

<b>Case Number:</b>	CM14-0045942		
<b>Date Assigned:</b>	08/06/2014	<b>Date of Injury:</b>	08/17/2007
<b>Decision Date:</b>	09/11/2014	<b>UR Denial Date:</b>	03/21/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/14/2014

### 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 Physical Medicine & Rehabilitation 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:

The patient is a 51-year-old-male who sustained injury on 08/17/2007. No mechanism of injury was mentioned. The patient complains of continued lower back pain radiating to bilateral buttocks, hamstrings, and calves and rates the pain as 8-9/10. Pain increases to a 9/10 with walking, sitting, and standing for no more than 5 minutes. The patient also reports tingling and weakness in the bilateral legs. Lumbar exam reveals no sagittal imbalance. Muscle spasms are palpable next to the spinous processes with the patient relaxed lying prone. Range of motion (ROM): Flexion and extension is limited due to pain in the lumbosacral region. Patient is unable to extend past neutral. Lower extremity motor power shows iliopsoas, quadriceps, tibialis anterior 5/5 bilaterally. Extensor hallucis longus was 4/5 bilaterally. Peroneus longus was 5/5 bilaterally. Sensory test on right and left shows diminished sensation to light touch and pinprick over the lateral calf. Reflexes: Patellar 2+ bilaterally and Achilles was 0+ bilaterally. Medications include Norco, Omeprazole, Terocin patch, Menthoderm gel, Cyclobenzaprine, Theramine, Trepadone, Sentra AM, Sentra PM, and Gabadone. His condition has established the need for compounded topical medications including Terocin Capsaicin / Methylsalicylate / Menthol /Lidocaine percent), Flurbi (NAP) cream-LA Flurbiprofen / Lidocaine, Amitriptyline and Gabacyclotram and Somnicin Melatonin / Pyridoxine / Magnesium, Gabapentin / Cyclobenzaprine / Tramadol, Genicin. The patient is allergic to Vicodin. Diagnoses are Lumbar spinal stenosis; lumbar radiculitis; and lumbar sprain/strain. UR determination for items non-certified are: Terocin patches qty20; Theramine qty.180; Trepadone qty.120; Omeprazole 20mg, qty.120; Menthoderm Gel (qty unspecified); Sentra AM (qty) unspecified; Sentra PM (qty) unspecified; and Gabadone (qty unspecified). For items partially certified are Norco 2.5/325mg. qty120 modified to generic Norco 2.5/325mg qty60; Cyclobenzaprine Hydrochloride 7.5mg

qty.120 modified to initiate downward titration and discontinuation of medication as long-term use is not supported.

## **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Terocin patches, #20:** 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.

**Decision rationale:** According to the references, Terocin patches contain lidocaine and menthol. The CA MTUS state only Lidocaine in the formulation of Lidoderm patch may be considered for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an antiepileptic drug (AED) such as gabapentin or Lyrica). The guidelines state no other commercially approved topical formulations of lidocaine are indicated for neuropathic pain. Only FDA-approved products are currently recommended. Topically applied lidocaine is not recommended for non-neuropathic pain. The medical records do not establish this topical patch is appropriate and medically necessary for this patient. There is no documentation of any significant improvement in pain or function with prior use. The request of Terocin Patches is not medically necessary.

**Theramine, #180:** 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 Workers Compensation (ODG-TWC), Pain Procedure Summary (Updated 03/18/20014), 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.

**Decision rationale:** Not recommended. Theramine is a medical food that is a proprietary blend of gamma-aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. However, there is no high quality peer-reviewed literature to prove the efficacy. This medication is not indicated in current references for pain or inflammation. Until there are higher quality studies of the ingredients in Theramine, it remains not recommended.

**Trepadone, #120:** 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 Workers Compensation (ODG-TWC), Pain Procedure Summary (Updated 03/18/20014), 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.

**Decision rationale:** Trepadone is a medical food that is a proprietary blend of L-arginine, L-glutamine, choline bitartrate, L-serine and gamma-Aminobutyric acid [GABA]. It is intended for use in the management of joint disorders associated with pain and inflammation. However, there is no high quality peer-reviewed literature to prove the efficacy. This medication is not indicated in current references for joint disorders associated with pain and inflammation. Until there are higher quality studies of the ingredients in Trepadone, it remains not recommended.

**Norco 2.5/325mg, #120:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74, 91.

**Decision rationale:** Hydrocodone is indicated for moderate to severe pain. It is classified as short-acting opioids, which are seen as an effective method in controlling chronic pain. They are often used for intermittent or breakthrough pain. These agents are often combined with other analgesics such as acetaminophen and aspirin. Guidelines indicate "four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids; pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors)." The medical records do not establish failure of non-opioid analgesics, such as NSAIDs or acetaminophen. In addition, there is no mention of ongoing attempts with non-pharmacologic means of pain management. There is no documentation of any significant improvement in pain or function with prior use to demonstrate the efficacy of this medication. The medical documents do not support continuation of opioid pain management. Therefore, the medical necessity for hydrocodone has not been established based on guidelines and lack of documentation.

**Cyclobenzaprine Hydrochloride 7.5mg, qty 120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain). Decision based on Non-MTUS Citation Official Disability Guidelines - Treatment in Workers Compensation (ODG-TWC), Pain Procedure Summary (Updated 03/18/20014), Muscle relaxants.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Flexeril  
Page(s): 41.

**Decision rationale:** According to the guidelines, antispasmodics are used to decrease muscle spasms. Flexeril is recommended as an option, using a short course. The medical records do not document the presence of muscle spasm on examination. The medical records do not demonstrate the patient presented with exacerbation unresponsive to first-line interventions. The medical records demonstrate the patient has been prescribed Flexeril on an ongoing basis. There is no documentation of any significant improvement in spasm or function with prior use. Chronic use of muscle relaxants is not recommended by the guidelines. Furthermore, the medical necessity for Flexeril is not established.

**Omeprazole 20mg, #120:** 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 Workers Compensation (ODG-TWC), Pain Procedure Summary (Updated 03/18/20014), Proton Pump Inhibitors.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs  
Page(s): 68.

**Decision rationale:** The CA MTUS guidelines state proton pump inhibitors (PPI) medications such as Omeprazole (Prilosec) may be indicated for patients at risk for gastrointestinal events, which should be determined by the clinician: 1) age > 65 years; (2) history of peptic ulcer, gastrointestinal (GI) bleeding or perforation; (3) concurrent use of aspirin (ASA), corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). The guidelines recommend GI protection for patients with specific risk factors; however, the medical records do not establish the patient is at significant risk for GI events. In the absence of documented any GI symptoms such as abdominal pain, vomiting or bleeding and the absence of the frequency and duration of NSAIDs intake, the request is not medically necessary according to the guidelines.

**Menthoderm Gel (qty unspecified):** 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.

**Decision rationale:** Menthoderm gel is a topical methyl salicylate and menthol. The efficacy of NSAIDs in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. There are no long-term studies of their

effectiveness or safety. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Voltaren Gel 1% (diclofenac) is FDA-approved agents, indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. There is no documentation of any significant improvement in pain or function with prior use. Therefore, the request is not medically necessary according to the guidelines.

**Sentra AM (qty unspecified): 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 Workers Compensation (ODG-TWC), Pain Procedure Summary (Updated 03/18/20014), 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.

**Decision rationale:** Sentra AM is a medical food intended for use in management of sleep disorders associated with depression that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. However, there is no high quality peer-reviewed literature to prove the efficacy. This medication is not indicated in current references for depression. Until there are higher quality studies of the ingredients in Sentra AM, it remains not recommended.

**Sentra PM (qty unspecified): 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 Workers Compensation (ODG-TWC), Pain Procedure Summary (Updated 03/18/20014), 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.

**Decision rationale:** Sentra PM is a medical food intended for use in management of sleep disorders associated with depression that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. However, there is no high quality peer-reviewed literature to prove the efficacy. This medication is not indicated in current references for depression. Until there are higher quality studies of the ingredients in Sentra PM, it remains not recommended.

**Gabadone (qty unspecified): 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 Workers Compensation (ODG-TWC), Pain Procedure Summary (Updated 03/18/20014), 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.

**Decision rationale:** GABAdone is a medical food from [REDACTED], CA, 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. However, there is no high quality peer-reviewed literature to prove the efficacy. This medication is not indicated in current references for the above indications. Until there are higher quality studies of the ingredients in GABAdone, it remains not recommended.