

Case Number:	CM15-0065556		
Date Assigned:	04/13/2015	Date of Injury:	07/26/2003
Decision Date:	06/18/2015	UR Denial Date:	04/06/2015
Priority:	Standard	Application Received:	04/06/2015

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 55 year old female, who sustained an industrial injury on July 26, 2003. Treatment to date has included modified activities, medications, orthotics, and lumbar spine surgery. Currently the injured worker complains of low back pain and abdominal pain. She underwent an unsuccessful lumbar spine surgery and fusion followed by gastric bypass to improve her body mechanics. She developed post-operative wound dehiscence requiring multiple surgeries and has continued back and abdominal pain. Diagnoses associated with the request included failed lumbar spine surgery, status post abdominoplasty and status post gastric sleeve procedure. Her treatment plan includes daily walking, use of brace/cane, rest, medications and spine surgeon evaluation.

IMR ISSUES, DECISIONS AND RATIONALES

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

Lomotil 2.5mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use Page(s): 77.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Physicians Desk Reference / Lomotil.

Decision rationale: The MTUS / ACOEM and ODG did not specifically address the use of Lomotil in the injured worker and therefore other guidelines were consulted. Per the PDR, Lomotil is an anticholinergic/ opioid used as adjunctive therapy for the treatment of diarrhea. However there is no clear indication for the use of this medication in the injured worker, there is also no documentation of clinical response to the use of this medication. Therefore the request for the continued use of this medication is not medically necessary.

MS Contin (unspecified dose and qty): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use Page(s): 80.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96 (78, 89, 95).

Decision rationale: Per the MTUS, opioids should be discontinued if there is no overall improvement in function, unless there are extenuating circumstances, Opioids should be continued if the patient has returned to work or has improved functioning and pain. Ongoing management actions should include prescriptions from a single practitioner, taken as directed and all prescriptions from a single pharmacy. The lowest possible dose should be prescribed to improve pain and function. Documentation should follow the 4 A's of analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors. Long term users of opioids should be regularly reassessed. In the maintenance phase the dose should not be lowered if it is working. Also, patients who receive opioid therapy may sometimes develop unexpected changes in their response to opioids, which includes development of abnormal pain, change in pain pattern, persistence of pain at higher levels than expected when this happens opioids can actually increase rather than decrease sensitivity to noxious stimuli. It is important to note that a decrease in opioid efficacy should not always be treated by increasing the dose or adding other opioids, but may actually require weaning. Unfortunately the request is not accompanied by a dosing regimen and quantity and without this information it is not medically necessary.

Lyrica (unspecified dose and qty): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs Page(s): 16.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AED's) Page(s): 16-22.

Decision rationale: Per the MTUS, antiepilepsy drugs are recommended for neuropathic pain. "The choice of specific agents reviewed below will depend on the balance between effectiveness and adverse reactions. A "good" response to the use of AEDs has been defined as a 50% reduction in pain and a "moderate" response as a 30% reduction. It has been reported that a 30%

reduction in pain is clinically important to patients and a lack of response of this magnitude may be the "trigger" for the following: (1) a switch to a different first-line agent (TCA, SNRI or AED are considered first-line treatment); or (2) combination therapy if treatment with a single drug agent fails.(Eisenberg, 2007) (Jensen, 2006) After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects." Unfortunately the request is not accompanied by a dose, treatment regimen and quantity and without this information the request is not medically necessary.

Dexilant (unspecified dose and qty): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) / Proton Pump Inhibitors (PPIs).

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. Prilosec (omeprazole), Prevacid (lansoprazole) and Nexium (esomeprazole magnesium) are PPIs. Healing doses of PPIs are more effective than all other therapies, although there is an increase in overall adverse effects compared to placebo. Nexium and Prilosec are very similar molecules. (Donnellan, 2010) In this RCT omeprazole provided a statistically significantly greater acid control than lansoprazole. (Miner, 2010) In general, the use of a PPI should be limited to the recognized indications and used at the lowest dose for the shortest possible amount of time. 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)" Unfortunately the request is not accompanied by a dose, treatment regimen and quantity and without this information it is impossible to determine medical necessity. Therefore the request is not medically necessary.

Lorazepam (unspecified dose and qty): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24.

Decision rationale: The MTUS does not recommend long term use of benzodiazepines, long term efficacy is unproven and there is a risk of dependence most guidelines limit use to 4 weeks. Tolerance to all of its effects develop within weeks to months, and long term use may actually increase anxiety; a more appropriate treatment for anxiety disorder is an antidepressant. Chronic benzodiazepines are the treatment of choice in very few conditions. However the request is not accompanied by a dose, frequency or quantity and without this information the request is not medically necessary.

Celebrex (unspecified dose and qty): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-inflammatory medications Page(s): 22.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, NSAIDs, GI symptoms and Cardiovascular risk Page(s): 67-68, 68-69.

Decision rationale: Per the MTUS, NSAIDs and COX-2 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. (Chen, 2008) (Laine, 2008) 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 this. However there is no way to begin to determine medical necessity as there is no accompanying dose or quantity. Therefore the request is not medically necessary.

Referral to a spine surgeon: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Part 1: Introduction Page(s): 1.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints
Page(s): 305.

Decision rationale: Per MTUS/ ACOEM, referral for surgical consultation is indicated for patients who have: Severe and disabling lower leg symptoms in a distribution consistent with abnormalities on imaging studies (radiculopathy), preferably with accompanying objective signs of neural compromise, Activity limitations due to radiating leg pain for more than one month or extreme progression of lower leg symptoms, clear clinical, imaging, and electrophysiologic evidence of a lesion that has been shown to benefit in both the short and long term from surgical repair, failure of conservative treatment to resolve disabling radicular symptoms. With or without surgery, more than 80% of patients with apparent surgical indications eventually recover. Although surgery appears to speed short- to mid-term recovery, surgical morbidity (recovery and rehabilitation time and effects) and complications must be considered. Surgery benefits fewer than 40% of patients with questionable physiologic findings. Moreover, surgery increases the need for future surgical procedures with higher complication rates. The injured worker is s/p lumbar spine surgery which failed and is being referred to a spine surgeon for evaluation for possible hardware removal, therefore based on the guidelines and the injured workers complex clinical presentation the request for referral to a spine surgeon is medically necessary and appropriate.