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| Case Number: | CM14-0084465 | | |
| Date Assigned: | 07/21/2014 | Date of Injury: | 09/18/2006 |
| Decision Date: | 09/24/2014 | UR Denial Date: | 05/13/2014 |
| Priority: | Standard | Application Received: | 06/06/2014 |

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 Medicine and is licensed to practice in Texas. 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 68 year old female injured on 09/18/06 when a bench fell hitting her right knee then right ankle. The injured worker reported swelling and severe pain in the right knee and was treated with pain medication and therapy. The injured worker underwent right knee and ankle surgeries in 2009 followed by right ankle surgery in 2013. Current diagnoses included right ankle capsulitis, sinus tarsi syndrome, and right knee pathology. Clinical note dated 03/05/14 indicated the injured worker presented complaining of increased pain with standing and walking and swelling with standing and walking to the right knee. The injured worker reported continued home exercise and stretching on a daily basis. The injured worker reported pain in the tip of the toes with blankets and sheets on them. The injured worker related she had to leave her feet out from under the blankets and sheets due to increased pain. Objective findings included severe pain with palpation the right sinus tarsi and significant pain with palpation to right ankle capsule on the posterior aspect, pain with palpation medial and lateral gutter, smooth and supple skin without evidence of fissures or ulcers, nails within normal limits in regards to color and thickness, no hair on toes and feet bilaterally, decreased tone and turgor in the right ankle on anterior aspect, neurological examination demonstrated decreased sharp dull and light touch on anterior ankle. Prior clinical documentation indicated the injured worker utilized Naprosyn and Tramadol for pain management purposes. The initial request for Theramine- trial of 2 tablets for pain was non-certified on 03/05/14.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine- trial of 2 tablets for pain: 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), Treatment Index, 12th Edition 9web), 2014, Pain Chapter, Medical foods, Theramine.

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- trial of 2 tablets for pain cannot be recommended as medically necessary.