

Case Number:	CM13-0057336		
Date Assigned:	12/30/2013	Date of Injury:	11/20/2012
Decision Date:	04/03/2014	UR Denial Date:	11/15/2013
Priority:	Standard	Application Received:	11/25/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Anesthesiology and Pain Management and is licensed to practice in Florida. 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 physician 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 patient is a 51 year old female who reported injury on 11/20/2012. The mechanism of injury was noted to be that the patient was lifting a heavy object when she injured her back and neck. The patient was treated with physical therapy and oral medications. The medications were noted to be Norco, Zanaflex and Relafen. The patient's diagnosis was a sprain in the lumbar region. The office notes submitted with the request was handwritten and difficult to read. The pharmacy request was for 2 compounded medications.

IMR ISSUES, DECISIONS AND RATIONALES

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

Topical Compound (capsaicin 0.025%, flurbiprofen 15%, tramadol 15%, menthol 2%, camphor 2%) 240 gm with 1 refill: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Flurbiprofen, Topical analgesics, Topical Capsaicin, Topical Salicylates, Tramadol Page(s): 7.

Decision rationale: California MTUS indicates topical analgesics are 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....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. Flurbiprofen is classified as a non-steroidal anti-inflammatory agent. 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 - National Institute of Health (NLM-NIH) database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration... Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments.... California MTUS guidelines recommend Topical Salicylates. Methyl Salicylate 2% and camphor 2% are two of the ingredients of this compound. 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. The clinical documentation failed to indicate the duration the patient had been on the medication or if this was a new prescription. There was a lack of documentation indicating a necessity for two topical preparations with both Flurbiprofen and Tramadol. There was a lack of documentation indicating the necessity for a refill without re-evaluation and documentation that the patient had trialed and failed antidepressants and anticonvulsants or was intolerant to other treatments. As the topical Flurbiprofen is not supported by the FDA or treatment guidelines and topical Tramadol is not supported by the FDA the request for topical compound (capsaicin 0.025%, flurbiprofen 15%, tramadol 15%, menthol 2%, camphor 2%) 240gm with 1 refill is not medically necessary.

Topical Compound (flurbiprofen 25%, Tramadol 15%) 240gm with 1 refill: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Flurbiprofen, Topical analgesics, Tramadol Page(s): 72, 111, 82.

Decision rationale: California MTUS indicates topical analgesics are 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. 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. Flurbiprofen is classified as a non-steroidal anti-inflammatory agent. 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 - National Institute of Health (NLM-NIH) database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration. 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. The clinical documentation failed to indicate the duration the patient had been on the medication or if this was a new prescription. There was a lack of documentation indicating a necessity for two topical preparations with both Flurbiprofen and Tramadol. There was a lack of documentation

indicating the necessity for a refill without re-evaluation and documentation that the patient had trialed and failed antidepressants and anticonvulsants or was intolerant to other treatments. As the topical Flurbiprofen is not supported by the FDA or treatment guidelines and topical Tramadol is not supported by the FDA the request for topical compound (flurbiprofen 25%, tramadol 15%) 240gm with 1 refill is not medically necessary.