

Case Number:	CM13-0018233		
Date Assigned:	10/11/2013	Date of Injury:	11/19/2005
Decision Date:	01/30/2014	UR Denial Date:	08/16/2013
Priority:	Standard	Application Received:	08/29/2013

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 Physical Medicine & Rehabilitation 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 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 60-year-old female who reported an injury on 11/19/2005. The mechanism of injury was not stated. The patient was noted to have ongoing pain to the back and knees. The patient was noted to have lumbar spine tenderness, spasm, and tightness in the paralumbar musculature. The diagnoses were noted to include cervical disc bulge at C5-6 and C6-7, lumbar facet arthropathy, thoracic disc bulge, and insomnia. The treatment plan was noted to include 1 prescription of TGHOT 180 gm cream, 1 prescription of Fluriflex 180 gm cream, 1 prescription of Omeprazole 20 mg #100, and 1 prescription of Lunesta 3 mg #30.

IMR ISSUES, DECISIONS AND RATIONALES

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

Omeprazole 20 mg #100: 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 Page(s): 68.

Decision rationale: California MTUS guidelines recommend PPI treatment of dyspepsia secondary to NSAID use. The clinical documentation submitted for review failed to provide the patient had signs and symptoms of dyspepsia. Additionally, it failed to provide the efficacy of

the requested medication. Given the above, the request for 1 prescription of omeprazole 20 mg #100 is not medically necessary.

Lunesta 3 mg #30: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Insomnia Treatments

Decision rationale: California MTUS Guidelines do not address sedative-hypnotics. Per Official Disability Guidelines the use of medications such as Lunesta are for first line treatment of insomnia. The clinical documentation submitted for review indicated the patient had been taking Lunesta for insomnia; however, it failed to provide the efficacy of the requested medication. Given the above, the request for 1 prescription of Lunesta 3 mg #30 is not medically necessary.

Hydrocodone/APAP 10/325 mg #60: 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 Page(s): 78,91.

Decision rationale: California MTUS Guidelines recommend hydrocodone/acetaminophen for moderate to moderately severe pain and it indicates that for ongoing management, there should be documentation of the 4 A's including analgesia, activities of daily living, adverse side effects and aberrant drug taking behavior. The clinical documentation submitted for review failed to provide documentation of the ongoing management of the "4 A's." The patient was noted to have pain in the back and knees. The objective examination revealed that the patient had bilateral knee pain, tenderness in the lumbar spine along with spasms and tightness. Given the above and lack of exceptional factors to warrant non-adherence to guideline recommendations, the request for 1 prescription of hydrocodone/APAP 10/325 mg #60 is not medically necessary.

Fluriflex 180 gm cream: Upheld

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

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

Decision rationale: Fluriflex contains Flurbiprofen 15% Cyclobenzaprine 10% per the physician order. Flurbiprofen is classified as a non-steroidal anti-inflammatory agent. The CA

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." 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... California MTUS 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." Given the above, the request for 1 prescription of Fluriflex 180 gm cream is not medically necessary.

TGHot 180 gm cream: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 82, 105, 111, 112, 113.

Decision rationale: TGHot ingredients per MD order are Tramadol 8%, Gabapentin 10%, Menthol 2%, Camphor 2% and Capsaicin 0.05%.The California MTUS states, "Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety....Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended....Topical Salicylates are recommended...Tramadol is not recommended as a first line therapy...Gabapentin: Not recommended. There is no peer-reviewed literature to support use... Capsaicin: 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 and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. California MTUS guidelines recommend Topical Salicylates." Given the lack of documentation to support non-adherence to guideline recommendations, there is no medical necessity for this compound.