

<b>Case Number:</b>	CM14-0047958		
<b>Date Assigned:</b>	08/08/2014	<b>Date of Injury:</b>	01/20/2013
<b>Decision Date:</b>	09/17/2014	<b>UR Denial Date:</b>	03/19/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/16/2014

### 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 Illinois. 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 44-year-old female who reported an injury on 01/20/2013. The mechanism of injury was the injured worker was transferring a client from a bed to a wheelchair. The injured worker was noted to undergo a magnetic resonance imaging (MRI) of the lumbar spine, and MRIs of the bilateral knees. The injured worker's diagnoses were noted to include lumbosacral spine sprain and strain and sprain and strain of the shoulder and upper arm. The other therapies included physical therapy, chiropractic treatment, and medications. The injured worker underwent urine drug screens. The documentation indicated the injured worker was utilizing Sentra AM, Theramine, and GABAdone, as well as Terocin patches as of at least 12/2013. The documentation of 01/27/2014 revealed the injured worker had complaints of low back pain radiating to the left lower extremity and frequent left knee pain. The injured worker indicated the pain without the medication was 7/10 and with the medication was 4/10. The injured worker indicated she had no side effects from the medications. The injured worker indicated with the topical creams and patches she was able to walk longer, sit longer, increase sleep, and decrease oral medication intake. The physical examination revealed the lumbar spine had tenderness to palpation. The diagnoses included lumbar radiculopathy and left knee internal derangement. The treatment plan included Terocin patches, Cyclobenzaprine 7.5 mg, Methoderm 240 grams, Colace 100 mg, chiropractic manipulation 2 times a week for 4 weeks, physical therapy 2 times a week for 4 weeks, and other medications. There was no request for authorization for the requested medications and urine drug screen.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Gabadone #60: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Decision rationale:** The Official Disability Guidelines do not recommend GABAdone. The duration of use was at least 1 month. There was a lack of documented rationale and exceptional factors for the requested medication. There was a lack of documentation of objective functional benefit. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for GABAdone #60 is not medically necessary.

**Sentra AM #60: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Medical Foods  
<http://www.marvistahealthcenter.com/medicalfoods/SentraAMProductMonograph.pdf>.

**Decision rationale:** Per Marvista health center.com, Sentra AM is a blend of choline bitartrate and glutamate, acetyl-L-carnitine, cocoa powder, ginkgo biloba and grape seed extract and is utilized in the treatment of chronic and generalized fatigue, fibromyalgia, post-traumatic stress disorder. Per the Official Disability Guidelines, to be considered a medical food the product must be a food for oral or tube feeding, must be 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. The clinical documentation submitted for review failed to meet criteria for medical food. The duration of use was at least 1 month. There was a lack of documented efficacy. There was a lack of documented rationale and exceptional factors for the requested medication. The request as submitted failed to indicate the frequency for the requested product. Given the above, the request for Sentra AM #60 is not medically necessary.

**Sentra PM #60: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Decision rationale:** The Official Disability Guidelines indicates that Sentra PM and is intended for use in management of sleep disorders associated with depression. It is a blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. Glutamic acid is used in complementary medicine for digestive disorders. 5-hydroxytryptophan is possibly effective in treatment of anxiety disorders, fibromyalgia, obesity and sleep disorders. The clinical documentation submitted for review indicated the injured worker had utilized Sentra PM for at least 1 month. There was a lack of documented efficacy for the requested medication. There was a lack of documented rationale and exceptional factors for the requested medication. The request as submitted failed to indicate the frequency for the requested Sentra PM. Given the above, the request for Sentra PM #60 is not medically necessary.

**Theramine #90:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Decision rationale:** The Official Disability Guidelines indicate that Theramine is not recommended. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. The duration of use was at least 1 month. There was a lack of documented efficacy. There was a lack of documented rationale and exceptional factors for the requested medication. The request as submitted failed to indicate the frequency for the medical food. Given the above, the request for Theramine #90 is not medically necessary.

**Terocin Patch #20:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate Topicals, Topical Analgesic, Lidocaine Page(s): 105, 111, 112. Decision based on Non-MTUS Citation <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=100ceb76-8ebe-437b-a8de-37cc76ece9bb>.

**Decision rationale:** The California MTUS Guidelines indicate that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants

have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The guidelines indicate that topical lidocaine (Lidoderm) may be 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). No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. The guidelines recommend treatment with topical salicylates. Per [dailymed.nlm.nih.gov](http://dailymed.nlm.nih.gov), Terocin patches are topical lidocaine and menthol. The clinical documentation submitted for review indicated the injured worker had neuropathic pain. The pain without medication was 7/10 and with medication 4/10. The documentation indicated the topical patches allowed the injured worker to walk longer, sit longer, increase sleep, and decrease oral medication intake. The documentation indicated the injured worker had utilized the Terocin patches since at least 09/2013. This request would be supported. However, the request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Terocin patch #20 is not medically necessary.

**Urine Drug Screen:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Ongoing Management Page(s): 78.

**Decision rationale:** The California MTUS Guidelines recommend urine drug screens for injured workers who have documented issues of abuse, addiction, or poor pain control. The clinical documentation submitted for review failed to meet the above criteria. There was a lack of documented medications to support the necessity for a urine drug screen. The request as submitted failed to indicate the quantity of urine drug screens being requested. Given the above, the request for urine drug screen is not medically necessary.