

Case Number:	CM14-0060211		
Date Assigned:	06/20/2014	Date of Injury:	01/18/2001
Decision Date:	07/22/2014	UR Denial Date:	03/06/2014
Priority:	Standard	Application Received:	03/14/2014

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 Occupational 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:

The claimant was injured on 01/18/01. She was prescribed trazodone and Theramine and they are under review. She has chronic pain. She has also been prescribed other medications including Norco and Butrans. She has chronic low back and right knee pain. She has been diagnosed with lumbar radiculopathy, right knee pain and internal derangement, chronic pain syndrome, insomnia and sexual dysfunction. She also had myofascial syndrome and neuropathic pain. She stated Ketoflex ointment helped with her pain. The opioids were certified. The medical foods were non-certified. There is no documentation in the file of any nutritional deficits. She has tried multiple other medications. She has a history of hypertension and thyroid disease. Her weight was stable in July 2013. She did report bowel and bladder problems but they are not identified. She has reported that Norco gives her significant pain relief and in September 2013 she was able to stop the Butrans patches. There is a note dated 03/25/14 in which she indicated that she was not taking the medical foods as they were prescribed. She was given Trepadone and Theramine for joint and nerve pain, respectively. She stated that Butrans was helping her so much that she did not have to take as much Norco. She stated she was not sure how to take the medical foods and she was given instructions. These medical foods were recommended for 2 months.

IMR ISSUES, DECISIONS AND RATIONALES

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

1 prescription of Trepadone #120- Non-certified: 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 (Chronic); Medical Foods.

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 Other Medical Treatment Guideline or Medical Evidence: FDA; US NIH NLM PubMed 2010.

Decision rationale: The history and documentation do not objectively support the request for Trepadone #120. The ODG, Pain - Medical Foods, state that these products are intended for dietary management of a specific disease or condition for which distinctive nutritional requirements are established by medical evaluation. ODG quoting the FDA specifically states "To be considered the product must, at a minimum, meet the following criteria, (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements." Trepadone is a medical food comprised of a number of amino acids, neurotransmitter metabolites and herbals. While ODG does recognize the possible efficacy for some of these components, there is no documented medical efficacy or benefit for these combinations or these doses when added to conventional medications such as NSAIDs, opioid narcotics, muscle relaxants, or proton pump inhibitors. A search of US NIH NLM PubMed 2010 did not result in any high-quality research studies supporting the use of Trepadone under these clinical conditions. Therefore, Trepadone cannot be certified as a medically necessary agent. There is no medical necessity for any medication containing this food supplement.

1 prescription of Theramine #120- Non-certified: 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 (Chronic)- Theramine.

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 Other Medical Treatment Guideline or Medical Evidence: FDA; US NIH NLM PubMed 2010.

Decision rationale: The history and documentation do not objectively support the request for Theramine #120. The ODG, Pain - Medical Foods, state that these products are intended for dietary management of a specific disease or condition for which distinctive nutritional requirements are established by medical evaluation. ODG quoting the FDA specifically states "To be considered the product must, at a minimum, meet the following criteria, (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements." Theramine is a medical food comprised of a number of amino acids, neurotransmitter metabolites and herbals. While ODG does recognize the possible efficacy for some of these components, there is no documented medical efficacy or benefit for these combinations or these doses when added to conventional

medications such as NSAIDs, opioid narcotics, muscle relaxants, or proton pump inhibitors. A search of US NIH NLM PubMed 2010 did not result in any high-quality research studies supporting the use of Theramine under these clinical conditions. Therefore, Theramine cannot be certified as a medically necessary agent. There is no medical necessity for any medication containing this food supplement.