

<b>Case Number:</b>	CM15-0028617		
<b>Date Assigned:</b>	02/20/2015	<b>Date of Injury:</b>	11/12/2013
<b>Decision Date:</b>	04/07/2015	<b>UR Denial Date:</b>	02/09/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/17/2015

### 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: California

Certification(s)/Specialty: Internal Medicine

### 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 who sustained an industrial injury on 11/12/13. The injured worker reported symptoms in the back. The diagnoses included lumbar pain, lumbago-low back pain, low back syndrome; lumbalgia, thoracic or lumbosacral neuritis or radiculitis unspecified. Treatments to date include topical ointments, oral pain medications, activity modification, and oral analgesics. In a progress note dated 1/14/15 the treating provider reports the injured worker was with "5/10 dull, sharp low back pain radiating to right leg with numbness, tingling and weakness." On 2/6/15 Utilization Review non-certified the request for Flector patch 1.3% (apply 1 patch to affected area every 12 hours) quantity of 60 for 30 days. The Official Disability Guide was cited.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flector patch 1.3% (apply 1 patch to affected area every 12 hours) #60 for 30 days, UR DOS 2-2-15: 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 (diclofenac epolamine), NSAIDs.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page 111-113. NSAIDs (non-steroidal anti-inflammatory drugs) Page 67-73. Decision based on Non-MTUS Citation FDA Prescribing Information Flector Patch <http://www.drugs.com/pro/flector.html>.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. The efficacy in clinical trials of topical NSAIDs has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be either not superior to placebo after two weeks, or with a diminishing effect after two weeks. For osteoarthritis of the knee, topical NSAID effect appeared to diminish over time. There are no long-term studies of their effectiveness or safety for chronic musculoskeletal pain. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Topical NSAIDs are not recommended for neuropathic pain as there is no evidence to support use. All non-steroidal anti-inflammatory drugs (NSAIDs) have the U.S. Boxed Warning for associated risk of adverse cardiovascular events, including myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment (FDA Medication Guide). It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time. Per FDA guidelines, Flector Patch is indicated for the topical treatment of acute pain. Medical records document that the occupational injuries are chronic. Medical records document the long-term use of NSAIDs. Per MTUS, it is generally recommended that the lowest dose be used for NSAIDs for the shortest duration of time. Long-term NSAID use is not recommended by MTUS. The use of the topical NSAID Flector is not supported by MTUS guidelines. Therefore, the request for Flector patch is not medically necessary.