

Case Number:	CM14-0162648		
Date Assigned:	10/07/2014	Date of Injury:	06/20/2010
Decision Date:	11/24/2014	UR Denial Date:	09/25/2014
Priority:	Standard	Application Received:	10/03/2014

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 Preventive Medicine, has a subspecialty in Occupational Medicine and is licensed to practice in Iowa. 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 patient is a 54 year old employee with date of injury of 6/20/2010. Medical records indicate the patient is undergoing treatment for s/p lumbar surgery. Subjective complaints include low back pain radiating to left lower extremities. The patient complains of numbness and tingling with a pain rating of 6/10. Objective findings include lumbar range of motion was (in degrees); flexion, 50; extension and right and left lateral flexion, 15. His lumbar spine was tender and SLR was positive bilaterally. His bilateral lower extremities sensation was decreased at L5-S1. Ambien was discontinued and the patient says medical foods help with sleeping. The patient is waiting for authorization for a lumbar spine fusion. Treatment has consisted of Cyclobenzaprine, Fioricet, Norco, Colace, Theramine, and Percocet. Terocin pain patches are applied for minor pain. The patient received a Toradol and B12 injection into the gluteus on 6/14. The utilization review determination was rendered on 9/25/14 recommending non-certification of Gabadone once a day. # 60; Trepadone once a day. # 120; Terocin Patch # 20 and Sentra PM once a day #60.

IMR ISSUES, DECISIONS AND RATIONALES

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

Gabadone once a day. # 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- PAIN- GABADONE

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

Decision rationale: MTUS is silent concerning Gabadone. 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 Gabadone directly, "Not recommended. Gabadone is a medical food from [REDACTED] that is a proprietary blend of Choline Bitartrate, Glutamic Acid, 5-Hydroxytryptophan, and GABA. It is intended to meet the nutritional requirements for inducing sleep, promoting restorative sleep and reducing snoring in patients who are experiencing anxiety related to sleep disorders. (Shell, 2009) See Medical food, Choline, Glutamic Acid, 5-hydroxytryptophan, and Gamma-aminobutyric acid (GABA)." The ODG guidelines do not support the use of Gabadone. As such the request for Prospective request for Gabadone once a day # 60 is not medically necessary.

Trepadone once a day. # 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- PAIN- TREPADONE

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

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 off 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 to treat. Additionally, there are several components of this medication that are not recommended per guidelines. As such, the request for Trepadone once a day # 120 is not medically necessary.

Terocin Patch # 20: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-112.

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: Terocin lotion is topical pain lotion that contains lidocaine and menthol. ODG states regarding lidocaine topical patch, "This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia". Medical documents do not document the patient as having post-herpetic neuralgia. Additionally, Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The treating physician did not document a trial of first line agents and the objective outcomes of these treatments. MTUS states regarding topical analgesic creams, "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." In this case, Terocin Patch # 20 is not indicated. As such the request for Terocin Patch # 20 is not medically necessary.

Sentra PM once a day #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- PAIN- SENTRA PM OFFICIAL DISABILITY GUIDELINES- PAIN- 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) Pain, Medical Food

Decision rationale: ODG states "Sentra PM is a medical food from [REDACTED] intended for use in management of sleep disorders associated with depression, that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan". 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." 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 to treat. As such, the request for Sentra PM once a day #60 is not medically necessary.