

<b>Case Number:</b>	CM15-0034552		
<b>Date Assigned:</b>	03/02/2015	<b>Date of Injury:</b>	07/02/2012
<b>Decision Date:</b>	04/15/2015	<b>UR Denial Date:</b>	01/28/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/23/2015

### 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: Arizona, Michigan

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 24-year-old female, who sustained an industrial injury on 7/02/2012. She reported injury to her neck and low back, due to repetitive tasks and/or prolonged sitting. The diagnoses have included other and unspecified disc disorder, cervical region. Treatment to date has included conservative measures. Currently, the injured worker complains of left shoulder pain, right elbow pain, headache, neck pain, low back pain, and numbness in her lower extremities. She also reported shaking, numbness, and tingling in her hands. She was able to stand erect and gait was slightly antalgic. Exam of the cervical spine noted mild torticollis bilaterally, positive head compression sign, positive Spurling's maneuver bilaterally, and tenderness with spasm bilaterally. Biceps reflex was diminished and bicep and wrist strengths were diminished. Exam of the lumbar spine noted tenderness from the thoracolumbar spine to the base of the pelvis and paralumbar musculature was slightly tight bilaterally. The treatment plan included Sumatriptan for headache problem, noting a fair amount of nausea with accompanying headaches, and recommendation for Ondansetron. Other medications included Diclofenac XR, Tramadol, and pain compound cream. Radiographic imaging reports were not noted. On 1/28/2015, Utilization Review non-certified a request for Diclofenac XR 100mg #30, modified a request for Tramadol/APAP 37.5/325mg #100 to #90, modified a request for Ondansetron ODT 8mg #10 to #9, non-certified a request for Sumatriptan 50mg #9, and non-certified a request for Ketoprofen 10%/Cyclobenzaprine 2%/Diclofenac 5%/Lidocaine 5% cream 180 grams, noting the lack of compliance with MTUS Chronic Pain Medical Treatment Guidelines and Non-MTUS Guidelines.

## IMR ISSUES, DECISIONS AND RATIONALES

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

### **Diclofenac extended release 100 mg QTY: 30:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 67.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAID's Page(s): 67-68.

**Decision rationale:** Per the MTUS, NSAIDs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. A review of the injured workers medical records that are available to me reveal subjective and objective documentation of the injured workers pain and the use of an NSAID would be appropriate in the injured worker, therefore the request for Diclofenac extended release 100 mg QTY: 30 is medically necessary.

### **Sumatriptan 50 mg QTY: 9:** Overturned

**Claims Administrator guideline:** Decision based on MTUS ACOEM,Chronic Pain Treatment Guidelines ODG-TWC,ODG treatment; integrated treatment/disability duration guidelines, [HTTP://www.nlm.nih.gov/druginfo/meds/a6011116.html](http://www.nlm.nih.gov/druginfo/meds/a6011116.html).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Head / Triptans.

**Decision rationale:** The MTUS /ACOEM did not specifically address the use of sumatriptan in the injured worker therefore, other guidelines were consulted. Per the ODG, triptans are recommended for migraine sufferers. At marketed doses, all oral triptans (e.g., sumatriptan, brand name Imitrex) are effective and well tolerated. Differences among them are in general relatively small, but clinically relevant for individual patients. A poor response to one triptan does not predict a poor response to other agents in that class. Rizatriptan (Maxalt) has demonstrated, in a head-to-head study, higher response rates and a more rapid onset of action than sumatriptan, together with a favorable tolerability profile. While the Maxalt brand of rizatriptan therapy is more expensive than other triptans, the economic value of rizatriptan

depends on the payer's perspective, as the greatest savings can be expected to be achieved in terms of reduced migraine-related loss of work productivity compared with less effective treatments. According to the FDA Orange Book, equivalent generics have been approved for Maxalt, so generic rizatriptan would be recommended. A review of the injured workers medical records show that she does have headaches that appear to be cervicogenic in origin and may benefit from the use of sumatriptan. Based on her clinical presentation and the guidelines the request for Sumatriptan 50 mg QTY: 9 is medically necessary.

**Ketoprofen 10%, Cyclobenzaprine 2%, Diclofenac 5%, Lidocaine 5% cream 180 g: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** Per the MTUS, topical analgesics are recommended as an option, they are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. There is no evidence for use of any muscle relaxants as a topical product. A review of the injured workers medical records that are available to me does not show a trial of recommended first line agents that have failed, therefore the request for Ketoprofen 10%, Cyclobenzaprine 2%, Diclofenac 5%, Lidocaine 5% cream 180 g is not medically necessary.

**Tranadol/Acetaminophen 37.5/325 mg QTY: 100: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78, 93, 94 113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96 (78,95).

**Decision rationale:** Per the MTUS, Opioids should be continued if the patient has returned to work or has improved functioning and pain. Ongoing management should follow the 4 A's of analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors. Long term users of opioids should be regularly reassessed. Also, patients who receive opioid therapy may sometimes develop unexpected changes in their response to opioids, which includes development of abnormal pain, change in pain pattern, persistence of pain at higher levels than expected. when this happens opioids can actually increase rather than decrease sensitivity to noxious stimuli. it is important to note that a decrease in opioid efficacy should not always be treated by increasing the dose or adding other opioids, but may actually require weaning. A review of the injured workers medical records that are available to me, shows that the injured worker appears to be having persistent pain despite opioid treatment and does not appear to be

having a satisfactory response to opioids, also there is no documentation according to the MTUS recommendation for ongoing management of patients on opioids. Therefore based on the injured workers clinical presentation and the guideline recommendations the request for Tramadol/Acetaminophen 37.5/325 mg QTY: 100 is not medically necessary.

**Ondansetron Orally Disintegrating Tablet 8 mg QTY: 10: Upheld**

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

**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<sup>®</sup> 1/2).

**Decision rationale:** Regarding the request for ondansetron, a search of the MTUS failed to reveal relevant recommendations and the ODGs have been consulted. Guidelines indicate this medication 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 postoperative use and acute use is FDA-approved for gastroenteritis. The patient does not appear to be a candidate for the use of ondansetron. Guidelines recommend the use of this medication for patients undergoing cancer treatment, postoperatively, and acutely for gastroenteritis. None of the above conditions are mentioned within the most recently submitted clinical documentation. Therefore, use of ondansetron would not fall within guideline recommendations and is not medically necessary.