

<b>Case Number:</b>	CM14-0061095		
<b>Date Assigned:</b>	07/09/2014	<b>Date of Injury:</b>	12/19/2003
<b>Decision Date:</b>	08/25/2014	<b>UR Denial Date:</b>	04/11/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/01/2014

### 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. The expert reviewer is Board Certified in Physical Medicine and Rehabilitation, has a subspecialty in Pain Management, and is licensed to practice in Oklahoma and Texas. 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 65-year-old who reported an injury on December 19, 2003. The mechanism of injury was noted to be a constant operation of machinery. The diagnoses included cervical disc herniation with myelopathy, lumbar spondylosis with myelopathy, thoracic spondylosis without myelopathy, a partial tear of the rotator cuff tendon of the left shoulder, carpal tunnel syndrome of the left hand, and lateral epicondylitis as well as tendinitis of the left hand and wrist. The documentation of 03/19/2014 revealed the injured worker had participated in conservative therapy. The injured worker had pain in the cervical spine, lumbar spine, left shoulder, left elbow, left wrist, and left hand. The physical examination revealed tenderness to the bilateral paraspinal muscles from C2-7, bilateral occipital muscles, and left shoulder muscles. There were +3 spasms. The injured worker had decreased range of motion in the cervical spine. The axial compression test and distraction test were positive bilaterally. The shoulder depression test was positive on the left. The bilateral triceps reflexes were decreased. The cervical dermatomes and myotomes were within normal limits bilaterally. The physical examination revealed +4 spasm and tenderness to the bilateral thoracic paraspinal muscles from T1 through T11. The physical examination of the lumbar spine revealed +4 spasms and tenderness to the bilateral lumbar paraspinal muscles from L1 through S1 and multifidus and decreased range of motion. The Kemp's testing was positive bilaterally. The straight leg raise test was positive on the right. The Yeoman's test was positive bilaterally and the Braggard's test was positive on the right. The bilateral Achilles reflexes were decreased. The lumbar dermatomes and myotomes were within normal limits. The physical examination of the shoulders revealed +3 spasms and tenderness to the left rotator cuff muscles and left upper shoulder muscles. There was decreased range of motion. The Speed's test and supraspinatus test were positive on the left. The

examination of the elbow revealed there was +3 spasm and tenderness to the left lateral epicondyle. There was decreased range of motion in flexion. The Cozen's test was positive on the left. The examination of the wrist and hand revealed +3 spasm and tenderness to the left anterior wrist and left posterior extensor tendons. There was decreased range of motion in flexion and extension that was painful. The injured worker had positive Tinel's, bracelet's and Phalen's tests on the left. The treatment plan included physical medicine for 12 visits with continuation dependent on functional improvement' an inflammation topical compound including Lidocaine 6% gabapentin 10%, tramadol 10% (apply a thin layer to the affected area twice daily as directed by physician) with 180 gm with 2 refills; and a muscular pain topical compounding including flurbiprofen 15%, cyclobenzaprine 2%, baclofen 2%, and lidocaine 5% (apply a thin layer to the affected area twice a day as directed by physician) 180 gm with 2 refills; as well as a sleep number bed.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Lidocaine 6%/ Gabapentin 0%/ Tramadol 10% QTY: 180gm with two refills:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol page 82, Topical Salicylates, page 105 Topical Analgesics, page 111, Gabapentin page 113, Lidocaine, page 112 Page(s): 82; 105; 111; 113; 112. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence:FDA.gov.

**Decision rationale:** The Chronic Pain Medical Treatment 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 Salicylates are recommended... 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....Gabapentin: Not recommended. There is no peer-reviewed literature to support use. The Chronic Pain Medical Treatment 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 [serotonin-norepinephrine reuptake inhibitor] anti-depressants or an AED [anti-epileptic drugs] such as gabapentin or Lyrica). No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. The clinical documentation submitted for review failed to indicate the injured worker had neuropathic pain and had a trial and failure of antidepressants and anticonvulsants. There was a lack of documentation of exceptional factors to warrant nonadherence to guideline recommendations. Additionally, there was a lack of documentation indicating a necessity for two topicals with Lidocaine and for 2 refills without re-evaluation. The request as submitted failed to indicate the frequency for the requested medication. The duration of use was noted as this was a new

prescription. Given the above, the request for Lidocaine 6%/gabapentin 0%/tramadol 10% quantity of 180 gm with two refills is not medically necessary or appropriate.

**Flurbiprofen 15%/ Cyclobenzaprine 2%/ Baclofen 2%/ Lidocaine 5% QTY: 180gm with two refills:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines , Cyclobenzaprine, page 41, Topical Analgesics, page 111, Lidocaine, page 112, Baclofen, page 113, Flurbiprofen, page 72 Page(s): 41; 111; 112; 113; 72.

**Decision rationale:** The Chronic Pain Medical Treatment Guidelines 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 antidepressants and anticonvulsants have failed...Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended... There is no peer-reviewed literature to support the use of topical baclofen...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 Chronic Pain Medical Treatment 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 [serotonin-norepinephrine reuptake inhibitor] anti-depressants or an AED [anti-epileptic drugs] such as gabapentin or Lyrica). No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Regarding topical flurbiprofen...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. Topical NSAIDs (non-steroidal anti-inflammatory drugs) 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 two week period. Any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended The clinical documentation submitted for review failed to indicate the injured worker had neuropathic pain and had a trial of an antidepressant and an anticonvulsant that had failed. There was a lack of documentation indicating a necessity for two topical muscle relaxants. There was a lack of documentation indicating a necessity for two topicals containing Lidocaine. the request as submitted failed to indicate the frequency for the requested medication. This was noted to be a new medication. There was a lack of documentation indicating the necessity for 2 refills without re-evaluation. Given the above, the request for flurbiprofen 15%/cyclobenzaprine 2%/baclofen 2%/Lidocaine 5% quantity of 180 gm with two refills is not medically necessary or appropriate.

