

<b>Case Number:</b>	CM15-0207670		
<b>Date Assigned:</b>	10/26/2015	<b>Date of Injury:</b>	01/02/2015
<b>Decision Date:</b>	12/14/2015	<b>UR Denial Date:</b>	09/30/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/21/2015

### 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: Massachusetts

Certification(s)/Specialty: Anesthesiology, Pain Management

### 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 is a 56 year old male with a date of injury of January 2, 2015. A review of the medical records indicates that the injured worker is undergoing treatment for right ankle sprain and right closed cuboid fracture. Medical records dated August 25, 2015 indicate that the injured worker complained of right ankle pain. Records also indicate that the injured worker could tolerate thirty minutes of standing and one hour of walking on even ground. A progress note dated September 23, 2015 documented that the injured worker reported feeling improved. Per the treating physician (September 23, 2015), the employee had work restrictions that included no running, no jumping, no climbing ladders, no prolonged standing or walking, no walking on uneven ground, and no going up or down ramps or stairs. The physical exam dated August 25, 2015 reveals a normal gait for short distances, decreased range of motion of the right ankle, and tenderness over the cuboid and lateral ankle region. The progress note dated September 23, 2015 documented a physical examination that showed a mildly antalgic gait that was improved from the previous visit, decreased range of motion of the right ankle that was improved from the last visit, and discomfort at end range of right ankle inversion. Treatment has included medications (Flector patches since August of 2015) and transcutaneous electrical nerve stimulator unit. The utilization review (September 30, 2015) non-certified a request for Flector patches #6.

### IMR ISSUES, DECISIONS AND RATIONALES

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

## **Retro Flector Patches #6: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Chronic, Flector.

**Decision rationale:** According to the official disability guidelines, Flector patch is not recommended as a first-line treatment. See the Diclofenac listing, where 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) On 12/07/09 the FDA issued warnings about the potential for elevation in liver function tests during treatment with all products containing diclofenac. Postmarketing surveillance has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure. Physicians should measure transaminases periodically in injured workers receiving long-term therapy with diclofenac. (FDA, 2009) 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. See also Topical analgesics, Non-steroidal antiinflammatory agents (NSAIDs), and the diclofenac topical listing. [Flector ranked #17 in amount billed for WC in 2011. (Coventry, 2012)] According to the documents available for review, the injured worker has none of the aforementioned MTUS approved indications for the use of this medication. Therefore, at this time, the requirements for treatment have not been met and medical necessity has not been established. The request is not medically necessary.