

<b>Case Number:</b>	CM15-0174446		
<b>Date Assigned:</b>	09/16/2015	<b>Date of Injury:</b>	05/29/2012
<b>Decision Date:</b>	11/06/2015	<b>UR Denial Date:</b>	08/19/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/04/2015

### 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 57 year old male, who sustained an industrial injury on 5-29-2012. The injured worker was diagnosed as having hypertension, gastritis, headache, not otherwise specified, and hemorrhoids. Treatment to date has included diagnostics, physical therapy, shoulder injection, right shoulder surgery in 12-2012 and 5-2014, hernia surgery in 2-2014, cervical facet rhizotomy, extracorporeal shockwave therapy, and medications. Per the Agreed Medical Re-Examination (6-17-2015), the injured worker complained of constant headaches and dizziness, constant neck pain (localized and occasionally radiated down both shoulders), constant bilateral shoulder pain (right greater than left), constant left inguinal pain, and constant low back pain that radiated down both sides of legs to the knees (left greater than right). It was noted that he had hemorrhoids, constipation, and heartburn, which he attributed to the use of Norco. He continued to have trouble sleeping, attributed to stress, and only was able to sleep in five hour intervals. He was started on Sonata in 3-2015. A neurology report (8-25-2014) was referenced and noted daily headaches, noting normal electroencephalogram, non-specific findings on brain magnetic resonance imaging, an abnormal Videonystagmography (VNG) study, and a nonfocal neurologic examination. It was documented that future medical care should include treatment for his headaches, which could include Midrin or substitution with Excedrin migraine. Currently (7-27-2015), the injured worker presented for follow up visit regarding his blood pressure, gastrointestinal symptoms, and headaches. Specific complaints were not noted on 7-27-2015. He was taking medications as directed. His blood pressure was 146 over 87, pulse 66, and weight was 206 pounds. He was alert and oriented times 3 and in no acute distress. His pupils

were equal and reactive to light. The treatment plan included to continue current medications, except discontinue Zantac and start Protonix. Urine toxicology (6-16-2015) was inconsistent with prescribed medications and did not detect Hydrocodone. The request for authorization (7-27-2015) was for Losartan, Norco 10-325mg (every 8 hours) #90, Protonix 20mg twice daily #60, Sonata 10mg at bedtime #60, and Isometheptene-Dichloralphen twice daily #60. The request for authorization (6-15-2015) noted Zantac 150mg #60, Norco, Isometheptene-Dichloralphen, Losartan, and Sonata. On 8-19-2015, Utilization Review non-certified the requests for Norco, Isometheptene-Dichloralphen, Sonata, and Zantac.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Norco 10/325mg #90:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

**Decision rationale:** Per the MTUS, opioids should be discontinued if there is no overall improvement in function, unless there are extenuating circumstances, Opioids should be continued if the patient has returned to work or has improved functioning and pain. Ongoing management actions should include prescriptions from a single practitioner, taken as directed and all prescriptions from a single pharmacy. The lowest possible dose should be prescribed to improve pain and function. Documentation 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. In the maintenance phase the dose should not be lowered if it is working. 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, and 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 do not reveal documentation of improvement in pain and function with the use of opioids as well as ongoing management actions as required by the guidelines. Without this information it is not possible to establish medical necessity, therefore the request for Norco 10/325mg #90 is not medically necessary.

**Isometheptene-Dichloralphen #60:** 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 UpToDate / Acetaminophen, isometheptene, and dichloralphenazone.

**Decision rationale:** The MTUS /ACOEM and ODG did not address the use of this medication, therefore other guidelines were consulted. Per Up-to-date Acetaminophen, isometheptene, and dichloralphenazone is used in the treatment of migraine. However a review of the injured workers medical records that are available for review did not reveal a clear rationale for the use of this medication, neither was there documentation of an improvement in pain and function with the use of this medication. Without this information it is not possible to establish medical necessity, therefore the request for Isometheptene-Dichloralphen #60 is not medically necessary.

**Sonata #60:** 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 / Insomnia treatment.

**Decision rationale:** The MTUS did not specifically address the use of Sonata, therefore other guidelines were consulted. Per the ODG, " Not recommended for long-term use, but recommended for short-term use. Recommend limiting use of hypnotics to three weeks maximum in the first two months of injury only, and discourage use in the chronic phase. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term. Zaleplon (Sonata) reduces sleep latency. Side effects: headache, drowsiness, dizziness, fatigue, confusion, abnormal thinking. Sleep-related activities have also been noted such as driving, cooking, eating and making phone calls. Abrupt discontinuation may lead to withdrawal. Dosing: 10 mg at bedtime (5 mg in the elderly and patients with hepatic dysfunction). (Morin, 2007) Because of its short half-life (one hour), may be readministered upon nocturnal waking provided it is administered at least 4 hours before wake time. (Ramakrishnan, 2007) This medication has a rapid onset of action. Short-term use (7-10 days) is indicated with a controlled trial showing effectiveness for up to 5 weeks." However a review of the injured workers medical records that are available to me did not reveal any quantifiable documentation of improvement in sleep with the use of Sonata, therefore the request for Sonata #60 is not medically necessary.

**Zantac 150mg #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) / Proton Pump Inhibitors (PPIs).

**Decision rationale:** Per the MTUS, Clinicians should weigh the indications for NSAIDs against both GI and cardiovascular risk factors according to specific criteria listed in the MTUS and a selection should be made based on these criteria: 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). Per the ODG, PPI's are "Recommended for patients at risk for gastrointestinal events. Prilosec (omeprazole), Prevacid (lansoprazole) and Nexium (esomeprazole magnesium) are PPIs. Healing doses of PPIs are more effective than all other therapies, although there is an increase in overall adverse effects compared to placebo. Nexium and Prilosec are very similar molecules. (Donnellan, 2010) In this RCT omeprazole provided a statistically significantly greater acid control than lansoprazole. (Miner, 2010) In general, the use of a PPI should be limited to the recognized indications and used at the lowest dose for the shortest possible amount of time. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. Studies suggest, however, that nearly half of all PPI prescriptions are used for unapproved indications or no indications at all. Many prescribers believe that this class of drugs is innocuous, but much information is available to demonstrate otherwise. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi, 2008) A trial of omeprazole or lansoprazole had been recommended before prescription Nexium therapy (before it went OTC). The other PPIs, Protonix, Dexilant, and Aciphex, should be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. (AHRQ, 2011)." However a review of the injured workers medical records that are available for review do not reveal a clear rationale for the use of an H2 blocker rather than the guideline recommended PPI, therefore the request for Zantac is not medically necessary.