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| <b>Case Number:</b>   | CM15-0167792 |                              |            |
| <b>Date Assigned:</b> | 09/08/2015   | <b>Date of Injury:</b>       | 03/07/2013 |
| <b>Decision Date:</b> | 10/13/2015   | <b>UR Denial Date:</b>       | 08/20/2015 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 08/26/2015 |

### 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 45 year old male who sustained an industrial injury on 3-7-13 with current complaints of burning radicular lower back pain and muscle spasms. Diagnoses are low back pain, lumbar spine herniated nucleus pulposus, and radiculitis-lower extremity. Previous treatment includes physical therapy, MRI -lumbar spine, oral and topical medication, urine toxicology screening, and acupuncture. In a progress report dated 7-9-15, the primary treating physician notes low back pain is rated as 4-5 out of 10 and described as constant and moderate to severe. It travels down both legs and is associated with numbness and tingling, left greater than right. He reports the symptoms persist but the medications offer temporary relief of pain and improve his ability to have a restful sleep. His gait is antalgic. The lumbar spine exam notes tenderness to palpation with paravertebral spasms, decreased range of motion and a positive straight leg raise at 30 degrees on the left. The treatment plan is shockwave therapy, referral to pain management, and to continue taking medications for pain. The requested treatment is Capsaicin 0.025%, Flurbiprofen 15%, Gabapentin 10%, menthol 2%, Camphor 2%, quantity of 180 grams and Cyclobenzaprine 2%, Gabapentin 15%, Amitriptyline 10%, quantity of 180 grams.

### IMR ISSUES, DECISIONS AND RATIONALES

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

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

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** Per the MTUS guidelines, capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. 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.

**Cyclobenzaprine 2%, Gabapentin 15%, Amitriptyline 10% quantity 180gm: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** Per MTUS p113 with regard to topical gabapentin: "Not recommended. There is no peer-reviewed literature to support use." 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 article "Topical Analgesics in the Management of Acute and Chronic Pain" published in Mayo Clinic Proceedings (Vol 88, Issue 2, p 195-205), "Studies in healthy volunteers demonstrated that topical amitriptyline at concentrations of 50 and 100 mmol/L produced a significant analgesic effect ( $P < .05$ ) when compared with placebo and was associated with transient increases in tactile and mechanical nociceptive thresholds." Amitriptyline may be indicated. 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 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." As cyclobenzaprine and gabapentin are not recommended, the request is not medically necessary.