

<b>Case Number:</b>	CM15-0174838		
<b>Date Assigned:</b>	09/29/2015	<b>Date of Injury:</b>	05/29/2012
<b>Decision Date:</b>	11/30/2015	<b>UR Denial Date:</b>	08/10/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/20/2015

### 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, with a reported date of injury of 05-29-2012. The diagnoses include cervical spine myoligamentous injury, post-traumatic headaches, rule out traumatic brain injury, displacement of cervical disc, lumbar intervertebral disc syndrome, high blood pressure, insomnia, and gastritis. Treatments and evaluation to date have included Isometheptene (since at least 05-2015), Dichlorophenazone (since at least 05-2015), Norco (since at least 05-2015), Topiramate, Diazepam, and Ranitidine. The diagnostic studies to date have included a urine drug screen on 07-28-2015 with inconsistent findings; and a urine drug screen on 06-16-2015 with inconsistent findings. The progress report dated 07-27-2015 indicates that the injured worker was taking his medications as directed. The injured worker complained of gastritis. The objective findings included alert and oriented, no abnormalities detected, and pupils equal, round, reactive to light. The treatment plan included the start of Protonix. The progress report dated 07-28-2015 indicates that the injured worker had constant, severe cervical spine pain with radiation to the bilateral shoulders, right shoulder pain, constant low back pain with radiation to the bilateral hips, difficulty sleeping due to pain, stress, anxiety, and depression. The objective findings included cervical flexion at 45 degrees, cervical extension at 50 degrees, tenderness to palpation of the cervical spinous process bilaterally; spasm of the bilateral cervical paravertebral muscles; decreased right shoulder range of motion; positive right Apley Scratch test; positive right supraspinatus test; positive bilateral spasm of the thoracolumbar spine paravertebral muscles; lumbar flexion at 50 degrees; lumbar extension at 10 degrees; and positive bilateral straight leg raise test. The injured worker remained temporarily totally disabled until 09-22-2015. The request for authorization was dated 07-27-2015. The

treating physician requested Isometheptene- Dichloralphen #60, Sonata 10mg #60, Protonix 20mg, and Norco #40. On 08-10-2015, Utilization Review (UR) non-certified the request for Isometheptene- Dichloralphen #60, Sonata 10mg #60, Protonix 20mg, and Norco #40.

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

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

#### **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 did not address the use of this medication, therefore other guidelines were consulted. Per UpToDate Acetaminophen, isometheptene, and dichloralphenazone is used in the management of tension, vascular or migrainous headaches. In this case it is reported that the injured worker has post traumatic headaches, however there is no documentation of pain or functional improvement with the use of this medication, without this information it is not possible to determine medical necessity for continued use, therefore the request for Isometheptene-Dichloralphen #60 is not medically necessary.

#### **Sonata 10mg #60: 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): Mental Illness & Stress Chapter: (Online version) Insomnia Treatment.

**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) / insomnia treatment.

**Decision rationale:** The MTUS did not specifically address the use of Sonata (Zaleplon), therefore other guidelines were consulted. Per the ODG, Zaleplon is a prescription short-acting non-benzodiazepine hypnotic, which is recommended for short-term (7-10 days) treatment of insomnia. Proper sleep hygiene is critical to the individual with chronic pain and often is hard to obtain. Various medications may provide short-term benefit. 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, however given the risks there is no clear indication for the continued use of this medication in the injured worker, the risks outweigh the benefits and the continued use of Sonata is not medically necessary.

**Protonix 20mg #60: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**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) NSAIDs, GI symptoms and cardiovascular risk.

**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, PPIs 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)" A review of the injured workers medical records reveal that the injured worker has complaints of gastritis for which the use of a PPI is appropriate, the continued use of Protonix is medically necessary.

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

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**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, 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. Unfortunately, a review of the injured workers medical records do not reveal documentation of improvement in pain and function with the use of this medication, there are also no ongoing management actions as required by the guidelines, therefore the request for Norco 10/325mg #90 is not medically necessary.