

<b>Case Number:</b>	CM15-0061409		
<b>Date Assigned:</b>	04/07/2015	<b>Date of Injury:</b>	05/09/2012
<b>Decision Date:</b>	05/08/2015	<b>UR Denial Date:</b>	03/06/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/31/2015

### 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 47-year-old male, who sustained an industrial injury on 05/09/2012. He reported injury to his right shoulder after being struck by a pallet. The injured worker is currently diagnosed as having right shoulder joint pain, major depression, and history of gastritis. Treatment to date has included right shoulder surgery, right shoulder MRI, Transcutaneous Electrical Nerve Stimulation Unit, home exercise program, and medications. In a progress note dated 02/26/2015, the injured worker presented with complaints of right shoulder pain that radiates to his right tricep intermittently. The treating physician reported requesting authorization for Transcutaneous Electrical Nerve Stimulation Unit patches, Lidopro, and Omeprazole.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Lidopro 121gm #2 (capsaicin, lidocaine, menthol, and methyl salicylate): 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 Official Disability Guidelines (ODG) 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." Lidopro is a topical medication containing Lidocaine, Capsaicin, 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." 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. Additionally, ODG states "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." 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, lidocaine is not supported for topical use per guidelines. As such, the request for Lidopro 121gm #2 (capsaicin, lidocaine, menthol, and methyl salicylate) is not medically necessary.

**Omeprazole 20mg #60 x 2:** Upheld

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

**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 Official Disability Guidelines (ODG) 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 Omeprazole 20mg #60 x 2 is not medically necessary.

**TENS patch #2:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Transcutaneous electrotherapy. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), TENS, chronic pain (transcutaneous electrical nerve stimulation).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Shoulder, Durable Medical Equipment (DME) and Other Medical Treatment Guidelines Medicare.gov, durable medial equipment.

**Decision rationale:** MTUS and ACOEM are silent regarding the medical necessity of TENS patches, but does address TENS unit. ODG does state regarding durable medical equipment (DME), "Recommended generally if there is a medical need and if the device or system meets Medicare's definition of durable medical equipment (DME) below" and further details "Exercise equipment is considered not primarily medical in nature."Medicare details DME as: durable and can withstand repeated use-used for a medical reason-not usually useful to someone who isn't sick or injured-appropriate to be used in your home. While TENS patches do meet criteria as durable medical equipment, the medical notes do not establish benefit from ongoing usage of a TENS unit. Given lack of documented improvement, the continued usage of TENS does not appear to be indicated and therefore the associated patches also do not appear to be indicated. As such, the request for TENS patch #2 is not medically necessary.