

Case Number:	CM14-0204029		
Date Assigned:	12/16/2014	Date of Injury:	09/08/2008
Decision Date:	02/03/2015	UR Denial Date:	11/26/2014
Priority:	Standard	Application Received:	12/05/2014

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 Rehab 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 51 year old male who reported a work injury to his lower back on 09/08/2008. Past medical treatment included Magnetic Resonance Imaging of the cervical spine, lumbar spine, and right knee, abdominal ultrasound, transthoracic echocardiogram, and internal medicine evaluation. Diagnosis are documented as cervical spine herniated disc, lumbar spine herniated disc, right knee osteoarthritis, hypertension, hyperlipidemia, shortness of breath secondary to anxiety, abdominal pain, acid reflux secondary to stress, rule out ulcer-anatomical alteration, weight gain, sleep disorder, rule out obstructive sleep apnea, mitral stenosis, gastritis, pterygium-ophthalmology, and fatty liver. Prior treatments have included physical therapy, epidural steroid injections, acupuncture, chiropractic care, and medications. The treating physician' progress note dated 11/17/2014 states the injured worker complained of insomnia, fatigue, and pain rated 7/10. On examination the cervical and lumbar spine range of motion was decreased and spasms were noted. The right knee range of motion was also decreased. Of note the physician's examination note was hand written and difficult to read. The request is for Gabadone quantity of 60 that a Utilization Review denied on 11/26/2014 because the submitted documentation did not indicate that the injured worker had a nutritional deficiency that could be address with medical food. ODG Pain Guidelines were utilized in the decision making.

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 (ODG), Pain, GABA done

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.