

Case Number:	CM14-0024670		
Date Assigned:	06/11/2014	Date of Injury:	01/23/2008
Decision Date:	08/12/2014	UR Denial Date:	02/07/2014
Priority:	Standard	Application Received:	02/26/2014

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 Physical Medicine & Rehabilitation, has a subspecialty in Pain Medicine and is licensed to practice in Texas and Oklahoma. 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:

The injured worker is a 49-year-old female who reported an injury of continuous trauma on 01/23/2008. On 02/25/2014, her complaints included constant low back pain which radiated into the posterior aspect of her thighs. She had pain in both sacroiliac joints. She rated her pain at a constant 3/10. She describes her pain as achy and occasionally stabbing at the midline into the sacrum area bilaterally. There was no numbness, weakness or tingling of the lower extremities. She stated that she was frequently awakened during the night with low back pain. She stated she could sit for 30 minutes, stand for 10 minutes and walk for 20 minutes. Her medications included Opana 5 mg, Lorzone 750 mg, Flector patches and Voltaren gel. She was also participating in a home exercise program. She reported that radiofrequency ablations had helped her so much that she was managing her low back pain and did not require extensive medications. She had undergone multiple radiofrequency ablations at various levels on her spine and was so satisfied with the pain relief she has received from those treatments that they were performed every 6 months. The plan was to continue conservative treatment which included facet blocks, radiofrequency ablations and her medications. On 04/18/2014, her medications included Flector 1.3% patch, Lorzone 750 mg, Norco 10/325 mg, Lidoderm 5% patch, Viibryd 10 mg and Xanax XR 0.5 mg. Urine drug screens were consistent with her taking opioids as prescribed. Her diagnoses included sacroilitis, sacroiliac pain, lumbar facet syndrome and low back pain. She reported a greater than 50% degree of pain relief with use of a TENS unit. On 05/16/2014, it was noted that her lumbar range of motion was restricted due to pain. Paravertebral muscles were tender and in spasm on palpation and there was pain in the tailbone. Lumbar facet loading was positive on right side and straight leg raising test was negative bilaterally. There was mild pain to the SI joint with Faber's test. At that time her Norco was discontinued and she was

started on Percocet 10/325 mg. The plan was to continue her Lorzone because she had failed trials of Robaxin and Zanaflex. The plan also included continuing with the Flector patch which gave her adequate pain relief. She alternated the Flector patches and the Lidoderm patches every other day at bedtime. A Request for Authorization dated 05/28/2014 was included with the documents.

IMR ISSUES, DECISIONS AND RATIONALES

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

LORZONE 750 MG #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 63.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 63-64.

Decision rationale: The California MTUS recommends non-sedating muscle relaxants with caution as a second line option for short term treatment of acute exacerbations in patients with chronic lower back pain. Muscle relaxants may be effective in reducing pain and muscle tension and increasing mobility. However, in most low back pain cases they show no benefit beyond NSAIDs in pain and overall improvement. Also, there is no additional benefit shown in the combination with NSAIDs. Efficacy appeared to be diminish overtime, and prolonged use of some medications in this class may led to dependence. Drugs with the most limited published evidence in terms of clinical effectiveness include chlorzoxazone, which is the generic formula for Lorzone. Chlorzoxazone works primarily in the spinal cord and the subcortical areas of the brain. The mechanism of action is unknown but the effect is thought to be due to general depression of the central nervous system. Advantages over other muscle relaxants include reduced sedation and less evidence for abuse. In this case, the claimant is using Lorzone for chronic low back pain and there was no indication of a recent exacerbation of that pain. Additionally, the request did not contain frequency of administration. Therefore, the request for Lorzone 750 mg #90 is not medically necessary and appropriate.

FLECTOR PATCH 1.3% #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Flector Patch (diclofenac epolamine).

Decision rationale: The California MTUS Guidelines refer topical analgesics as largely experimental with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include lack of

systemic side effects, absence of drug interactions and no need to titrate. Any compounded product that contains at least 1 drug or drug class that is not recommended, is not recommended. Regarding topical nonsteroidal anti-inflammatory agents, the efficacy and clinical trials for this treatment modality have been inconsistent and most of the studies are small and of short duration. Topical NSAIDS have been shown in meta-analysis 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. They are recommended for short term use (4 to 12 weeks). There is little evidence to use topical NSAIDS for treatment of osteoarthritis of the spine, hip or shoulder. They are not recommended for neuropathic pain as there is no evidence to support their use. The FDA has approved diclofenac but in the form of 1% Voltaren gel for the relief of osteoarthritis pain in joints that lend themselves to topical treatment such as the ankle, elbow, foot, hand, knee, and wrist. It has not been evaluated for treatment of the spine, hip or shoulder. In the Official Disability Guidelines, the Flector patch is not recommended as a first line treatment. Flector patch is FDA approved and indicated for acute strains, sprains and contusions. The FDA has issues warnings about the potential for elevation in liver function tests during treatment with all products containing diclofenac. Post-marketing surveillance has recorded cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure. Physicians should measure transaminase periodically in injured workers receiving long term therapy with diclofenac. There was no data that substantiated the use of Flector patches and its efficacy beyond 2 weeks. In this case, there were no records of any physician's monitoring this worker's liver function. Additionally, the request did not contain directions for frequency of administration. Therefore, the request for Flector patch 1.3% #30 is not medically necessary and appropriate.