

<b>Case Number:</b>	CM14-0198804		
<b>Date Assigned:</b>	12/04/2014	<b>Date of Injury:</b>	05/12/2014
<b>Decision Date:</b>	02/02/2015	<b>UR Denial Date:</b>	10/29/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/26/2014

### 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. The expert reviewer is Board Certified in Anesthesiology, has a subspecialty in Acupuncture & Pain Medicine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

24y/o male injured worker with date of injury 5/12/14 with related lumbar spine pain. Per progress report dated 9/4/14, the injured worker complained of dull aching pain, sharpness, and stabbing sensation in the lumbar spine that was unchanged or worse from previous exams that radiated down the legs, rated 6/10 in intensity. Per physical exam, tenderness was noted about the lumbar paraspinals and quadratus lumborum. Straight leg raising test was positive. The documentation submitted for review did not state whether physical therapy was utilized. Treatment to date has included medication management. The date of UR decision was 10/29/14.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Omeprazole 20 mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI Symptoms & Cardiovascular Risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI Symptoms & Cardiovascular Risk Page(s): 64.

**Decision rationale:** In the treatment of dyspepsia secondary to NSAID therapy, the MTUS recommends stopping the NSAID, switching to a different NSAID, or considering the use of an H2-receptor antagonist or a PPI. The MTUS Chronic Pain Medical Treatment Guidelines

recommend the use of proton pump inhibitors in conjunction with NSAIDs in situations in which the patient is at risk for gastrointestinal events including: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). CPMTG guidelines further specify: "Recommendations: Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g, ibuprofen, naproxen, etc.) Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxyn plus low-dose aspirin plus a PPI. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007)" As there is no documentation of peptic ulcer, GI bleeding or perforation, or cardiovascular disease in the records available for my review, the injured worker's risk for gastrointestinal events is low, as such, medical necessity cannot be affirmed. While the documentation indicates that the injured worker complained of heartburn, it was noted that he discontinued NSAID therapy because it was not effective. There is no documentation of peptic ulcer, GI bleeding or perforation, or cardiovascular disease in the records available for my review, the injured worker's risk for gastrointestinal events is low. The request is not medically necessary.

**Tramadol 150mg #60: Overturned**

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47-48, Chronic Pain Treatment Guidelines Tramadol (Ultram, Ultram ER) and Opioids. Decision based on Non-MTUS Citation Official Disability Guidelines, Treatment in Worker's Compensation, Pain Chapter, Opioids

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78,91.

**Decision rationale:** The documentation submitted for review indicates that this is the first prescription for tramadol. Per MTUS Chronic Pain Medical Treatment Guidelines p76 regarding therapeutic trial of opioids, questions to ask prior to starting therapy include "(a) Are there reasonable alternatives to treatment, and have these been tried? (b) Is the patient likely to improve? (c) Is there likelihood of abuse or an adverse outcome?" Per progress report dated 7/2/14, it was noted that the injured worker had been taking Ibuprofen 600mg and felt that it was not helping. Tramadol is indicated for the injured worker's 6/10 pain. The request is medically necessary.

**GABAdone #60: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Treatment in Worker's Compensation (2013) Pain Chapter, Medical Food

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), GABAdone.

**Decision rationale:** The MTUS is silent on the use of Gabadone. Per ODG: "Not recommended. GABAdone is a medical food from [REDACTED], that is a proprietary blend of Choline Bitartrate, Glutamic Acid, 5-Hydroxytryptophan, and GABA. It is intended to meet the nutritional requirements for inducing sleep, promoting restorative sleep and reducing snoring in patients who are experiencing anxiety related to sleep disorders. (Shell, 2009) See Medical food, Choline, Glutamic Acid, 5-hydroxytryptophan, and Gamma-aminobutyric acid (GABA)." As the requested medication is not recommended, it is not medically necessary.

**Sentra AM #60:** 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 Chapter, Medical Food and Healthouch Online

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Medical Food.

**Decision rationale:** The MTUS is silent on the topic of medical food. With regard to chronic pain, the ODG guidelines say this about medical foods: medical foods are not considered medically necessary except in those cases in which the patient has a medical disorder, disease or condition for which there are distinctive nutritional requirements. The records submitted for review do not include evidence that the injured worker has any distinctive nutritional requirements. The request is not medically necessary.

**Sentra PM #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Mental Illness & Stress Chapter, Insomnia and ODG, Pain Chapter, Medical Food

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Medical Foods.

**Decision rationale:** The MTUS is silent on the topic of medical food. With regard to chronic pain, the ODG guidelines say this about Sentra PM: "Sentra PM is a medical food from



tendinitis, or joint pain. 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." 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 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 camphor is 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.

**Topical Compound consisting of Ketoprofen/Cyclobenzaprine/Lidocaine 10%/ 3%/ 5% 120 grams:** 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:** With regard to topical Ketoprofen, the MTUS CPMTG states "This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. (Diaz, 2006) (Hindsen, 2006)". Per MTUS p113 with regard to topical cyclobenzaprine, "There is no evidence for use of any muscle relaxant as a topical product." Regarding topical lidocaine, MTUS states (p112) "Neuropathic pain: Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Non-neuropathic pain: Not recommended. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. (Scudts, 1995)." 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. 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. As cyclobenzaprine is not recommended, the request is not medically necessary.