

<b>Case Number:</b>	CM14-0202723		
<b>Date Assigned:</b>	12/15/2014	<b>Date of Injury:</b>	06/26/2012
<b>Decision Date:</b>	01/30/2015	<b>UR Denial Date:</b>	11/17/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/04/2014

### 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. The expert reviewer is Board Certified in Family Practice and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### 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 patient is a 38 year-old woman who was injured at work on 6/26/2012. The injury was primarily to her back, hips and lower extremities. She is requesting review of denial for the following medications: Naproxen Sodium 550 mg #90; Pantoprazole 20 mg #90; Hydrocodone 10/325 mg #50 with 2 Refills; and Cyclobenzaprine 7.5 mg #90. Medical records corroborate ongoing care for her injuries. These records include the Primary Treating Physician's Progress Reports. Her chronic diagnoses include the following: Right Hip Dysplasia with Superimposed Degenerative Arthritis; Left Distal Tibia Fracture, Derivative Status Post Fall as a result of left hip; Protrusion L5-S1 with S1 Radiculopathy; Left Knee Pain; Left Ankle/Foot Pain; and Reactive Depression/Anxiety. In the Utilization Review process, the justification for denial for each of these medications was as follows: For hydrocodone; there was no documented objective functional improvement such as return to work or change in work status with the use of hydrocodone to warrant its continued use. Moreover, recent urine drug screen to monitor any aberrant behaviors was not provided. For naproxen; there is no clear documentation provided on how long the patient has been taking NSAIDs, as long-term use is not warranted. For pantoprazole; there were no documented complaints that are suggestive of dyspepsia. Further, the patient denied past medical history of ulcer. For cyclobenzaprine; this medication is not recommended to be used for longer than 2-3 weeks.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Naproxen Sodium 550 #90:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67-68.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of non-steroidal anti-inflammatory drugs (NSAIDs) such as Naproxen Sodium. These guidelines state the following: "Specific recommendations: Osteoarthritis (including knee and hip): 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 gastrointestinal [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. "Back Pain - Acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute LBP. For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician. "Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another."In this case, the records indicate that Naproxen is being used as a long-term treatment for this patient's condition. As the above cited guidelines indicate, NSAIDs such as Naproxen are recommended as an option for short-term symptomatic relief. Therefore, the chronic use of Naproxen Sodium 550 mg is not considered as a medically necessary treatment.

**Pantoprazole 20mg #90:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk Page(s): 68-69.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of proton pump inhibitors (PPIs) when patients are concurrently taking an NSAID, such as Naproxen. These guidelines state the following: "NSAIDs, GI symptoms & cardiovascular risk Recommend with precautions as indicated below. Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (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). Recommendations: Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g., ibuprofen, naproxen, etc.) Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxyn plus low-dose aspirin plus a PPI." In this case, the patient is under 65 and there is no documentation to indicate that she is having any gastrointestinal symptoms. There is no documentation that the patient has had an ulcer, a gastrointestinal bleed or perforation or is concurrently using aspirin, a corticosteroid and/or an anticoagulant. There is no documentation that the patient is on high dose/multiple NSAIDs. Given that the above cited information places this patient at low-risk for a gastrointestinal event, there is no medical justification for the use of a PPI such as pantoprazole. Pantoprazole is not considered as a medically necessary treatment.

**Hydrocodone 10/325mg #50 with 2 refills:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 76-78, 80.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the long-term use of opioids. These guidelines have established criteria of the use of opioids for the ongoing management of pain. Actions should include: prescriptions from a single practitioner and from a single pharmacy. The lowest possible dose should be prescribed to improve pain and function. There should be an ongoing review and documentation of pain relief, functional status, appropriate medication use and side effects. Pain assessment should include: current pain, the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of

function, or improved quality of life. There should be evidence of documentation of the "4 A's for Ongoing Monitoring." These four domains include: pain relief, side effects, physical and psychological functioning, and the occurrence of any potentially aberrant drug-related behaviors. Further, there should be consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain that does not improve on opioids in 3 months. There should be consideration of an addiction medicine consult if there is evidence of substance misuse (pages 76-78). Finally, the guidelines indicate that for chronic pain, the long-term efficacy of opioids is unclear. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy (page 80). Based on the review of the medical records, there is insufficient documentation in support of these stated MTUS/Chronic Pain Medical Treatment Guidelines for the ongoing use of opioids. The treatment course of opioids in this patient has extended well beyond the timeframe required for a reassessment of therapy. There is insufficient documentation in support of ongoing monitoring for aberrant drug-related behaviors. In summary, there is insufficient documentation to support the chronic use of an opioid in this patient. Treatment with Hydrocodone/APAP 10/325 mg #50 with 2 refills is not considered as medically necessary.

**Cyclobenzaprine 7.5mg #90:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41-42.

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the use of cyclobenzaprine. Cyclobenzaprine, also known as Flexeril, is recommended as an option, using a short course of therapy. The effect of cyclobenzaprine 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. Per guidelines, treatment should be brief. The addition of cyclobenzaprine to other agents is not recommended. In this case, the use of cyclobenzaprine has exceeded the MTUS guidelines for duration of use; specifically, that "treatment should be brief." Under these conditions, the long-term use of cyclobenzaprine is not supported by the MTUS guidelines and cyclobenzaprine is not considered as a medically necessary treatment.