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| <b>Case Number:</b>   | CM14-0136068 |                              |            |
| <b>Date Assigned:</b> | 09/03/2014   | <b>Date of Injury:</b>       | 03/10/2006 |
| <b>Decision Date:</b> | 12/05/2014   | <b>UR Denial Date:</b>       | 08/11/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 08/23/2014 |

### 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 Preventive Medicine, has a subspecialty in Occupational Medicine and is licensed to practice in Iowa. 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:

This patient is a 59 year old employee with date of injury of 3/10/2006. Medical records indicate the patient is undergoing treatment for right knee sprain, lumbar sprain, and myospasm and sleep disturbance. Subjective complaints include pain while walking rated 9/10. The patient feels stiff and tender radiating to coccyx. Pain is sharp (9/10) when moving from a sitting to standing position. Objective findings include tenderness to right knee with tender paraspinal muscles. There was spasm at L3-L5. The patient had limited range of motion, swelling and tenderness over the supra and inferior to the patella. Treatment has consisted of Theramine, Sentra, topical cream, right knee brace and chiropractic care. The utilization review determination was rendered on 8/11/2014 recommending non-certification of Theramine, QTY: 90, 2 bottles; Flurbiprofen/Capsaicin/Camphor 10/0.25percent, 2 percent, 1 percent, 120mg; Sentra PM QTY: 60, 1 bottle and Ketoprofen, Cyclobenzaprine, Lidocaine 10 percent, 3 percent, 5 percent 120 mg.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Theramine, QTY: 90, 2 bottles:** 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 (updated 07/10/14), Theramine

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

**Decision rationale:** ODG states that a medical food is "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". ODG comments on Theramine directly, "Not recommended. Theramine is a medical food from [REDACTED], that is a proprietary blend of gamma-aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. See Medical food, Gamma-Aminobutyric acid (GABA), where it says, "There is no high quality peer-reviewed literature that suggests that GABA is indicated"; Choline, where it says, "There is no known medical need for choline supplementation"; L-Arginine, where it says, "This medication is not indicated in current references for pain or inflammation"; & L-Serine, where it says, "There is no indication for the use of this product." In this manufacturer study comparing Theramine to Naproxen, Theramine appeared to be effective in relieving back pain without causing any significant side effects. (Shell, 2012) Until there are higher quality studies of the ingredients in Theramine, it remains not recommended." The ODG guidelines do not support the use of Theramine. As such the request for Theramine, QTY: 90, 2 bottles is not medically necessary.

**Flurbiprofen/Capsaicin/Camphor 10/0.25percent, 2 percent, 1 percent, 120mg: 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 (updated 07/10/14), Topical Analgesics Compounded

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound Creams

**Decision rationale:** MTUS and ODG recommend usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anti-convulsants. MTUS states, "There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." MTUS recommends topical Capsaicin "only as an option in patients who have not responded or are intolerant to other treatments." There is no indication that the patient has failed oral medication or is intolerant to other treatments. Additionally, ODG states "Topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns, a new alert from the FDA warns." As such, the request for Flurbiprofen/Capsaicin/Camphor 10/0.25percent, 2 percent, 1 percent, 120mg is not medically necessary.

**Sentra PM QTY: 60, 1 bottle:** 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 (updated 07/10/14), Sentra PM

**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:** MTUS is silent regarding Sentra PM. ODG states that Sentra PM is a medical food from Targeted Medical Pharma Inc., Los Angeles, CA, intended for use in management of sleep disorders associated with depression that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. In addition ODG states that a medical food is "Definition: 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 externally 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. To be considered the product must, at a minimum, meet the following criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision." ODG specifically states "Choline is a precursor of Acetylcholine. 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." Medical records do not indicate that the patient meets these criteria. The medical records do not indicate the specific dietary disease or condition for which there is a distinctive nutritional requirement that the medication would be used for. Additionally, there is a component of this medication that is not recommended per guidelines. As such, the request for Sentra PM QTY: 60, 1 bottle is not medically necessary.

**Ketoprofen, Cyclobenzaprine, Lidocaine 10 percent, 3 percent, 5 percent 120 mg:** 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 based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound Creams

**Decision rationale:** MTUS and ODG recommend usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." MTUS states regarding topical muscle relaxants,

"Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Topical Cyclobenzaprine is not indicated for this usage, per MTUS. As such, the request for Ketoprofen, Cyclobenzaprine, Lidocaine 10 percent, 3 percent, 5 percent 120 mg is not medically necessary.