

Case Number:	CM14-0103308		
Date Assigned:	09/05/2014	Date of Injury:	02/08/2010
Decision Date:	10/28/2014	UR Denial Date:	06/20/2014
Priority:	Standard	Application Received:	07/03/2014

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 Anesthesiology, has a subspecialty in pain medicine and is licensed to practice in Massachusetts. 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:

According to the documents available for review, the patient is a 50 year old female. The date of injury is February 8, 2010. The patient sustained an injury to the left knee and left foot. The specific mechanism of injury was not fully elaborated on in the notes available for review. The patient carries a current diagnosis of medial meniscus tear, lateral meniscal tear, synovitis and patellofemoral degenerative change. The patient currently complains of pain in the left knee ankle and foot. The patient is maintained on the multimodal pain medication regimen including capsaicin cream, Diclofenac, Nabumetone, Protonix and buprenorphine. A request for capsaicin cream, Diclofenac, Nabumetone, Protonix and buprenorphine was denied.

IMR ISSUES, DECISIONS AND RATIONALES

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

Capsaicin 0.75% cream #2: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin, Topical Page(s): 28-29.

Decision rationale: According to the MTUS, Capsaicin topical is recommended only as an option in patients who have not responded or are intolerant to other treatments. Indications:

There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. The number needed to treat in musculoskeletal conditions was 8.1. The number needed to treat for neuropathic conditions was 5.7. (Robbins, 2000) (Keitel, 2001) (Mason-BMJ, 2004) The results from this RCT support the beneficial effects of 0.025% capsaicin cream as a first-line therapy for OA pain. (Altman, 1994) Mechanism of action: Capsaicin, which is derived from chili peppers, causes vasodilation, itching, and burning when applied to the skin. These actions are attributed to binding with nociceptors, which causes a period of enhanced sensitivity followed by a refractory period of reduced sensitivity. Topical capsaicin is superior to placebo in relieving chronic neuropathic and musculoskeletal pain. Capsaicin produces highly selective regional anesthesia by causing degeneration of capsaicin-sensitive nociceptive nerve endings, which can produce significant and long lasting increases in nociceptive thresholds. (Maroon, 2006). According to the documents available for review, there is no specific indication that the patient has not responded to the current oral regimen or is intolerant to current oral regimen. Therefore, Capsaicin 0.75% cream #2 is not medically necessary and appropriate.

Nabumetone-Relafen 500mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines nonsteroidal anti-inflammatory drug (NSAIDs) Page(s): 70. Decision based on Non-MTUS Citation Official Disability Guidelines - online version Integrated Treatment/Disability Duration Guidelines Pain (Chronic) Proton pump inhibitors (PPIs)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): p67, 70-73.

Decision rationale: According to the MTUS Anti-inflammatories are the traditional first line of treatment, to reduce pain so activity and functional restoration can resume, but long-term use may not be warranted. (Van Tulder-Cochrane, 2000) Recommended with cautions below. Disease-State Warnings for all NSAIDs: All NSAIDs have [U.S. Boxed Warning]: for associated risk of adverse cardiovascular events, including, MI, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs should never be used right before or after a heart surgery (CABG - coronary artery bypass graft). NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment (FDA Medication Guide). See NSAIDs, GI Symptoms and Cardiovascular Risks. Other disease-related concerns (non-boxed warnings): Hepatic: Use with caution in patients with moderate hepatic impairment and not recommended for patients with severe hepatic impairment. Borderline elevations of one or more liver enzymes may occur in up to 15% of patients taking NSAIDs. Renal: Use of NSAIDs may compromise renal function. FDA Medication Guide is provided by FDA mandate on all prescriptions dispensed for NSAIDs. Routine Suggested Monitoring: Package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile (including liver and renal function tests). There has been a recommendation to measure liver transaminases within 4 to 8 weeks after starting therapy, but the interval of repeating lab tests after this treatment duration has not been

established. Routine blood pressure monitoring is recommended. Overall Dosing Recommendation: It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time consistent with the individual patient treatment goals. According to the documents available for review, it appears that the patient is taking this medication for long-term therapy of a chronic condition. Given the increased risks associated with long-term use of this medication and no documented evidence that the lowest possible dose is being used for the shortest period of time, the request of Nabumetone-Relafen 500mg #90 is not medically necessary and appropriate.

Buprenorphine 0.1mg sublingual Troches #30 Quantity 90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Narcotic Analgesic Page(s): 77.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) ODG, Chronic Pain, Buprenorphine

Decision rationale: According to the ODG, Buprenorphine is recommended as an option for treatment of chronic pain (consensus based) in selected patients (not first-line for all patients). Suggested populations: (1) Patients with a hyperalgesic component to pain; (2) Patients with centrally mediated pain; (3) Patients with neuropathic pain; (4) Patients at high-risk of non-adherence with standard opioid maintenance; (5) For analgesia in patients who have previously been detoxified from other high-dose opioids. According to the documents available for review, the patient has none of the aforementioned indications for the use of buprenorphine. Therefore, at this time, the Buprenorphine 0.1 mg sublingual Troches #30 Quantity 90 is not medically necessary and appropriate.

Pantoprazole-Protoxin 20mg Quantity 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 - online version Integrated Treatment/Disability Duration Guidelines Pain (Chronic) Proton pump inhibitors (PPIs)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines PPI Page(s): 68-69.

Decision rationale: The MTUS makes the following recommendations for the use of proton pump inhibitors. 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). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastroduodenal lesions. 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. Cardiovascular disease: A non-pharmacological choice should be the first option in patients with cardiac risk factors. It is then suggested that acetaminophen or aspirin be used for short term needs. An opioid also remains a short-term alternative for analgesia. Major risk factors (recent MI, or coronary artery surgery, including recent stent placement): If NSAID therapy is necessary, the suggested treatment is Naproxyn plus low-dose aspirin plus a PPI. Mild to moderate risk factors: If long-term or high-dose therapy is required, full-dose naproxen (500 mg twice a day) appears to be the preferred choice of NSAID. If Naproxyn is ineffective, the suggested treatment is (1) the addition of aspirin to Naproxyn plus a PPI, or (2) a low-dose Cox-2 plus ASA. According to the records available for review the patient does not meet any of the guidelines required for the use of this medication therefore, at this time, the Pantoprazole (Protonix) 20mg #60 is not medically necessary and appropriate.