

Case Number:	CM13-0029745		
Date Assigned:	11/01/2013	Date of Injury:	12/11/2008
Decision Date:	06/30/2014	UR Denial Date:	08/27/2013
Priority:	Standard	Application Received:	09/25/2013

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:

Based on the Official Disability Guidelines (ODG) Therapentin is a convenience pack comprised of Gabapentin and Theramine, a medical food proprietary blend of Gamma-Aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. According to the ODG guidelines, Theramine is not recommended. It is noted in the literature that there is no high quality peer-reviewed literature that suggests that GABA is indicated, and there is no known medical need for choline supplementation. Furthermore, the medical records demonstrate that the patient has been maintained on several medications including medical foods, however the records would support that he has not obtained any benefit with use. Therefore, the request for Therapentin-90 #150 is not medically necessary and appropriate.

IMR ISSUES, DECISIONS AND RATIONALES

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

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) Pain Chapter.

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

Decision rationale: According to the medical literature, a medical food is a product that 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. Sentra PM is a medical food, intended for use in management of sleep disorders associated with depression. The medical records do not establish that the patient suffers from nutritional deficiency as to suggest this product is indicated. Furthermore, the medical records document the patient has been on this medical food for a prolonged period, however, objective functional benefit or improvement with use of this medication, has not been shown. In absence of benefit, continuing this medication is not supported. Therefore, the request for Sentra PM #60 is not medically necessary and appropriate.

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) Pain Chapter.

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

Decision rationale: According to the Official Disability Guidelines, Trepadone is a medical food that is a proprietary blend of L-arginine, L-glutamine, choline bitartrate, L-serine and gammaaminobutyric acid [GABA]. The medical records do not establish the patient has nutritional deficiency as to warrant consideration of a medical food. In addition, the guidelines state there is no high quality peer-reviewed literature that suggests that GABA is indicated, and also state there is no known medical need for choline supplementation. Furthermore, the medical records document the patient's treatment course has included several medications. The documentation supports that he has been maintained on several medications concurrently, however he has not obtained functional improvement despite continued use. Continuing an ineffective treatment intervention is not recommended by the guidelines. Therefore, the request for Trepadone #90 is not medically necessary and appropriate.

Therapentin-90 #150: 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) Pain Chapter.

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

Decision rationale: Based on the Official Disability Guidelines (ODG) Therapentin is a convenience pack comprised of Gabapentin and Theramine, a medical food proprietary blend of Gamma-Aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. According to the ODG guidelines, Theramine is not recommended. It is noted in the literature that there is no high quality peer-reviewed literature that suggests that GABA is indicated, and there is no

known medical need for choline supplementation. Furthermore, the medical records demonstrate that the patient has been maintained on several medications including medical foods, however the records would support that he has not obtained any benefit with use. Therefore, the request for Therapentin-90 #150 is not medically necessary and appropriate.