

Case Number:	CM14-0038884		
Date Assigned:	08/01/2014	Date of Injury:	08/24/2007
Decision Date:	10/15/2014	UR Denial Date:	03/06/2014
Priority:	Standard	Application Received:	04/02/2014

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 Management 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 an injured female worker. The date of injury is August 24, 2007. The patient sustained an injury to the lumbar spine and rib cage. The specific mechanism of injury was not elaborated on in the notes available for review. The patient is status post right rib fracture and right rib surgery. The patient currently complains of pain in the low back and right rib cage worse with movement. The patient is maintained on the multimodal pain medication regimen including, Naproxen, Flexeril, Sumatriptan, Zofran, Omeprazole, Terocin patch and Hydrocodone. A request for naproxen, Flexeril, Sumatriptan, Zofran, Omeprazole, Terocin patch and Hydrocodone was denied.

IMR ISSUES, DECISIONS AND RATIONALES

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

Naproxen Sodium tablets 550mg, # 100: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67, 70-73,.

Decision rationale: According to the MTUS Anti-inflammatories is the traditional first line of treatment, to reduce pain so activity and functional restoration can resume, but long-term use

may not be warranted. 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 requirements for treatment have not been met and medical necessity has not been established.

Cyclobenzaprine Hydrochloride tablets 7.5mg, # 120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants. Decision based on Non-MTUS Citation Official Disability Guidelines Low Back- Muscle Relaxants

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

Decision rationale: Accordingly to the MTUS, current treatment guidelines recommend this medication is an option for chronic pain using a short course of therapy. The effect of Flexeril is great is the first four days of treatment, suggesting a shorter course as many better. This medication is not recommended as an addition to other medications. Longer course of Flexeril also are not recommended to be for longer than 2 to 3 weeks as prolonged use me lead to dependence. According to the records, the patient has been taking his medication chronically. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

Surmatriptan Succinate tablets 25mg, # 9 x 2: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines Head, Migraines

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

Decision rationale: According to the ODG, Triptans are recommended for migraine sufferers. At marketed doses, all oral Triptans (e.g., Sumatriptan, brand name Imitrex) are effective and well tolerated. Differences among them are in general relatively small, but clinically relevant for individual patients. A poor response to one Triptans does not predict a poor response to other agents in that class. Rizatriptan (Maxalt) has demonstrated, in a head-to-head study, higher response rates and a more rapid onset of action than Sumatriptan, together with a favorable tolerability profile. Meta-analyses of double-blind placebo-controlled studies have confirmed the superior efficacy of Rizatriptan. (Gbel, 2010) While the Maxalt brand of Rizatriptan therapy is more expensive than other Triptans, the economic value of Rizatriptan depends on the payer's perspective, as the greatest savings can be expected to be achieved in terms of reduced migraine-related loss of work productivity compared with less effective treatments. (Mullins, 2007) (McCormack, 2005) According to the FDA Orange Book, equivalent generics have been approved for Maxalt, so generic Rizatriptan would be recommended. (FDA, 2013) See also Migraine pharmaceutical treatment. According to the documents available for review, the patient does not have a documented history of migraine. Therefore at this time the requirements for treatment have not been met and medical necessity has not been established.

Ondansetron ODT tablets 8mg, # 30 x 2: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines - Pain

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

Decision rationale: Accordingly to the ODG, Zofran is a serotonin 5-HT₃ receptor antagonist. It is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also FDA-approved for postoperative use. Acute use is FDA-approved for gastroenteritis. According to the documents available for review, the patient does not have any of the FDA approved indications for the use of this medication. Therefore at this time the requirements for treatment have not been met and medical necessity has not been established.

Omeprazole delayed release capsules 20mg, # 120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines PPI, Page(s): p68-69.

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 cardio protection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is Naprosyn 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 Naprosyn 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 Naprosyn is ineffective, the suggested treatment is (1) the addition of aspirin to Naprosyn 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 requirements for treatment have not been met and medical necessity has not been established.

Terocin Patch # 10: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Page(s): p111-113.

Decision rationale: According to the MTUS, there is little to no research to support the use of topical compounded creams. Terocin also contain menthol, a non-recommended topical agent. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. Topical analgesics are largely experimental and there are a few randomized controlled trials to determine efficacy or safety. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

Hydrocodone/Acetaminophen (Norco) 2.5/325mg, # 90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, On-Going Management, Page(s): 74-97.

Decision rationale: According to the MTUS Chronic Pain Medical Treatment Guidelines section on Opioids, On-Going Management, p 74-97, (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy. (b) The lowest possible dose should be prescribed to improve pain and function. (c) Office: 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. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management. (e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control.(f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion).(g) Continuing review of overall situation with regard to non-opioid means of pain control. (h) 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 does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Additionally, the MTUS states that continued use of opioids requires (a) the patient has returned to work, (b) the patient has improved functioning and pain. There is no current documentation of baseline pain, pain score with use of opioids, functional improvement on current regimen, side effects or review of potentially aberrant drug taking behaviors as outlined in the MTUS and required for ongoing treatment. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.