

Case Number:	CM14-0050318		
Date Assigned:	06/25/2014	Date of Injury:	06/02/2003
Decision Date:	07/25/2014	UR Denial Date:	03/13/2014
Priority:	Standard	Application Received:	03/24/2014

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 Psychiatry, 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:

The claimant is a 60 year old female injured worker with date of injury 6/2/03 related low back pain. Per 3/7/14 progress report, she had chronic low back pain with radiation into the legs and rheumatoid arthritis. The relevant objective findings included bilateral tenderness and spasms of the L3-L5 paraspinal muscles. Examination of the lumbar spine showed decreased range of motion in all planes. Pain was present with palpation of the right sciatic notch and there was a positive FABERs maneuver. Her diagnoses include lumbar radiculopathy; rheumatoid arthritis; and lumbago. To avoid prescribing more meds, the primary treating physician has prescribed medical foods. Theramine was prescribed to help absorption of NSAIDs and meds, Sentra PM to help with sleep and energy, and Sentra AM to help with alertness and energy. Treatment to date has included NSAIDs, opioids, chiropractic.

IMR ISSUES, DECISIONS AND RATIONALES

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

KETOPROFEN CREME 20 %: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines CHRONIC PAIN MEDICAL TREATMENT GUIDELINES.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

Decision rationale: With regard to topical Ketoprofen, the MTUS CPMTG states This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. Absorption of the drug depends on the base it is delivered in. Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. As this agent is not FDA approved, it is not recommended. The California MTUS supports topical NSAIDs for joint pain primarily, not for lower back pain. Medical necessity cannot be affirmed. Therefore, the request is not medically necessary.

THERAMINE, # 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.

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), Theramine.

Decision rationale: The California MTUS is silent on the topic of medical food. With regard to the treatment of chronic pain, the Official Disability Guidelines guideline says this about theramine: Not recommended. Theramine is a medical food from [REDACTED], that is a proprietary blend of gamma-aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. See Medical food, Gamma-aminobutyric acid (GABA), where it says, There is no high quality peer-reviewed literature that suggests that GABA is indicated; Choline, where it says, There is no known medical need for choline supplementation; L-Arginine, where it says, This medication is not indicated in current references for pain or inflammation; & L-Serine, where it says, There is no indication for the use of this product. Theramine is not recommended by the Official Disability Guidelines and thus the request is not medically necessary.

SENTRA PM: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES.

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: The California MTUS Guidelines is silent on the topic of medical food. With regard to chronic pain, the Official Disability Guidelines say this about Sentra PM: 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. The Official Disability Guidelines states that medical foods are not considered medically necessary except in those cases in which the

patient has a medical disorder, disease or condition for which there are distinctive nutritional requirements. The records submitted for review do not include evidence that the injured worker has any distinctive nutritional requirements. The request is not medically necessary.

SENTRA AM: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation OFFICIAL DISABILITY GUIDELINES.

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: The California MTUS is silent on the topic of medical food. With regard to chronic pain, the Official Disability Guidelines say this about medical foods: medical foods are not considered medically necessary except in those cases in which the patient has a medical disorder, disease or condition for which there are distinctive nutritional requirements. The records submitted for review do not include evidence that the injured worker has any distinctive nutritional requirements. The request is not medically necessary.