

Case Number:	CM15-0171762		
Date Assigned:	09/14/2015	Date of Injury:	02/01/2011
Decision Date:	10/30/2015	UR Denial Date:	08/11/2015
Priority:	Standard	Application Received:	08/31/2015

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: Tennessee, Florida, Ohio
 Certification(s)/Specialty: Surgery, Surgical Critical Care

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 34 year old male, who sustained an industrial injury on 2-1-11. The injured worker was diagnosed as having cervical discopathy with radiculitis, lumbar discopathy with radiculitis, carpal tunnel syndrome, and right shoulder impingement syndrome. Treatment to date was not discussed in the submitted medical records. On 5-8-15 and 6-16-15 cervical pain, low back pain, and right shoulder pain were rated as 7 of 10. Bilateral wrist pain was rated as 5 of 10. Currently, the injured worker complains of pain in the cervical spine, low back, right shoulder, and bilateral wrists. The treating physician requested authorization for retrospective Naproxen Sodium 550mg #120, Omeprazole 20mg #120, Orphenadrine ER 100mg #120, Ondansetron 8mg #30, and Terocin Patches #30 all for the date of service 6-26-15. On 8-11-15, the requests were non-certified. Regarding Naproxen, the utilization review (UR) physician noted "the continued use of naproxen is not warranted, as there is no demonstration of functional improvement." Regarding Omeprazole, the UR physician noted "there are no symptoms or risk factors for gastrointestinal disorders documented." Regarding Ondansetron, the UR physician noted the "patient is not postoperative or receiving cancer chemotherapy or radiation." Regarding Orphenadrine, the UR physician noted, "there is no documentation of an acute exacerbation." Regarding Terocin patches, the UR physician noted, "there are limited studies on the efficacy of topical agents for chronic pain. It is not considered first line treatment."

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective request for Naproxen Sodium 550mg #120 (DOS: 6/26/15): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of treatment of this medication for this patient. The California MTUS guidelines address the topic of NSAID prescriptions by stating, "A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics." The MTUS guidelines do not recommend routine use of NSAIDs due to the potential for adverse side effects (GI bleeding, ulcers, renal failure, etc). The medical records do not support that the patient has a contraindication to other non-opioid analgesics and chronic NSAID use is not documented to have lead to functional improvement. Therefore, medical necessity for Naproxen prescription has not been established and therefore is not medically necessary.

Retrospective request for Omeprazole 20mg #120 (DOS: 6/26/15): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of the requested prescription for this patient. The clinical records submitted do not support the fact that this patient has refractory GERD resistant to H2 blocker therapy or an active h. pylori infection. The California MTUS guidelines address the topic of proton pump prescription. In accordance with California MTUS guidelines, PPI's (Proton Pump Inhibitors) can be utilized if the patient is concomitantly on NSAIDs and if the patient has gastrointestinal risk factors. This patient is not on NSAIDs. Additionally, per the Federal Drug Administration's (FDA) prescribing guidelines for Nexium use, chronic use of a proton pump inhibitor is not recommended due to the risk of developing atrophic gastritis. Short-term GERD symptoms may be controlled effectively with an H2 blocker unless a specific indication for a proton pump inhibitor exists. This patient's medical records do not support that this patient has GERD. There is no documentation of why chronic PPI therapy is necessary. The reason for the medication is unclear. The patient has not failed H2 blocker therapy and he has no records that

indicate an active h. pylori infection. Since chronic NSAID use is not indicated, PPI therapy is also not indicated. Therefore, based on the submitted medical documentation, the request for omeprazole prescription is not medically necessary.

Retrospective request for Orphenadrine ER 100mg #120 (DOS: 6/26/15): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. In accordance with the California MTUS guidelines, Orphenadrine is a muscle relaxant and muscle relaxants are not recommended for the treatment of chronic pain. From the MTUS guidelines: "Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic back pain". Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence." This patient has been diagnosed with chronic back pain of the cervical spine, shoulder and wrists. Per MTUS, the use of a muscle relaxant is not indicated. Therefore, based on the submitted medical documentation, the request for orphenadrine ER is not medically necessary.

Retrospective request for Ondansetron 8mg #30 (DOS: 6/26/15): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Zofran FDA Prescribing Guidelines <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm271924.htm>.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. The California MTUS guidelines, the ACOEM Guidelines and the Official Disability Guidelines (ODG) do not address this topic. According to its FDA prescribing recommendations, "Ondansetron is used to prevent nausea and vomiting caused by cancer chemotherapy, radiation therapy and surgery." It is in a class of medications called 5-HT3 receptor antagonists and works by blocking the action of serotonin, a natural substance that may cause nausea and vomiting. This patient has cervical pain, which is currently being treated with multiple medications. He had not undergone surgery or been diagnosed with the need for chemotherapy/radiation. Thus, the requested medication is being prescribed against FDA indications. Therefore, based on the submitted medical documentation, the request for Ondansetron is not medically necessary.

Retrospective request for Terocin Patch #30 (DOS: 6/26/15): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this medication for this patient. Per the California MTUS Chronic Pain guidelines, topical analgesics are recommended as an option and are largely experimental in use with few randomized control trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug or drug class that is not recommended is not recommended as a whole. Terocin cream is a combination of methyl salicylate, capsaicin, menthol, and lidocaine. Topical lidocaine, in the formulation of a dermal patch, has been designated for neuropathic pain by the FDA. No other commercially approved topical formulation of lidocaine is indicated for neuropathic pain. The clinical information submitted for review fails to provide evidence of a failure to respond to antidepressants or anticonvulsants prior to the request for an initiation of a topical analgesic. Hence, the request for Terocin is not appropriate or indicated by MTUS guidelines. Therefore, based on the submitted medical documentation, the request for Terocin is not medically necessary.