

<b>Case Number:</b>	CM15-0161744		
<b>Date Assigned:</b>	08/27/2015	<b>Date of Injury:</b>	08/27/2009
<b>Decision Date:</b>	10/05/2015	<b>UR Denial Date:</b>	07/22/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/17/2015

### 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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:  
 State(s) of Licensure: New York  
 Certification(s)/Specialty: Anesthesiology

### 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 62 year old male who sustained an industrial injury on 8-27-09. The injured worker was diagnosed as having cervicgia, rule out cervical disc displacement, and rule out cervical spine radiculopathy, lumbar disc displacement, lumbar spine degenerative disc disease, and lumbar radiculopathy. Currently, the injured worker reported pain in the neck and low back. Previous treatments included medication management, shockwave therapy, and nonsteroidal anti-inflammatory drugs. Previous diagnostic studies included functional capacity testing. Work status was noted as temporary totally disabled. The injured workers pain level was noted as 4 to 5 out of 10. Physical examination was notable for tenderness to palpation to the trapezius, splenius, scalene and sternocleidomastoid muscles as well as lumbar paraspinal muscles and lumbosacral junction, decreased lumbar and cervical range of motion noted. The plan of care was for topical cream compound HMPC2 (240 grams), compound HNPC1 240 grams, Ketoprofen 20% cream 167 grams and Cyclobenzaprine 5% cream 110 grams.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Topical Cream compound HMPC2 (240gms): 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 Page(s): 111-113.

**Decision rationale:** The request is for topical analgesic compound HMPC2 (240 grams). Currently, the injured worker reported pain in the neck and low back. CA MTUS Guidelines indicate that topical NSAIDs are indicated for osteoarthritis of the knees, elbow or other joints that are amenable to topical treatments. According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. The requested topical analgesic compound for this patient contains: Flurbiprofen 20%, Baclofen 10%, Dexamethasone Micro 0.2%, and Hyaluronic Acid 0.2%. There are no clinical studies to support the safety or effectiveness of Flurbiprofen in a topical delivery system (excluding ophthalmic). In addition, Flurbiprofen, used as a topical NSAID, has been shown in a meta-analysis to be superior to placebo during the first two weeks of treatment for osteoarthritis but either, not afterward, or with diminishing effect over another two-week period. Medical necessity for the requested topical compounded medication has not been established. The requested topical analgesic compound is not medically necessary.

**Compound HNPC1 240gms:** 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 Page(s): 111-113.

**Decision rationale:** The request is for compound HNPC1 240 grams. Currently, the injured worker reported pain in the neck and low back. CA MTUS Guidelines indicate that topical NSAIDs are indicated for osteoarthritis of the knees, elbow or other joints that are amenable to topical treatments. According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. The requested topical analgesic compound for this patient contains: Amitriptyline 10%, Gabapentin 10%, Bupivacaine 5%, and Hyaluronic Acid 0.2%.

Gabapentin is not recommended as a topical agent per CA MTUS Guidelines. There is no peer-reviewed literature to support its use. Medical necessity for the requested topical compounded medication has not been established. The requested topical analgesic compound is not medically necessary.

**Ketoprofen 20% cream 167gms: Upheld**

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

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

**Decision rationale:** Ketoprofen topical cream 20% is not medically necessary. According to California MTUS guidelines, does not cover "topical analgesics that are largely experimental in use with a 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". Additionally, Per CA MTUS page 111 states that topical analgesics such as Ketoprofen, is indicated for Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment. It is also recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of pain associated with the spine, hip or shoulder. The limitation of use was not specified in the medical records. Medical necessity for the requested topical analgesic cream has not been established. The request for the topical analgesic cream is not medically necessary.

**Cyclobenzaprine 5% cream 110gms: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain, Cyclobenzaprine (Flexeril).

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

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. In this case, the requested compounded topical agent is Cyclobenzaprine 5% cream. Cyclobenzaprine is not FDA approved for use as a topical application. There is no evidence for the use of any muscle relaxant as a topical agent. Medical necessity for the requested topical analgesic cream has not been established. The request for the compounded topical analgesic cream is not medically necessary.