

Case Number:	CM14-0069605		
Date Assigned:	08/11/2014	Date of Injury:	10/13/2002
Decision Date:	09/18/2014	UR Denial Date:	04/28/2014
Priority:	Standard	Application Received:	05/14/2014

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 Medicine, and is licensed to practice in Arizona. 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 is a 47 year old male with a date of injury of 10/13/2002. Diagnosis is of lumbar radiculopathy, and idiopathic peripheral autonomic neuropathy. Subjective complaints are of thoracic and lumbar pain. Patient also reported pain in the wrists, hands, and thighs. Physical exam showed tenderness over the lumbar spine with mild reduction in range of motion. Straight leg raise was positive, and strength and reflexes were normal. Prior treatment has included physical therapy, acupuncture, and water therapy. Request is for multiple medical food supplements.

IMR ISSUES, DECISIONS AND RATIONALES

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

Theramine, #90: 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) PAIN, THERAMINE.

Decision rationale: The ODG indicates that 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. For choline the ODG states that there is no known medical need for choline supplementation. For GABA the ODG states it is indicated for epilepsy, spasticity and tardive dyskinesia. Therefore, due to these ingredients not being consistent with guideline recommendations or the patient's diagnoses, the medical necessity of Theramine is not established.

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) PAIN, MEDICAL FOODS.

Decision rationale: Sentra AM is a blend of choline, glutamate, cocoa powder, acetyl-l carnitine and other extracts. The ODG states that there is no known medical need for choline supplementation. For glutamate, the ODG states that its treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. Therefore, the use of this medication is not consistent with guideline recommendations or the patient's diagnoses, and the medical necessity of Sentra AM is not established.

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) PAIN, SENTRA PM.

Decision rationale: Sentra PM is a medical food intended for use in management of sleep disorders associated with depression that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. The ODG states that there is no known medical need for choline supplementation. For 5-hydroxytryptophan, the ODG states that this product has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity and sleep disorders. For glutamate, the ODG states that its treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. Therefore, the use of this medication is not consistent with guideline recommendations or the patient's diagnoses, and the medical necessity of Sentra PM is not established.

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) PAIN, MEDICAL FOOD/GABADONE.

Decision rationale: The ODG indicates that GABAdone is a medical food that 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. For Choline the ODG states that there is no known medical need for choline supplementation. For GABA there is no high quality peer-reviewed literature that suggests that GABA is indicated for treatment of insomnia. Therefore, due to these ingredients not being consistent with guideline recommendations, the medical necessity of Gabadone is not established.

Trepadone, #90: 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) PAIN, MEDICAL FOODS.

Decision rationale: Trepadone is a medical food from that is a proprietary blend of L-arginine, L-glutamine, choline bitartrate, L-serine and gamma amino butyric acid [GABA]. It is intended for use in the management of joint disorders associated with pain and inflammation. For Choline, the ODG states that there is no known medical need for choline supplementation. For GABA there is no high quality peer-reviewed literature that suggests that GABA is indicated for treatment of insomnia. The ODG states that there is no known medical need for choline supplementation. Therefore, due to these ingredients not being consistent with guideline recommendations, the medical necessity of Trepadone is not established.

Genicin, #90 (Glucosamine 500mg): Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines GLUCOSAMINE Page(s): 50.

Decision rationale: CA MTUS recommends glucosamine as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. For this patient the submitted documentation does not show evidence of ongoing osteoarthritis, and does not identify the intended use of this product. Therefore, the medical necessity of Genicin is not established.

Somnicin, #30 (Melatonin 2mg, 5HTP 50mg, L-tryptphen 100mg, Pyridoxine 10mg & Manesium 50mg): 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) PAIN, MEDICAL FOODS.

Decision rationale: It is documented that this medication is taken for insomnia, anxiety, and muscle relaxation. The ODG states that medical food 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 is no indication that the patient has nutritional deficits that would require medical foods such as pyridoxine, magnesium, or l-tryptophan. Therefore, the medical necessity of Somnicin is not established.