

<b>Case Number:</b>	CM14-0192967		
<b>Date Assigned:</b>	11/26/2014	<b>Date of Injury:</b>	07/23/2012
<b>Decision Date:</b>	01/14/2015	<b>UR Denial Date:</b>	11/03/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/18/2014

### 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 Family Medicine and is licensed to practice in Colorado. 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:

50 year old female with date of injury 7/23/2012 continues care with the treating physician. Patient has ongoing complaints of neck pain, bilateral shoulder pain (worse on left), left arm and wrist pain, low back pain resulting from work related injury. Patient is considered to have reached maximum medical improvement as of 7/9/2013. Patient is status post right carpal tunnel release and right ulnar nerve decompression which alleviated virtually all of her right sided symptoms except some residual numbness in right middle finger. Documented exam confirms numbness in right middle finger, tenderness along left carpal tunnel, swelling and decreased range of motion in left shoulder with positive impingement sign left shoulder. The records supplied for review do not include an assessment of pain improvement or functional improvement with patient's current regimen. The records also indicate patient has had sleep problems for years related to her pain, treated with Ambien. The treating physician requests ongoing approval for Protonix, Ambien, Ultram ER, and Voltaren.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Retrospective request for Protonix 220 mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Proton Pump Inhibitors (PPIs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 68.

**Decision rationale:** Per the Guidelines, a patient at intermediate risk for gastrointestinal event, but at no risk from cardiovascular event, would need a non-selective non-steroidal anti-inflammatory drug, and Proton Pump Inhibitor to protect stomach. Non-steroidal anti-inflammatory drugs do carry risks of gastrointestinal symptoms and cardiovascular and renal effects. Per the records for the patient of concern, the issue of gastrointestinal events was not addressed except in the Plan of the 9/2/2014 office visit, where it is indicated that patient had gastritis in the past related to non-steroidal anti-inflammatory drugs. (No known peptic ulcer disease or bleed) The other records supplied never mention gastrointestinal issue. She would still not meet the above criteria for proton pump inhibitor addition to non-steroidal anti-inflammatory drug use. Furthermore, as it is not recommended for patient of concern to continue non-steroidal anti-inflammatory drug use, then the protective proton pump inhibitor, Protonix, would not be medically necessary.

**Retrospective request for Ultram ER 150 mg #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 78-80, 85, 88-89, 93-94, 113.

**Decision rationale:** The Guidelines establish criteria for use of opioids, including long term use (6 months or more). When managing patients using long term opioids, the following should be addressed: Re-assess the diagnosis and review previous treatments and whether or not they were helpful. When re-assessing, pain levels and improvement in function should be documented. Pain levels should be documented every visit. Function should be evaluated every 6 months using a validated tool. Adverse effects, including hyperalgesia, should also be addressed each visit. Patient's motivation and attitudes about pain/work/interpersonal relationships can be examined to determine if patient requires psychological evaluation as well. Aberrant/addictive behavior should be addressed if present. Do not decrease dose if effective. Medication for breakthrough pain may be helpful in limiting overall medication. Follow up evaluations are recommended every 1-6 months. To summarize the above, the 4A's of Drug Monitoring (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking Behaviors) have been established. The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. As the guidelines make it clear that ongoing assessment and evaluation should continue once opioids prescribed, patient does require follow up visits to discuss pain issues and treatment, which should be every 2 weeks for 2-4 months, then every 1-2 months based on needs. For the patient of concern, no records were available for review that indicated patient's level of improvement in pain or function on her current regimen. Functional improvement was not quantified or verified with a validated assessment tool, and it is not made clear which medications helped her and how those medications helped her. There is also little indication that aberrant drug taking behavior is being monitored. (Urine drug screens done, but no other

discussion of possible aberrant behaviors) Without evidence of patient improvement and without evidence of monitoring as required by the guidelines, the request for Ultram ER is not medically indicated.

**Retrospective request for Ambien 10 mg #120: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Ambien Other Medical Treatment Guideline or Medical Evidence:  
<http://www.fda.gov/Drugs/default.htm>

**Decision rationale:** MTUS Guidelines and ACEOM do not address Ambien, so alternate references were consulted. Per the FDA, Ambien is indicated for short term treatment of insomnia. Ambien has been shown in quality controlled studies to decrease time to sleep for up to 35 days. Per the FDA dosage guidelines, lowest effective dose is recommended, 5mg for women and geriatric patients or patients with liver impairment, and 5mg-10mg for men. Patient should be re-evaluated and Ambien reconsidered if sleep is not improved after 7-10 days. Likewise, the ODG recommends Ambien only for short term use, 2-6 weeks. Long term use of Ambien is not supported because of risks of tolerance and dependence as well as risks of worsening depressive symptoms. Per the ODG, good sleep hygiene is also considered an important recommendation to be used in conjunction with Ambien. Per the records supplied for review, the patient of concern has been taking Ambien, at a dose exceeding the recommended maximum, long term, greater than 6 weeks, at the time of the request for refill. As above, long term use is not an FDA-approved indication or ODG recommended use for Ambien, so the Ambien request is not medically indicated.

**Retrospective request for Voltaren 100 mg #30: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 67-638, 71. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter

**Decision rationale:** Per the ODG, Diclofenac (Voltaren) is not a recommended non-steroidal anti-inflammatory drug as first line, because of its increased risk profile. Per the MTUS Guidelines, non-steroidal anti-inflammatory drugs are recommended as second line agents for pain, after trial of Acetaminophen, (particularly for those patients at risk for gastrointestinal events, cardiac events, and renal disease), to be taken at the lowest effective dose for shortest period of time. Non-steroidal anti-inflammatory drugs may be first line for moderate to severe pain, based on available evidence, though studies cannot consistently confirm that non-steroidal anti-inflammatory drugs are superior to Acetaminophen. There is no evidence that any of the

non-steroidal anti-inflammatory drugs are effective long term for pain relief or functional improvement. There is no consistent evidence that non-steroidal anti-inflammatory drugs are useful for long term management of neuropathic pain. Per the MTUS Guidelines, based off of the dosing recommendations for Voltaren, total daily dosage should not exceed 150 mg per day, regardless of formulation/diagnosis. Per the records supplied for patient of concern, there is no documentation of functional improvement or lasting pain relief from her current regimen which includes Diclofenac times 6 months or more. Without objective findings of improvement, non-steroidal anti-inflammatory drugs should not be continued long term, given the risk profile. There is also no documentation indicating patient ever tried Acetaminophen prior to non-steroidal anti-inflammatory drugs. For the above reasons, the Diclofenac is not medically indicated.