

<b>Case Number:</b>	CM13-0056398		
<b>Date Assigned:</b>	12/30/2013	<b>Date of Injury:</b>	07/18/1997
<b>Decision Date:</b>	12/31/2014	<b>UR Denial Date:</b>	11/19/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/22/2013

### 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 Occupational and Environmental Medicine and is licensed to practice in West Virginia and Ohio. 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 individual is a 54 year old male who sustained an industrially related injury on November 5th, 2013 involving his left and right lower extremities. He has ongoing complaints of right knee and left ankle pain with stiffness. He is status post talonavicular fusion on the left. The latest available examination provided in the record (1/6/14) notes an antalgic gait with minimally reduced strength in the left lower extremity (5-/5). An earlier examination (8/29/13) notes full extension of the right knee and normal strength on the right. It is noted in the available record that the pain in his right knee is compensatory due to the continued pain and instability of the left ankle. This request is for protonix for GI prophylaxis, terocin and lidopro for pain and replacement pads to allow for continued use of TENS therapy.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Protonix 20mg, QTY 120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI symptoms and 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 Official Disability Guidelines (ODG) Pain (Chronic), NSAIDS, GI symptoms & cardiovascular risk

**Decision rationale:** Protonix is the brand name version of Pantoprazole, which is a proton pump inhibitor. 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 (200g 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 patient does not meet the age recommendations for increased GI risk. The medical documents provided establish the patient has experienced GI discomfort, but is nonspecific and does not indicate history of peptic ulcer, GI bleeding or perforation. Medical records do not indicate that the patient is on ASA, corticosteroids, and/or an anticoagulant; or high dose/multiple NSAID. Additionally per guidelines, Pantoprazole is considered second line therapy and the treating physician has not provided detailed documentation of a failed trial of omeprazole and/or lansoprazole. As such, the request for Pantoprazole 20mg #120 is deemed not medically necessary.

**TENS unit replacement pads, QTY 2:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Transcutaneous electrotherapy Page(s): 114-121.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Transcutaneous electrotherapy Page(s): 54,114-116,118-120. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, TENS chronic pain (transcutaneous electrical nerve stimulation)

**Decision rationale:** MTUS states regarding TENS unit, "Not recommended as a primary treatment modality, but a one-month home-based TENS trial may be considered as a noninvasive conservative option, if used as an adjunct to a program of evidence-based functional restoration, for the conditions described below." For pain, MTUS and ODG recommend TENS (with caveats) for neuropathic pain, phantom limb pain and CRPS II, spasticity, and multiple sclerosis. The medical records do not indicate any of the previous conditions. ODG further outlines recommendations for specific body parts: Knee: Recommended as an option for osteoarthritis as adjunct treatment to a therapeutic exercise program, Ankle and foot: Not recommended. Medical records do not indicate knee osteoarthritis and TENS is not recommended for the ankle and foot.

As such replacement pads to allow the continued use of TENS therapy is deemed not medically necessary.

**Terocin patches, QTY 40:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesic Page(s): 111-113.

**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 recommend 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." Terocin lotion is topical pain lotion that contains lidocaine and menthol. ODG states regarding lidocaine topical patch, "This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia". Medical documents do not document the patient as having post-herpetic neuralgia. Additionally, Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The treating physician did not document a trial of first line agents and the objective outcomes of these treatments. As such the request for terocin patches #40 is deemed not medically necessary.

**Lidopro lotion 4oz, QYT 2:** Upheld

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

**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 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." As such, the request for lidopro lotion 4 oz. x2 is deemed not medically necessary.