

<b>Case Number:</b>	CM15-0149943		
<b>Date Assigned:</b>	08/13/2015	<b>Date of Injury:</b>	06/09/2008
<b>Decision Date:</b>	10/02/2015	<b>UR Denial Date:</b>	07/20/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/03/2015

### 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 53 year old male who sustained an industrial injury on 06-09-2008. The mechanism of injury was not mentioned. Treatment provided to date has included: chiro-physio medications, and conservative therapies and care. Recent diagnostic testing was not available for review, and not discussed in the clinical notes. There were no noted comorbidities or other dates of injury noted. On 05-29-2015, physician progress report noted that the injured worker was seen for follow-up and refill of medications. Although the location of pain was not mentioned, the injured worker rated his pain as 8 out of 10 in severity without medications and 6 out of 10 with medication. The pain was described as dull, tingling, intense, numbness, discomfort and throbbing. Current medications were not mentioned, but the injured worker reported that his medications help control his pain and allow for him to help out around the house and take care of his personal hygiene. The physical exam revealed an elevated blood pressure; spinal restriction(s) and subluxation(s): T4, T5, T6, T7, T8, T9, T10, T11, T12, L1, L2, L3, L4, L5, sacrum and coccyx; extra spinal restrictions and subluxations: bilateral lumbar radiculitis; pain and tenderness in the lower lumbar area; lumbar curve to the left, lumbar curve to the right, high left hip and high right hip; moderate muscle spasms in the left mid-thoracic, right mid-thoracic, left lower thoracic, lower thoracic, right lower thoracic, left lumbar, lumbar, left sacroiliac, right lumbar, right sacroiliac, left posterior pelvis and hip, sacral rea, right posterior pelvis and hip, left buttock, left posterior thigh, left posterior knee, , right posterior thigh and knee, left calf, right ankle, left ankle, and right plantar foot. The provider noted diagnoses of myofascial pain, bilateral lumbar radiculitis, and intervertebral disc disease. Plan of care includes follow-up in one

month, and additional electrical stimulation and chiro-physio massage visits. The injured worker's work status remained modified with restrictions. The request for authorization and IMR (independent medical review) includes: Protonix 20mg #30 and Flector patches 1% #30.

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

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

#### **Protonix 20mg #30: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS (Non-Steroidal Anti-Inflammatory Drugs) GI (Gastrointestinal) Symptoms & Cardiovascular Risk Page(s): 68.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI symptoms and cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (chronic) / Proton Pump Inhibitors.

**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)" A review of the injured workers medical records reveal he was on omeprazole, it is not really clear why he was switched to protonix, there is also no indication that the injured worker is at increased risk for a gastrointestinal event, therefore the request for Protonix 20mg #30 is not medically necessary.

#### **Flector patches 1% #30: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-112.

**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. 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, there is also no documentation of specific improvement in pain or function with the use of Flector patch therefore the request for Flector patches 1% #30 is not medically necessary.