

<b>Case Number:</b>	CM15-0136213		
<b>Date Assigned:</b>	07/24/2015	<b>Date of Injury:</b>	10/23/2014
<b>Decision Date:</b>	08/31/2015	<b>UR Denial Date:</b>	06/22/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/14/2015

### 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: California, District of Columbia, Maryland  
 Certification(s)/Specialty: Anesthesiology, Pain Management

### 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 35 year old female, who sustained an industrial injury on October 23, 2014. She reported immediate pain in her head with buzzing and popping in her ears. The injured worker was diagnosed as having coccydynia, cervical spine sprain/strain, lumbar spine sprain/strain, muscle spasms, headaches, memory loss, blurry vision, rule out post concussion syndrome, jaw pain, head contusion and peripheral neuropathy of the bilateral lower extremities. Treatment to date has included diagnostic studies, acupuncture and medication. On May 11, 2015, the injured worker complained of low back pain with radiation, numbness and tingling down her legs. She rated her pain currently as a 2 on a 1-10 pain scale. She reported neck pain rated as a 2/10 on the pain scale and hand pain. Medication and rest helps to decrease her pain. Acupuncture was noted to help decrease her pain temporarily and allows her to perform more activities of daily living. The treatment plan included acupuncture at two times a week for six weeks, neurology consultation, medications and a follow-up visit. On June 22, 2015, Utilization Review non-certified the request for one prescription Cyclobenzaprine 2% Flurbiprofen 25% 180 gm and one prescription Capsaicin 0.025% Flurbiprofen 15% Gabapentin 10% Menthol 2% Camphor 2% 180 gm, citing California MTUS Guidelines.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Cyclobenzaprine 2%, Flurbiprofen 25% quantity 180gm:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Non Steroidal Anti Inflammatory Drugs.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): 60, 111-112.

**Decision rationale:** Fluriflex contains flurbiprofen and cyclobenzaprine. Per MTUS with regard to Flurbiprofen (p112), "These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder." Flurbiprofen may be indicated. Per MTUS CPMTG p113, "There is no evidence for use of any other muscle relaxant as a topical product [besides baclofen, which is also not recommended]" Cyclobenzaprine is not indicated. The MTUS Chronic Pain Medical Treatment Guidelines state that topical medications 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. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists,  $\alpha$ -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually. Because topical cyclobenzaprine is not indicated, the compound is not recommended. This request is not medically necessary.

**Capsaicin 0.025%, Flurbiprofen 15%, Gabapentin 10%, Menthol 2%, Camphor 2% quantity 180gms:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines  
Topical Analgesics Page(s): 60, 111-112.

**Decision rationale:** Capsaicin may have an indication for chronic lower back pain in this context. Per MTUS p 112 "Indications: There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy." Per MTUS with regard to Flurbiprofen (p112), "(Biswal, 2006) these medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder." The documentation contains no evidence of osteoarthritis or tendinitis. Flurbiprofen is not indicated. Per MTUS p113 with regard to topical gabapentin: "Not recommended. There is no peer-reviewed literature to support use." Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually. The CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of menthol or camphor. It is the opinion of this IMR reviewer that a lack of endorsement, a lack of mention, inherently implies a lack of recommendation, or a status equivalent to "not recommended". Since several components are not medically indicated, then the overall product is not indicated per MTUS as outlined below. Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The request is not medically necessary.