

Case Number:	CM14-0073984		
Date Assigned:	07/16/2014	Date of Injury:	10/10/2012
Decision Date:	03/24/2015	UR Denial Date:	04/22/2014
Priority:	Standard	Application Received:	05/21/2014

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California, Washington

Certification(s)/Specialty: Physical Medicine & Rehabilitation, Pain Management

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 62-year-old female who reported an injury on 10/10/2012. The mechanism of injury was the injured worker fell down a flight of stairs at work. The injured worker underwent an open reduction and internal fixation of an ankle fracture. Prior therapies included physical therapy. The most recent documentation was dated 04/02/2014 which revealed the injured worker had a right antalgic gait. Examination of the thoracolumbar spine revealed a normal posture. The injured worker had minimal patellar crepitus. The quadriceps angle was slightly elevated at 12 degrees. The leg length and circumference were equally bilaterally. The injured worker had positive McMurray's, Steinman's, Apley's compression, and Apley's distraction tests bilaterally. There was tenderness in the anterior aspect of the ankle. Range of motion was limited. The injured worker underwent x-rays of the right knee and tibia which revealed mild compartment narrowing. The injured worker underwent an x-ray of the right foot and ankle which revealed the injured worker was status post open reduction and internal fixation with plate and screw fixation. The injured worker underwent x-rays of the thoracolumbar spine which revealed mild degenerative disc disease at L4-5. The diagnoses included bimalleolar fracture of the right ankle, status post open reduction and internal fixation with painful synovitis and retained hardware, medial meniscus tear of the right knee, and possible disc herniation of the lumbar spine at L5-S1. The treatment plan included Dyotin 250 mg #60, Flurbetac 100/100 mg #60, Theraflex cream 120 gm, and Keratek gel 4 ounces. There was no Request for Authorization for the requested medications.

IMR ISSUES, DECISIONS AND RATIONALES

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

Dyotin 200MG, count 60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepileptic Drugs Page(s): 16.

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines recommend antiepilepsy medications as a first line medication for the treatment of neuropathic pain. There should be documentation of an objective decrease in pain of at least 30% to 50% and objective functional improvement. There was a lack of documentation of objective functional improvement and an objective decrease in pain and there was a lack of documentation indicating the injured worker had a neuropathic condition to support the use of the medication. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Dyotin 200 mg count 60 is not medically necessary.

Flurbetac 100/100MG, count 60: Upheld

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

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, Medical foods

Decision rationale: The Official Disability Guidelines indicate that medical foods are not recommended for chronic pain. The contents of the Flurbetac were not provided. As such, there could be no application of a specific guideline due to this fact. Additionally, the request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Flurbetac 100/100 mg count 60 is not medically necessary.

Theraflex Cream 120GM: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Flurbiprofen, Topical analgesics, Cyclobenzaprine, Tramadol Page(s): 72,111,41, 82.

Decision rationale: The California Medical Treatment Utilization Schedule indicates 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 anti-

depressants and anticonvulsants have failed. 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 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 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 and failure of anticonvulsants and antidepressants. There was a lack of documentation of exceptional factors to warrant nonadherence to guideline recommendations. As multiple components of the medication are not supported, this request would not be supported. The duration of use could not be established. The request as submitted failed to indicate the frequency for the requested medication and the body part to be treated. Given the above, the request for Theraflex cream 120 gm is not medically necessary.

Keratek Gell 4OZ bottle: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate Topicals, Topical Analgesic Page(s): 105, 111.

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines indicate that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The guidelines recommend treatment with topical salicylates. The clinical documentation submitted for review failed to indicate the injured worker had a trial and failure of anticonvulsants and antidepressants. There was a lack of documentation of exceptional factors to warrant nonadherence to guideline recommendations. The duration of use could not be established. The request as submitted failed to indicate the body part to be treated and the frequency. Given the above, the request for Keratek gel 4 ounce bottle is not medically necessary.