

Case Number:	CM14-0207950		
Date Assigned:	12/19/2014	Date of Injury:	08/12/2011
Decision Date:	02/11/2015	UR Denial Date:	11/13/2014
Priority:	Standard	Application Received:	12/12/2014

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 Emergency Medicine 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:

Patient with reported date of injury on 8/12/2011. Mechanism of injury was not documented. Patient has a diagnosis of lumbar disc displacement, L shoulder impingement, L middle finger osteoarthritis, rotator cuff sprain and displacement of cervical spine. Medical reports reviewed. Last report available until 10/16/14. Recent progress notes are hand written and limited by poor legibility. Patient has neck, low back and L shoulder pain. Exam reveals tenderness to palpation to spinous process C3-6 with bilateral paraspinal pain. Decreased range of motion (ROM), cervical compression is positive. L shoulder with tenderness, positive impingement and decreased ROM. Lumbar spine has tenderness from L1-5 with spasms. Decreased ROM. Straight raise is reportedly positive bilaterally. Provider has failed to document why non-evidence based "medical foods" with no evidence for efficacy or safety was requested for this patient. Medications include naproxen, omeprazole and gabapentin. Unknown creams. Independent Medical Review is for Sentra AM #60, Theramine #60 and Gabardone #60. Prior Utilization Review on 11/13/14 recommended non-certification.

IMR ISSUES, DECISIONS AND RATIONALES

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

Sentra AM #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), Treatment Index, 11th Edition (web), 2014, Pain / Sentra AM, Medical Food

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 Foods

Decision rationale: Sentra PM is an supplement marketed as a "medical food" containing Choline Bitartrate, Glutamic Acid, 5-hydroxytyptophan, Acetyl L-Carnitine, Ginkgo Biloba, Griffonia Extract (5HTP 95%), Hawthorn Berry and Cocoa(from the company's website: http://tmedpharma.com/docs/monographs-10-09/Sentra_PM_Monograph_v_Final_10-15-2009.pdf). It is marketed as a sleep aid for people with "nutritional deficiencies associated with sleep disorders." It is not recommended with little to no evidence to support these claims by the manufacturer. It is marketed as a medical food/non-medicinal supplement. Similar to many of these "medical food" products, it makes multiple vague claims so as not to require FDA trials. There are no supporting good quality studies on the efficacy of this product. The studies often quoted are poorly designed studies. The ODG indicates medical food is defined as "a food which is formulated to be consumed or internally 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." ODG reviews the evidence for each component of Sentra PM for insomnia and concludes that all components have little to no evidence for use in insomnia except for some poor evidence of insomnia improvement in 5-hydroxytryptophan. Documentation states that patient has sleep problems but there are no details as to the severity of the sleep problem or any significant deficiencies or disability from it. There is no information of other attempted treatments for the sleep problem. Patient (pt) has no documented nutritional deficiency causing insomnia. Documentation reports that pt's insomnia may be due to sleep apnea and obesity therefore a "medical food" is not indicated since there is no nutritional deficiency or documented nutritional special requirements. Sentra PM is an non-evidenced based non-medicinal substance with unknown efficacy or safety profile and is not medically necessary.

Theramine #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), Treatment Index, 11th Edition (web), 2014, Pain / Theramine Medical Food

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Medical Food

Decision rationale: Theramine is a brand name product, being sold by Targeted Medical Pharma, containing multiple non-prescription generic substances including "amino acids and polyphenol ingredients" claimed by its manufacturer to aid in various "inflammatory conditions" and pains. It is marketed as a medical food/non-medicinal supplement. Similar to many of these "medical food" products, it makes multiple vague claims so as not to require FDA trials. There are no supporting good quality studies on the efficacy of this product. The studies often quoted are poorly designed studies. There are no corresponding sections in ACOEM or MTUS

concerning these substances. The ODG indicates medical food is defined as "a food which is formulated to be consumed or internally 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." ODG reviewed each individual component in Theramine and found no evidence to support its use and does not recommend the use of Theramine. Patient has no documented nutritional deficiency causing pain. A "medical food" is not indicated since there is no nutritional deficiency or documented nutritional special requirements. Theramine is an unevidenced non-medicinal substance with unknown efficacy or safety profile and is not medically necessary.

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), Treatment Index, 11th Edition (web), 2014, Pain / Gabadone, Medical Food

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Medical Food

Decision rationale: Gabadone is a brand name product, being sold by Targeted Medical Pharma, containing multiple non-prescription generic substances including "amino acids and polyphenol ingredients" claimed by its manufacturer to aid in various "sleep conditions" and anxiety. There is only marketing information available online. It is marketed as a medical food/non-medicinal supplement. Similar to many of these "medical food" products, it makes multiple vague claims so as not to require FDA trials. There are no supporting good quality studies on the efficacy of this product. The studies often quoted are poorly designed studies. There are no corresponding sections in ACOEM or MTUS concerning these substances. The ODG indicates medical food is defined as "a food which is formulated to be consumed or internally 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." Patient has no documented nutritional deficiency causing sleep problems or anxiety. A "medical food" is not indicated since there is no nutritional deficiency or documented nutritional special requirements. Gabadone is an unevidenced non-medicinal substance with unknown efficacy or safety profile and is not medically necessary.