

<b>Case Number:</b>	CM15-0198828		
<b>Date Assigned:</b>	10/15/2015	<b>Date of Injury:</b>	09/01/1998
<b>Decision Date:</b>	12/22/2015	<b>UR Denial Date:</b>	09/30/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/09/2015

### 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 60 year old female, who sustained an industrial injury on 9-1-98. She reported right knee pain. The injured worker was diagnosed as having right knee chondromalacia, lumbar strain, and status post right knee arthroscopy with poor functional recovery. Treatment to date has included TENS, right knee Supartz injections, and medication including Diclofenac, Lidopro, Cyclobenzaprine, and Omeprazole. Physical examination findings on 8-13-15 included right knee range of motion from 0-120 degrees, a palpable cyst in the posterior fossa, and tenderness to palpation in the medial joint line. Anterior drawer and Lachman's tests were negative. McMurray's and patellar grind test were positive. Tenderness to palpation of the right lumbar paravertebral musculature with mild spasm on the right was noted. On 8-13-15 pain was rated as 7 of 10. On 9-17-15 the treating physician noted pain "improves with rest and current medication 50%". The injured worker had been taking Diclofenac, Lidopro, and Omeprazole since at least June 2015 and Cyclobenzaprine since at least July 2015. On 9-17-15, the injured worker complained of low back pain and right knee pain. On 9-17-15 the treating physician requested authorization for Omeprazole 20mg #60, Diclofenac 100mg #60, Lidopro 121g #1, and Cyclobenzaprine 7.5mg #60. On 9-30-15 utilization review non-certified all requests.

### IMR ISSUES, DECISIONS AND RATIONALES

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

### **Omeprazole 20mg #60: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & 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, PPI's are "Recommended for patients at risk for gastrointestinal events. 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 omeprazole decreases GERD side effects due to NSAIDS, the use of omeprazole in this setting is appropriate therefore the request for omeprazole 20mg #60 is medically necessary.

### **Diclofenac 100mg #60: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steriodal anti-inflammatory drugs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steriodal 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. It is noted that the injured worker experiences up to 50% pain relief with her current regimen which includes Diclofenac, the continued use is appropriate, therefore the request for Diclofenac 100mg #60 is medically necessary.

**Lidopro 121gm #1: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**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. Lidocaine is approved for use in the form of a dermal patch. Gels, creams or lotions are not indicated for neuropathic pain and lidocaine is not recommended for non neuropathic pain. A review of the injured workers medical records reveal that she is experiencing up to 50% pain relief with her current regimen which includes Lidopro, in this current situation the continued use of Lidopro is appropriate, therefore the request for Lidopro 121gm #1 is medically necessary.

**Cyclobenzaprine 7.5mg #60: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Cyclobenzaprine (Flexeril).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Cyclobenzaprine (Flexeril).

**Decision rationale:** Per the MTUS, Cyclobenzaprine is recommended as an option in the treatment of chronic pain using a short course of therapy. It is more effective than placebo in the management of back pain, the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment suggesting that shorter courses may be better. Treatment should be brief. Treatment is not recommended for longer than 2-3 weeks. A review of the injured workers medical records reveal lumbar paravertebral muscle spasm and this prescription is for as needed when she has spasm, the prn (as needed) use of this medication is appropriate, therefore the request for Cyclobenzaprine 7.5mg #60 is medically necessary.