

<b>Case Number:</b>	CM14-0211337		
<b>Date Assigned:</b>	12/24/2014	<b>Date of Injury:</b>	03/10/2006
<b>Decision Date:</b>	03/05/2015	<b>UR Denial Date:</b>	11/26/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/17/2014

### 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. 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: Internal 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 patient is an injured worker with thoracic and lumbar back complaints. Date of injury was March 10, 2006. The patient sustained an industrial injury on 03/10/06 and is receiving treatment for degeneration of thoracic and lumbar intervertebral disc and displacement of thoracic intervertebral disc without myelopathy. On 11/18/14, patient reports subjective complaints of constant sharp bilateral low back pain that radiates to the right lower extremities with numbness and tingling and stiffness in lower back. Pain is worsened by standing, walking, and weather change. Pain is better with acupuncture, medications, and rest. Patient notes he is exercising, stretching, and swimming which help relieve pain. Acupuncture significantly decreases numbness pain. It is noted that patient needs moderate assistance with some activities of daily living including, housekeeping, shopping, and yard work. Medications included Lunesta, Meloxicam, Paxil, Ranitidine, Tizanidine, Voltaren, and Zofran. Objective findings included normal gait. Treatment plan includes request to continue medications. Utilization review determination date was November 26, 2014.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Tizanidine 4mg #60 with 5 refills: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-spasticity drugs.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47-49, Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63-66.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) addresses muscle relaxants. American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) states that muscle relaxants seem no more effective than NSAIDs for treating patients with musculoskeletal problems. Muscle relaxants may hinder return to function by reducing the patient's motivation or ability to increase activity. Table 3-1 states that muscle relaxants are not recommended. Chronic Pain Medical Treatment Guidelines (Page 63-66) addresses muscle relaxants. Muscle relaxants should be used with caution as a second-line option for short-term treatment. Tizanidine (Zanaflex) is associated with hepatotoxicity. Liver function tests (LFT) should be monitored. Medical records document the long-term use of Tizanidine for chronic occupational injuries. MTUS guidelines do not support the long-term use of muscle relaxants. ACOEM guidelines do not recommend long-term use of muscle relaxants. MTUS and ACOEM guidelines do not support the use of the muscle relaxant Tizanidine (Zanaflex). Therefore, the request for Tizanidine 4mg #60 with 5 refills is not medically necessary.

**Paxil 40mg #30 with 5 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-depressants for chronic pain.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain Page(s): 13-16.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines addresses selective serotonin reuptake inhibitors (SSRIs) for chronic low back pain. SSRIs have not been shown to be effective for low back pain. There was not a significant difference between SSRIs and placebo. SSRIs do not appear to be beneficial. Medical records document a history of chronic low back pain. The progress report dated 11/18/14 documented that the patient denies feeling anxious. The patient denies feeling depressed. The physical examination section did not document a musculoskeletal examination of the lumbar back. The 11/18/14 progress report does not provide clinical support for the request for Paxil. Therefore, the request for Paxil 40mg #30 with 5 refills is not medically necessary.

**Meloxicam 15mg #30 with 5 refills:** 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 (non-steroidal anti-inflammatory drugs) Page(s): 67-73.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines addresses NSAIDs (non-steroidal anti-inflammatory drugs). All NSAIDs have the U.S. Boxed Warning for associated risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Use of NSAIDs may compromise renal function. FDA package inserts for NSAIDs recommend periodic lab monitoring of a CBC complete blood count and chemistry profile including liver and renal function tests. Routine blood pressure monitoring is recommended. It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time. Medical records document the long-term use of NSAIDs. Per MTUS, it is generally recommended that the lowest dose be used for NSAIDs for the shortest duration of time. No musculoskeletal physical examination of the lumbar back was documented in the 11/18/14 progress report. The 11/18/14 progress report does not provide physical examination findings that support for the request for the NSAID Meloxicam (Mobic) quantity thirty with five refills. Long-term NSAID use is not recommended by MTUS. The use of the NSAID Meloxicam (Mobic) is not supported by MTUS guidelines. Therefore, the request for Meloxicam 15mg #30 with 5 refills is not medically necessary.

**Zofran 4mg #30 with 5 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 (ODG)

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Ondansetron (Zofran); FDA Prescribing Information Zofran (Ondansetron) <http://www.drugs.com/pro/zofran.html>.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) does not address Zofran (Ondansetron). The Official Disability Guidelines (ODG) state that Ondansetron (Zofran) is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment, and for postoperative use. Medical records do not document symptoms of nausea or vomiting associated with chemotherapy or radiation treatment or postoperative use. No cancer chemotherapy or radiotherapy was documented. Zofran was not being prescribed for postoperative use. The request for Ondansetron (Zofran) is not supported by the medical records and ODG and FDA guidelines. Therefore, the request for Zofran 4mg #30 with 5 refills is not medically necessary.

**Voltaren 1% topical gel 100gm, #2 with 2 refills: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs), Topical Analgesics Page(s): 67-73, 111-113.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address topical analgesics. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The efficacy in clinical trials of topical NSAIDs has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be either not superior to placebo after two weeks or with a diminishing effect after two weeks. For osteoarthritis of the knee, topical NSAID effect appeared to diminish over time. There are no long-term studies of their effectiveness or safety for chronic musculoskeletal pain. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Topical NSAIDs are not recommended for neuropathic pain as there is no evidence to support use. MTUS Chronic Pain Medical Treatment Guidelines addresses NSAIDs (non-steroidal anti-inflammatory drugs). All NSAIDs have the U.S. Boxed Warning for associated risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Use of NSAIDs may compromise renal function. FDA package inserts for NSAIDs recommend periodic lab monitoring of a CBC complete blood count and chemistry profile including liver and renal function tests. Routine blood pressure monitoring is recommended. It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time. Medical records document the long-term use of NSAIDs. Per MTUS, it is generally recommended that the lowest dose be used for NSAIDs for the shortest duration of time. No musculoskeletal physical examination of the lumbar back was documented in the 11/18/14 progress report. The 11/18/14 progress report does not provide physical examination findings that support for the request for the topical NSAID Voltaren. Long-term NSAID use is not recommended by MTUS. The use of the topical NSAID Voltaren is not supported by MTUS guidelines. Therefore, the request for Voltaren 1% topical gel 100gm, #2 with 2 refills is not medically necessary.

**Ranitidine 75mg #60 with 5 refills:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation [www.drugs.com/ranitidine.html](http://www.drugs.com/ranitidine.html)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation FDA Prescribing Information Zantac (Ranitidine) [http://www.accessdata.fda.gov/drugsatfda\\_docs/labe/2005/018703s065,019675s031,020251s016lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/labe/2005/018703s065,019675s031,020251s016lbl.pdf).

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address NSAIDs and gastrointestinal risk factors. Proton Pump Inhibitor (PPI), e.g. Omeprazole (Prilosec), is recommended for patients with gastrointestinal risk factors. MTUS does not address Ranitidine (Zantac). FDA Prescribing Information documents that Zantac (Ranitidine) is indicated for treatment of gastric ulcer and maintenance therapy for gastric

ulcer.No physical examination of the abdomen was documented in the 11/18/14 progress report. The 11/18/14 progress report does not provide physical examination findings that support for the request for the Ranitidine (Zantac). FDA Prescribing Information documents that Zantac (Ranitidine) is indicated for treatment of gastric ulcer and maintenance therapy for gastric ulcer. The 11/18/14 progress report does not document the existence of a gastric ulcer. The request for Ranitidine (Zantac) is not supported. Therefore, the request for Ranitidine 75mg #60 with 5 refills is not medically necessary.