

Case Number:	CM14-0192947		
Date Assigned:	11/26/2014	Date of Injury:	09/24/1997
Decision Date:	01/13/2015	UR Denial Date:	11/06/2014
Priority:	Standard	Application Received:	11/18/2014

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. The expert reviewer is Board Certified in Family Medicine and is licensed to practice in Ohio. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 case involves a 65 year old male who sustained an industrial related injury on 9/24/97. The treating physician's report dated 5/14/14, noted the injured worker had complaints of constant severe low back pain. The physician noted a Flector patch decreased pain, decreased muscle spasms, increased function, and allowed the injured worker to walk more frequently. Diagnoses included low back pain, left elbow epicondylitis, carpal tunnel syndrome and lumbar stenosis. A physician's report dated 10/30/14, noted there was no change in the injured worker's pain level. The physician noted low back pain with right greater than left posterior lower extremity pain. Pain in the foot in the L5-S1 distribution with worsening symptoms of numbness and tingling in the bilateral buttocks and lower extremities was also noted. Diffuse myofascial tenderness and pain was noted on movement of the lower extremities and a straight leg raise was positive bilaterally reproducing pain in the L5-S1 distribution. The physician noted that examination suggests myofascial pain, facet joint pain, sacroiliac joint pain, lower extremity radicular pain, and possible radiculopathy. An electromyogram study done on 7/24/12 was noted to be normal. Moderate to severe left and moderate right L4-5 neural foraminal stenosis was noted. The injured worker has been using Naprelan, Cymbalta, Opana, and Lyrica. Flector patches have been prescribed for the elbow and back pain. On 11/6/14 the utilization review (UR) physician denied the request for Flector patch #60. The UR physician referenced the Official Disability Guidelines that state Flector patches are not recommended as a first line treatment.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flector Patch # 60, one every 12 hrs: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic), Flector [®] Patch (Diclofenac Epolamine)

Decision rationale: Flector patch is FDA indicated for acute strains, sprains, and contusions. 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. 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 patients receiving long-term therapy with diclofenac. In this instance, the Flector patch has been prescribed for at least 6 months continuously. The cited guidelines do not support the use of Flector patches beyond 2 weeks because of safety concerns regarding possible liver damage. In addition, the submitted record does not contain a liver panel drawn within the last 6 months. Therefore, this request is not medically necessary. In this instance, the Flector patch has been prescribed for at least 6 months continuously. The cited guidelines do not support the use of Flector patches beyond 2 weeks because of safety concerns regarding possible liver damage. The submitted record does not contain a liver panel drawn within the last 6 months. Therefore, Flector Patch # 60, one every 12 hours is not medically appropriate or necessary.