

Case Number:	CM14-0204076		
Date Assigned:	12/16/2014	Date of Injury:	01/13/2010
Decision Date:	02/03/2015	UR Denial Date:	11/11/2014
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 Family Practice 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:

61 yr. old female claimant sustained a work injury on 1/13/10 involving the neck, back and left shoulder. She was diagnosed with cervical disc protrusion, lumbar disc protrusion, left shoulder impingement and cervical radiculitis. Progress note on 11/10/ 2014 indicated the claimant had 5/10 pain involved areas. Exam findings were notable for cervical spasms. There was limited range of motion in the lumbar spine. The left shoulder had impingement findings. The physician requested topical compound creams, MRI if the neck, shoulder, lumbar spine and the use of medical foods (Theramine, Gabadone, Sentra AM, and Sentra PM).

IMR ISSUES, DECISIONS AND RATIONALES

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

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)

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

Decision rationale: Theramine is a medical food containing 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. According to the ODG guidelines it is not recommended. Choline is a precursor of acetylcholine. There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. GABA is indicated for epilepsy, spasticity and tardive dyskinesia. There is no high quality peer-reviewed literature that suggests that GABA is indicated for treatment of insomnia. There is poor evidence to support its use and no diagnoses to indicate the need. The use of Theramine is not medically necessary.

Sentra PM #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)

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

Decision rationale: Sentra PM is a medical food containing amino acids including choline, L-carnitine, and L-glutamate). It is intended to be used for controlling sleep. According to the ODG guidelines, choline is a precursor of acetylcholine. There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. Glutamate is used for treatment of hypochlorhydria and achlorhydria. There is no indication that the claimant has the above diagnoses. There is insufficient evidence to define the benefit of Sentra PM. The use of Sentra PM 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)

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

Decision rationale: Per guidelines, Gabadone is a nutraceutical used as a sleep aid. It is a proprietary blend of Choline Bitartrate, Glutamic Acid, 5-Hydroxytryptophan, and GABA. It is intended to meet the nutritional requirements for inducing sleep, promoting restorative sleep and reducing snoring in patients who are experiencing anxiety related to sleep disorders. There is no known need for these products and they are not supported by evidence-based literature. GABA for instance supplement is indicated for epilepsy, spasticity and tardive dyskinesia. There is no high quality peer-reviewed literature that suggests that GABA is indicated for treatment of insomnia. The details or etiology of the underlying disorder requiring Gabadone are not identified and the diagnoses do not correlate with the claimant's. The Gabadone is therefore not medically necessary.

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)

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

Decision rationale: Sentra AM contains choline and L-glutamate. According to the ODG guidelines, Choline is a precursor of acetylcholine. There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency. Glutamic Acid: This supplement is used for treatment of hypochlorhydria and achlorhydria. In this case, the claimant does not have the above diagnoses. There is lack of evidence to support the use of Sentra AM and it is not medically necessary.