

<b>Case Number:</b>	CM13-0067843		
<b>Date Assigned:</b>	01/03/2014	<b>Date of Injury:</b>	06/10/2009
<b>Decision Date:</b>	06/02/2014	<b>UR Denial Date:</b>	11/26/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/17/2013

### 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 Anesthesiology, Pain Medicine and is licensed to practice in Florida. 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 46-year-old female who reported an injury on 06/10/2009. The mechanism of injury was the injured worker was lifting a trashcan to dump out the trash when it fell and struck her in the knee and injured her low back. The prior treatments included physical therapy, epidural injections, and a spinal cord stimulator, as well as medications. The diagnoses included complex regional pain syndrome in the right lower extremity, right knee medial meniscal tear, right ankle and foot regional pain syndrome, lumbar pain stimulator in place, lumbar secondary to abnormal gait and pain, stimulator surgery, right shoulder overuse with impingement and subacromial bursitis from cane use, right wrist and hand pain secondary to overuse of cane, anxiety/depression, insomnia, and morbid obesity. The treatment request per the documentation was for multiple powders for compounded medications for the date of 06/10/2009.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**FLURBIPROFEN POWDER 30GM, 20% 150GM CREAM: 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, Flurbiprofen Page(s): 111,72.

**Decision rationale:** The California MTUS indicates topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. 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. 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. There was no DWC form RFA, nor PR-2 submitted for the request service. There was no documentation indicating the injured worker had a trial and failure of antidepressants and anticonvulsants. The request as submitted failed to indicate the frequency for the requested medication. The duration of use could not be established with provided documentation. There was lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. Given the above, the request for flurbiprofen powder 30 gram 20% 150 gram cream is not medically necessary.

**CYCLOBENZAPRINE POWDER 12GM, 10% 120GM CREAM:** 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/CYCLOBENZAPRINE Page(s): 111,41.

**Decision rationale:** The California MTUS indicates topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed... California MTUS 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. There was no DWC form RFA, nor PR-2 submitted for the request service. There was no documentation indicating the injured worker had a trial and failure of antidepressants and anticonvulsants. The request as submitted failed to indicate the frequency for the requested medication. There was lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. The duration of use could not be established with provided documentation. Given the above, the request for cyclobenzaprine powder 12gm, 10% 120gm cream is not medically necessary.

**GABAPENTIN POWDER 12GM, 10% 120GM CREAM:** 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/GABAPENTIN Page(s): 111-113.

**Decision rationale:** The California MTUS indicates topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. 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. Gabapentin is not recommended. There is no peer-reviewed literature to support use. There was no DWC form RFA, nor PR-2 submitted for the request service. There was no documentation indicating the injured worker had a trial and failure of antidepressants and anticonvulsants. The request as submitted failed to indicate the frequency for the requested medication. The duration of use could not be established with provided documentation. There was lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. Given the above, the request for gabapentin powder 12 grams 10% 120 gram cream is not medically necessary.

**TRAMADOL POWDER 30GM, 20%150GM CREAM.:** 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(s): 72. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), does not address topical Tramadol.

**Decision rationale:** The California MTUS indicates topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. 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. A thorough search of FDA.gov, did not indicate there was a formulation of topical Tramadol that had been FDA approved. Tramadol is recommended for oral use, not for topical use. There was no DWC form RFA, nor PR-2 submitted for the request service. There was no documentation indicating the injured worker had a trial and failure of antidepressants and anticonvulsants. The request as submitted failed to indicate the frequency for the requested medication. The duration of use could not be established with provided documentation. There was lack of documentation of exceptional factors to warrant non-adherence to FDA and California MTUS Guidelines. Given the above, the request for tramadol powder 30 grams 20% 150 gram cream is not medically necessary.