

<b>Case Number:</b>	CM14-0146415		
<b>Date Assigned:</b>	10/14/2014	<b>Date of Injury:</b>	07/23/2003
<b>Decision Date:</b>	11/13/2014	<b>UR Denial Date:</b>	08/14/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/12/2014

### 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 Anesthesiology, has a subspecialty in Pain Medicine and is licensed to practice in Massachusetts. 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:

According to the documents available for review, the patient is a 62 year old male. The date of injury is July 23, 2003. The injured worker sustained an injury to the low back, bilateral hips and bilateral knees. The specific mechanism of injury was not fully elaborated on in the notes available for review. The injured worker currently complains of pain in the abdomen, lumbar spine, bilateral hips, and bilateral knees. The injured worker is maintained on the multimodal pain medication regimen including Nizatidine, Ondansetron and Xolido 2% cream. A request for Nizatidine, Ondansetron and Xolido 2% cream was denied.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Nizatidine 150mg Capsule, Unknown Quantity:** 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 PPI Page(s): 68-69.

**Decision rationale:** The MTUS makes the following recommendations for the use of proton pump inhibitors. Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (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). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastroduodenal lesions. According to the records available for review the injured worker does meet the guidelines required for the use a PPI. Concurrent use of an H2 blocker such as Nizatidine would not be indicated. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established. The request for Nizatidine 150mg Capsule, Unknown Quantity is not medically necessary.

**Ondansetron 4mg Tablet, Unknown Quantity:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chronic, Zofran

**Decision rationale:** Accordingly to the ODG, Zofran is a serotonin 5-HT<sub>3</sub> receptor antagonist. It is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also FDA-approved for postoperative use. Acute use is FDA-approved for gastroenteritis. According to the documents available for review, the injured worker does not have any of the FDA approved indications for the use of this medication. Therefore at this time the requirements for treatment have not been met and medical necessity has not been established. The request for Ondansetron 4mg Tablet, Unknown Quantity is not medically necessary.

**Xolido 2% Cream, Unknown Quantity:** 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 Lidoderm Page(s): 56; 112.

**Decision rationale:** Accordingly to the MTUS Lidoderm Patch (and cream) is 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). Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. In February 2007 the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical lidocaine. According to the documents available for review, the injured worker has

none of the aforementioned MTUS approved indications for the use of this medication. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established. The request for Xolido 2% Cream, Unknown Quantity is not medically necessary.