

<b>Case Number:</b>	CM15-0029602		
<b>Date Assigned:</b>	02/23/2015	<b>Date of Injury:</b>	05/20/2014
<b>Decision Date:</b>	06/17/2015	<b>UR Denial Date:</b>	01/14/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/18/2015

### 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

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

### 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 33 year old male who sustained an industrial injury on May 20, 2014. He has reported injury to the right knee and has been diagnosed with right knee sprain/strain. Treatment has included medication, home IF therapy, medical imaging, physical therapy, and modified work duty. Examination of the right knee showed no bruising, swelling, atrophy, or lesion present at the right knee. X-rays of the right knee showed no fractures. No lesions noted. There is maintenance of joint spaces in the medial, lateral, and patellofemoral compartments. MRI of the right knee revealed a tear of the posterior horn of the medial meniscus. The treatment request included topical medications.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flurbiprofen 20%/Baclofen 5%/Dexamine 2%/Menthol 2%/Camphor 2%/Capsaicin 0.025% 210 grams, quantity of one: 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 NSAIDs (non-steroidal anti-inflammatory drugs), Capsaicin, Topical Analgesics, Muscle relaxants for pain Page(s): 28-9, 63-66, 67-73, 111-113.

**Decision rationale:** Flurbiprofen-Baclofen-Dexamine-Menthol-Camphor-Capsaicin Topical Cream is a combination product formulated for use as a topical analgesic. It is made up of capsaicin (topical analgesic), flurbiprofen (a non-steroidal anti-inflammatory (NSAID) medication), Baclofen (a muscle relaxant), and three topical analgesics, menthol, camphor and capsaicin. Topical analgesic medications have been shown to give local analgesia. The use of topical agents to control pain is considered an option by the MTUS although it is considered largely experimental, as there is little to no research to support their use and their use is primarily recommended for osteoarthritis or neuropathic pain when trials of antidepressants and anticonvulsants have failed. Flurbiprofen is classified as non-steroidal anti-inflammatory drug (NSAID) and studies have shown NSAIDs have been effective when given topically in short-term use trials for chronic musculoskeletal pain. However, long-term use of topical NSAIDs has not been adequately studied. Baclofen is indicated for oral use to treat muscle spasms caused by multiple sclerosis or spinal cord injuries but the MTUS does not recommend its use as a topical agent. Menthol is a topical analgesic medication with local anesthetic and counter-irritant qualities. The MTUS does not recommend for or against its use for chronic pain. Camphor is a topical medication with local anesthetic and antimicrobial properties. The MTUS does not recommend for or against its use for chronic pain. Capsaicin is a capsaicinoid compound with analgesic properties usually formulated as 0.025% for osteoarthritis or 0.075% for neuropathic pain. It is used medically in the form of a topical ointment, spray or patch and is indicated for the temporary relief of minor aches and pains of muscles and joints. It has also been used to treat the itching and inflammation caused by psoriasis. When compared to a placebo, its use has been superior in relieving chronic neuropathic pain and musculoskeletal pain. However, there are no evidence-based studies using 0.0375% preparations and no evidence that this higher dose formulation is superior to 0.025%. The MTUS recommends its use as option for treating pain in patients intolerant to other treatments. It is important to note the MTUS states, "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Since baclofen is not recommended for topical use, this product is not recommended. Medical necessity has not been established for use of this medication.

**Gabapentin 10%/Amitriptyline 10%/Bupivacaine 5% in cream base, 210 grams, quantity of one:** 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 Antidepressants for chronic pain, Antiepilepsy drugs (AEDs), Topical Analgesics Page(s): 13-6, 16-22, 111-113.

**Decision rationale:** Gabapentin-Amitriptyline-Bupivacaine Cream is a combination product formulated for topical use. It is made up of gabapentin, an anticonvulsant and analgesic, amitriptyline, an antidepressant, and bupivacaine, a topical anesthetic. The use of topical agents

to control pain is considered an option although it is considered largely experimental, as there is little to no research to support their use. They are primarily recommended for the treatment of neuropathic pain when first line agents such as antidepressants or antiepileptics have failed. Even though the MTUS describes use of gabapentin as an effective medication in controlling neuropathic pain, it does not recommend its use topically. The MTUS does not address the topical use of amitriptyline but notes that when used systemically, amitriptyline use should be considered first line therapy for neuropathic pain. Topical bupivacaine is not specifically mentioned by the MTUS but it does note use of topical local anesthetics is effective for local pain relief. It is important to note the MTUS states, "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Since topical use of gabapentin is not recommended use of this product is not recommended. Medical necessity for use of this product has not been established.