

<b>Case Number:</b>	CM14-0017154		
<b>Date Assigned:</b>	04/14/2014	<b>Date of Injury:</b>	04/25/2013
<b>Decision Date:</b>	05/30/2014	<b>UR Denial Date:</b>	01/28/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/11/2014

### 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 & Rehabilitation, has a subspecialty in Pain Medicine and is licensed to practice in 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 56-year-old female who reported injury on 04/25/2013. The mechanism of injury was repetitively lifting heavy boxes. The injured worker underwent an L4-5 and L5-S1 decompressive laminectomy and had 16 sessions of postoperative physical therapy. The documentation of 11/15/2013 revealed the injured worker's medications were Norco, Keflex, and Soma. The diagnoses included degenerative disc disease with spinal stenosis at L4-5 and L5-S1 with facet arthropathy, right knee myoligamentous sprain/strain rule out internal derangement, status post laminectomy at L4-5 and L5-S1 bilaterally on 10/02/2013, cellulitis and rule out persistent medial meniscus tear right knee. The treatment plan included finishing the antibiotics, an MRI scan of the right knee, Norco, Ultracet, and starting Flurbiprofen 20% gel 120 grams, ketoprofen 20%/ketamine 10% gel 120 grams, and gabapentin 10%/cyclobenzaprine 10%/capsaicin 0.0375% capsaicin 120 grams to be applied on affected area 2 to 3 times a day as directed by physician.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**FLURBIPROFEN 20 % GEL 120GM:** Upheld

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

**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 and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Topical NSAIDs 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 2-week period. This agent is not currently FDA approved for a topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. The clinical documentation submitted for review failed to indicate the injured worker had neuropathic pain and the trials of antidepressants and anticonvulsants had failed. There was a lack of documentation indicating the injured worker had osteoarthritis. There was a lack of documentation indicating the rationale for two topical products containing NSAIDs. Given the above, the request for Flurbiprofen 20% gel 120 gm is not medically necessary.

**KETOPROFEN 20 % PLUS KETAMINE 10%GEL 120 GM,:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Ketoprofen, Ketamine Page(s): 111-113.

**Decision rationale:** California MTUS indicates topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety and 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. Ketoprofen is an NSAID and is not currently FDA approved for a topical application. The compound also included topical Ketamine which is under study and is only recommended in treatment of neuropathic pain which is refractory to all primary and secondary treatment. The clinical documentation submitted for review failed to indicate a necessity for 2 NSAIDs. The clinical documentation submitted for review failed to indicate the injured worker had a trial and failure of antidepressants and anticonvulsants. There was lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. Given the above, the request for ketoprofen 20% plus ketamine 10% gel 120 gm is not medically necessary.

**GABAPENTIN 10% + CYCLOBENZAPRINE 10% WITH .0375% CAPSAICIN 120 GM:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Topical Analgesics, Gabapentin, Topical Capsaicin Page(s): 41,111,113,28.

**Decision rationale:** California MTUS indicates that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety and 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. Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. Gabapentin is not recommended as there is no peer-reviewed literature to support its topical use. Cyclobenzaprine is not recommended as a topical medication as there is no evidence for use of any muscle relaxant as a topical product. 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 is a lack of documentation indicating the injured worker had not responded or was intolerant to other treatments. Given the above, the request for gabapentin 10% + cyclobenzaprine 10% with .0375% capsaicin 120 gm is not medically necessary.