

<b>Case Number:</b>	CM14-0173757		
<b>Date Assigned:</b>	10/27/2014	<b>Date of Injury:</b>	06/20/2008
<b>Decision Date:</b>	12/03/2014	<b>UR Denial Date:</b>	09/24/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/21/2014

### 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 case is a 56 year old male with a date of injury on 6/20/2008. A review of the medical records indicate that the patient has been undergoing treatment for double crush syndrome, bilateral shoulder impingement syndrome, lumbar discopathy, knee pain, ankle pain, foot pain. Subjective complaints (1/27/2014) include neck pain, shoulder pain, bilateral extremity pain, and bilateral knee pain. Objective findings (2010) include EGD and revealed no ulceration or bleeding, (1/27/2014) decreased shoulder range of motion, decreased shoulder strength bilaterally. Treatment has included cervical fusion, tramadol (since at least 2010), NSAID (since at least 2010), Cyclobenzaprine (since at least 1/2014), bilateral knee surgery. A utilization review dated 9/24/2014 non-certified the following:- Fenoprofen Calcium 400mg #120- Omeprazole delayed release capsules 20mg #120- Ondansetron ODT tablets 8mg #30- Cyclobenzaprine Hydrochloride tablets 7.5mg #120 And partially certified for Tramadol ER 150mg #60 (original request for Tramadol Hydrochloride ER 150mg #90).

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Fenoprofen Calcium 400 mg #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67-72. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Fenoprofen (Nalfon®)

**Decision rationale:** MTUS recommends the use of NSAIDs for the acute exacerbation of back pain at the lowest effective dose for the shortest amount of time due to the increased cardiovascular risk, renal, hepatic and GI side effects associated with long term use. The patient does have documented back pain. Medical records do indicate that the patient has been on NSAID for several years and would not be considered shortest amount of treatment time. Additionally, the medical records do not subjectively define the pain well and does not subjectively or objectively annotate improvement. As such, the request for Fenoprofen Calcium 400 mg #120 is not medically necessary.

**Omeprazole delayed release capsules 20 mg #120:** 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 NSAIDs, GI symptoms and cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), NSAIDs, GI symptoms & cardiovascular risk

**Decision rationale:** The medical documents provided do not establish the patient as having documented GI bleeding/perforation/peptic ulcer or other GI risk factors as outlined in MTUS. While the patient is on long term NSAIDs, medical notes from the last year do not document GI complaints. An EGD performed in 2010 reported no ulceration/bleeding or perforation. As such, the request for Omeprazole delayed release capsules 20 mg #120 is not medically necessary.

**Ondansetron ODT tablets 8 mg #30:** 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) Treatment in Workers Compensation (TWC) Pain Procedure Summary, updated 09/10/2014

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants, NSAIDs, GI symptoms, opioids Page(s): 68-69; 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, Antiemetics (for opioid nausea)

**Decision rationale:** Ondansetron (Zofran) is an antiemetic used to decrease nausea and vomiting. Nausea is a known side effect of chronic opioid use and some Serotonin-norepinephrine reuptake inhibitors (SNRIs). The patient is on tramadol, which is an opioid. ODG does not recommend use of antiemetic for "nausea and vomiting secondary to chronic opioid use". Additionally, "This drug is a serotonin 5-HT<sub>3</sub> receptor antagonist. It is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also FDA-

approved for post-operative use." There is no evidence that patient is undergoing chemotherapy/radiation treatment or is post-operative. MTUS is specific regarding the gastrointestinal symptoms related to NSAID usage. If criteria are met, the first line treatment is to discontinue usage of NSAID, switch NSAID, or consider usage of proton pump inhibitor. There is no documentation provided that indicated the discontinuation of NSAID. Treatment notes from 1/2014 indicate that the patient was on Protonix, but no additional details are provided. Given the lack of documented nausea/vomiting, the request for Ondansetron ODT tablets 8 mg #30 is not medically indicated.

### **Cyclobenzaprine Hydrochloride tablets 7.5 mg #120: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Treatment in Workers Compensation (TWC) Pain Procedure Summary, updated 09/10/2014

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Medications for chronic pain, Antispasmodics Page(s): 41-42, 60-61, 64-66. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Cyclobenzaprine (Flexeril®) and on Other Medical Treatment Guideline or Medical Evidence: UpToDate, Flexeril

**Decision rationale:** MTUS Chronic Pain Medical Treatment states for Cyclobenzaprine, "Recommended as an option, using a short course of therapy. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. (Browning, 2001) Treatment should be brief." The medical documents indicate that patient is far in excess of the initial treatment window and period. Additionally, MTUS outlines that "Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity. Before prescribing any medication for pain the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005)" Uptodate "flexeril" also recommends "Do not use longer than 2-3 weeks". Medical documents do not fully detail the components outlined in the guidelines above and do not establish the need for long term/chronic usage of cyclobenzaprine. ODG states regarding cyclobenzaprine, "Recommended as an option, using a short course of therapy" The addition of Cyclobenzaprine to other agents is not recommended." Several other pain medications are being requested, along with Cyclobenzaprine, which ODG recommends against. As such, the request for Cyclobenzaprine Hydrochloride tablets 7.5 mg #120 is not medically necessary.

### **Tramadol Hydrochloride ER 150 mg #90: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Tramadol, Ultram Page(s): 74-96, 113, 123. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) - Medications for acute pain (analgesics), Tramadol (Ultram<sup>®</sup>)

**Decision rationale:** Tramadol is classified as a central acting synthetic opioid. MTUS states regarding tramadol that "A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals." ODG further states, "Tramadol is not recommended as a first-line oral analgesic because of its inferior efficacy to a combination of Hydrocodone/ acetaminophen." The treating physician did not provide sufficient documentation that the patient has failed a trial of non-opioid analgesics at the time of prescription or in subsequent medical notes. Additionally, no documentation was provided which discussed the setting of goals for the use of Tramadol prior to the initiation of this medication. As such, the request for Tramadol Hydrochloride ER 150 mg #90 is not medically necessary.