

<b>Case Number:</b>	CM15-0108230		
<b>Date Assigned:</b>	06/12/2015	<b>Date of Injury:</b>	10/11/2001
<b>Decision Date:</b>	07/14/2015	<b>UR Denial Date:</b>	05/09/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/04/2015

### 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: North Carolina  
Certification(s)/Specialty: Family Practice

### 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 62 year old male, who sustained an industrial injury on 10/11/2001. He has reported subsequent right ankle and foot pain and was diagnosed with degenerative joint disease of the ankle/foot, idiopathic peripheral neuropathy, Achilles tendinitis on the right and right ankle pain. Treatment to date has included oral and topical pain medication, orthotics and surgery. In a progress note dated 04/24/2015, the injured worker complained of right ankle and toe pain. Objective findings were notable for no motion at the fusion site, generalized pain of the foot and toe and chronic arch and ankle pain without detectable motion at the fusion sites. The physician noted that the injured worker had developed pain and fusiform edema over the right Achilles tendon that inhibited his ability to walk and perform daily activities without pain. The injured worker was noted to be awakened at night due to Achilles pain. A request for authorization of Flector patches, 1 evaluation of the right Achilles for ESCWT and PRP injection and Zolpidem was submitted.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**1 prescription of Flector 1.3% patches #30 with 2 refills:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain: Flector, Pennsaid, Voltaren Gel (2015).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical NSAID Page(s): 111-112.

**Decision rationale:** The California chronic pain medical treatment guidelines section on topical analgesics states: Recommended as an option as indicated below. 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. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) 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. Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study, the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. (Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. Maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity and 16 g per joint per day in the lower extremity). The most common adverse reactions were dermatitis and pruritus. (Voltaren package insert) For additional adverse effects: See NSAIDs, GI symptoms and cardiovascular risk; & NSAIDs, hypertension and renal function. Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis. (Diaz, 2006) (Hindsen, 2006) Absorption of the drug depends on the base it is delivered in. (Gurol, 1996). Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. (Krummel 2000) Topical analgesic NSAID formulations are not indicated for long-term use and have little evidence for treatment of the spine, hip or shoulder.

This patient does not have a diagnosis of osteoarthritis or neuropathic pain that has failed first line treatment options. Therefore, criteria for the use of topical NSAID therapy per the California MTUS have not been met and the request is not medically necessary.

**1 Evaluation of the right achilles for ESCWT and PRP injection: Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 14 Ankle and Foot Complaints Page(s): 371.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 14 Ankle and Foot Complaints Page(s): 370.

**Decision rationale:** The ACOEM chapter on foot and ankle complaint states: Limited evidence exists regarding extracorporeal shock wave therapy (ESWT) in treating plantar fasciitis to reduce pain and improve function. While it appears to be safe, there is disagreement as to its efficacy. Insufficient high quality scientific evidence exists to determine clearly the effectiveness of this therapy. The requested service is not recommended per the ACOEM and therefore the request is not medically necessary.

**1 prescription of Zolpidem ER 12.5mg #30 with 2 refills: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain, Zolpidem (Ambien) (2015).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, ambien.

**Decision rationale:** The California MTUS and the ACOEM do not specifically address the requested medication. PER the ODG: Zolpidem is a prescription short-acting non-benzodiazepine hypnotic approved for the short-term treatment of insomnia. Proper sleep hygiene is critical to the individual with chronic pain. While sleeping pills, so-called minor tranquilizers and anti-anxiety medications are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. There is also concern that they may increase pain and depression over the long-term. The medication is not intended for use greater than 6 weeks. There is no notation or rationale given for longer use in the provided progress reports. There is no documentation of other preferred long-term insomnia intervention choices being tried and failed. For these reasons, the request is not medically necessary.