MAXIMUS Federal Services

Case Number:	CM14-0116692		
Date Assigned:	08/04/2014	Date of Injury:	10/22/2011
Decision Date:	09/12/2014	UR Denial Date:	07/16/2014
Priority:	Standard	Application Received:	07/22/2014

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 Physical Medicine and Rehabilitation, 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 26-year-old female who reported an injury on 10/22/2011. The mechanism of injury was not provided. Prior treatment included physical therapy and acupuncture. The injured worker was noted to have undergone an MRI of the bilateral hips and the lumbar spine. The medications included Naproxen and cyclobenzaprine. The documentation of 04/23/2014 revealed the injured worker had complaints of constant low back pain that was moderate and occasionally severe. The injured worker indicated the pain radiated to the bilateral hips with associated numbness and tingling. The physical examination revealed the injured worker had tenderness to palpation with spasms of the paraspinals and bilateral sacroiliac. The injured worker had limited range of motion secondary to pain and a positive sitting root test. The sensory dermatomes were noted to be intact. The diagnoses included lumbar spine sprain and strain with myospasms and lumbar spine disc desiccation. The treatment plan included transdermal compounds. The documentation indicated the injured worker had a urine sample that was collected and sent to the laboratory.

IMR ISSUES, DECISIONS AND RATIONALES

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

Lidocaine 5%, Gabapentin 10%, Tramadol 15% Penderm Base 240gm DOS 2/28/14: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol Topical Salicylates, Topical Analgesics, Gabapentin Lidocaine Page(s): 82, 105, 111, 113, 112. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence:FDA.gov.

Decision rationale: The California MTUS guidelines indicate that "topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety... are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." In addition, the MTUS states, "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended, Topical Salicylates are recommended," A thorough search of FDA.gov, did not indicate there was a formulation of topical Tramadol that had been FDA approved. The approved form of Tramadol is for oral consumption, which is not recommended as a first line therapy. Gabapentin is not recommended and there is no peer- reviewed literature to support use. The guidelines indicate that "topical Lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). No other commercially approved topical formulations of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain." The clinical documentation submitted for review failed to indicate the injured worker had a trial of antidepressants and anticonvulsants that had failed. There was a lack of documentation of exceptional factors to warrant no adherence to guideline recommendations. Additionally, the request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Lidocaine 5%, gabapentin 10%, tramadol 15% Penderm Base 240 grams DOS 2/28/14 is not medically necessary.

Flurbiprofen 25%, Cyclobenzaprine 2% 240gm DOS 2/28/14: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Flurbiprofen, Topical analgesics, Cyclobenzaprine Page(s): 72, 111, 41.

Decision rationale: This agent is not currently FDA approved for a topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine database demonstrated "no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration." The guidelines do not recommend the topical use of Cyclobenzaprine as a topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. The addition of cyclobenzaprine to other agents is

not recommended. The clinical documentation submitted for review failed to indicate the injured worker had a trial of antidepressants and anticonvulsants that had failed. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations and there was a lack of documented rationale. Additionally, the request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Flurbiprofen 25%, Cyclobenzaprine 2% 240 grams DOS 2/28/14 is not medically necessary.