

<b>Case Number:</b>	CM15-0170874		
<b>Date Assigned:</b>	09/11/2015	<b>Date of Injury:</b>	07/24/2014
<b>Decision Date:</b>	10/15/2015	<b>UR Denial Date:</b>	08/17/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/31/2015

### 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 57-year-old female who sustained an injury on 7-24-14 resulting when she was stacking eggs in containers and felt immediate sharp pain in her lower back. Treatment included pain injection, medication, physical therapy, chiropractic, and acupuncture but continued to have chronic low back pain and left leg and foot pain. Diagnoses are lumbar spine sprain, strain; lumbar spine degenerative disc disease and lumbar spine radiculopathy. The chiropractic examination on 7-14-15 indicate she complains of constant moderate neck pain; moderate upper mid back pain; constant low back pain with numbness extending down her left leg to her left heel and left foot pain. The recommendation was to refer her to physical therapy 2 x3 for the spine. Currently on 8-13-15, she complains of burning, radicular low back pain radiating to her left leg and rated the pain as 6 out of 10. The pain is constant, moderate to severe and associated with numbness and tingling of bilateral lower extremities. It was aggravated by prolonged sitting, standing, walking, bending ascending and descending stair and stooping. Activities of daily living including getting dressed and performing personal hygiene also increase the symptoms. There is tenderness to palpation at the lumbar paraspinal muscles; range of motion lumbar spine revealed flexion 50 degrees; bilateral neurologic showed sensory as slightly decreased to pin-prick and light touch at the L4.L5 and S1. The treatment plan was to continue use of medications; undergo a course of physical therapy and chiropractic treatment for the lumbar spine and continue using hot, cold unit. Medications included Depriazine; Dicopanol; Fanatrex; Synapryn; Tabradol; Cyclobenzaprine; Ketoprofen cream. Current requested treatments Capsaicin 0.025%, Flurbiprofen 15%, Gabapentin 10%, Menthol 2%, Camphor 180 gm; Cyclobenzaprine 2%, Gabapentin 15%, Amitriptyline 10%, 180 gm. Utilization review 8-17-15 requested treatments are non-certified.

## 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 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 anti-depressants 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%, 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. Per 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.