

Case Number:	CM15-0197587		
Date Assigned:	10/13/2015	Date of Injury:	11/10/2003
Decision Date:	11/24/2015	UR Denial Date:	09/30/2015
Priority:	Standard	Application Received:	10/07/2015

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: California, District of Columbia, Maryland
 Certification(s)/Specialty: Anesthesiology, Pain Management

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 68 year old female, who sustained an industrial injury on 11-10-2003. The injured worker is being treated for cervical spondylosis, lateral epicondylitis, sprain-strain left elbow and forearm, joint pain left wrist, trigger finger and cervical radiculopathy. Treatment to date has included medications. Per the Primary Treating Physician's Progress Report dated 9-23-2015 the injured worker presented for pain management follow-up. She reported neck and bilateral arm pain. She rated her pain as 6 out of 10 in severity on average and 8 out of 10 at its worst. Objective findings included tenderness in the cervical paravertebral region with decreased range of motion of the cervical spine. The notes from the provider do not document efficacy of the prescribed medications. Work status was permanent and stationary. The plan of care included medications including Norco for pain, Aciphex for heartburn related to the use of Norco and LidoPro for neuropathic pain, and follow-up evaluation. She has tried and failed gabapentin, Lyrica and antidepressant medications in the past. Authorization was requested on 9-23-2015 for LidoPro 4.5%-0.0325%-10% #2, Hydrocodone-APAP 10-325mg #30 and Aciphex 20mg #60. On 9-30-2015, Utilization Review non-certified the request for LidoPro 4.5%-0.0325%-10% #2, and Aciphex 20mg #60.

IMR ISSUES, DECISIONS AND RATIONALES

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

Lidopro 4.5%-0.0325%-10% quantity 2 tubes: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Capsaicin, topical, NSAIDs (non-steroidal anti-inflammatory drugs), Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

Decision rationale: Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually. LidoPro contains capsaicin, lidocaine, menthol, methyl salicylate. Per MTUS p 112 with regard to capsaicin, "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." Methyl salicylate may have an indication for chronic pain in this context. Per MTUS p105, "Recommended. Topical salicylate (e.g., Ben-Gay, methyl salicylate) is significantly better than placebo in chronic pain. (Mason-BMJ, 2004)" However, the other ingredients in LidoPro are not indicated. The preponderance of evidence indicates that overall this medication is not medically necessary. Regarding topical lidocaine, MTUS states (p112) "Neuropathic pain 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). 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)" The documentation submitted for review does not contain evidence of trial of first-line therapy to support the use of topical lidocaine. LidoPro topical lotion contains menthol. The CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of menthol. It is the opinion of this IMR reviewer that a lack of endorsement, a lack of mention, inherently implies a lack of recommendation, or a status equivalent to "not recommended". Since menthol is not medically indicated, then the overall product is not indicated per MTUS as outlined below. Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The request is not medically necessary.

Aciphex 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, Treatment in Workers' Compensation, Pain Procedure Summary, Proton Pump Inhibitors.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: In the treatment of dyspepsia secondary to NSAID therapy, the MTUS recommends stopping the NSAID, switching to a different NSAID, or considering the use of an H2-receptor antagonist or a PPI. The MTUS Chronic Pain Medical Treatment Guidelines recommend the use of proton pump inhibitors in conjunction with NSAIDs in situations in which the patient is at risk for gastrointestinal events including: (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). CPMTG guidelines further specify: "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 mg 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. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007)" Per ODG TWC, "many prescribers believe that this class of drugs is innocuous, but much information is available to demonstrate otherwise. A trial of omeprazole or lansoprazole is recommended before Nexium therapy. The other PPIs, Protonix, Dexilant, and Aciphex, should also be second-line." Per the medical records submitted for review, the injured worker reported gastrointestinal side effects with medication use and was taking Prilosec for relief. As noted per the guidelines, Aciphex is a second-line medication. The medical records do not establish whether the injured worker was refractory to treatment with omeprazole. The request is not medically necessary.