

<b>Case Number:</b>	CM13-0059450		
<b>Date Assigned:</b>	12/30/2013	<b>Date of Injury:</b>	09/10/2013
<b>Decision Date:</b>	04/30/2014	<b>UR Denial Date:</b>	11/19/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/02/2013

### 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 Internal 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:

This patient is a 38 year-old with a date of injury of 09/10/13. A progress report associated with the request for services, dated 10/30/13, identified subjective complaints of bilateral shoulder and knee pain, as well as pain in the cervical, thoracic, and lumbar spine. The examination of each of those body parts stated the same: "There is no bruising, swelling, atrophy, or lesion present of the ...". Diagnoses included cervical and lumbar sprain/strain with radiculopathy; bilateral shoulder impingement; bilateral knee sprain/strain with internal derangement; and sleep disorder. Treatment dispensed included oral NSAIDs, muscle relaxants and hypnotics as well as topical therapy.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**RETROSPECTIVE CAPSAICIN 0.025%, FLURBIPROFEN 30%, METHYL SALICYLATE 4% 30 GM:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Pain

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 308, Chronic Pain Treatment Guidelines Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)

**Decision rationale:** The MTUS Chronic Pain Guidelines state that topical analgesics are recommended as an option in specific circumstances. However, they do state that they are "Largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." Flurbiprofen 30% is an NSAID being used as a topical analgesic. The MTUS Chronic Pain Guidelines note that the efficacy of topical NSAIDs in clinical trials has been inconsistent and most studies are small and of short duration. The Official Disability Guidelines (ODG) also does not recommend them for widespread musculoskeletal pain. The only FDA approved topical NSAID is Diclofenac. Methylsalicylate is a non-steroidal anti-inflammatory being used as a topical analgesic. The MTUS Chronic Pain Guidelines do recommend topical salicylates as being significantly better than placebo in chronic pain. In osteoarthritis, salicylates are superior to placebo for the first two weeks, with diminishing effect over another two-week period. The Official Disability Guidelines also recommend topical salicylates as an option and note that they are significantly better than placebo in acute and chronic pain. They further note however, that neither salicylates nor capsaicin have shown significant efficacy in the treatment of osteoarthritis. Capsaicin 0.025% is an active component of chili peppers and acts as an irritant. The MTUS Chronic Pain Guidelines state that topical capsaicin is "Recommended only as an option in patients who have not responded or are intolerant to other treatments." It is noted that there are positive randomized trials with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific low back pain, but it should be considered experimental at very high doses. The Guidelines further note that although capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in combination with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. The Official Disability Guidelines (ODG) state that neither salicylates nor capsaicin has shown efficacy in the treatment of osteoarthritis. In this case, there is no documentation of the failure of conventional therapy or recommendation for all the ingredients of the compound. The MTUS Chronic Pain Guidelines further state: "Any compounded product that contains at least one drug (or drug class that is not recommended is not recommended." Therefore the request is not medically necessary and appropriate.

**RETROSPECTIVE FLURBIPROFEN 30%, TRAMADOL 20%, LIPODERM BASE 30GM: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Pain.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) section on Topical Analgesics.

**Decision rationale:** The requested compound consists of flurbiprofen, an NSAID, and tramadol, a centrally acting opioid analgesic, with the delivery vehicle Lipoderm. The MTUS Chronic Pain Guidelines state that topical analgesics are recommended as an option in specific circumstances. However, they do state that they are "Largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." Flurbiprofen

30% is an NSAID being used as a topical analgesic. The MTUS Guidelines note that the efficacy of topical NSAIDs in clinical trials has been inconsistent and most studies are small and or short duration. The Guidelines also state that there is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. The Official Disability Guidelines (ODG) also does not recommend them for widespread musculoskeletal pain. The only FDA approved topical NSAID is Diclofenac. Lacking definitive data on the efficacy of topical Tramadol, the medical record does not document neuropathic pain that has failed antidepressant or anticonvulsant therapy. Therefore, medical necessity for topical Tramadol has not been established. The MTUS Chronic Pain Guidelines further state: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore, in this case, there is no documentation of the failure of conventional therapy or recommendation for all the ingredients of the compound and therefore the request is not medically necessary and appropriate.

**RETROSPECTIVE 30 RESTONE 3/100MG:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Pain.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines Pain, section on Mental Illness & Stress.

**Decision rationale:** Restone contains the active ingredients melatonin, a naturally occurring hypnotic, and L-tryptophan, an amino acid that may be useful as a sleep aid. The Medical Treatment Utilization Schedule (MTUS) Guidelines do not specifically address hypnotics or these agents. The Official Disability Guidelines (ODG) state that treatment should be based upon etiology and only after careful evaluation of the potential causes of sleep disturbance. In this case, the cause of the insomnia was pain. L-tryptophan is not specifically addressed. They do note that melatonin is recommended as an option. Therefore, in this case, the medical record does not document the medical necessity for Restone consistent with the ODG. The request is not medically necessary and appropriate.