

<b>Case Number:</b>	CM14-0162503		
<b>Date Assigned:</b>	10/07/2014	<b>Date of Injury:</b>	12/08/2013
<b>Decision Date:</b>	12/12/2014	<b>UR Denial Date:</b>	09/15/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/02/2014

### 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 Medicine and is licensed to practice in Montana. 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:

The injured worker sustained an injury on 12/8/13 and 7/24/14. The injury on 7/24/14 occurred when he tripped and fell. He currently has low back pain radiating into the left lower extremity with numbness and tingling and left knee injury. Recent examinations have shown tenderness to palpation in the low back with spasm in the left low back and radiating pain in the left L5 and S1 dermatomes. Treatment has included physical therapy, aquatic therapy, TENS unit, tramadol, Neurontin, ibuprofen and lumbar epidural steroid injection on 7/10/14. The treating physician has requested Flector patch 1.3% twice a day for superficial pain and inflammation #30.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flector patch 1.3% BID for superficial pain and inflammation #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation ODG Pain (updated 09/10/14) Flector patch (diclofenac epolamine)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-112. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Drug Formulary, Flector Patch

**Decision rationale:** The MTUS recommends topical analgesics 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. 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.

Topical non-steroidal antiinflammatory 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. 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. The OGD guidelines note that Flector Patches (diclofenac epolamine) are not recommended as a first-line treatment. Topical diclofenac is recommended for osteoarthritis after failure of an oral NSAID or contraindications to oral NSAIDs, after considering the increased risk profile with diclofenac, including topical formulations. Flector patch is FDA indicated for acute strains, sprains, and contusions (FDA, 2007). The efficacy in clinical trials for topical NSAIDs 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. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. In addition, there is no data that substantiate Flector efficacy beyond two weeks. In this case the injured worker has been taking ibuprofen with no documentation of side effects or lack of efficacy. The treating physician has not documented failure of oral NSAID medications or contraindications. The request for Flector patch 1.3% BID for superficial pain and inflammation #30 is not medically necessary.