

<b>Case Number:</b>	CM15-0088836		
<b>Date Assigned:</b>	05/13/2015	<b>Date of Injury:</b>	12/03/2012
<b>Decision Date:</b>	07/03/2015	<b>UR Denial Date:</b>	04/16/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/08/2015

### 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: Indiana

Certification(s)/Specialty: Preventive Medicine, Occupational 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 injured worker is a 27 year old female, who sustained an industrial injury on 12/3/12. She reported a low back injury. The injured worker was diagnosed as having lumbar discopathy and radiculopathy. Treatment to date has included oral medications including NSAIDS and narcotics, intramuscular pain injections, two lumbar epidural blocks, physical therapy and acupuncture treatments. Currently, the injured worker complains of constant low back pain characterized as sharp with radiation to left greater than right lower extremity rated 7/10 and unchanged from previous visit. Physical exam noted tenderness across the iliac crest to the lumbosacral spine most pronounced on the left and extending into the left lower extremity, restricted range of motion of lumbosacral area is also noted. A request for authorization was submitted for Fenoprofen, Omeprazole, Ondansetron, Cyclobenzaprine and Tramadol.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Fenoprofen calcium (Nalfon) 400mg #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. Fenoprofen (Nalfon, generic available): 200, 600 mg. Dosing: osteoarthritis; (off-label use for ankylosing spondylitis); 300 - 600mg PO 3 to 4 times per day (Max daily dose is 3200mg). Improvement may take as long as 2 to 3 weeks. Mild to moderate pain (off-label use for bone pain): 200mg PO every 4 to 6 hours as needed. 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 is not medically necessary.

**Omeprazole 20mg #120:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs; GI risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** MTUS and ODG states, "Determine if the patient is at risk for gastrointestinal events: (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 NSAID (e.g., NSAID + low-dose ASA)." And "Patients at intermediate risk for gastrointestinal events and no cardiovascular disease:(1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 g four times daily) or(2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44)." 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. As such, the request is not medically necessary.

**Ondasetron 8mg #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), Pain Chapter, Ondasetron (Zofran), Antiemetics (for opioid nausea).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs; GI discomfort Page(s): 68-69. 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). ODG does not recommend use of antiemetic for "nausea and vomiting secondary to chronic opioid use." Additionally, "This drug is a serotonin 5-HT3 receptor antagonist. It is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also FDA-approved for postoperative use." There is no evidence that patient is undergoing chemotherapy/radiation treatment or postoperative. The notes indicate the GI distress could be due to NSAID usage. 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 or switching of NSAID occurred. Additionally, ondansetron is not a proton pump inhibitor and is not considered first line treatment. As such the request is not medically necessary.

**Cyclobenzaprine hydrochloride 7.5mg #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain), Antispasmodics, Cyclobenzaprine.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41-66. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Cyclobenzaprine (Flexeril) 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 Flexeril 7.5mg #120 is not medically necessary.

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

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for use of opioids.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Ultram; opioids Page(s): 74-123. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) - Medications for acute pain (analgesics), Tramadol (Ultram).

**Decision rationale:** Ultram is the brand name version of tramadol, which is classified as central acting synthetic opioids. 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 #90 is not medically necessary.