MAXIMUS Federal Services

Case Number:	CM13-0025298		
Date Assigned:	11/20/2013	Date of Injury:	04/28/2001
Decision Date:	06/23/2014	UR Denial Date:	08/20/2013
Priority:	Standard	Application Received:	09/18/2013

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 Pain Management 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:

This claimant suffered an industrial injury on 4/28/2001. He has been seen by multiple physicians since as he has multiple problems. His last examination as per documents was on 7/23/2013 by [redacted]. Subjectively no new complaints and problems of DM II and Hypertension were well controlled. His abdominal pain, dizziness headache, SOB, fatigue and GI symptoms and sexual dysfunction had no change. On Examination his vitals were stable and his sugar was well controlled. Systemic examination did not reveal any new findings. The most recent supplemental report dated 6/21/2013 from [redacted], stated: "I have been treating the above-named patient's industrially induced Fibromyalgia Syndrome for a long time. His initial consultation was on August 23, 2004 and his last follow-up visit was on June 05, 2013. As a part of his comprehensive treatment for Fibromyalgia, I recommended several medications. I have been asked to provide a specific treatment plan for those medications with prescription, quantity, and dosage of each of those medications. First is the Sentra PM. It is recommended to be taken orally two capsules before bedtime in the amount of 60 for a month. Second is Trepadone which is recommended to be taken orally one capsule three times a day in the amount of 90 for a month. Third is Therapentin which is recommended to be taken orally 5 capsules a day in the amount of 150 for a month. Fourth is Restasls eye drofls recommended one drop twice a day to each eye in the amount of one bottle for a month. Fifth is Biotene moisturizing mouthwash solution, I recommended to use twice daily in the amount of three bottles for a month. Sixth is Tramadol topical cream, I recommended to be used as a compounded cream that includes Tramadol 15%, Dextromethorphan 10%, and Capsaicin at 0.025%. I recommended this cream in conjunction with oral medications to provide treatment in reducing the impact in patients Gl system and side effects associated with oral medications."

IMR ISSUES, DECISIONS AND RATIONALES

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

1 PRESCRIPTION FOR SENTRA PM #60: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), ODG-TWC Pain (Chronic)-Medical Food and USFDA.

Decision rationale: Sentra PM has been prescribed as a sleep aid and medical food, however this type of treatment is not supported by evidence based guidelines. According to USFDA website, the term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which 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 documentation of any distinctive nutritional requirements based on recognized scientific principles that is deficient for which the medical food is being used as a supplement. Therefore the request for 1 prescription for Sentra PM #60 is not medically necessary and appropriate.

1 PRESCRIPTION OF THERAPENTIN # 90: 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 Anti-Epilepic Drug Page(s): 17. Decision based on Non-MTUS Citation Non-MTUS Official Disability Guidelines (ODG), ODG-TWC Pain (Chronic)-Medical Food and USFDA .

Decision rationale: According to USFDA website, the term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which 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 documentation of any distinctive nutritional requirements based on recognized scientific principles that is deficient for which the medical food is being used as a supplement. Therefore, the request for 1 prescription of Therapentin # 90 is not medically necessary and appropriate.

1 PRESCRIPTION OF TREPADONE # 90: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Non-MTUS Official Disability Guidelines (ODG), ODG-TWC Pain (Chronic)-Medical Food and USFDA.

Decision rationale: Trepadoneï¿½ is a medical food from [redacted], [redacted] that is a proprietary blend of L-arginine, L-glutamine, choline bitartrate, L-serine and gammaaminobutyric acid [GABA]. It is intended for use in the management of joint disorders associated with pain and inflammation. According to the USFDA website, the term medical food, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which 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 documentation of any distinctive nutritional requirements based on recognized scientific principles that is deficient for which the medical food is being used as a supplement. Therefore the request for 1 prescription of Trepadone # 90 between is not medically necessary and appropriate.