

<b>Case Number:</b>	CM14-0061073		
<b>Date Assigned:</b>	07/09/2014	<b>Date of Injury:</b>	11/30/2011
<b>Decision Date:</b>	09/12/2014	<b>UR Denial Date:</b>	04/10/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/01/2014

### 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. The expert reviewer is Board Certified in Family Medicine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This is a 41 year old female patient who reported an industrial injury to the right ankle on 11/30/2011, almost three years ago, attributed to the performance of customary job tasks. The patient subsequently underwent surgical intervention open reduction and internal fixation (ORIF) to the right ankle and had hardware removal on 9/27/2013. She received rehabilitation Physical Therapy (PT) post-operative to the right ankle, and complains of persistent pain to the right ankle. The objective findings on examination included; a well healed scar, minimal swelling, and limited range of motion (ROM). The patient is prescribed Ondasetron 8 mg; Terocin patches and Omeprazole.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Ondasetron 8 mg ODT #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for chronic pain Page(s): 80-82. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Section Pain Chapter opioids.

**Decision rationale:** The requesting treating physician provided no objective evidence to support the medical necessity of the prescribed Zofran/Ondasetron for nausea or vomiting. The prescription of Zofran for episodes of nausea and vomiting allegedly due to the prescribed medications is not medically necessary. Ondasetron is typically prescribed for the nausea and vomiting associated with chemotherapy and is not medically necessary for nausea suggested to be caused by medication side effects. There is no documentation of any medications caused such side effects or the use of typical generic medications generally prescribed for nausea or vomiting. The prescription was provided without objective evidence of medication side effects or any relation to the effects of the industrial injury. There is no documentation of the failure of more common anti-emetics. The prescription of Zofran is recommended only for the nausea and vomiting associated with chemotherapy and is not Food and Drug Administration (FDA) approved for the use of general nausea secondary to medications in pain management. The use of the Zofran for the effects of the industrial injury is not supported with objective evidence that demonstrates medical necessity over conventionally prescribed anti-emetics. The patient is being prescribed Ondansetron for an off label purpose and does not meet the criteria recommended for the use of the anti-nausea medications developed for chemotherapy side effects.

**Terocin patch #10:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical salicylate; topical analgesics; anti-inflammatory medications Page(s): 105; 111-113; 67-68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) chronic pain salicylate topicals.

**Decision rationale:** The prescription for Terocin patches is not medically necessary for the treatment of the patient for pain relief for the orthopedic diagnoses of the patient. There is no Orthopedic clinical documentation submitted to demonstrate the use of the topical patches for appropriate diagnoses or for the recommended limited periods of time. It is not clear that the topical NSAID medications are medically necessary in addition to prescribed oral medications. There is no provided subjective/objective evidence that the patient has failed or not responded to other conventional and recommended forms of treatment for relief of the effects of the industrial injury. Only if the subjective/objective findings are consistent with the recommendations of the Official Disability Guidelines (ODG), then topical use of topical preparations is only recommended for short-term use for specific orthopedic diagnoses. The request for Terocin patches is not medically necessary for the treatment of the patient for the diagnosis of chronic back pain. The patient is 8 years date of injury (DOI) and has exceeded the time period recommended for topical treatment. There are alternatives available over the counter (OTC) for the prescribed topical analgesics. The volume applied and the times per day that the patches are applied are variable and do not provide consistent serum levels consistent with effective treatment. There is no medical necessity for the addition of patches to the oral medications in the same drug classes. There is no demonstrated evidence that the topicals are more effective than generic oral medications. The prescription for Terocin patches is not medically necessary for the treatment of the patient's pain complaints. The prescription of Terocin patches is not

recommended by the CA MTUS and the Official Disability Guidelines. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or appropriate-noting the specific comment that "There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder." The objective findings in the clinical documentation provided do not support the continued prescription for the treatment of chronic pain. There is no documented medical necessity for the prescribed Teroцин patches for the effects of the industrial injury.

**Omeprazole 20 mg tablet #120:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines anti-inflammatory medication Page(s): 67-68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter-medications for chronic pain; NSAIDs.

**Decision rationale:** The MTUS Chronic Pain Medical Treatment Guidelines section on anti-inflammatory medications and gastrointestinal symptoms states; "Determine if the patient is at risk for gastrointestinal events." The medical records provided for review do not provide additional details in regards to the above assessment needed for this request. No indication or rationale for gastrointestinal prophylaxis is documented in the records provided. There are no demonstrated or documented GI issues attributed to NSAIDs for this patient. The patient was prescribed Omeprazole 20 mg #120 routinely for prophylaxis for the prescribed pain management medications. The protection of the gastric lining from the chemical effects of NSAIDs is appropriately accomplished with the use of the proton pump inhibitors such as Omeprazole. The patient is not documented to be taking NSAIDs. There is no industrial indication for the use of Omeprazole due to "stomach issues" or stomach irritation. The proton pump inhibitors provide protection from medication side effects of dyspepsia or stomach discomfort brought on by NSAIDs. The use of Omeprazole is medically necessary if the patient were prescribed conventional NSAIDs and complained of GI issues associated with NSAIDs. Whereas 50% of patients taking NSAIDs may complain of GI upset, it is not clear that this patient was prescribed Omeprazole automatically. The prescribed opioid analgesic, not an NSAID, was accompanied by a prescription for Omeprazole without documentation of complications. There were no documented GI effects of the NSAIDs to the stomach of the patient and the Omeprazole was dispensed or prescribed routinely. There is no demonstrated medical necessity for the prescription for omeprazole 20 mg #120.