

<b>Case Number:</b>	CM15-0148474		
<b>Date Assigned:</b>	08/11/2015	<b>Date of Injury:</b>	08/15/2007
<b>Decision Date:</b>	10/14/2015	<b>UR Denial Date:</b>	07/06/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/30/2015

### 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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

### 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 59 year old male who sustained an industrial/work injury on 8-15-07. He reported an initial complaint of back pain. The injured worker was diagnosed as having lumbar spine stenosis and lumbar radiculopathy. Treatment to date includes medication, surgery (hemilaminectomy with decompression of bilateral L4-5 and left L5-S1 with revision decompression and microforaminotomy on 5-7-15). Currently, the injured worker complained of a flare up of symptoms of constant low back pain rated 8 out of 10 with numbness and tingling. Per the primary physician's report (PR-2) on 6-10-15, exam noted lumbar range of motion of flexion of 30 degrees, right lateral flexion of 10 degrees, left internal flexion of 10 degrees, tenderness in the lumbar spine, and positive straight leg raise on the left. The requested treatments include follow-up evaluation with a pain management specialist (lumbar), Genicin, Somnicin, Terocin 120 ml (Capsaicin / Methyl Salicylate / Menthol / Lidocaine), Flurbi cream, Gabacyclotram, Theramine, Sentra PM, Theramine, and Sentra PM.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Follow-up evaluation with a pain management specialist (lumbar): 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.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Chronic Pain Disorder Medical Treatment Guidelines, State of Colorado Department of Labor and Employment, 04/27/2007, pg. 56.

**Decision rationale:** The California MTUS makes no recommendations regarding referral to a pain management specialist. Alternative guidelines have been referenced. The guidelines state that referral to a pain specialist should be considered when the pain persists but the underlying tissue pathology is minimal or absent and correlation between the original injury and the severity of impairment is not clear. Consider consultation if suffering and pain behaviors are present and the patient continues to request medication, or when standard treatment measures have not been successful or are not indicated. Follow-up evaluation with a pain management specialist (lumbar) is not medically necessary.

**Genicin, ninety count:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Glucosamine (and Chondroitin Sulfate).

**Decision rationale:** According to the MTUS, glucosamine is recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulphate (GS) on all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride (GH). This patient does not suffer from the above indications. Genicin, ninety count is not medically necessary.

**Somnicin, thirty count:** 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.

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

**Decision rationale:** The Official Disability Guidelines recommend a melatonin as a single agent to improve sleep. The repeated administration of melatonin improves sleep and thereby may reduce anxiety, which leads to lower levels of pain. Somnicin is a compounded medication. Melatonin compounded with other substances is not recommended. Somnicin, thirty count is not medically necessary.

**Terocin 120 ml (Capsaicin / Methyl Salicylate / Menthol / Lidocaine):** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** According to the MTUS, there is little to no research to support the use of many of these compounded topical analgesics. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Capsaicin topical is recommended only as an option in patients who have not responded or are intolerant to other treatments. The medical record contains no documentation that the patient is intolerant of unresponsive to other treatments. Terocin 120 ml (Capsaicin / Methyl Salicylate / Menthol / Lidocaine) is not medically necessary.

**Flurbi cream:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** According to the MTUS, there is little to no research to support the use of many of these Compounded Topical Analgesics. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Flurbiprofen topical is not supported by the MTUS. Flurbi cream is not medically necessary.

**Gabacyclotram:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** According to the MTUS, there is little to no research to support the use of many of these compounded topical analgesics. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Gabapentin is not recommended. There is no peer-reviewed literature to support use. Gabacyclotram is not medically necessary.

**Theramine, ninety count:** 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 Procedure Summary.

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

**Decision rationale:** Theramine is a Food and Drug Administration regulated medical food designed to address the increased nutritional requirements associated with chronic pain syndromes and low back pain. Theramine is thought to promote the production of the neurotransmitters that help manage and improve the sensory response to pain and inflammation.

Medical food is defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Medical foods do not have to be registered with the FDA and as such are not typically subject to the rigorous scrutiny necessary to allow recommendation by evidence-based guidelines. Theramine, ninety count is not medically necessary.

**Sentra PM, sixty count:** 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 Procedure Summary.

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

**Decision rationale:** Sentra is a medical food. Medical food is defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) as a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Medical foods do not have to be registered with the FDA and as such are not typically subject to the rigorous scrutiny necessary to allow recommendation by evidence-based guidelines. Sentra PM, sixty count is not medically necessary.

**Theramine, ninety count, provided April 22, 2015:** 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 Procedure Summary.

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

**Decision rationale:** Theramine is a Food and Drug Administration regulated medical food designed to address the increased nutritional requirements associated with chronic pain syndromes and low back pain. Theramine is thought to promote the production of the neurotransmitters that help manage and improve the sensory response to pain and inflammation. Medical food is defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) as a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Medical foods do not have to be registered with the FDA and as such are not typically subject to the rigorous scrutiny necessary to allow recommendation by evidence-based guidelines. Theramine, ninety count, provided April 22, 2015 is not medically necessary.

**Sentra PM, sixty count, provided April 22, 2015: 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 Procedure Summary.

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

**Decision rationale:** Sentra is a medical food. Medical food is defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) as a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Medical foods do not have to be registered with the FDA and as such are not typically subject to the rigorous scrutiny necessary to allow recommendation by evidence-based guidelines. Sentra PM, sixty count, provided April 22, 2015 is not medically necessary.