

<b>Case Number:</b>	CM14-0129491		
<b>Date Assigned:</b>	08/18/2014	<b>Date of Injury:</b>	09/30/2009
<b>Decision Date:</b>	10/01/2014	<b>UR Denial Date:</b>	07/29/2014
<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 Physical Medicine and Rehabilitation, has a subspecialty in Pain 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 60-year-old female patient who sustained an industrial injury on 09/30/2009 when she misstepped while going up steps and fell, injuring the right arm. Diagnoses include right humeral commuted fracture, right shoulder pain, cervical degenerative disc disease. Previous treatment has included physical therapy, medications and exercise. MRI of the right shoulder performed on 07/03/14 revealed humeral fractures and minimal acromioclavicular joint arthropathy. A request for Nizatidien 150 mg #60 and Dendracin lotion 120 ml was non-certified at utilization review on 07/29/14. The reviewing physician noted that ODG guidelines indicate while histamine-2 receptor antagonists can be used to prevent stomach ulcers in patients taking NSAIDs, other first-line therapy, such as proton pump inhibitors are preferred. In this case there was no documentation of failed trials of proton pump inhibitors or any documentation of current gastrointestinal issues. Regarding Dendracin lotion, topical medications are considered experimental without proven efficacy and only recommended for the treatment of neuropathic pain after failed first-line therapy of antidepressants and anticonvulsants, which was not documented in this case. There is no documentation of intolerance to taking these medications on an oral basis. Progress note dated 06/13/14 indicated the patient feeling sore just from driving over for the appointment. She is doing a home exercise program. Pain was rated at 5/10, intermittent in nature and brought on with activity and decreased with rest. She is not in any active therapy and no new symptoms. Objective findings revealed tenderness over the right acromioclavicular joint and superolateral aspect of the shoulder. Range of motion was mildly restricted with right shoulder flexion and abduction. Motor strength testing was 5/5 bilaterally throughout the upper extremities. There was no evidence of impingement or instability. Reflexes were 2/4 in the bilateral upper extremities. Patient was prescribed ibuprofen and Nizatidine, and was also prescribed Dendracin ointment to apply locally. On 05/15/14, and was

noted that the patient is starting to have gastrointestinal upset with her medications. Plan was to stop Tylenol and Skelaxin and try her on ibuprofen with omeprazole.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Nizatidine 150 mg quantity: 60.00 (Retrospective: Date of Service (DOS) 6/13/14): 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)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS AND GASTROINTESTINAL SYMPTOMS Page(s): 68.

**Decision rationale:** The CA MTUS guidelines regarding NSAIDs and Gastrointestinal Symptoms states "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." In this case, records do indicate that on 05/15/14 the patient was starting to have gastrointestinal upset with medications. At that point, plan was to try her on ibuprofen with omeprazole. Omeprazole is considered a first line treatment option for gastrointestinal complaints related to NSAID use. There is no documentation regarding a lack of efficacy of omeprazole or any other documentation addressing the patient's response to treatment with omeprazole to support the medical necessity of Nizatidine, which is a histamine-2 blocker indicated for the treatment of ulcers and GERD. Has documentation does not describe failure of first-line proton pump inhibitors such as omeprazole to treat the patient's GI symptoms, the use of a histamine-2 blocker such as Nizatidine 150 mg quantity: 60.00 (Retrospective: Date of Service (DOS) 6/13/14) is not considered medically necessary. The request is non-certified.

**Dendracin lotion 120 ml (Retrospective: DOS 6/13/14): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-113.

**Decision rationale:** The CA MTUS states "Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed...Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) 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." In this case,

documentation does not identify failure of first-line oral agents in the antidepressant or anticonvulsant class to support the medical necessity of topical agents such as Dendracin lotion. There is no high-grade evidence to support the use of topical agents, and documentation lacks a rationale as to why the patient requires a topical lotion over traditional first line oral agents. Therefore, the requested Dendracin lotion 120 ml (Retrospective: DOS 6/13/14) is not medically necessary and is non-certified.