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| Case Number: | CM14-0111823 | | |
| Date Assigned: | 08/01/2014 | Date of Injury: | 02/06/1992 |
| Decision Date: | 10/07/2014 | UR Denial Date: | 06/17/2014 |
| Priority: | Standard | Application Received: | 07/17/2014 |

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 Internal 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:

The injured worker is a 67 year old female injured on 12/06/92 due to undisclosed mechanism of injury. Diagnoses included myalgia and myositis, myofascial pain syndrome, cervicgia, headache, spasm of muscle, and long term use of medications. Surgical history included right index finger amputation, thyroid surgery, hysterectomy, breast implants, bunionectomy, and partial sigmoidectomy. Clinical note dated 06/06/14 indicated the injured worker presented complaining of intense headaches for the previous two weeks due to neck pain. The note indicated injured worker reported spinal cord stimulator did not cover the area of complaint. Injured worker continued to complain of shorter pain and neck pain. Following initiation of medical foods including Theramine, Sentra AM, Sentra PM, and Trepadone the injured worker reported sleeping much better and without waking up. The injured worker reported pain in her right hand/wrist with shooting pain up the arm into the forearm. The injured worker reported without medications she was unable to get out of bed with frequent acute muscle spasms in the neck. The injured worker reported utilization of spinal cord stimulator continuously which was of great help; however, her pain would be intolerable. The injured worker had two hospitalizations for severe abdominal pain found to have impaired colon and was discharged on fentanyl patch and Fentora. The injured worker was later placed on Suboxone while attempting to wean the injured worker off of other medications including Dilaudid. The injured worker was also placed on Lyrica, Catapres, and baclofen. Current medications included Butrans 20mcg/week, Flexeril, Anaprox, morphine sulfate IR, Ketoprofen cream, medical foods, sprix. Physical examination revealed trigger points in left occipital count four, ability to move the neck approximately 15 degrees or less to the left, 25 degrees to the right, increase spasm of the shoulder and neck, bilateral tenderness and spasm of the cervical and trapezius muscles, increased swelling in the right hand below the wrist to the fingers, decreased sensory to the right

shoulder, deep tendon reflexes within normal limits. The requests for Sentra AM, Sentra PM, Theramine, and Trepadone were non-certified on 06/17/14.

IMR ISSUES, DECISIONS AND RATIONALES

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

Sentra AM qty 60: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ACOEM - online version, Chronic Pain, Herbal and other preparations

Decision rationale: Sentra AM is a medical food consisting of a proprietary formulation of amino acids and polyphenol ingredients for the dietary management of the metabolic processes associated with fatigue and cognitive disorders. Current guidelines do not recommend the use of herbal or medical foods as a first-line treatment. There is no indication the injured worker has failed previous prescription medications or has obvious contraindications that necessitate medical food/herbal use. As such, the request for Sentra AM qty 60 cannot be recommended as medically necessary.

Sentra PM qty #60: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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), Sentra PM

Decision rationale: As noted in the Pain chapter of the Official Disability Guidelines - Online version, the use of herbal medicines or medical foods is not recommended. Sentra PM is intended for use in management of sleep disorders associated with depression. It is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. Current guidelines do not recommend the use of herbal or medical foods as a first-line treatment. There is no indication the injured worker has failed previous prescription medications or has obvious contraindications that necessitate medical food/herbal use. As such, the request for Sentra PM qty #60 cannot be recommended as medically necessary.

Theramine qty #90: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disabilities guidelines

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), Theramine®

Decision rationale: As noted in the Pain Chapter of the Official Disability Guidelines, Theramine is not recommended for use in chronic pain management. Theramine is a medical food 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. There are no high quality studies that support the use of Theramine. The use of herbal medicines or medical foods is not recommended. Additionally, there is no indication the injured worker has failed previous prescription medications or has obvious contraindications that necessitate medical food/herbal use. As such, the request for Theramine qty #90 cannot be recommended as medically necessary.

Treadone qty #120: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disabilities guidelines

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), Treadone®

Decision rationale: As noted in the Pain Chapter of the Official Disability Guidelines, Treadone is a medical food that is a proprietary blend of L-arginine, L-glutamine, choline bitartrate, L-serine and gammaaminobutyric acid [GABA]. It is intended for use in the management of joint disorders associated with pain and inflammation. Additionally, the use of herbal medicines or medical foods is not recommended. Further, there is no indication the injured worker has failed previous prescription medications or has obvious contraindications that necessitate medical food/herbal use. As such, the request for Treadone qty #120 is not recommended as medically necessary.