

<b>Case Number:</b>	CM14-0218302		
<b>Date Assigned:</b>	01/08/2015	<b>Date of Injury:</b>	08/08/2006
<b>Decision Date:</b>	03/05/2015	<b>UR Denial Date:</b>	12/04/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/30/2014

### 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. 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: Iowa, Illinois, Hawaii

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Public Health & Gen Prev Med

### 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 51 year old male with a date of injury of August 8, 2006. Results of the injury include the lumbar and cervical spine. Diagnosis include status post L4 to S1 posterior lumbar interbody fusion, status post removal of lumbar spine hardware, and cervical discopathy. Treatment has included surgery, pain management and request for authorization for lumbar epidural steroid injections. Magnetic Resonance Imaging scan on the lumbar spine dated November 6, 2012 showed previous spinal fusion therapy at L4-L5 and L5-S1. Progress report dated May 24, 2013 showed tenderness at the cervical paravertebral muscles and upper trapezial muscles with spasm. Physical examination of the lumbar spine showed tenderness from the mid to distal lumbar segments. Work status was noted as full duty. The treatment plan included pain management and request for epidural steroid injection. Utilization review form dated December 3, 2014 non certified Ondansetron ODT 8 mg # 30, Omeprazole DR 20 mg # 120, Medrox ointment 120 gm # 2, and Cidaflex # 120 due non compliance with MTUS and Official Disability Guidelines.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Retrospective Ondansetron ODT 8mg #30 Date of service 12/3/10: 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), Pain

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants, NSAIDs, GI symptoms, opioids Page(s): 68-69, 74-96. Decision based on Non-MTUS Citation Chronic Pain, Antiemetics (for opioid nausea)

**Decision rationale:** Ondansetron (Zofran) is an antiemetic used to decrease nausea and vomiting. Nausea is a known side effect of chronic opioid use and some Serotonin/norepinephrine reuptake inhibitors (SNRIs). ODG does not recommend use of antiemetic for "nausea and vomiting secondary to chronic opioid use". Additionally, "This drug 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." There is no evidence that patient is undergoing chemotherapy/radiation treatment or postoperative. MTUS is specific regarding the gastrointestinal symptoms related to NSAID usage. If criteria are met, the first line treatment is to discontinue usage of NSAID, switch NSAID, or consider usage of proton pump inhibitor. There is no documentation provided that indicated the discontinuation of NSAID or switching of NSAID occurred. Additionally, ondansetron is not a proton pump inhibitor and is not considered first line treatment. As such the request for Retrospective Ondansetron ODT 8mg #30 Date of service 12/3/10 is not medically indicated.

**Retrospective Omeprazole DR 20mg #120 Date of service 12/3/10: 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), Pain

**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 Pain (Chronic), NSAIDs, GI symptoms & cardiovascular risk

**Decision rationale:** MTUS and ODG states, "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)." And "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)." The medical documents provided do not establish the patient has having documented GI bleeding, perforation, peptic ulcer, high dose NSAID, or other GI risk factors as outlined in MTUS. As such, the request for Retrospective Omeprazole DR 20mg #120 Date of service 12/3/10 is not medically necessary.

**Retrospective Medrox ointment 120gm #2 Date of service 12/3/10: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Pain, Compound creams

**Decision rationale:** MTUS and ODG recommends usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." The Medrox patches contain topical menthol, capsaicin, and salicylate. ODG recommends usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." MTUS recommends topical capsaicin "only as an option in patients who have not responded or are intolerant to other treatments." There is no indication that the patient has failed oral medication or is intolerant to other treatments. ODG only comments on menthol in the context of cryotherapy for acute pain, but does state "Topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns, a new alert from the FDA warns." MTUS states regarding topical Salicylate, "Recommended. Topical salicylate (e.g., Ben-Gay, methyl salicylate) is significantly better than placebo in chronic pain. (Mason-BMJ, 2004) See also Topical analgesics; & Topical analgesics, compounded." In this case, topical capsaicin is not supported for topical use per guidelines. As such, the request for Retrospective Medrox ointment 120gm #2 Date of service 12/3/10 is not medically necessary.

**Retrospective Cidaflex #120 Date of service 12/3/10: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine (and Chondroitin Sulfate) Page(s): 50.

**Decision rationale:** Regarding Glucosamine (and Chondroitin Sulfate), MTUS states: "Recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulfate (GS) on all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride." Cidaflex is a combination product of chondroitin and glucosamine. The specific dosing and formulation per web search contains Glucosamine hydrochloride 500mg, Chondroitin Sulfate 400mg. Per MTUS chronic pain, "Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulfate (GS) on all outcomes, including joint

space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride"... "The Glucosamine Chondroitin Arthritis Intervention Trial (GAIT) funded by the National Institutes of Health concluded that glucosamine hydrochloride (GH) and chondroitin sulfate were not effective in reducing knee pain in the study group overall; however, these may be effective in combination for patients with moderate-to-severe knee pain."... "Compelling evidence exists that GS may reduce the progression of knee osteoarthritis. Results obtained with GS may not be extrapolated to other salts (hydrochloride) or formulations (OTC or food supplements) in which no warranty exists about content, pharmacokinetics and pharmacodynamics of the tablets." As Cidaflex contains a component that is not advised (glucosamine hydrochloride), the product is thus not advised. The request for Retrospective Cidaflex #120 Date of service 12/3/10 is not medically necessary.