

<b>Case Number:</b>	CM13-0046421		
<b>Date Assigned:</b>	12/27/2013	<b>Date of Injury:</b>	10/20/2011
<b>Decision Date:</b>	03/11/2014	<b>UR Denial Date:</b>	10/31/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/12/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Physical Medicine and Rehabilitation and is licensed to practice in Illinois, Indiana, 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 physician 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 patient is a 54-year-old male who reported an injury on 10/20/2011. The mechanism of injury was not provided. The patient was noted to have increased low back pain as a result of doing exercises. The patient was noted to have mild numbness and tingling in the bilateral buttocks. However, the patient indicated that the low back pain was better since the last visit. The patient's medication was noted to be Naprosyn. The patient was note to have weakness in the bilateral wrist extensors, deltoids and biceps at 4/5. The patient's diagnoses were noted to include a herniated nucleus pulposus at L4-5 on the left with lower extremity radicular pain and paresthesias, cervical spine spondylosis at C3-7 with bilateral upper extremity radicular pain and paresthesias, cervical spine myoligamentous sprain/strain, rule out herniated nucleus pulposus, thoracic spine myoligamentous sprain/strain and status post left interlaminar laminotomy at L4-5 and microdiscectomy at L4-5 on 07/18/2013. The request was made for topical compounds.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**CMPD- Ketamine (anesthetic), Ketoprofen (NSAID), Ethoxy Diglycol, Pentraven Base, Topical Analgesic, 120mg, refills 00, day's supply 30, Route: Topicalm, NDC#; n/a: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Ketoprofen, Ketamine Page(s): 111, 112, 113.

**Decision rationale:** California MTUS indicates topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety...Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of ketoprofen: this agent is not currently FDA-approved for a topical application. The compound also included topical ketamine which is under study and is only recommended in the treatment of neuropathic pain which is refractory to all primary and secondary treatments. The clinical documentation submitted for review failed to indicate the necessity of 2 NSAIDs, as this is concurrently being reviewed with a request for flurbiprofen. Additionally, there was a lack of documentation indicating that the patient had prior treatment of neuropathic pain and that it remained refractory to all primary and secondary treatments. Additionally, as the FDA does not approve ketoprofen for topical application, there was a lack of documentation of exceptional factors to warrant nonadherence to guideline and FDA recommendations. Given the above, the request for compound: ketamine (anesthetic), ketoprofen (NSAID), Ethoxydiglycol, Pentravan base topical analgesic 120 mg with 0 refills and days supply of 30 via route Topicalm (NDC #: N/A) is not medically necessary.

**CMPD-Flurbiprofen (NSAID), Ethoxy diglycol, Pentravan Base, type of medication: Topical Analgesic, Qty 120mg, refills 00, day's supply 30, Route; Topical, NDC# n/a: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

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

**Decision rationale:** 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...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. 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 clinical documentation submitted for review failed to provide the documented rationale for 2 NSAIDs as this request is concurrently being reviewed with a request for ketoprofen. Additionally, there is a lack of documentation indicating that the patient had a trial of antidepressants and anticonvulsants that had failed. Given the above and the lack of documentation of exceptional factors to warrant nonadherence to guideline recommendations, the request for compound: flurbiprofen (NSAID), Ethoxydiglycol, Pentravan base (type of medication: topical analgesic)

with "Qty 120 mg," 0 refills and days' supply of 30 via route: topical (NDC #: N/A) is not medically necessary

**Medication** CMPD-Gabapentin (anticonvulsant), Cyclobenzaprine (muscle relaxant), Capsaicin, Ethoxy Diglycol, Pentraven Base, **Type of Medication: Topical Analgesic, qty 120mg, refills 00, day's supply 30 Route: Topical, NDC# n/a: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

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

**Decision rationale:** California MTUS indicates that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety...Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended...Gabapentin: not recommended. There is no peer-reviewed literature to support use. Other anti-epilepsy drugs: There is no evidence for use of any other anti-epilepsy drug as a topical product...do not recommend the topical use of Cyclobenzaprine as a topical muscle relaxant 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. Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. The clinical documentation failed to indicate that the patient had not responded to or are intolerant to other treatments. The clinical documentation submitted for review failed to provide documentation of exceptional factors to warrant nonadherence to the guideline recommendations. Given the above, the request for compound gabapentin (anticonvulsant), cyclobenzaprine (muscle relaxant), capsaicin, Ethoxydiglycol, Pentravan base, (type of medication: topical analgesic) with "qty 120 mg," 0 refills and days' supply of 30 via route: topical (NDC #: N/A) is not medically necessary.