

<b>Case Number:</b>	CM14-0130643		
<b>Date Assigned:</b>	09/22/2014	<b>Date of Injury:</b>	04/08/2009
<b>Decision Date:</b>	12/31/2014	<b>UR Denial Date:</b>	07/18/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/14/2014

### 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 39-year old woman reported multiple injuries due to a fall on 4/8/09. Treatment has included medications, physical therapy, chiropractic manipulation, cervical and lumbosacral epidural steroid injections, acupuncture, left shoulder surgery, cervical spine surgery and two lumbar spine surgeries. A 1/9/12 progress note is cited in a 7/18/14 UR report but the note itself is not part of the records provided. According to the UR report, on 1/9/12 the patient had ongoing, unchanged symptoms of the neck, low back and shoulders. Exam was positive for tenderness and spasm, restricted ranges of motion, focal dysesthesias and weakness in the lower limbs. Treatment included omeprazole DR capsules, one every 12 hours as needed for stomach upset; Ondansetron ODT 8 mg for nausea; sumatriptan for headaches; Carisoprodol every 8 hours as needed for muscle spasm; and Medrox pain relief ointment to be used topically for temporary relief. These medications were dispensed by the provider's office. The 7/18/14 UR report stated that Sumatriptan was certified and that Ondansetron, omeprazole and Medrox were non-certified. There are three other UR reports in the record that are dated 7/18/14. All three of them involve requests for Ondansetron and omeprazole; with dispense dates of 3/6/12, 5/7/12 and 7/16/12. Medrox was also dispensed on 5/7/12. The most recent notes in the available records from the primary and secondary treating physician are dated from January to April 2014. The patient continues to have neck, shoulder and low back pain. She is being treated with Oxycontin and Ambien by the secondary treating physician. The primary's notes state that medications are being requested under separate cover, and the requests are not included in the records. Therefore, it is unclear how many of the same medications are still being dispensed. The patient is totally disabled and has not returned to work after her injury.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Retrospective request for Ondansetron ODT Tablets 8mg #30 x 2 QTY = 60 date of service 1/9/12: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Antiemetic (for opioid nausea) Ondansetron (Zofran).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UptoDate ([www.uptodate.com](http://www.uptodate.com)), Ondansetron, Drug Information.

**Decision rationale:** According to the Ondansetron reference cited above, the medical indications for Ondansetron (Zofran) include prevention of nausea and vomiting associated with chemotherapy. It may also be used for prevention of postoperative nausea and vomiting and for severe or refractory hyperemesis gravidarum (Canada only). Common side effects include headache, malaise/fatigue, and constipation. The clinical findings do not support the provision of Ondansetron to this patient. There is no documentation that the patient has nausea, or of any evaluation for nausea. There is no evidence that the patient is undergoing chemotherapy or has hyperemesis gravidarum. She was definitely not in the immediate post-surgical period on 1/9/12, when Ondansetron was dispensed. Based on the citations above and on the clinical information provided for review, this request is not medically necessary.

**Retrospective request for Omeprazole delayed - release capsules 20mg #120 date of service 1/9/12: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk. Page(s): 68-69. Decision based on Non-MTUS Citation UptoDate ([www.uptodate.com](http://www.uptodate.com)), Omeprazole, Drug information

**Decision rationale:** Omeprazole is a proton pump inhibitor (PPI). The first guideline cited above states that clinicians should weight the indications for non-steroidal anti-inflammatory drugs (NSAIDs) against both gastrointestinal (GI) and cardiovascular risk factors. They should determine if the patient is at risk for GI events. Risk factors include age over 65 years; history of peptic ulcer, GI bleeding or perforation; concurrent use of aspirin, corticosteroids, or an anticoagulant; or high-dose or multiple NSAIDs, or an NSAID combined with aspirin. Patients with no GI risk factors and no cardiovascular disease may be prescribed a non-selective NSAID. Those at intermediate risk for GI disease should receive a non-selective NSAID plus a proton pump inhibitor (PPI) or misoprostol; or a Cox-2 selective NSAID. Patients at high GI risk should receive a Cox-2 selective NSAID and a PPI if an NSAID is absolutely necessary. This reference notes that long-term PPI use has been shown to increase the risk of hip fracture. The UptoDate reference cited above lists the indications for omeprazole as active duodenal ulcer,

gastric ulcer, erosive esophagitis, helicobacter pylori eradication, pathological hypersecretory conditions (such as Zollinger-Ellison syndrome), frequent heartburn, GERD or other acid-related disorders, NSAID-induced ulcer treatment, NSAID-induced ulcer prophylaxis, and stress ulcer prophylaxis in ICU patients. The last three indications are off label. Risks of long-term (usually over one year) use include atrophic gastritis, increased incidence of gastric carcinoid tumors, clostridium difficile-associated diarrhea, increased incidence of osteoporosis-related fractures of the hip, spine, or wrist; hypomagnesemia and Vitamin B12 deficiency. Based on the medical records provided for review, there is no clear explanation why the medication is being prescribed. GI upset symptoms may include nausea and constipation, for which omeprazole is not indicated. In addition, omeprazole does not have maximum effect for several days, and "as needed" dosing is ineffective. There is no documentation of the patient's risk for GI events. There is no documentation that she is taking an NSAID. There is no documentation of any condition likely to require a PPI prescription or of any symptoms suggestive of such a condition. Based on the evidence-based references cited above and the available clinical information, this request is not medically necessary.

**Retrospective request for Medrox Pain Relief Ointment 120gm x 2 date of service 1/9/12:**  
Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate Topicals; Topical Analgesic.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain, Topical Analgesics Page(s): 60; 111-113.

**Decision rationale:** Medrox lotion contains a combination of 20% menthol salicylate, 5% menthol and 0.0375% capsaicin. Per one of its major suppliers, Physician Dispensing Solutions, Medrox "is a must-have for any practice looking to generate ancillary income". Per the first citation above, medications should be started individually while other treatments are held constant, with careful assessment of function. There should be functional improvement with each medication in order to continue it. The second citation states that topical analgesics are largely experimental in use with few randomized controlled 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. Capsaicin is recommended as an option in patients who have not responded to or are intolerant to other treatments. It has been shown to have some efficacy in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain. There is no evidence supporting formulations which contain over 0.025% capsaicin. The clinical documentation in this case does not support the use of Medrox ointment. Using it means that three medications are being started at once, and that it would be impossible to determine which of them resulted in any beneficial or harmful effect. There is no documentation that the patient has not responded to or is intolerant of other treatments. The concentration of capsaicin in this ointment exceeds that recommended by MTUS. Lastly, the long-term use of Medrox has not resulted in any significant functional improvement in this patient. Based on the evidence-based guidelines cited above and the clinical documentation provided for review, this request is not medically necessary.

