

<b>Case Number:</b>	CM13-0060316		
<b>Date Assigned:</b>	12/30/2013	<b>Date of Injury:</b>	11/10/2010
<b>Decision Date:</b>	04/11/2014	<b>UR Denial Date:</b>	11/20/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/03/2013

### 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 Internal Medicine & 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 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 patient is a 58 year-old with a date of injury of 11/10/10. A progress report associated with the request for services, dated 11/06/13, identified subjective complaints of low back pain radiating into the right leg with numbness. Objective findings only included pain with range-of-motion of the lumbar spine. Diagnoses included lumbar disc disease with an L5-S1 radiculopathy; facet arthropathy; and neuroforaminal narrowing. A nerve conduction study on 08/13/13 was compatible with an L5-S1 radiculopathy. Treatment has included NSAIDs, oral analgesics, gabapentin, and muscle relaxants. A Utilization Review determination was rendered on 11/20/13 recommending non-certification of "Ultracet 37.5/325mg #90 with two refills; Naproxen 550mg #60 with two refills; Omeprazole 20mg #30 with two refills; Tizanidine 4mg#90 with two refills".

### IMR ISSUES, DECISIONS AND RATIONALES

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

**ONE PRESCRIPTION OF ULTRACET 37.5/325MG #90 WITH TWO REFILLS:** 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, Chapter 16 Eye Chapter Page(s): 308.

**Decision rationale:** Ultracet consists of acetaminophen and tramadol, a centrally acting synthetic opioid analgesic. 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 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)." Opioids are not recommended for more than 2 weeks and the Guidelines further state that tramadol is not recommended as a first-line oral analgesic. This patient has been on Tramadol in excess of 16 weeks. The documentation submitted lacked a number of the elements listed above, including the level of functional improvement afforded by the chronic opioid therapy in view of the recommendations to avoid long-term therapy; likewise, that other first-line oral analgesics have been tried and failed. Therefore, the record does not document the medical necessity for Ultracet.

**ONE PRESCRIPTION OF NAPROXEN 550MG #60 WITH TWO 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 Chronic Pain Treatment Guidelines NSAIDs Page(s): 67-73.

**Decision rationale:** Naproxen is a non-steroidal anti-inflammatory agent (NSAID). NSAIDs have been recommended for use in osteoarthritis. It is noted that they are: "Recommended at the lowest dose for the shortest period in patients with moderate to severe pain." They further state that there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. NSAIDs are also recommended as an option for short-term symptomatic relief on back pain. Again, no one NSAID was superior to another. There is no indication that the therapy is for a short period rather than what appears to be long-term. Since NSAIDs are recommended for short-term use only, there must be documented evidence of functional improvement to extend therapy beyond that. In this case, there is no documentation of the functional improvement related to naproxen and therefore no medical necessity.

**ONE PRESCRIPTION OF OMEPRAZOLE 20MG #30 WITH TWO REFILLS: Upheld**

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

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

**Decision rationale:** Omeprazole (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, there is no documentation of any of the above risk factors. Therefore, the medical record does not document the medical necessity for omeprazole.

**ONE PRESCRIPTION OF TIZANIDINE 4MG #90 WITH TWO REFILLS:** Overturned

**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 Muscle Relaxants Page(s): 63-66.

**Decision rationale:** Tizanidine (Zanaflex) is a centrally acting alpha<sub>2</sub>-adrenergic agonist antispasticity/antispasmodic muscle relaxant. Dosage recommended is 2-4 mg every eight hours up to a maximum of 36 mg per day. The Medical Treatment Utilization Schedule (MTUS) states that muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations of low back pain. However, eight studies have shown efficacy of tizanidine for low back pain (Chou 2007). The Official Disability Guidelines (ODG) also state that muscle relaxants are commonly used for treatment of low back problems. They also note that skeletal muscle spasm is not universally accepted as a cause of symptoms, and the most commonly used muscle relaxants have no peripheral effect on muscle spasm. The original denial of services was based upon a modification to wean the drug. However, the Guidelines do indicate medical necessity for tizanidine.