

<b>Case Number:</b>	CM15-0174439		
<b>Date Assigned:</b>	09/16/2015	<b>Date of Injury:</b>	04/12/2010
<b>Decision Date:</b>	11/09/2015	<b>UR Denial Date:</b>	08/20/2015
<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 44 year old male, who sustained an industrial injury on 4-12-2010. The injured worker was diagnosed as having shoulder impingement, hip sprain and strain, knee tendinitis or bursitis, carpal tunnel syndrome, intervertebral disc disorder, lumbosacral radiculopathy, intervertebral disc disorder, cervical radiculopathy, tear of cartilage or meniscus of knee, rotator cuff sprain and strain, and lumbar disc displacement without myelopathy. The request for authorization is for: Norflex 100mg #60 with 5 refills; Prilosec 20mg #60 with 5 refills; Tylenol #4 300-60mg #60 with 5 refills; Voltaren 100mg #60 with 5 refills. The UR dated 8-20-2015: non-certified the request for Norflex 100mg #60 with 5 refills and Tylenol #4 300- 60mg #60 with 5 refills; modified certification of Prilosec 20mg #30 with no refills and Voltaren 100mg #60 with one refill. The records indicate he has been utilizing Prilosec since at least April 2014, possibly longer. The records indicate he has been utilizing opioids since at least April 2014, possibly longer. On 8-10-2015, his work status is indicated to be modified. He reported pain to the low back, neck and shoulder. Objective findings are reported as "loss of range of motion". The provider reported that the injured worker used Norflex sparingly for intermittent flare-ups. It is reported that the injured worker has a history of gastroesophageal reflux disease and "it has been described as exacerbated with the medications prescribed". He reported a 30- 40% reduction in pain with the use of Tylenol #4 along with a noted "improved functional capacity with activities of daily living, self-grooming, and chores around the house". There are no adverse side effects documented, and there is notation of "no suspicion of any aberrant behaviors". The treatment and diagnostic testing to date has included: QME evaluation

(1-31-2012), electrodiagnostic studies (8-12-2010), magnetic resonance imaging of the right knee (9-7-2010), magnetic resonance imaging of the right shoulder (12-3-2010), magnetic resonance imaging of the lumbar spine (12-3-2010, 4-19-2013), magnetic resonance imaging of the cervical spine (12-3-2010), home exercise program, and medications.

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

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

**Norflex 100mg, 60 with 5 refills:** 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): Muscle relaxants (for pain).

**Decision rationale:** The MTUS recommends non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. (Homik, 2004) Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used with caution in patients driving motor vehicles or operating heavy machinery. Drugs with the most limited published evidence in terms of clinical effectiveness include chlorzoxazone, methocarbamol, dantrolene and baclofen. This medication is not recommended for long-term use, however it is noted that the injured worker only uses the medication sparingly for intermittent flare-ups, therefore the request for Norflex 100mg, 60 with 5 refills is medically necessary.

**Tylenol #4, 300/60mg, #60 with 5 refills:** 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): 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. A review of the injured workers medical records note that he reported a 30-40% reduction in pain with the use of Tylenol #4 along with "improved functional capacity with activities of daily living, self-grooming, and chores around the house". There are no adverse side effects documented, and there is notation of "no suspicion of any aberrant behaviors". Therefore, the request for Tylenol #4, 300/60mg, #60 with 5 refills is medically necessary.

**Prilosec 20mg, #60 with 5 refills:** 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) 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 Medium (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)." It is reported that the injured worker has a history of gastroesophageal reflux disease and "it has been described as exacerbated with the medications prescribed" the use of PPI is appropriate, therefore the request for Prilosec 20mg, #60 with 5 refills is medically necessary.

**Voltaren 100mg, #60 with 5 refills:** 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 (non-steroidal anti-inflammatory drugs).

**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. The injured worker has chronic moderate pain affecting multiple joints, the use of an NSAID is justified, and therefore the request for Voltaren 100mg, #60 with 5 refills is medically necessary.