

<b>Case Number:</b>	CM15-0035280		
<b>Date Assigned:</b>	03/03/2015	<b>Date of Injury:</b>	08/25/2000
<b>Decision Date:</b>	04/08/2015	<b>UR Denial Date:</b>	02/02/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/25/2015

### 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: Physical Medicine & Rehabilitation

### 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 51-year-old female, who sustained a work related injury on 8/25/00. She was carrying merchandise through a store and sustained injuries to low back, right leg and hip. The diagnoses have included depression, thoracolumbar scoliosis, kyphotic deformity, failed back surgery, sacroiliac arthropathy, and myelopathy lumbar region. Treatments to date have included MRI lumbar spine dated 6/26/13, medications including Flector patches, physical therapy, acupuncture, epidural injections trigger point injections given in 4/2014 and 8/2014, TENS unit therapy and lumbar spine surgery on 2001. In the PR-2 dated 1/21/15, the injured worker complains of headaches, right shoulder pain, right arm pain, lower back pain and pain that radiates down right leg. She rates overall pain a 5/10 on medications and a 7-8 without medications. She is having difficulty performing activities of daily living. She has tenderness to palpation of lumbar area musculature with spasm. The scoliosis is noted as she bends way over to the left. The request is for a renewal of a prescription for Flector patches. On 2/2/15, Utilization Review non-certified a request for Flector 1.3% patch, #30. The California MTUS, Chronic Pain Treatment Guidelines and ODG were cited.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flector 1.3% patch:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111 - 113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs), page(s) 22.

**Decision rationale:** Per Guidelines, The efficacy in clinical trials for this treatment modality has been inconsistent and no long-term studies have shown their effectiveness or safety. Flector patch (Diclofenac) is recommended for osteoarthritis after failure of an oral NSAID or contraindications to oral NSAIDs after consideration of increase risk profile of severe hepatic reactions including liver necrosis, jaundice, fulminant hepatitis, and liver failure (FDA, 2009), but has not been demonstrated here. The efficacy in clinical trials for topical NSAIDs has been inconsistent and most studies are small and short duration. Topical NSAIDs are not supported beyond trial of 2 weeks as effectiveness is diminished similar to placebo effect. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety beyond 2 weeks especially for this chronic injury. There is no documented functional benefit from treatment already rendered. The Flector 1.3% patch is not medically necessary and appropriate.