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| Case Number: | CM14-0185226 | | |
| Date Assigned: | 11/13/2014 | Date of Injury: | 01/02/2013 |
| Decision Date: | 12/15/2014 | UR Denial Date: | 10/28/2014 |
| Priority: | Standard | Application Received: | 11/06/2014 |

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 Physical Medicine and Rehabilitation 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:

This 44 year-old patient sustained an injury on 1/2/13 while employed by [REDACTED]. Request(s) under consideration include Gabadone #60 and Topical Compound Flurbiprofen/Flexeril ointment #240 gm. Diagnoses include hand contusion; right hand/finger pain; traumatic atrophy of right middle finger. There is urine toxicology report of 9/5/13 noting inconsistent findings with detected Amphetamines, Ranitidine and Tramadol not listed as prescribed. UDS of 11/5/13 again noted inconsistent detection of unlisted Cyclobenzaprine, barbituates, and opiates with false negative Tricyclic antidepressant. Report of 12/16/13 noted unchanged hand complaints; attending hand therapy with pain rated at 6-9/10. Exam showed redness gone; reduced swelling of hand with inability to make fist from pain. Diagnoses included right hand contusion; traumatic arthropathy and right hand/finger pain. Treatment included topical compounded creams, analgesics and hand therapy with patient remaining TTD. Latest report from the provider noted the patient with unchanged symptom complaints with pain rated at 5-6/10 with and 10/10 without medications without neurological deficits identified. The request(s) for Gabadone #60 and Topical Compound Flurbiprofen/Flexeril ointment #240 gm were non-certified on 10/28/14 citing guidelines criteria and lack of medical necessity.

IMR ISSUES, DECISIONS AND RATIONALES

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

Gabadone # 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, chronic 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, Medical food, Gabadone, pages 729, 758-759

Decision rationale: Gabadone is a Medical Food product that provides amino acids, precursors to the neurotransmitters that have been depleted due to certain disease states or as a result of certain drug side effects. This Medical Food stimulates the body to produce the neurotransmitters that induce sleep, promote restorative sleep, and reduce snoring. Patients with sleep disorders frequently experience a nutritional deficiency of tryptophan and choline. Patients with sleep disorders frequently show reduced blood levels of serotonin and 5-hydroxytryptophan. Choline deficiency has also been associated with sleep disorders, particularly those associated with sleep apnea syndromes. Gabadone aids in the nutritional management of serotonin, acetylcholine and GABA production deficiencies in patients with sleep disorders and anxiety. Gabadone is considered a medical food, used for the treatment of disease states with known nutritional deficiencies. Based on a review of the available medical reports, there is no evidence to suggest that this patient has any type of nutritional deficiency. According to the FDA website, "specific requirements for the safety or appropriate use of medical foods have not yet been established". Also per the FDA Gabadone are not FDA approved for any indication. Therefore, the use of any medical food or medical food combination would be considered experimental. Guidelines state this formulated food may be recommended for specific dietary management of a disease or condition for which distinctive nutritional requirements have been established by medical evaluation based on scientific principles. The provider had not documented the indication, clinical findings, diagnoses or medical necessity consistent with evidence-based, peer-reviewed, nationally recognized treatment guideline for this medical food. The Gabadone #60 is not medically necessary and appropriate.

Compounded flurbiprofen/flexeril ointment # 240 gm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical NSAIDs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: Per California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Guidelines, the efficacy in clinical trials for topical analgesic treatment modality has been inconsistent and most studies are small and of short duration. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. There is little evidence to utilize topical compound analgesic over oral NSAIDs or other pain relievers for a patient with spinal and multiple joint pain without contraindication in taking oral medications. Submitted reports have not adequately demonstrated the indication or medical need for this topical analgesic for this chronic injury of 2013 without documented functional

improvement from treatment already rendered. The Topical Compound Flurbiprofen/Flexeril ointment #240 gm is not medically necessary and appropriate.