

Case Number:	CM15-0013577		
Date Assigned:	01/30/2015	Date of Injury:	12/18/2005
Decision Date:	04/10/2015	UR Denial Date:	12/31/2014
Priority:	Standard	Application Received:	01/22/2015

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 male, who sustained an industrial injury on 12/18/2005. On provider visit dated 12/10/2014, the injured worker has reported low back pain. On examination he was noted to have tenderness across the lumbar paraspinal muscles bilaterally, pain along the facets and pain with facet loading more on the left side. The diagnoses have included discogenic lumbar conditional with radiculitis with negative electromyogram and positive MRI, SI joint inflammation, especially on the left and chronic pain syndrome. Treatment plan included lumbar back support and back support insert, LidoPro Lotion 4 ounces, Terocin Patches #20, Tramadol ER 150mg #30, Nalfon 400mg #60 and Protonix 20mg #60. On 12/30/2014, Utilization Review non-certified lumbar back support and back support insert, LidoPro Lotion 4 ounces, Terocin Patches #20, Tramadol ER 150mg #30, Nalfon 400mg #60 and Protonix 20mg #60. The CA MTUS, ACOEM, Chronic Pain Medical Treatment Guidelines and ODG were cited.

IMR ISSUES, DECISIONS AND RATIONALES

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

Lumbar back support and back support insert: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back, Lumbar supports.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) low back, lumbar supports.

Decision rationale: The official disability guidelines only recommend the use of a lumbar support for the treatment of spondylolisthesis, documented instability, and compression fractures. The attached medical record does not indicate that the injured employee has any of these conditions. As such, this request for a lumbar support is not medically necessary.

LidoPro lotion 4 ounces, as prescribed on 12/10/14: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 105, 111, 112, 113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 93, 94 of 127.

Decision rationale: Lidopro lotion is a compound containing capsaicin, menthol, and methyl salicylate. Capsaicin may have an indication for chronic low back pain in this context. Per MTUS p 112 However, 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. It would be optimal to trial each medication individually. For these multiple reasons, this request for Lidopro is not medically necessary.

Terocin Patches #20, as prescribed on 12/10/14: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 105, 111, 112, 113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 93, 94 of 127.

Decision rationale: Terocin patches are a compound of lidocaine and menthol. According to the California Chronic Pain Medical Treatment Guidelines the only topical analgesic medications indicated for usage include anti-inflammatories, lidocaine, and capsaicin. There is no known efficacy of any other topical agents to include menthol. Additionally, topical lidocaine is only indicated as a second line agent after the failure of treatment with antidepressants and anti-

epilepsy drugs. There is no documentation that the injured employee has failed to improve with these medications. Per the MTUS, when one component of a product is not necessary the entire product is not medically necessary. Considering this, the request for Terocin patches is not medically necessary.

Tramadol ER 150mg #30, as prescribed on 12/10/14: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opiates Page(s): 93, 94 of 127.

Decision rationale: Review of the available medical records reveals no documentation to support the medical necessity of tramadol ER nor any documentation addressing the '4 A's' domains, which is a recommended practice for the on-going management of opioids. Specifically, the notes do not appropriately review and document pain relief, functional status improvement, appropriate medication use, or side effects. The MTUS considers this list of criteria for initiation and continuation of opioids in the context of efficacy required to substantiate medical necessity, and they do not appear to have been addressed by the treating physician in the documentation available for review. Furthermore, efforts to rule out aberrant behavior (e.g. CURES report, UDS, opiate agreement) are necessary to assure safe usage and establish medical necessity. There is no documentation comprehensively addressing this concern in the records available for my review. As MTUS recommends to discontinue opioids if there is no overall improvement in function, medical necessity cannot be affirmed.

Nalfon 400mg #60, as prescribed on 12/10/14: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67-68, 71.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 22, 67-70 of 127.

Decision rationale: Nalfon is an anti-inflammatory medication. The California MTUS guidelines recommend anti-inflammatory medications as a first-line agent to treat pain and improve function, and does not require documentation of function, nor restrict use to short term only. Considering the injured employees diagnosis of low back pain and chronic pain syndrome, this request for Nalfon is medically necessary.

Protonix 20mg #60, as prescribed on 12/10/14: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk Page(s): 68-69 of 127.

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 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. (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." As there is no documentation of peptic ulcer, GI bleeding or perforation, or cardiovascular disease in the records available for my review, the injured worker's risk for gastrointestinal events is low, as such, medical necessity cannot be affirmed. Furthermore, as noted per the guidelines, Protonix is a second-line medication. The medical records do not establish whether the patient has failed attempts at first line PPIs, such as omeprazole or lansoprazole, which should be considered prior to prescribing a second line PPI such as Protonix. The request is not medically necessary.