

<b>Case Number:</b>	CM14-0039190		
<b>Date Assigned:</b>	08/01/2014	<b>Date of Injury:</b>	03/06/2003
<b>Decision Date:</b>	09/11/2014	<b>UR Denial Date:</b>	03/31/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/03/2014

### 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 injured worker is a 54-year-old female who sustained injury on 03/06/03 while working as a CNA for [REDACTED]. She complains of constant headaches, constant neck pain with radiation to the upper extremities with numbness and tingling, and constant low back pain with radiation to the lower extremities with numbness and tingling. She also has bilateral shoulder pain. Medications include Norco, Soma, Theramine, Trepadone, Sentra AM, Sentra PM, Gabadone, Methoderm gel, and Teracin patch. Physical exam: Cervical range of motion reveals flexion 40, extension 50, right rotation 60, left rotation 60, right lateral flexion 35, left lateral flexion 35. Tender cervical spine with spasms was noted. Lumbar spine range of motion: flexion 35, extension 15, right lateral flexion 15, left lateral flexion 15. SLR is positive bilaterally. Lumbar spine with spasms noted. Bilateral lower extremities motor was 4/5 at L5. Left lower extremity sensation decreased at L5-S1. Diagnoses are: Headache; status post cervical surgery; lumbar sprain/strain; lumbar radiculopathy; and bilateral shoulder internal derangement. Treatment plan includes continuing the same. UR request for Drug screening, Theramine, Trepadone, Sentra AM, Sentra PM, Gabadone, Methoderm gel, and Teracin patch are denied due to lack of medical necessity. The request for Norco and Soma was modified to #60 and #30 respectively.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Drug Screening:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids. Decision based on Non-MTUS Citation Official disability Guidelines Pain Chapter - Urine drug testing.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria Page(s): 74. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain.

**Decision rationale:** As per CA MTUS guidelines and ODG, urine drug screening is recommended to assess for the use or the presence of illegal drugs and to monitor compliance with prescribed substances. As per ODG, patients at "low risk" of addiction/aberrant behavior should be tested within six months of initiation of therapy and on a yearly basis thereafter. Patients at "moderate risk" for addiction/aberrant behavior are recommended for point-of-contract screening 2 to 3 times a year with confirmatory testing for inappropriate or unexpected results. Patients at "high risk of adverse outcomes may require testing as often as once a month. In this case, this patient has chronic pain and is taking opioids chronically. The urine drug screening is appropriate for patients taking opioids; however, this patient had urine drug screen about three months prior to request. There is no documentation of any aberrant behavior or drug diversion. There is no evidence of non-compliance with medications. Therefore, frequent urine drug screen sooner than 6 months period is not medically necessary and is non-certified.

**Norco 10/325mg #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 nonadherent) 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.

**Soma 350mg #90:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Soma Page(s): 29.

**Decision rationale:** This medication is not indicated for long-term use. Carisoprodol is a commonly prescribed, centrally acting skeletal muscle relaxant whose primary active Metabolite is Meprobamate (a schedule-IV controlled substance). It has been suggested that the main effect is due to generalized sedation and treatment of anxiety. Abuse has been noted for sedative and relaxant effects. In regular abusers the main concern is the accumulation of Meprobamate. Carisoprodol abuse has also been noted in order to augment or alter effects of other drugs. This includes the following: (1) increasing sedation of benzodiazepines or alcohol; (2) use to prevent side effects of cocaine; (3) use with Tramadol to produce relaxation and euphoria; (4) as a combination with Hydrocodone, an effect that some abusers claim is similar to heroin (referred to as a "Las Vegas Cocktail"); & (5) as a combination with codeine (referred to as "Soma Coma"). In this case, there is no substantial evidence of spasm requiring treatment with this medication. There is no documentation of any significant improvement in pain or function with prior use. Therefore, the request is not medically necessary per guidelines.

**Theramine:** 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 Foods.

**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:** 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 Foods.

**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.

**Sentra AM:** 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 Foods.

**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:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter Medical Foods.

**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:** 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 Foods.

**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 Physician Therapeutics, Los Angeles, 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.

**Methoderm gel #240:** 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:** Methoderm 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.

**Pain Terocin Patch #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 Lidocaine Page(s): 56.

**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 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.