

Case Number:	CM14-0192426		
Date Assigned:	11/26/2014	Date of Injury:	06/20/2010
Decision Date:	01/12/2015	UR Denial Date:	11/07/2014
Priority:	Standard	Application Received:	11/18/2014

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 New Jersey. 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 worker is a 54 year old female who was injured on 2/6/2008. She was diagnosed with lumbar pain with radiculopathy, cervical strain, cervical and lumbar degenerative disc disease, right shoulder impingement syndrome, and left shoulder tendinitis. She was treated with surgery (left shoulder, lumbar), medications, and physical therapy. She was also treated with topical medications and medical food supplements (Gabadone, Sentra PM, Sentra AM, Trepadone, Theramine) by her pain management physician. The medical food supplements were first seen in the documents as being recommended on 5/21/14. Later, on 6/18/14, the worker reported the "medical foods helping with sleep and pain." Again on 7/16/14, the worker was recommended to continue them after no report on her medical food product use and symptoms or function. Her pain reported pain levels from all of these dates when these medical foods were prescribed to her were all 8/10 on the pain scale, without change. Later, on 8/13/14, there again was no report on function with the use of the medical foods and a reported low back pain with radiation to left leg this time reporting a pain level of 7/10 on the pain scale, and again her provider recommended continuation of the medical foods, including Trepadone and Gabadone.

IMR ISSUES, DECISIONS AND RATIONALES

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

Trepadone #120: 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 section, Medical food

Decision rationale: Trepadone is a combination medical food product which includes ingredients such as GABA, 5-HTP, L-arginine, choline, cocoa, glucosamine, chondroitin, and many others and is used for the treatment of joint disorders. The MTUS is silent regarding Trepadone or its ingredients individually. The ODG, however, states that medical food may be recommended in certain situations where there is a distinctive nutritional requirement. Choline, one of the ingredients in Trepadone is only recommended for long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency, and is not generally recommended yet for other indications. Choline as well as many of the other amino acids and other ingredients found in Trepadone are found in foods, which can be prescribed to patients as well, so there is no need for a specific product for most patients. In the case of this worker, Trepadone was recommended and used for at least a few months with a vague report of benefit with the use of this and all the other medical foods collectively for sleep and pain but this was not quantified or divided up between medical food products which numbered five in total. Considering these products are generally not recommended for cases without nutritional deficiency, and there was incomplete reporting of functional benefit, the Trepadone 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), Pain section, Medical food, and Gabadone

Decision rationale: Gabadone is a medical food product which includes the following ingredients: 5-Hydroxytryptophan, choline bitartrate, gamma aminobutyric acid, cocoa extract, l-glutamic acid, whey protein, griffonia extract, valerian root, acetyl l-carnitine, ginkgo biloba, and grape seed extract, which are all generally recognized as safe. Gabadone is formulated for the treatment of sleep disorders. The MTUS is silent in regards to Gabadone. The ODG states that some individual medical foods may be recommended in special circumstances where there is a clear nutritional deficiency. However, Gabadone is not recommended by the ODG. None of these ingredients found in Gabadone, however, are considered first-line therapy for sleep disorders, mostly due to limited quality studies. Since the specific product, Gabadone, includes multiple ingredients that together have even less evidence of benefit and safety, it is unreasonable to suggest this as an approved product for recommendation. In the case of this worker, Gabadone was recommended and used for at least a few months with a vague report of benefit with the use of this and all the other medical foods collectively for sleep and pain but this was not quantified or divided up between medical food products which numbered five in total.

Considering these products are generally not recommended for cases such as this worker's, and there was incomplete reporting of functional benefit, the Gabadone is not medically necessary.