

Case Number:	CM14-0136473		
Date Assigned:	09/03/2014	Date of Injury:	02/21/2013
Decision Date:	10/31/2014	UR Denial Date:	08/07/2014
Priority:	Standard	Application Received:	08/25/2014

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, has a subspecialty in Pain Medicine 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 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 40-year-old female who reported an injury on 02/21/2013. The mechanism of injury was a slip and fall. Prior therapies included acupuncture, chiropractic, and physical modality therapy. The injured worker was utilizing topical compounds and transdermal medications, as well as tramadol and cyclobenzaprine as of early 2014. The injured worker underwent an MRI of the lumbar spine, cervical spine, left knee, right ankle, and left shoulder. The documentation of 06/28/2014 revealed the injured worker had shoulder pain, low back pain, knee pain, and ankle pain. The documentation indicated the injured worker had been taking cyclobenzaprine and tramadol in addition to topical creams. The physical examination revealed the injured worker had an abnormal gait and the heel toe walk was abnormal. The injured worker had mild scoliosis and paraspinous tenderness to palpation of the lumbar spine. The injured worker had decreased range of motion of the lumbar spine. The injured worker had tenderness to palpation of the right knee with mild swelling. Motor strength of the knee was 3/5. The injured worker had decreased range of motion in the right knee. The injured worker had a positive compression test, grind test, drawer test, Lachman's test, and McMurray's test. There is mild swelling of the right ankle and foot and tenderness to palpation. The injured worker had decreased range of motion in the right foot. Sensory examination was within normal limits. The diagnoses included cervical spine sprain and strain; cervical disc syndrome without myelopathy; right shoulder supraspinatus, infraspinatus, and subscapularis tendinitis with subacromial bursitis; carpal tunnel syndrome of the right wrist and hand; lumbar spine sprain and strain; lumbar herniated disc syndrome without myelopathy; lumbar radiculitis with radiculopathy to both lower extremities. The treatment plan included a continuation of the topical compounds and transdermal medications including a compound of flurbiprofen 20%, tramadol 20%, and cyclobenzaprine 4% in cream base 180 grams; compound amitriptyline 10%, dextromethorphan

10%, and gabapentin 10% in cream base 180 grams; Terocin 3 boxes. There was no Request for Authorization or rationale submitted for review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retro Compound Flurbiprofen 20% Tramadol 20%: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Flurbiprofen, Topical analgesics, Tramadol Page(s): 72, 111, 82. Decision based on Non-MTUS Citation 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.... 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. 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 submitted for review indicated the injured worker was using oral tramadol. There was a lack of documentation indicating necessary for both a topical and oral form of tramadol. There was a lack of documentation indicating the injured worker had difficulty with oral medications and would have a necessity for topical medications. The duration of use was since at least 03/2014. There was a lack of documented objective functional benefit and an objective decrease in pain. There was a lack of documentation of exceptional factors to warrant nonadherence to guideline recommendations. The request as submitted failed to indicate the frequency, quantity, and body part to be treated. Given the above, the request for retro compound flurbiprofen 20% and tramadol 20% is not medically necessary.

Retro Compound Amitriptyline 10% Dextromethorphan 10%: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Antidepressants, does not address topical dextromethorphan or topical antide.

Decision based on Non-MTUS Citation Skolnick P (1999) Antidepressants for the new millennium. Eur J Pharmacol 375:31-40. <http://www.drugs.com/dextromethorphan.html>

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... Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended...Peer reviewed literature states that while local peripheral administration of antidepressants has been demonstrated to produce analgesia in the formalin model of tonic pain; a number of actions, to include inhibition of noradrenaline (NA) and 5-HT reuptake, inhibition of NMDA, nicotinic, histamine, and 5-HT receptors, and block of ion channels and even combinations of these actions, may contribute to the local peripheral efficacy of antidepressant; therefore the contribution of these actions to analgesia by antidepressants, following either systemic or local administration, remains to be determined. Per Drugs.com, "Dextromethorphan is a cough suppressant. It affects the signals in the brain that trigger cough reflex." The clinical documentation submitted for review failed to provide documentation of exceptional factors to warrant nonadherence to guideline recommendations. There was a lack of documentation indicating the rationale for the use of the topical cream. There was a lack of documentation indicating the injured worker could not utilize oral medications. The request as submitted failed to indicate the frequency, body part, and quantity of medication being requested. Additionally, the duration of use was since at least 03/2014 and there was a lack of documentation of objective functional benefit. Given the above, the request for retro compound amitriptyline 10% and dextromethorphan 10% is not medically necessary.

Retro Terocin Patch X3 Boxes: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate Topicals, Topical Analgesic, Lidocaine Page(s): 105, 111, 112. Decision based on Non-MTUS Citation <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=100ceb76-8ebe-437b-a8de-37cc76ece9bb>

Decision rationale: The California MTUS 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 indicate that topical lidocaine (Lidoderm) 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 guidelines recommend treatment with topical salicylates. Per dailymed.nlm.nih.gov, Terocin patches are topical Lidocaine and Menthol. The clinical documentation submitted for review indicated the injured worker had utilized this medication for an extended duration of time. There was a lack of documentation of objective

functional benefit that was received. The request as submitted failed to indicate the body part to be treated and the frequency for the requested medication. Additionally, there was a lack of documentation indicating the date of retro service being requested. Given the above, the request for retro Terocin patches x3 boxes is not medically necessary.