

Case Number:	CM13-0065063		
Date Assigned:	01/03/2014	Date of Injury:	10/04/2001
Decision Date:	05/16/2014	UR Denial Date:	11/13/2013
Priority:	Standard	Application Received:	12/12/2013

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, has a subspecialty in Sports Medicine, and is licensed to practice in Texas. 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 64-year-old female who reported an injury on 10/4/01. The injured worker's medication history included Tramadol, topical Flurbiprofen, capsaicin, lidocaine, topical Tramadol, capsaicin, and Dextromethorphan as of May 2013. Omeprazole, NSAIDs, and Cyclobenzaprine were added as of August 2013. The documentation of 10/8/13 revealed that the injured worker had dull to sharp pain in the back radiating to the left lower extremity, and dull to sharp pain in the bilateral knees with swelling and burning sensations. The diagnoses included tear of the medial meniscus, status post-op scope as of 6/11/07, and myoligamentous strain of the lumbar spine as of 10/4/01 with aggravation on 2/5/05, 1/14/08, and February of 2010. The injured worker had a myoligamentous strain of the lumbar spine in February 2010. The treatment recommendations included Omeprazole, naproxen, Cyclobenzaprine, Tramadol, and Flurbiprofen, lidocaine, menthol, camphor, and capsaicin cream, as well as Tramadol, Dextromethorphan, and capsaicin cream.

IMR ISSUES, DECISIONS AND RATIONALES

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

30 OMEPRAZOLE 20MG: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 69.

Decision rationale: The California MTUS guidelines recommend proton pump inhibitors (PPIs) for the treatment of dyspepsia secondary to NSAID therapy. The clinical documentation submitted for review indicated that the injured worker had been utilizing the medication for more than two months. There was lack of documented efficacy for the requested medication. The request as submitted failed to indicate the frequency for the requested medication. The request was submitted for concurrent review with an oral NSAID, which was found to be medically unnecessary. Given the above, the request for Omeprazole is not medically necessary.

30 NAPROXEN 550MG: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 66 ,73.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 67.

Decision rationale: The California MTUS guidelines recommend NSAIDs for the treatment of chronic pain for short-term symptomatic relief. There should be documentation of objective functional improvement and an objective decrease in pain. The clinical documentation submitted for review indicated that the injured worker had been utilizing the medication for greater than two months. There was a lack of documented objective functional benefit as well as a decrease in pain. The request was submitted concurrently with the request for a topical NSAID. There was a lack of documentation indicating the necessity for both an oral and topical NSAID. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Naproxen is not medically necessary.

30 CYCLOBENZAPRINE 7.5MG: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 41,64.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 63.

Decision rationale: The California MTUS Guidelines recommend muscle relaxants as a second line option for the short-term treatment of acute low back pain. Their use is recommended for less than three weeks. There should be documentation of objective functional improvement. The clinical documentation submitted for review indicated the injured worker had been utilizing the medication for two months. There was a lack of documented functional benefit. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Cyclobenzaprine is not medically necessary.

30 TRAMADOL 325MG: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78, 93-94.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 60, 78.

Decision rationale: The California MTUS guidelines recommend opioids for the treatment of chronic pain. There should be documentation of an objective improvement in function, an objective decrease in pain, and evidence that the patient is being monitored for aberrant drug behavior and side effects. The clinical documentation submitted for review indicated that the injured worker had been utilizing the medication for five months. There was a lack of documentation of an objective improvement in function, objective decrease in pain, and evidence the injured worker was being monitored for aberrant drug behavior and side effects. There was a lack of documentation indicating the necessity for both a topical and oral form of Tramadol. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Tramadol is not medically necessary.

COMPOUNDED CREAM (FLURBIPROFEN 20%/LIDOCAINE 5%/ MENTHOL 5%/ CAMPHOR/ CAPSAICIN .025%) 10MG: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 28, 72, 105, 111-112. Decision based on Non-MTUS Citation National Library of Medicine - National Institute of Health.

Decision rationale: The California MTUS indicates that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. They also state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first two weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another two 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 is recommended only as an option in patients who have not responded or are intolerant to other treatments. Lidocaine is only approved topically in the form of Lidoderm patches. The California MTUS guidelines recommend topical salicylates. Menthol 5% and camphor are two of the ingredients of this compound. The clinical documentation submitted for review failed to provide documentation of a trial and failure of antidepressants and anticonvulsants. There was a lack of documentation indicating the necessity for two topicals with

capsaicin and the necessity for two forms of NSAID. The clinical documentation indicated that the injured worker had been utilizing the topical for five months. There was a lack of documentation of objective functional benefit received from the medication. The request as submitted failed to indicate a frequency for the requested medication. Given the above, the request for compounded cream (Flurbiprofen 20%/lidocaine 5%/ menthol 5%/ camphor/ capsaicin .025%) is not medically necessary.

COMPOUNDED LIPOBASE CREAM (TRAMADOL 15%/ DEXTROMETHORPHAN 10%/ CAPSAICIN .025%) 30GM: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 28, 82, 105, 111. Decision based on Non-MTUS Citation FDA.gov; and Drugs.com

Decision rationale: The California MTUS indicated that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. They also state that 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. Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation of capsaicin, but there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. Per Drugs.com, Dextromethorphan is used to treat a cough. The clinical documentation submitted for review indicated that the injured worker had been utilizing the medication for five months. There was a lack of documentation indicating a necessity for two topical creams with capsaicin, and two forms of Tramadol. This request was concurrently being reviewed with a request for an oral form of Tramadol. There was a lack of documentation indicating the necessity for Dextromethorphan, and the rationale for Dextromethorphan. There was a lack of documented objective functional benefit and a lack of documentation indicating that the injured worker had trialed and failed antidepressants and anticonvulsants. There was a lack of documentation indicating the injured worker had not responded or was intolerant to other treatments. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for compounded lipobase cream (Tramadol 15%/ Dextromethorphan 10%/ capsaicin .025%) is not medically necessary.