

Case Number:	CM14-0140312		
Date Assigned:	09/10/2014	Date of Injury:	08/10/1992
Decision Date:	11/14/2014	UR Denial Date:	08/02/2014
Priority:	Standard	Application Received:	08/29/2014

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 42 year old male. The date of injury is August 10, 1992. The patient sustained an injury to the lumbar spine. The specific mechanism of injury was not elaborated on in the notes available for review. The patient's current diagnosis is lumbosacral neuritis not otherwise specified. The patient currently complains of the lumbar back pain and associated decreased range of motion in the lumbar spine. The patient is maintained on the multimodal pain medication regimen including Prilosec and tramadol. A request for Prilosec and tramadol was denied.

IMR ISSUES, DECISIONS AND RATIONALES

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

Prilosec (20mg, #30 with 2 refills): Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Proton-Pump Inhibitors (PPIs) Page(s): 68-69.

Decision rationale: The California Medical Treatment Utilization Schedule (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 requirements for treatment have not been met and medical necessity has not been established.

Tramadol (50mg, #60 with 2 refills): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol (Ultram).

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

Decision rationale: According to the 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 nonadherent) 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. (Passik, 2000) (d) 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 nonopioid 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. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established.

Naprosyn (500mg, #60 with 2 refills): 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 (Chronic), non-steroidal anti-inflammatory drugs (NSAIDs)

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

Decision rationale: According to the MTUS Antiinflammatories 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 requirements for treatment have not been met and medical necessity has not been established.

Topical Lidoderm Patches (#30 with 2 refills): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (lidocaine patch).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm Page(s): 56;112.

Decision rationale: Accordingly to the Lidoderm Patch is recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. In February 2007 the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical lidocaine. Those at particular risk were individuals that applied large amounts of this substance over large areas, left the products on for long periods of time, or used the agent with occlusive dressings. Systemic exposure was highly variable among patients. Only FDA-approved products are currently recommended. (Argoff, 2006) (Dworkin, 2007) (Khaliq-Cochrane, 2007) (Knotkova, 2007) (Lexi-Comp, 2008) Non-neuropathic pain: Not recommended. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. (Scudds, 1995) According to the documents available for review, the patient has none of the aforementioned MTUS 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.