

Case Number:	CM14-0121004		
Date Assigned:	09/30/2014	Date of Injury:	04/22/2002
Decision Date:	10/28/2014	UR Denial Date:	07/02/2014
Priority:	Standard	Application Received:	07/31/2014

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:

This case is a 67 year old female with a date of injury on 4/22/2002. A review of the medical records indicate the patient undergoing treatment for lumbar pain, myofascial syndrome, chronic pain related insomnia, chronic pain related depression, radiculopathy, chronic pain related anxiety, chronic pain syndrome, and narcotic dependence. Subjective findings (7/1/2014, 7/22/2014) include "low back pain and pain in her legs", 4/10 pain with an average of 4/10 and 10+/10 pain without medication, and 4/10 pain with medications. Objective findings (6/2/2104, 7/1/2014, 7/22/2014) include vital sign readings only. Treatment has included surgical consult (she was not a candidate), gabapentin, norco, ms contin, fluriflex, centra am, trepidone, and topical ointments. A utilization review dated 7/2/2014 non-certified the request for: 1) Centra AM #60 due to lack of establishing medical necessity for component parts 2) Trepidone #120 due to lack of establishing medical necessity for component parts 3) FLURIFLEX OINTMENT # 240 GM due to lack of guidelines support for topical muscle relaxants.

IMR ISSUES, DECISIONS AND RATIONALES

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

CENTRA AM #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) Pain, Medical Food

Decision rationale: Sentra AM is a medical food that contains choline and acetylcarnitine as in intended to maintain production of acetylcholine in the central and peripheral nervous system. MTUS and ODG are silent specifically regarding Sentra AM. In addition ODG states that a medical food is "Definition: Defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) as "a food which is formulated to be consumed or administered eternally 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. To be considered the product must, at a minimum, meet the following criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision." ODG specifically states "Choline is a precursor of acetylcholine. There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency." Medical records do not indicate that the patient meets these criteria. The medical records do not indicate the specific dietary disease or condition for which there is a distinctive nutritional requirement that the medication would be used for. Additionally, there is a component of this medication that is not recommended per guidelines. As such, the request for Centra AM #60 is not medically necessary.

TREPIDONE # 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, MEDICAL FOOD

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

Decision rationale: MTUS is silent concerning Trepadone. ODG states that a medical food 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". ODG comments on Trepadone directly, "Trepadone is a medical food from [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. See Medical food, L-Arginine, Glutamic Acid, Choline, L-Serine, and Gamma-aminobutyric acid (GABA)." ODG states, "Gamma-aminobutyric acid (GABA): This supplement is indicated for epilepsy, spasticity and tardive dyskinesia." Medical records do not indicate that this medication would be used to treat epilepsy, spasticity and tardive dyskinesia. ODG states, "L-

Serine: There is no indication in Micromedex, Clinical Pharmacology, or AltMedDex for the use of this supplement." This component is not indicated. ODG states, "L-Arginine: This supplement is not indicated in current references for pain or "inflammation. It is indicated to detoxify urine. Other indications include in use for angina, atherosclerosis, coronary artery disease, hypertension, migraines, obesity, and metabolic syndrome." Medical records do not indicate that this medication would be utilized for urine detoxification or for treatment of the other indicated reasons. The medical records do not indicate the specific dietary disease or condition for which there is a distinctive nutritional requirement that the medication would be used for. Additionally, there are several components of this medication that are not recommended per guidelines. As such, the request for TREPIDONE # 120 is not medically necessary.

FLURIFLEX OINTMENT # 240 GM: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound creams

Decision rationale: Flurflex is a topical compound made of Flurbiprofen and Cyclobenzaprine. ODG recommends usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." MTUS states regarding topical muscle relaxants, "Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Topical cyclobenzaprine is not indicated for this usage, per MTUS. MTUS states that the only FDA-approved NSAID medication for topical use includes diclofenac, which is indicated for relief of osteoarthritis pain in joints. Flurbiprofen would not be indicated for topical use in this case. This compound contains two substances which are not indicated for topical usage per MTUS, which would non-recommend the whole compound. As such, the request for FLURIFLEX OINTMENT # 240 GM is not medically necessary.