

<b>Case Number:</b>	CM15-0120523		
<b>Date Assigned:</b>	07/01/2015	<b>Date of Injury:</b>	04/12/2011
<b>Decision Date:</b>	08/13/2015	<b>UR Denial Date:</b>	06/16/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/22/2015

### 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: California  
 Certification(s)/Specialty: Emergency 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 64-year-old male, who sustained an industrial injury on 4/12/11. Initial complaint was of a left ankle injury. The injured worker was diagnosed as having pain in left ankle osteochondritis dissecans defect 9mm lateral talar dome; right ankle pain; joint ankle/foot; osteochondritis dissecans; bilateral plantar fasciitis. Treatment to date has included status post left ankle ligament reconstructive surgery with microfractures/chondroplasty (11/17/11); left ankle brace; physical therapy; medications. Diagnostics studies included X-ray right and left ankle (3/28/14); MRI left ankle 3/28/14). Currently, the PR-2 notes dated 4/14/15 indicated the injured worker is on Coumadin for his heart and he will discontinue the Diclofenac. He will be prescribed Pensaid and Cyclobenzaprine for short term pain relief. He will follow-up in one month. He has a recent cardiac converted procedure which has helped his atrial fibrillation but continues to have significant left ankle pain. He ambulates with a cane and recently bought a new brace that is giving him stability but not much pain relief. The cane gives him balance to avoid further falls and feels 20% improvement with the new brace. The left foot/ankle notes a well-healed scar and positive antalgic gait; ambulating with a cane. He has positive tenderness over the plantar fascia. The provider notes positive tenderness over the anterior talofibular ligament and plantar flexion and inversion. The right foot/ankle appears normal with positive tenderness over the plantar fascia; positive pain with plantar flexion and inversion; positive pain with plantar flexion and inversion. The treatment plan included request for the new ankle support reimbursement, continue heart medications and requesting a podiatry consult for second opinion; discussion of cardiac clearance for surgery for the left ankle arthroscopy. No medications were requested secondary to his heart. The provider is requesting authorization of Retrospective Terocin patches x 3 month supply (3 boxes containing 30 patches) DOS 6/11/15 and Retrospective Lidopro gel (Camphor 30%, Menthol 2.5%) x 3 month supply (1 box, 2 bottles-

240ml) DOS 6/11/15.

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

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

**Retrospective Terocin patches x 3 month supply (3 boxes containing 30 patches) DOS 6/11/15: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111, 112-113.

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

**Decision rationale:** The requested product is a patch composed of multiple medications. As per MTUS guidelines, "Any compounded product that contain one drug or drug class that is not recommended is not recommended." Terocin contains capsaicin, lidocaine, Methyl Salicylate and Menthol. 1) Capsaicin: Data shows efficacy in muscular skeletal and neuropathic pain and may be considered if conventional therapy is ineffective. There is no documentation of treatment failure. It requires documentation of a successful 1month trial. It is not recommended due to no documentation of prior treatment failure or effectiveness. 2) Lidocaine: Topical lidocaine is recommended for post-herpetic neuralgia only although it may be considered as off-label use as a second line agent for peripheral neuropathic pain. It may be considered for peripheral neuropathic pain only after a trial of 1st line agent. There is no documentation of failure with a 1st line agent and there is no documentation consistent with neuropathic pain. It is therefore not recommended. 3) Methyl-Salicylate: Shown to be superior to placebo. It should not be used long term. There may be some utility for patient's pain. 4) Menthol: There is no data on Menthol in the MTUS. It is unclear why the provider has decided to use a non-FDA approved compounded product as opposed to the available FDA formulations. It is unclear why the provider has prescribed a patch and a gel with the same active compounds. This will lead to a higher risk of overdose and toxicity. Multiple components are not recommended, the combination medication Terocin lidocaine patch, as per MTUS guidelines, is not medically necessary.

**Retrospective Lidopro gel (Camphor 30%, Menthol 2.5%) x 3 month supply (1box, 2 bottles-240ml) DOS 6/11/15: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111, 112-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), pain chapter.

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

**Decision rationale:** The requested product is a patch composed of multiple medications. As per MTUS guidelines, "Any compounded product that contain one drug or drug class that is not recommended is not recommended." Lidopro contains lidocaine, Capsaicin and methyl-salicylate. 1) Capsaicin: Data shows efficacy in muscular skeletal and neuropathic pain and may be considered if conventional therapy is ineffective. There is no documentation of treatment failure. It requires documentation of a successful 1 month trial. It is not recommended due to no documentation of prior treatment failure or effectiveness. 2) Lidocaine: Topical lidocaine is

recommended for post-herpetic neuralgia only although it may be considered as off-label use as a second line agent for peripheral neuropathic pain. It may be considered for peripheral neuropathic pain only after a trial of 1st line agent. There is no documentation of failure with a 1st line agent and there is no documentation consistent with neuropathic pain. It is therefore not recommended.3) Methyl-Salicylate: Shown to be superior to placebo. It should not be used long term. There may be some utility for patient's pain. It is unclear why the provider has decided to use a non-FDA approved compounded product as opposed to the available FDA formulations. It is unclear why the provider has prescribed a patch and a gel with the same active compounds. This will lead to a higher risk of overdose and toxicity. Lidopro is not medically necessary.