MAXIMUS Federal Services

Case Number:	CM15-0008552		
Date Assigned:	01/27/2015	Date of Injury:	11/13/2013
Decision Date:	03/25/2015	UR Denial Date:	11/07/2014
Priority:	Standard	Application Received:	12/01/2014

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, 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 29 year old male, who sustained an industrial injury on 11/13/2013. The mechanism of injury was not provided. The diagnoses include cervical, thoracic and lumbar musculoligamentous strain/sprain and bilateral knee strain/sprain. Treatment to date has included acupuncture, chiropractic treatment, physical therapy, epidural steroid injections and pain medications. According to the doctor's first report of occupational injury or illness from 11/4/2014, the injured worker had complaints of neck pain, back pain, bilateral hip pain, bilateral knee pain, abdominal pain and weight loss. Objective findings revealed tenderness to palpation to the abdomen, cervical spine tenderness to palpation and spasm, thoracic spine tenderness to palpation and spasm and lumbar spine tenderness to palpation and spasm. Prescription was given for Fluriflex 180gm, TGHot 180gm and Terocin patches.

IMR ISSUES, DECISIONS AND RATIONALES

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

TG Hot 180gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Capsaicin, Gabapentin Page(s): 111,112, 113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol, Gabapentin, Topical Capsaicin, Topical Analgesics, Topical Salicylates Page(s): 28, 82. Decision based on Non-MTUS Citation FDA.gov

Decision rationale: The California MTUS guidelines indicates that topical analgesics are largely experimental in use, however, they been be recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The guidelines continue to state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. This topical medication is a combination of tramadol, gabapentin, menthol, camphor and capsaicin. Topical Salicylates are currently recommended by the treatment guidelines. After a thorough search of the FDA.gov website, there is no indication of an approved topical formulation of Tramadol. The currently approved form of Tramadol is for oral consumption, which is not recommended as a first line therapy. The treatment guidelines also state that topical formulation of gabapentin is not currently recommended as there is no peer-reviewed literature to support use it use. Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. This requested topical compounded medication includes non-recommended and non-approved formulations of medications. Additionally, there is no rationale regarding the use of this medication. Therefore, the request for TG Hot 180gm is not medically necessary.

Terocin patches (Menthol 4 percent/Lidocaine 4 percent), quantity: 30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111, 112. Decision based on Non-MTUS Citation DailyMed http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=100ceb76-8ebe-437b-a8de-37cc76ece9bb

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 www.dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=100ceb76-8ebe-437b-a8de-37cc76ece9bb

Decision rationale: Per dailymed.nlm.nih.gov, Terocin patches are topical Lidocaine and Menthol. The California MTUS guidelines indicates that topical analgesics are largely experimental in use, however, they been be recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The guidelines continue to state that 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 in the form of Lidoderm may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy; there is no other commercially approved topical formulations of lidocaine indicated for use. The guidelines recommend treatment with topical salicylates. Per dailymed.nlm.nih.gov, Terocin patches are topical Lidocaine and Menthol. This topical medication includes a non-commercially approved topical formulation of lidocaine. Additionally, there is no indication within the documentation that the injured worker had tried and failed trails of antidepressants and anticonvulsants. Furthermore, there is no rationale provided regarding the use of this medication.

Therefore, the request for Terocin patches (Menthol 4 percent/Lidocaine 4 percent), quantity: 30 in not medically necessary.

Fluriflex 180gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Non-Steroidal Antinflammatory Agents (NSAIDS).

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

Decision rationale: The California MTUS guidelines indicates that topical analgesics are largely experimental in use, however, they been be recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The guidelines continue to state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. This product is a combination drug that includes Flurbiprofen and cyclobenzaprine. According to the treatment guidelines topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis. Flurbiprofen 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. The guidelines also do not recommend the topical use of Cyclobenzaprine as a topical muscle relaxants as there is no evidence of its efficacy as a topical product and the addition of cyclobenzaprine to other agents is not recommended. This topical medication includes non-approved and non-supported formulation of medications. In addition, there is no rationale provided regarding the use of this medication. Therefore, the request for Fluriflex 180gm is not medically necessary.