

Case Number:	CM14-0171176		
Date Assigned:	10/23/2014	Date of Injury:	08/15/2008
Decision Date:	11/25/2014	UR Denial Date:	10/07/2014
Priority:	Standard	Application Received:	10/16/2014

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 Physical Medicine and Rehabilitation, has a subspecialty in Pain 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:

The injured worker is a 57 year-old male with a date of injury of August 15, 2008. The medical records were reviewed. The patient's industrially related diagnoses include back pain, lumbar spinal stenosis, and lumbar spine degenerative disc disease. The disputed issues are Sentra AM #60, Theracodophen-325 #300, and Therabenzaprime-90 #150. A utilization review determination on 10/7/2014 had non-certified these requests. The stated rationale for the denial was: "There are no medical records of an established disease or medical condition for this patient that requires the combination of amino acids contained in Sentra or Theramine.... Sentra consists of a proprietary blend of Choline Bitartrate, Glutamate, and 5-Hydroxytryptophan. Theramine is an amino acid based medical food consisting of the following ingredients: Choline Bitartrate, L-Glutamine, 5-Hydroxytryptophan, -Serine, -Arginine, cinnamon, GABA, grape seed extract, and cocoa. The medical guidelines specifically do not recommend the use of Theramine. Both Theramine and Sentra contain multiple supplements which are not recommended by the medical guidelines and the medical food, either individually or co-packaged with a medication, is not indicated."

IMR ISSUES, DECISIONS AND RATIONALES

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

Sentra AM #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, Integrated Treatment/ Disability Duration Guidelines, Pain (Chronic) - 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) Chronic Pain Chapter, Medical Food

Decision rationale: In regard to the request for Sentra AM, California MTUS does not address the issue. Per Official Disability Guidelines, "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." Additionally, "Glutamic Acid...is used for treatment of hypochlorhydria and achlorhydria. Treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer, and critical illnesses. It is generally used for digestive disorders in complementary medicine." In the submitted medical records, the treating physician prescribed Sentra AM 1-2 tabs Q4-6h #60 for chronic fatigue. However, there is no documentation of a condition for which the components of Sentra AM would be supported. In the absence of such documentation, the request for Sentra AM is not medically necessary.

Therabenzaprine-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, Integrated Treatment/ Disability Duration Guidelines, Pain (Chronic) - Medical Food

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain Chapter, Medical Food

Decision rationale: Therabenzaprine-90 includes Theramine 2 tablets Q6h #90 and Cyclobenzaprine 10mg QHS #60. In regard to Theramine, California MTUS and ACOEM Guidelines do not contain criteria for the use of medical foods. The Official Disability guidelines state that Theramine is not recommended. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. Cyclobenzaprine is a muscle relaxant. The MTUS Chronic Pain Medical Treatment Guidelines support the use of non-sedating muscle relaxants to be used with caution as a second line option for the short-term treatment of acute exacerbations of pain. Guidelines go on to state that Cyclobenzaprine specifically is recommended for a short course of therapy. In the submitted medical records, it does not appear that this medication is being prescribed for the short-term treatment of an acute exacerbation as the injured worker has been prescribed Therabenzaprine-90 since July 2014 on a monthly basis. Based on the guidelines, the request for Therabenzaprine-90 is not medically necessary.

Theracodophen-325 #300: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Integrated Treatment/ Disability Duration Guidelines, Pain (Chronic) - Medical Food

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 75-80. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Chronic Pain Chapter, Medical Food

Decision rationale: Theracodophen-325mg #300 is a combination of Theramine 2 tablets Q6h #180 and Norco 10/325mg 2 tablets Q6h #120. In regard to Theramine, California MTUS and ACOEM Guidelines do not contain criteria for the use of medical foods. Official Disability Guidelines states Theramine is not recommended. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. Norco 10/325mg (Hydrocodone/Acetaminophen) is an opioid which was recently rescheduled in October 2014 from Schedule III to the more restrictive Schedule II of the Controlled Substances Act. Norco is recommended for moderate to severe pain. In regard to the use of Norco, the California Chronic Pain Medical Treatment Guidelines state the following about on-going management with opioids: "Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs". Guidelines go on to recommend discontinuing opioids if there is no documentation of improvement in function and pain. In the submitted medical records, there was no specific documentation to support that Norco provided pain relief in terms of percent pain reduction or reduction in numeric rating scale, and no specific examples of functional improvement were provided. There was no discussion regarding possible aberrant drug-related behavior. There is no documentation of a signed opioid agreement, no urine drug screen to assess for the use or the presence of illegal drugs, and no CURES report to confirm that the injured worker is only getting opioids from one practitioner. Based on the guidelines and lack of documentation, medical necessity for Theracodophen-325mg #300 cannot be established at this time. Although it not medically necessary at this time, since it contains an opioid, it should not be abruptly halted and the requesting provider should start a weaning schedule as he or she sees fit.