment profile, attempts at weaning/tapering, and an updated and signed pain contract.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Diclofenac XR 100mg #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 46. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter

**Decision rationale:** CA MTUS states that NSAIDs are effective, although they can cause gastrointestinal irritation or ulceration or, less commonly, renal or allergic problems. Studies have shown that when NSAIDs are used for more than a few weeks, they can retard or impair bone, muscle, and connective tissue healing and perhaps cause hypertension. However, ODG states that Voltaren is not recommended as first line due to increased risk profile. A large systematic review of available evidence on NSAIDs confirms that Diclofenac, a widely used NSAID, poses an equivalent risk of cardiovascular events to patients as did rofecoxib (Vioxx), which was taken off the market. Voltaren (Diclofenac) when used orally or topically, may increase liver dysfunction, and has resulted in liver failure and death. In addition, there was no documentation of failed trials of safer, first line NSAID use such as Naproxen or Ibuprofen. Therefore, the request for Diclofenac XR 100mg #60 was not medically necessary.

**Omeprazole 20mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms and Cardiovascular Risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter Other Medical Treatment Guideline or Medical Evidence: FDA Prilosec

**Decision rationale:** MTUS and the FDA support proton pump inhibitors in the treatment of patients with GI disorders such as; gastric/duodenal ulcers, GERD, erosive esophagitis, or patients utilizing chronic NSAID therapy. Prilosec is a proton pump inhibitor, PPI, used in treating reflux esophagitis and peptic ulcer disease. There is no comment that relates the need for the proton pump inhibitor for treating gastric symptoms associated with the medications used in treating this industrial injury. In general, the use of a PPI should be limited to the recognized indications and used at the lowest dose for the shortest possible amount of time. The FDA states that it is indicated for the treatment of GI disorders such as gastric/duodenal ulcers, GERD, etc. It is also commonly utilized to prevent/treat gastric irritation common in patients utilizing chronic NSAID therapy. However, the patient was prescribed Diclofenac XR, which is not supported by guidelines for use in this patient and not approved. There was no noted

documentation of GI symptoms and with the non-certification of Diclofenac XR, Omeprazole use cannot be supported by guideline recommendations. Therefore, the request for Omeprazole 20mg #60 was not medically necessary.

**Tramadol XR 150mg #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78-81.

**Decision rationale:** CA MTUS Chronic Pain Medical Treatment Guidelines do not support ongoing opioid treatment unless prescriptions are from a single practitioner and are taken as directed; are prescribed at the lowest possible dose; and unless there is ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. However, there is no documentation of functional improvement or continued analgesia with the use of opiates. There is no documentation of lack of adverse side effects or aberrant behavior. There is no documentation of CURES Report or an opiate pain contract. In addition, there were no noted urine drug screens performed. Therefore, the request for Tramadol XR 150mg #60 was not medically necessary.