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| <b>Case Number:</b>   | CM14-0079362 |                              |            |
| <b>Date Assigned:</b> | 07/18/2014   | <b>Date of Injury:</b>       | 02/06/1992 |
| <b>Decision Date:</b> | 09/24/2014   | <b>UR Denial Date:</b>       | 04/29/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 05/29/2014 |

### 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 Occupational Medicine 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:

Patient is a 66 year-old female with date of injury 02/06/1992. The medical document associated with the request for authorization, a primary treating physician's progress report, dated 03/14/2014, lists subjective complaints as pain in the neck, right shoulder, arm, and wrist. Objective findings: Examination of the cervical spine revealed decreased range of motion and increased spasms of shoulder and neck. 5 trigger points noted. Bilateral tenderness and spasms of the cervical and trapezius muscles. Decreased range of motion and sensory of the right shoulder. Diagnosis: 1. Myalgia and myositis 2. Myofascial pain syndrome 3. Cervicalgia 4. Headache 5. Spasm of muscle. The medical records supplied for review document that the patient had not been prescribed the following medication before the request for authorization on 03/14/2014. Medications: 1. Sentra AM, #60 SIG: bid 2. Sentra PM, #60 SIG: bid 3. Theramine, #90 SIG: tid.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**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 (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)). food which is formulated to be consumed or administered entirely 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 therefore, this request 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 (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 entirely 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 therefore, this request is not medically necessary.

**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, pain.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation (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 therefore, this request is not medically necessary.

