

<b>Case Number:</b>	CM14-0029088		
<b>Date Assigned:</b>	04/07/2014	<b>Date of Injury:</b>	11/05/2012
<b>Decision Date:</b>	05/27/2014	<b>UR Denial Date:</b>	01/09/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/17/2014

### 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, has a subspecialty in Sports Medicine, and is licensed to practice in Texas. 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 24-year-old male who reported an injury on 11/05/2012. The mechanism of injury was rotating/twisting, and resulted in a popping sensation with inability to stand upright, for approximately 20 minutes. The patient was initially prescribed medications and a course of physical therapy. Due to the failure of his symptoms to resolve, the injured worker was referred for pain management and evaluation by an orthopedic specialist. The injured worker is also noted to have received chiropractic and acupuncture therapy, as well as unspecified injections. An MRI (magnetic resonance imaging) of the lumbar spine obtained on 03/08/2013 revealed small bilateral foraminal disc protrusions with slight impingement of the exiting left L4 nerve root, at L4-5; no other abnormalities were found. A NCV (nerve conduction velocity) of the bilateral lower extremities was obtained on 06/12/2013. This study revealed evidence of right peroneal motor nerve deficits, in comparison with the left. The patient currently utilizes multiple medications for pain control.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**TEROCIN PAIN PATCH BOX #20:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** The California MTUS guidelines recommend topical analgesics in treating primarily neuropathic and osteoarthritic pain. The MTUS guidelines state that any topical compound that contains at least 1 drug or drug class that is not recommended, deems the entire product not recommended. The current request for Terocin patch is a compounded medication consisting of methyl salicylate, capsaicin, menthol, and lidocaine 2.50%. Currently, topical lidocaine is only indicated for treatment of neuropathic pain after there has been evidence of a failure of a first-line therapy, such as an antidepressant or anti-epileptic medication. Additionally, the only topical lidocaine approved for use is in the dermal patch formulation of Lidoderm 5%. Although the current request is for a dermal patch, the clinical information submitted for review did not provide evidence of the failure of an antidepressant or anti-epileptic drug for treating the patient's neurologic symptoms. Furthermore, the formulation of lidocaine in this compounded medication is 2.50%, less than the 5% approved for topical use. Without evidence of the failure of first-line therapies, this topical analgesic is not indicated at this time. As such, the request for Terocin pain patch box #20 is non-certified.

**THERAMINE #90:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation NON-MTUS.

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

**Decision rationale:** The California MTUS/ACOEM Practice Guidelines do not specifically address the need for Theramine; therefore, the Official Disability Guidelines (ODG) was supplemented. The ODG does not recommend Theramine in the treatment of pain conditions, as there is no high quality peer-reviewed literature to support its use. Until there are higher quality studies detailing the efficacy of this medication, it will remain non-recommended. As such, the request for Theramine #90 is non-certified.

**SENTRA AM:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation NON-MTUS.

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

**Decision rationale:** The California MTUS/ACOEM Practice Guidelines do not specifically address the need for Sentra AM; therefore, the Official Disability Guidelines (ODG) was supplemented. The ODG states that medical foods must meet certain criteria to be qualified as such. These criteria include a product for oral or tube feeding; labeled for dietary management of

a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and the product must be used under medical supervision. Sentra AM is a compounded product containing choline bitartrate, L-glutamate, acetyl-L-carnitine, L-glutamate, and cocoa powder, and is used to treat multiple illnesses. The OGD states that choline provides no known medical benefit, except in the case of long term parenteral nutrition for individuals with a choline deficiency secondary to a liver deficiency. Additionally, glutamine is a precursor to gamma-aminobutyric acid (GABA); guidelines state that there is no medical need for GABA. As this medication contains substances that have no trial-tested evidence of benefit, and there is no indication that the injured worker has a verified choline deficiency, use of this medication is not indicated. As such, the request for Sentra AM is non-certified.

**SENTRA PM:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation NON-MTUS.

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

**Decision rationale:** The California MTUS/ACOEM Practice Guidelines do not specifically address the need for Sentra PM; therefore, the Official Disability Guidelines (ODG) was supplemented. The ODG states that medical foods must meet certain criteria to be qualified as such. These criteria include a product for oral or tube feeding; labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and the product must be used under medical supervision. Sentra PM is a compounded product containing choline bitartrate, 5-hydroxytryptophan, L-glutamate, acetyl-L-carnitine, L-glutamate, and cocoa powder, and is used to treat multiple illnesses. Guidelines state that choline provides no known medical benefit except in the case of longterm parenteral nutrition for individuals with a choline deficiency secondary to liver deficiency. Although 5-hydroxytryptophan may aid sleep onset, there is not enough evidence to support its use. As this medication contains substances that have no trial-tested evidence of benefit, and there is no indication that the injured worker has a verified choline deficiency or sleep difficulty, the use of this medication is not indicated. As such, the request for Sentra PM is non-certified.

**GABADONE:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation NON-MTUS.

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

**Decision rationale:** The California MTUS/ACOEM Practice Guidelines do not specifically address the need for Gabadone; therefore, the Official Disability Guidelines (ODG) was supplemented. The ODG does not recommend Gabadone for treating conditions such as

insomnia or anxiety, as there are no high quality peer-reviewed studies to support its use. Additionally, the desired quantity was not submitted with the request. As such, the request for Gabadone is non-certified.