

<b>Case Number:</b>	CM15-0196242		
<b>Date Assigned:</b>	10/09/2015	<b>Date of Injury:</b>	01/29/2014
<b>Decision Date:</b>	12/17/2015	<b>UR Denial Date:</b>	09/09/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/06/2015

### 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: Arizona, Michigan

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 37 year old male who sustained an industrial injury on 1-29-14. A review of the medical records indicates he is undergoing treatment for right lateral epicondylitis. Medical record (8-17-15) indicates that the injured worker reports that he "can only lift, carry, push and pull light objects, and perform moderate activity for at least two minutes". The record states that he has "some difficulty" with reaching and grasping something off a shelf at chest level and overhead, as well as gripping, grasping, holding and manipulating objections with his hands, and with forceful activities with his arms and hands with repetitive motions. He reports that his sleep is "mildly" disturbed and he has had "moderate" change in his sexual function. He reports that his pain is "moderate" most of the time. He also reports that his pain interferes with his ability to engage in social activities and with his concentration and thinking. He rates his pain "4-5 out of 10". The treatment has included physical therapy, shockwave therapy, epicondyle straps, and epicondylar injections, as well as medications. His medications include topical cream Flurbiprofen-Menthol-Capsaicin, Theramine twice daily, and Sentra PM at bedtime. A left wrist brace was given to be used on a "part-time basis". The utilization review (9-9-15) includes requests for authorization of the topical cream, Theramine twice daily, Sentra PM at bedtime, and the left wrist brace. All were denied.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Theramin twice a day Qty: 1.00: 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), Chronic pain - 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 / Theramine / Medical food.

**Decision rationale:** The MTUS / ACOEM did not address the use of Theramine, therefore other guidelines were consulted. Per the ODG "Not recommended for the treatment of chronic pain. Theramine is a medical food that contains 5-hydroxytryptophan 95%, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine, gamma-aminobutyric acid (GABA), whey protein concentrates, grape seed extract 85%, cinnamon, and cocoa (theobromine 6%). It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. The proposed mechanism of action is that it increases the production of serotonin, nitric oxide, histamine, and gamma-aminobutyric acid by providing these precursors." Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The FDA defines a medical food 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." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. This medication is not indicated in this injured worker, therefore the request is not medically necessary.

**Sentra PM at bedtime Qty: 60.00: 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), Chronic pain - Medical food US national institutes of health (NIH) national library of medicine (NLM) (<http://www.ncbi.nlm.nih.gov/pubmed/>).

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

**Decision rationale:** The MTUS / ACOEM did not address the use of Sentra, therefore other guidelines were consulted. Per the ODG it is not recommended. Sentra PM is a medical food from [REDACTED], intended for use in management of sleep disorders associated with depression. It is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan, hawthorn berry, cocoa, ginkgo biloba, and acetyl L-carnitine. Medical foods are not recommended for treatment of chronic pain as they have not been shown to

produce meaningful benefits or improvements in functional outcomes. The FDA defines a medical food 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." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. This medication is not indicated in this injured worker, therefore the request is not medically necessary.

**Flubiprofen/Capsaicin/Menthol cream Qty: 1.00: Upheld**

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

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

**Decision rationale:** Per the MTUS, topical analgesics are recommended as an option, they are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. A review of the injured workers medical records that are available to me does not show a trial of recommended first line agents that have failed, therefore the request for Flubiprofen/Capsaicin/Menthol cream Qty: 1.00 is not medically necessary.

**Left wrist brace Qty: 1.00: 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), Carpal tunnel syndrome.

**MAXIMUS guideline:** Decision based on MTUS Forearm, Wrist, and Hand Complaints 2004, Section(s): Physical Methods.

**Decision rationale:** Per the MTUS/ ACOEM Initial treatment of CTS should include night splints. Day splints can be considered for patient comfort as needed to reduce pain, along with work modifications. However, a review of the injured workers medical records that are available do not reveal a clear rationale for ordering this brace, therefore the request is not medically necessary.