

<b>Case Number:</b>	CM15-0084854		
<b>Date Assigned:</b>	05/07/2015	<b>Date of Injury:</b>	05/16/2014
<b>Decision Date:</b>	06/12/2015	<b>UR Denial Date:</b>	04/22/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/04/2015

### 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: 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:

The injured worker is a 53-year-old male with an industrial injury dated 5/16/2014. The injured worker's diagnoses include neck pain, shoulder pain and thoracic pain. Treatment consisted of diagnostic studies, Magnetic Resonance Imaging (MRI) scan of the shoulder, prescribed medications, steroid joint injection to the shoulder, 6 sessions of acupuncture, 10 sessions of physical therapy, home exercise therapy and periodic follow up visits. In a progress note dated 4/02/2015, the injured worker chief complaints include pain in his neck, upper back, mid-back, right shoulder, right arm, right elbow, right wrist and right hand. The injured worker rated pain 3/10 with medications and a 5/10 without medications. Cervical spine exam revealed hypertonicity, spasm, tenderness, tight muscle band and trigger points. Thoracic spine revealed right side spasm. Shoulder exam revealed tenderness, restricted range of motion due to pain, and positive Hawkin's test. The treating physician reported ongoing pain at the right shoulder, which had failed physical therapy and previous steroid injection. The treating physician prescribed services for Norco 10/325 mg #90 and Flector 1.3% #30 patches now under review.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flector 1.3% #30 patches:** Upheld

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

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

**Decision rationale:** ODG, Pain, Chronic, Flector Patch: 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. Post marketing 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 anti-inflammatory 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.