MAXIMUS Federal Services

Case Number:	CM15-0005951		
Date Assigned:	01/20/2015	Date of Injury:	05/18/2013
Decision Date:	03/19/2015	UR Denial Date:	12/17/2014
Priority:	Standard	Application Received:	01/12/2015

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

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 46-year-old female with a reported date of injury on 06/09/2013; the mechanism of injury was not provided. The injured worker's diagnoses were documented as right wrist carpal tunnel syndrome with neuropathy, right elbow lateral epicondylitis, right shoulder supraspinatus and infraspinatus tendinitis, lumbar spine sprain/strain, and lumbar herniated disc syndrome without myelopathy. The previous treatments were noted to include physical therapy, chiropractic treatment, gabapentin, and naproxen. It was also noted the injured worker has been utilizing topical compounded creams since at least 09/06/2013. The most recent clinical note dated 11/21/2014 noted the injured worker had subjective complaints of pain to the right wrist, right elbow, right shoulder, and low back. The examination of the elbow was noted to demonstrate tenderness on palpation, as well as decreased range of motion. There was positive tennis elbow test and Phalen's sign. Examination of the right shoulder demonstrated reduced range of motion, as well as reduced range of motion. Examination of the wrist and hands demonstrated tenderness to the right wrist and pain and radial deviation. It was also noted there was decreased range of motion of the right wrist, as well as positive Tinel's test at the ulnar nerve and median nerve. Additionally, it was noted the Finkelstein's test, bracelet test, and Phalen's test were also positive at the right wrist. Examination of the lumbar spine demonstrated tenderness to paraspinal musculature and reduced range of motion. Under the treatment plan, it was noted that the injured worker was recommended to continue topical compounded creams and transdermal medications.

IMR ISSUES, DECISIONS AND RATIONALES

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

Terocin Patches #30 (Lidocaine 4%): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, and Lidocaine Indications.

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 Other Medical Treatment Guideline or Medical Evidence: http://dailymed.nlm.nih.gov/dailymed/lookup.cfmsetid=100ceb76-8ebe-437b-a8de-37cc76ece9bb.

Decision rationale: According to the Daily Med website reviewed, Terocin patches are topical patch made of lidocaine and methanol. The California MTUS Guidelines indicate that topical analgesics are largely experimental; however, may be recommended primarily for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The guidelines continue to state any compounded medication that contains at least 1 drug or drug class that is not recommended is not recommended, the entire product is not recommended. In addition, the guidelines continue to state that topical lidocaine in the form of Lidoderm may be recommended for localized peripheral pain after there has been evidence of a trial of first line therapy; however, there is no other commercially approved topical formulations of lidocaine recommended for use. Furthermore, the guidelines recommend treatment with topical salicylates. This requested medication cannot be supported. It was noted in the documentation that the injured worker has been taking this medication since 09/06/2013; however, there is no documentation provided demonstrating measured therapeutic effect of the medication. In addition, this medication contains a form of non-approved topical lidocaine and there is no evidence within the documentation that the injured worker had tried and failed first line therapy. Therefore, the request for Terocin patches #30 (lidocaine 4%) is not medically necessary.

Topical Compound Cream 180gm (Flurbiprofen 20%-Lidocaine 5-Amitriptilyne 5%): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, and Lidocaine Indication.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesic, Topical NSAIDS, Lidocaine Page(s): 111-112. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Skolnick P (1999) Antidepressants for the new millennium. Eur J Pharmacol 375:31?40.

Decision rationale: The California MTUS Guidelines indicate topical analgesics are largely experimental in use; however, they may be recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The guidelines continue to state that topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of

treatment for osteoarthritis. The guidelines continue to state that any compounded product that contains at least 1 drug or drug class that is not recommended, the entire product is not recommended. Flurbiprofen is not currently FDA approved for topical application. The FDA approved formulation for flurbiprofen includes oral tablets and ophthalmic solution. A search of the National Library of Medicine/National Institute of Health Database demonstrated no high quality human studies evaluating the safety and adequacy of this medication through dermal patches or topical administration. The guidelines also indicate that topical lidocaine (Lidoderm) may be recommended for localized peripheral pain if there has been evidence of a trial of first line therapy. However, there is no other commercially approved topical formulations of lidocaine currently recommended. In addition, per the referenced medical literature, it found that while local peripheral administration of antidepressants have been demonstrated to produce analgesic effects in formalin model of pain, the efficacy of the use of antidepressant in topical form remains to be determined. This requested medication cannot be supported for use. It was noted that the injured worker has been taking this compounded medication since 09/06/2013 yet there is no documentation provided that this topical compounded cream had provided the injured worker a measurable objective therapeutic benefit. In addition, the medication contains non-approved forms of medication and there is lack of evidence the injured worker had tried and failed first line treatment for neuropathic pain prior to consideration of the compounded medication. Therefore, the request for topical compound cream 180gm (flurbiprofen 20%-lidocaine 5-amitriptilyne 5%) is not medically necessary.

Gabacyclotram 180gm (Gabapentin 10%-Cyclobenzaprine 6%-Tramadol 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 Analgesic, Gabapentin, Tramadol. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: FDA.gov

Decision rationale: The California MTUS Guidelines indicate that topical analgesics are largely experimental; however, may be recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The guidelines also indicate that any compounded product that contains at least 1 drug or drug class that is not recommended, the entire product is not recommended. Additionally, the treatment guidelines go on to state that gabapentin in topical form is not currently recommend as there is no peer reviewed literature to support its use. Furthermore, a thorough search of FDA.gov did not indicate there is a formulation of topical tramadol that has been FDA approved. The currently approved formulation of tramadol is for oral consumption, which is not currently recommended as a first line therapy. This requested medication cannot be supported. It was noted the patient had been taking this medication since 09/06/2013; however, there is no documentation provided that it provided a measurable objective therapeutic benefit. In addition, the medication contains non-approved or supported topical forms of medication. Therefore, the request for Gabacyclotram 180gm (gabapentin 10%-cyclobenzaprine 6%-tramadol 10%) is not medically necessary.