

Case Number:	CM15-0162718		
Date Assigned:	08/31/2015	Date of Injury:	11/15/1996
Decision Date:	10/13/2015	UR Denial Date:	08/04/2015
Priority:	Standard	Application Received:	08/19/2015

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 66 year old female patient, who sustained an industrial injury on 11-15-1996. The diagnoses include disc derangement of the lumbar spine with radiculopathy. According to the progress report dated 7-27-2015, she had complains of worsening and severe low back pain with radiation down her lower extremity associated with numbness. The physical examination of the lumbar spine revealed antalgic gait, localized tenderness of the right L4-5 paraspinal level, tenderness over the right sciatic notch and sacroiliac joint, positive sciatic stretch test, increased pain with trendelenburg and bending laterally at 20 degrees on the right, positive straight leg raise at 30 degrees, and decreased sensation to the L4-5 nerve root distribution of the right lower extremity. The current medications are Ultram, flector patch and Motrin. There is documentation of ongoing treatment with Flector patch since at least 4-27-2015. Treatment to date has included medication management, x-rays, heat, ice, stretches, MRI studies, TENS unit, and epidural steroid injections. Work status is described as full duty with no limitations or restrictions. A request for Flector patch has been submitted.

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 Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter: Pain (updated 10/05/15) Flector patch (diclofenac epolamine).

Decision rationale: Flector 1.3% patch: 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 antidepressant for this injury is not specified in the records provided. Any intolerance or contraindication to oral medications (other than NSAIDs) 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 1.3% patch is not fully established for this patient at this juncture.