

Case Number:	CM14-0074713		
Date Assigned:	07/16/2014	Date of Injury:	03/23/2010
Decision Date:	12/08/2014	UR Denial Date:	04/29/2014
Priority:	Standard	Application Received:	05/22/2014

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 Occupational Medicine and is licensed to practice in California. 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:

104 pages provided for this review. The application for independent medical review was signed on May 22, 2014. It was for a prescription of Flector 1.3% number 60 and also Dendracin cream 120 ml, both of which were non certified. There was a utilization review from April 29, 2014. Per the records provided, the patient was described as a 51-year-old man injured in 2010, now four years ago. . He is status post an April 25, 2013 transforaminal posterior lumbar interbody fusion L4-L5 with laminectomy at L3-L4, and chronic ongoing spine and lower extremity complaints. There is documentation of increasing low back and left lower extremity pain at nine out of 10 and paresthesias and increasing gastrointestinal complaints reportedly secondary to oral medicines. There is notation of radiating dysesthesias in the left lower extremity in the L5 distribution, tenderness to palpation in the left distal lumbar paraspinal musculature with well-maintained strength and some mild weakness of the left tibialis anterior. There was prior surgical intervention and there has been the use of medicines to include proton pump inhibitors, opiates, anti-epileptics and various custom compounded medicines as well as multiple sessions of physical therapy and acupuncture.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flector patches 1.3%, # 60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Non-steroidal antiinflammatory agents (NSAIDS) 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 section, under Flector Patches

Decision rationale: The current California web-based MTUS collection was reviewed in addressing this request. The guidelines are silent in regards to this request. Therefore, in accordance with state regulation, other evidence-based or mainstream peer-reviewed guidelines will be examined. Regarding Flector patches, the ODG notes in the pain section: Not recommended as a first-line treatment. It is not clear what other agents had been exhausted before moving to this patch. Further, the Flector patch is FDA indicated for acute strains, sprains, and contusions. (FDA, 2007), not for chronic issues. The significant side effects noted in the 12/07/09 the FDA warnings, are not addressed. It is not clear this risk has been addressed in this case with measurements of transaminases periodically in patients receiving long-term therapy with diclofenac. Also, the benefit of topical NSAIDS is good for about two weeks, and studies are silent on longer term usage, therefore a long term usage as in this case is not supported. There simply is no data that substantiate Flector efficacy beyond two weeks. This request was appropriately not medically necessary.

Dendracin cream 120ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111 OF 127.

Decision rationale: Dendracin is a compounded topical analgesic which contains Methyl Salicylate 30 percent, Capsaicin 0.0375 percent, Menthol USP 10 percent and other proprietary ingredients. Per the Chronic Pain Medical Treatment Guidelines, page 111 of 127, the MTUS notes topical analgesic compounds are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Experimental treatments should not be used for claimant medical care. MTUS notes they are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed, but in this case, it is not clear what primary medicines had been tried and failed. Also, there is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended, is not certifiable. This compounded medicine contains several medicines untested in the peer review literature for effectiveness of use topically. Moreover, the MTUS notes that the use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. The provider did not describe each of the agents, and how they would be useful in this claimant's case for specific goals. Further, each of these agents making up Dendracin are available in over the counter preparations; special prescription formulations are unnecessary. This request was appropriately not medically necessary.

