

<b>Case Number:</b>	CM15-0072814		
<b>Date Assigned:</b>	04/23/2015	<b>Date of Injury:</b>	07/23/2013
<b>Decision Date:</b>	05/20/2015	<b>UR Denial Date:</b>	03/17/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/16/2015

### 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 & General Preventive Medicine

### 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 44 year old female, who sustained an industrial injury on 7/23/2013. The current diagnoses are disc herniation at C5-C6, lateral epicondylitis of the left elbow, and carpal tunnel syndrome. According to the most current progress report dated 11/17/2014, the injured worker complains of pain in the cervical spine, left wrist, and right shoulder. The current medications are Hydrocodone, Cyclobenzaprine, Diclofenac, Tramadol, and Pantoprazole. Treatment to date has included medication management, X-rays, MRI studies, and physical therapy. The plan of care includes Keratek Tek gel and Flurbiprofen/Omeprazole.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Keratek Tek Gel 4 OZ:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate, Topical analgesic Page(s): 105, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Salicylate topicals, Topical analgesics.

**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 anti-convulsants. 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." Kera-Tek Gel is the brand name version of a topical analgesic medication containing menthol and methyl 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." 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." The medical documents do not support the use of this topical compound agent. As such, the request for Keratek Tek Gel 4 OZ is not medically necessary.

**Flurbiprofen/Omeprazole 100/10 MG Qty 60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-73. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), NSAIDs (non-steroidal anti-inflammatory drugs) and Pain (Chronic), NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** MTUS recommends NSAIDs for osteoarthritis "at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy." MTUS further specifies that NSAIDs should be used cautiously in patients with hypertension. ODG states, "Recommended as an option. Naproxen is a non-steroidal anti-inflammatory drug (NSAID) for the relief of the signs and symptoms of osteoarthritis." MTUS 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)." ODG states "If a PPI is used, omeprazole OTC tablets or lansoprazole 24HR OTC are recommended for an equivalent clinical efficacy and significant cost savings. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi, 2008) A trial of omeprazole or lansoprazole is recommended before Nexium therapy. The other PPIs, Protonix, Dexilant, and Aciphex, should also be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. (AHRQ, 2011)". The medical documents provided do not establish the patient has having documented GI bleeding/perforation/peptic ulcer or other GI risk factors as outlined in MTUS. While the NSAID may be considered appropriate, the appropriateness of omeprazole has not been established. The treating physician has failed to provide documentation of objective functional improvement with the use of this medication to warrant ongoing usage. As such, the request for Flurbiprofen/Omeprazole 100/10 MG Qty 60 is not medically necessary.