

Case Number:	CM14-0159829		
Date Assigned:	10/03/2014	Date of Injury:	01/09/2013
Decision Date:	04/07/2015	UR Denial Date:	09/02/2014
Priority:	Standard	Application Received:	09/29/2014

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

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 35-year-old female injured worker suffered and industrial injury on 1/9/2013. The diagnoses were lumbar strain/sprain, lumbar radiculopathy, and idiopathic peripheral autonomic neuropathy. The diagnostic studies were lumbar magnetic resonance imaging and electromyography. The treatments were medications, physical therapy, and acupuncture. The treating provider reported constant low back pain 6/10 radiating to the right lower extremity with numbness and tingling. The exam revealed reduced lumbar range of motion with decreased sensation to the right lower extremity. The spine was tender with spasms. The Utilization Review Determination on 9/2/2014 non-certified: 1.Trepadone #90, ODG; 2. Theramine #90, ODG.

IMR ISSUES, DECISIONS AND RATIONALES

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

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, Pain, Trepadone.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disability guidelines chapter 'Pain (chronic)' and topic 'Trepadone'.

Decision rationale: The 35 year old patient presents with constant low back pain, rated at 6/10, that radiates to right lower extremity to produce numbness and tingling, as per progress report dated 06/19/14. The request is for TREPADONE # 90. There is no RFA for this case, and the patient's date of injury is 01/09/13. The patient has been diagnosed with lumbar disc protrusion, lumbar radiculopathy, adjustment disorder, and insomnia. Medications, as per progress report dated 05/22/14, included Terocin patch, Gabacyclotram, Flurbi (NAP) cream, and Somnicin. The patient is not working, as per the same progress report. ODG guidelines, chapter 'Pain (chronic)' and topic 'Trepadone', states that the medical food is "Not recommended. Trepadone is a medical food that is suggested for use in the management of joint disorders associated with pain and inflammation. It is a proprietary blend of L-arginine, L-glutamine, L-histidine, choline bitartrate, 5-hydroxytryptophan, L-serine, gamma-aminobutyric acid, grape seed extract, cinnamon bark, cocoa, omega-3 fatty acids, histidine, whey protein hydrolysate, glucosamine, chondroitin and cocoa." The guidelines also state that "There is insufficient evidence to support use for osteoarthritis or for neuropathic pain." In this case, Trepadone is noted in progress reports dated 06/19/14 and 05/22/14. The treater, however, does not discuss the purpose of this prescription. Additionally, ODG guidelines do not support the use of this medical food for neuropathic pain. Hence, the request IS NOT medically necessary.

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, Pain, Theramine.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disability guidelines chapter 'Pain (Chronic)' and topic 'Medical Foods'www.nutrientpharmacology.com/PDFs/monographs/theramine-monograph.pdf.

Decision rationale: The 35 year old patient presents with constant low back pain, rated at 6/10, that radiates to right lower extremity to produce numbness and tingling, as per progress report dated 06/19/14. The request is for THERAMINE #90 There is no RFA for this case, and the patient's date of injury is 01/09/13. The patient has been diagnosed with lumbar disc protrusion, lumbar radiculopathy, adjustment disorder, and insomnia. Medications, as per progress report dated 05/22/14, included Terocin patch, Gabacyclotram, Flurbi (NAP) cream, and Somnicin. The patient is not working, as per progress report dated 05/22/14. MTUS and ACOEM guidelines are silent on medical foods. However, ODG guidelines, chapter 'Pain (Chronic)' and topic 'Medical Foods', state that medical foods such as Theramine are "Not recommended for chronic pain. Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes." In this case, Theramine is noted in progress reports dated 06/19/14 and 05/22/14. The treater, however, does not discuss the purpose of this prescription. Theramine is a medical food containing a proprietary formulation of neurotransmitter precursors (L-arginine, L-glutamine, L-histidine,

choline bitartrate, 5-hydroxytryptophan), neurotransmitters (gamma-aminobutyric acid [GABA]), and a neuromodulator (L-serine); polyphenolic antioxidants (grape seed extract, cinnamon bark, cocoa); anti-inflammatory and immunomodulatory peptides (whey protein hydrolysate); and adenosine antagonists (cocoa, metabromine), as per <http://www.nutrientpharmacology.com/PDFs/monographs/theramine-monograph.pdf>. While the ODG guidelines do not discuss every ingredient found in Theramine, they state that L-arginine is not indicated in current references for pain or 'inflammation.' Regarding L-serine, the guidelines state "There is no indication in Micromedex, Clinical Pharmacology, or AltMedDex for the use of this supplement." Regarding GABA, the guidelines state that "This 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. Adverse reactions associated with treatment include hypertension, increased heart rate and anxiety." Additionally, the guidelines do not recommend medical foods for the treatment of chronic pain. Thus, Theramine IS NOT medically necessary.