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| Case Number: | CM14-0093151 | | |
| Date Assigned: | 09/12/2014 | Date of Injury: | 12/17/2003 |
| Decision Date: | 10/22/2014 | UR Denial Date: | 05/16/2014 |
| Priority: | Standard | Application Received: | 06/19/2014 |

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 Physical Medicine and Rehabilitation and is licensed to practice in Illinois. 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 57 year old female who reported a date of injury of 12/17/2003. The mechanism of injury was not indicated. The injured worker had diagnoses of postlaminectomy syndrome of lumbar region, pain in joint of lower leg, chronic pain syndrome, knee, leg, ankle and foot injury not otherwise specified, lumbago and sprains and strains of the lumbar region. Prior treatments included physical therapy. Diagnostic studies were not indicated within the medical records provided. Surgeries included unspecified arthroscopy and total joint replacement of unknown dates. The injured worker had complaints of pain in the low back, bilateral knees with swelling of the left knee and left upper extremity and rated the pain 8/10. The clinical note dated 02/10/2014 noted the injured worker had a negative Spurling's test, symmetrical contour of the shoulders, 5/5 strength in all extremities, mild swelling and tenderness to palpation of the left knee. Medications included Terocin lotion, Duragesic patches, Mobic, Appttrim and Theramine. The treatment plan included the physician's recommendation to continue with physical therapy, a urine drug screen and for the injured worker to follow up in 4 weeks. The rationale and request for authorization form were not provided within the medical records received.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective Appttrim caps 40mg #120 DOS: 4/9/14: 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, Medical food.

Decision rationale: The injured worker had complaints of pain in the low back, bilateral knees with swelling of the left knee and left upper extremity and rated the pain 8/10. Apptrim is a formulated medical food which provides amino acids. The Official Disability guidelines indicate medical foods are not recommended for chronic pain. Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. FDA defines a medical food 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." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. The requesting physician's rationale for the request is not indicated within the provided documentation. There is a lack of documentation which demonstrates the injured worker's need for the medication. As such, the request is not medically necessary.

Thramine caps 101.5mg #90 DOS: 4/9/14: 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, Theramine.

Decision rationale: The injured worker had complaints of pain in the low back, bilateral knees with swelling of the left knee and left upper extremity and rated the pain 8/10. Theramine is a formulated medical food. Theramine is comprised of Choline Bitartrate, L-Arginine, L-Histidine, L-Glutamine, L-Serine, GABA, Griffonia Seed (20% 5HTP), Whey Protein, Grape Seed Extract, Ginkgo Biloba, Cinnamon, and Cocoa. The Official Disability Guidelines note Theramine is not recommended. 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 is no high quality peer-reviewed literature that suggests that GABA is indicated. There is no known medical need for choline supplementation. L-Arginine is not indicated in current references for pain or inflammation. There is no indication for the use of L-Serine. Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. The guidelines do not recommend the use of Theramine; therefore, the request for this medication would not be indicated at this time. Additionally, the request does not indicate the frequency at which the medication is prescribed in order to determine the necessity of the medication. The requesting physician's rationale for the request is not indicated within the provided documentation. As such, the request is not medically necessary.

