

<b>Case Number:</b>	CM14-0162036		
<b>Date Assigned:</b>	10/07/2014	<b>Date of Injury:</b>	12/28/2004
<b>Decision Date:</b>	10/31/2014	<b>UR Denial Date:</b>	09/23/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/02/2014

### 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 Pain Management 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:

According to the records made available for review, this is a 50-year-old male with a 5/8/07 date of injury. At the time (9/20/14) of request for authorization for Theramine #90, Unknown Prescription of Medrox Ointment, Sentra AM # 60, and Sentra PM # 60, there is documentation of subjective (low back pain with spasm) and objective (bilateral tenderness and spasm over paraspinous muscle with decreased range of motion, positive lumbar facet tenderness, and decreased sensory exam over right lateral leg) findings, current diagnoses (lumbar radiculopathy and lumbar degenerative disc disease), and treatment to date (medications (including ongoing treatment with Gabapentin, Anaprox, Prilosec, Flexeril, Tramadol, Feneprofen, Theramine, Sentra PM, and Sentra AM)). Medical report identifies that Sentra AM helps with alertness and energy; and Sentra PM helps with sleep and energy. Regarding Sentra AM, there is no documentation that the product is a food for oral or tube feeding; to be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; to be used under medical supervision; and functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Sentra AM use to date. Regarding Sentra PM, there is no documentation that the product is a food for oral or tube feeding; to be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; to be used under medical supervision; and functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Sentra PM use to date.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**THERAMINE #90:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES, MEDICAL FOOD

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

**Decision rationale:** MTUS does not address the issue. ODG identifies that Theramine is a medical food and is not recommended. Within the medical information available for review, there is documentation of diagnoses of lumbar radiculopathy and lumbar degenerative disc disease. In addition, there is ongoing treatment with Theramine. However, Theramine is a medical food that is not recommended. Therefore, based on guidelines and a review of the evidence, the request for Theramine #90 is not medically necessary.

**UNKNOWN PRESCRIPTION OF MEDROX OINTMENT:** Upheld

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

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

**Decision rationale:** Medrox cream is a compounded medication that includes 0.0375% Capsaicin, 20% Menthol, and 5% Methyl Salicylate. MTUS Chronic Pain Medical Treatment Guidelines identifies documentation that many agents are compounded as monotherapy or in combination for pain control; that ketoprofen, lidocaine (in creams, lotion or gels), capsaicin in a 0.0375% formulation, baclofen and other muscle relaxants, and gabapentin and other antiepilepsy drugs are not recommended for topical applications; and that any compounded product that contains at least one drug (or drug class) that is not recommended, is not recommended. Within the medical information available for review, there is documentation of diagnoses of lumbar radiculopathy and lumbar degenerative disc disease. However, Medrox cream contains at least one drug (capsaicin in a 0.0375% formulation) that is not recommended. Therefore, based on guidelines and a review of the evidence, the request for Unknown Prescription of Medrox Ointment 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, 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 Chapter, Medical Food Other Medical Treatment Guideline or Medical Evidence: Title 8, California Code of Regulations, section 9792.20; and <http://www.ptlcentral.com/medical-foods-products.php>

**Decision rationale:** An online source identifies Sentra AM as a Medical Food, consisting of a proprietary formulation of amino acids and polyphenol ingredients in specific proportions, for the nutritional management of the altered metabolic processes associated with fatigue and cognitive disorders. MTUS does not address the issue. MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. ODG identifies that 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 must be used under medical supervision; as criteria to support the medical necessity of medical food. Within the medical information available for review, there is documentation of diagnoses of lumbar radiculopathy and lumbar degenerative disc disease. However, there is no documentation that the product is a food for oral or tube feeding; to be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and to be used under medical supervision. In addition, despite documentation that ongoing treatment with Sentra AM helps with alertness and energy, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Sentra AM use to date. Therefore, based on guidelines and a review of the evidence, the request for Sentra AM # 60 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, 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 Chapter, Medical Food Other Medical Treatment Guideline or Medical Evidence: Title 8, California Code of Regulations, section 9792.20; and <http://www.ptlcentral.com/medical-foods-products.php>

**Decision rationale:** An online source identifies Sentra PM as a Medical Food, consisting of a proprietary formulation of amino acids and polyphenol ingredients in specific proportions, for the nutritional management of the altered metabolic processes of sleep disorders associated with depression. MTUS does not address the issue. MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. ODG identifies that 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 must be used under medical supervision; as criteria to support the medical necessity of medical food. Within the medical information available for review, there is documentation of diagnoses of lumbar radiculopathy and lumbar degenerative disc disease. However, there is no documentation that the product is a food for oral or tube feeding; to be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and to be used under medical supervision. In addition, despite documentation that ongoing treatment with Sentra PM to help with sleep and energy, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Sentra PM use to date. Therefore, based on guidelines and a review of the evidence, the request for Sentra PM # 60 is not medically necessary.