

<b>Case Number:</b>	CM15-0055078		
<b>Date Assigned:</b>	03/30/2015	<b>Date of Injury:</b>	03/01/2012
<b>Decision Date:</b>	05/06/2015	<b>UR Denial Date:</b>	03/05/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/23/2015

### 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: Texas, California  
 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:

This is a 42-year-old female patient, who sustained an industrial injury on 3/1/12. The diagnoses include pain in joint and spasm muscle. She sustained the injury while moving shrink wrapped material. Per the doctor's note dated 2/9/15, she had complaints of increased pain since last visit with poor sleep. The physical examination revealed left shoulder- tenderness, decreased range of motion, positive Hawkin, Neer and Speed test; left elbow, full range of motion, tenderness over the lateral epicondyle. Per the PR-2 dated 1/9/15, she had complains of pain over the lumbar spine area, left shoulder and left elbow. She rates her pain a 5/10 on medications and an 8/10 without medications. Physical examination revealed trigger point pain with radiating pain and twitch response on palpation of bilateral trapezius muscles, some limited range of motion in left shoulder, tenderness to palpation of left shoulder joint and tenderness to palpation of left lateral epicondyle. The medications list includes vicodin; butrans patch; flector patch; lidoderm patch; nortriptyline and lexapro. She has had Magnetic Resonance Imaging (MRI) of the left shoulder on 1/25/13 and Magnetic Resonance Imaging (MRI) of the left elbow on 2/26/2013. She has had physical therapy, acupuncture and massage therapy for this injury. She has had urine drug screen on 7/2/2014.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flector Patch (Diclofenac Epolamine patch) 1.3%, #30: 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).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter: Pain (updated 04/06/15) Flector patch (diclofenac epolamine).

**Decision rationale:** Request: Flector Patch (Diclofenac Epolamine patch) 1.3%, #30 Flector patch contains diclofenac. The MTUS Chronic Pain Guidelines regarding topical analgesics state, "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." Failure of antidepressants and anticonvulsants for this injury is not specified in the records provided. Any intolerance or contraindication to oral medications is not specified in the records provided. In addition, according to the ODG guidelines, flector patch is "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) 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." The medical necessity of Flector Patch (Diclofenac Epolamine patch) 1.3%, #30 is not fully established for this patient at this juncture.