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| <b>Case Number:</b>   | CM14-0065528 |                              |            |
| <b>Date Assigned:</b> | 07/11/2014   | <b>Date of Injury:</b>       | 04/01/2007 |
| <b>Decision Date:</b> | 09/22/2014   | <b>UR Denial Date:</b>       | 04/17/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 05/08/2014 |

### 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 Anesthesiology, has a subspecialty in Pain Management 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 64 year old male injured on 04/01/07 due to an undisclosed mechanism of injury. Diagnoses include industrial related fibromyalgia. Treatment to date includes right knee arthroscopy, hernia surgery, squamous cell carcinoma, and colonoscopy. The clinical note dated 03/19/14 indicated the injured worker presented complaining of wide-spread pain above and below the waist rated at 8/10 with associated poor sleep, memory problems, and left elbow greater than right elbow pain. The documentation indicated the injured worker is opioid dependent requiring Percocet 10/325mg 1 tablet every 6 hours in addition to medical food such as Theramine 3 times daily for pain. The injured worker complained of fatigue for which he utilized Sentra AM and Wellbutrin 150mg. The injured worker utilized Flexeril and Diazepam for fibromyalgia and Lunesta for sleep disorder. Additionally, the injured worker utilized Tramadol, Cialis, Tamsulosin, baby Aspirin, and Flector patch. Physical examination revealed 5/5 muscle strength to the bilateral upper and lower extremities and pain and grimace to all areas of body tested. Future medical treatment requested included L-body therapy equipment to include Swiss ball, Theraband resistant bands, full length femoral/neck/back heating pads, bolster/leg wedge, TENS unit, stretch banding, gym membership with a warm water pool, trigger point injections, injections in the bilateral elbows and epicondyles, sleep consult, interdisciplinary fibromyalgia treatment program consultation, acupuncture, B12 injections, and neuropsychological evaluation. The initial request for Theramine 3 times a day #90 was initially non-certified on 04/17/14.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Theramine, three times a day, #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113. 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 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, three times a day, #90 cannot be recommended as medically necessary.