

Case Number:	CM15-0048104		
Date Assigned:	03/20/2015	Date of Injury:	03/31/2008
Decision Date:	05/01/2015	UR Denial Date:	03/05/2015
Priority:	Standard	Application Received:	03/13/2015

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: Pennsylvania
 Certification(s)/Specialty: Internal 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 61-year-old male who has reported low back pain after a lifting injury on 3/31/2008. The diagnoses include lumbar degenerative disc disease; lumbosacral sprain/strain, neuritis or radiculitis; lumbosacral or thoracic neuritis; subluxation of the sacrum (sacroiliac joint); myalgia/myositis, myofascial pain; and insomnia. Treatments to date have included consultations, a heating pad, chiropractic, TENS, and medication. Bimonthly reports during 20104 from the treating physician record ongoing low back and leg pain, working full time, partial pain relief with unspecified pain medications, and ongoing prescribing of diclofenac or naproxen and omeprazole in quantities reflecting daily use. Terocin was also prescribed. Reports refer to the lack of side effects from medications. A report of 6/10/14 refers to "lab work" done at an outside facility. A work status report is for modified duty. Naproxen was changed to diclofenac on 8/12/14, with no explanation in the records. Per a "Peer-to-Peer phone sheet" on 9/2/14, the treating physician noted that there were no side effects from omeprazole. No reports discuss the specific intake pattern or results of using any medication. No reports discuss any specific gastrointestinal symptoms or signs. Per the PR2 of 12/16/14, there was ongoing low back and leg pain. Unspecified medications helped with pain and there were no side effects. NSAIDs are not tolerated without omeprazole. He is working full time. Two bottles each of omeprazole and diclofenac (probably #60 per bottle) were dispensed, with a follow-up in 2 months. TENS patches and an electric heat pad were dispensed. Per the PR2 of 2/16/15, there was ongoing low back and leg pain. Unspecified medications helped with pain and there were no side effects. NSAIDs are not tolerated without omeprazole. He is working full time. Oral pain

medications were used "minimally". The cream was very helpful in keeping his functionality. Two bottles each of omeprazole and diclofenac were dispensed, with a follow-up in 2 months. On 3/5/15, Utilization Review partially certified omeprazole and diclofenac, and non-certified LidoPro and TENS patches. There were insufficient indications for TENS or LidoPro per the MTUS.

IMR ISSUES, DECISIONS AND RATIONALES

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

Omeprazole 20mg #60 x 2: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms and Cardiovascular Risk.

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

Decision rationale: There are no medical reports, which adequately describe the relevant signs and symptoms of possible gastrointestinal disease. There is no examination of the abdomen. There are many possible etiologies for gastrointestinal symptoms; the available reports do not provide adequate consideration of these possibilities. Co therapy with an NSAID is not indicated in patients other than those at high risk. No reports describe the specific risk factors present in this case, as presented in the MTUS. Recent reports are contradictory, as they refer to the lack of side effects from medications as well as unspecified problems with NSAIDs that require omeprazole. The actual symptoms or signs from NSAIDs are never discussed. One of the recent reports stated that NSAIDs were used only minimally, yet additional diclofenac was dispensed in quantities presuming daily, maximal intake. If one were to presume that a medication were to be the cause of the undescribed gastrointestinal symptoms, the treating physician would be expected to change the medication regime accordingly, at least on a trial basis to help determine causation. Note the MTUS recommendation regarding the options for NSAID-induced dyspepsia, which include stopping the NSAID, switching to a different NSAID, or consideration of H2 receptor antagonists or a proton pump inhibitor (PPI). In this case, there is no evidence of any attempts to determine the cause of symptoms, including minimal attempts to adjust medications. PPIs are not benign. The MTUS, FDA, and recent medical literature have described a significantly increased risk of hip, wrist, and spine fractures; pneumonia, Clostridium-difficile-associated diarrhea, and hypomagnesemia in patients on proton pump inhibitors. This PPI is not medically necessary based on lack of medical necessity and risk of toxicity. An adequate evaluation of any gastrointestinal symptoms has not occurred and NSAID dispensing has not changed in response to any proposed gastrointestinal problems. Therefore, the request is not medically necessary.

Diclofenac sodium ER 100mg #60 x 2: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-inflammatory medications.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, NSAIDs for Back Pain - Acute exacerbations of chronic pain, Back Pain - Chronic low back pain, NSAIDs, specific drug list & adverse effects Page(s): 60,68,70.

Decision rationale: Per the MTUS for chronic pain, page 60, medications should be trialed one at a time, and there should be functional improvement with each medication. No reports show any specific benefit, functional or otherwise. The reports refer only to partial pain relief from unspecified medications, with no specific results for any single medication. One of the recent reports stated that NSAIDs were used only minimally, yet additional diclofenac was dispensed in quantities presuming daily, maximal intake. Advocacy of maximal daily intake is not indicated in a patient using only minimal quantities and who reportedly needs some sort of gastrointestinal protection. Systemic toxicity is possible with NSAIDs. The FDA and MTUS recommend monitoring of blood tests and blood pressure. There is no evidence that the prescribing physician is adequately monitoring for toxicity as recommended by the FDA and MTUS, particularly for diclofenac, which has an elevated cardiovascular risk profile. Diclofenac has a higher cardiovascular risk profile than many other NSAIDs, and should not be the first choice for an NSAID. The treating physician has not provided any indications for using diclofenac rather than other, safer NSAIDs. The MTUS does not recommend chronic NSAIDs for low back pain. NSAIDs should be used for the short term only. Acetaminophen is the drug of choice for flare-ups, followed by a short course of NSAIDs. The treating physician has been dispensing large quantities of NSAIDs for many months at least, which is counter to the recommendations of the MTUS for treatment of back pain. This NSAID is not medically necessary based on the MTUS recommendations against chronic use, lack of specific functional and symptomatic benefit, and prescription not in accordance with the MTUS and the FDA warnings.

TENS patch, 2 pairs x 2: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for use of TENS.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TENS, chronic pain (transcutaneous electrical nerve stimulation) Page(s): 114-117.

Decision rationale: No physician reports address the specific medical necessity for a TENS unit. None of the reports discusses ongoing use of transcutaneous electrical stimulation (TENS). The MTUS for Chronic Pain lists the indications for TENS, which are primarily neuropathic pain, a condition not present in this patient. Other recommendations, including specific components of the treatment plan, are listed in the MTUS. The necessary kind of treatment plan is not present, including a focus on functional restoration with a specific trial of TENS alone. Given the lack of clear indications in this injured worker (primary reason), the lack of any clear benefit, and the lack of any clinical trial or treatment plan per the MTUS (secondary reason), a TENS unit is not medically necessary, and therefore the requested TENS patches are not medically necessary.

Lidopro Ointment 121gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Medications Page(s): 60,111-113.

Decision rationale: No physician reports discuss the specific indications and medical evidence in support of the topical medications prescribed in this case. The ingredients appear to include capsaicin, lidocaine, menthol, and methyl salicylate. The treating physician has not discussed the ingredients of this topical agent and the specific indications for this injured worker. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. The Official Disability Guidelines state, "Custom compounding and dispensing of combinations of medicines that have never been studied is not recommended, as there is no evidence to support their use and there is potential for harm." The compounded topical agent in this case is not supported by good medical evidence and is not medically necessary based on this Official Disability Guidelines recommendation. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical lidocaine, only in the form of the Lidoderm patch, is indicated for neuropathic pain (which is not present in this case). The MTUS states that the only form of topical lidocaine that is recommended is Lidoderm. The topical lidocaine prescribed in this case is not Lidoderm. Topical anesthetics like the ones dispensed are not indicated per the FDA, are not FDA approved, and place injured workers at an unacceptable risk of seizures, irregular heartbeats and death. Capsaicin has some indications, in the standard formulations readily available without custom compounding. It is not clear what the indication is in this case, as the injured worker does not appear to have the necessary indications per the MTUS. The MTUS also states that capsaicin is only recommended when other treatments have failed. This injured worker has not received adequate trials of other, more conventional treatments. The treating physician did not discuss the failure of other, adequate trials of other treatments. Capsaicin is not medically necessary based on the lack of indications per the MTUS. The topical compounded medication prescribed for this injured worker is not medically necessary based on the MTUS, the Official Disability Guidelines, lack of medical evidence, and lack of FDA approval.