

Case Number:	CM14-0152718		
Date Assigned:	09/22/2014	Date of Injury:	06/28/2004
Decision Date:	10/23/2014	UR Denial Date:	09/13/2014
Priority:	Standard	Application Received:	09/18/2014

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 Family Medicine and is licensed to practice in Colorado. 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:

37 year old female with years of chronic low back pain, from date of unspecified injury June 28, 2004, and years of "all over pain" determined to be fibromyalgia of industrial origin 2012, returned to treating physician for restart of care. Patient was treated for years with high doses of opioids, until 2012 when detoxification and weaning were recommended by treating physician, and patient was started on buprenorphine to decrease use of opioids. Patient continued with routine office visits and had urine drug testing when requested. Urine drug testing for patient was inconsistent on 5 occasions between June 2013 and May 2014. (3 of the 5 urine drug tests were negative for prescribed medications and 4 of the 5 were also positive for other medications, not prescribed by the treating physician.) The treating physician then discontinued all prescriptions when patient advised him she was 5 months pregnant in May 2014. She was then in the care of OB/GYN and had no opioids or other pain medications documented until birth of her child in August 2014. She then returned to her original treating physician requesting restart of opioids. Patient complaints at August 28, 2014 visit included severe neck pain radiating into bilateral shoulders and numbness/tingling in bilateral hands, as well as severe low back pain with numbness/tingling in left leg. Treating physician documented that patient complaints of numbness / tingling and weakness in left leg were new for her in last few weeks (since delivery of her baby). Insomnia was also mentioned as a recent symptom for patient at August visit. No physical findings consistent with radiculopathy were documented for the August visit, and character and previous treatment of insomnia not documented as well. Treating physician then placed request for Sentra PM, Norco, Urine Drug Screen, Prednisone, Percura, and MRI of Lumbar spine.

IMR ISSUES, DECISIONS AND RATIONALES

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

Sentra PM. QTY unknown: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (acute & chronic)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Medline literature review: Sentra PM (a Medical Food) and Trazodone in the Management of Sleep Disorders. Shell WE, May LA, Bullias DH, Pavlik SL, Silver DS. J Cent Nerv Syst Dis. 2012 Apr 23; 4:65-72. DOI: 10.4137/JCNSD.S9381. Print 2012.

Decision rationale: California MTUS Guidelines do not address Sentra PM, so review of available literature in Medline was conducted for evidence-based information. Treating physician requested Sentra PM for patient complaint of insomnia, though no history was provided in the records about exact type of sleep issues or interventions already tried. Sentra PM is a supplement, a combination of a choline, glutamate, and 5-hydrotryptophan, categorized as a medical food. The only research article found in Medline, involving human study, was to evaluate use of Sentra PM with and without Trazodone to help with sleep. Slight improvement in ability to fall asleep was noted in that one trial. However, one small trial does not establish evidence-based recommendation. As a medical food, Sentra PM could also be indicated for specific nutrient deficiency, if documented, though no evidence-based articles support its efficacy for nutrient replacement. In Amendment to the FDA Orphan Drug Act, medical food is defined as "a food which is formulated to be consumed or administered orally or by tube feedings, 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." (21 U.S.C. 360ee (b) (3))The FDA Nutrition Labeling and Education Act included the medical foods definition and established criteria for use: 1) Medical foods must be processed products, not used in naturally occurring state.2) Medical foods are intended for "dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone"3) Medical foods provide nutritional support specifically for the need a patient has based on medical evaluation4) Medical foods are only to be used under medical supervision.5) Medical foods are only to be used by patients in ongoing medical care.The records reviewed do not indicate that any assessment of patient's nutritional needs was made, nor were the source and character of sleep issues defined. Without additional information and given lack of evidence-based support for its use, the Sentra PM is not considered medically necessary for patient.

Norco 10/325mg #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 (ODG), pain (acute & chronic)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Part 2 - Pain Interventions and Treatments Page(s): 76-77, 85, 87-88,109.

Decision rationale: Patient has long history of high dose opioid use with little to no improvement documented in her symptoms over time. She has been opioid-free for 4 months during pregnancy, and no documentation has been supplied indicating non-narcotic therapies have been trialed since off narcotics. Records reviewed also indicate that patient has exhibited aberrant drug use behavior in the past including escalating dose requiring early refills, reporting stolen medications, and inconsistent urine drug testing on at least 5 occasions. Per the MTUS Guidelines, when considering initiation / trial of opioids, several factors should be considered, including other medication options and whether or not they have been tried, likelihood of improvement with opioids, and likelihood of abuse / misuse. Also, likelihood that patient can be weaned from opioids if not improved, should be considered, and baseline evaluation / treatment plan should be completed. The records reviewed did not indicate physical exam findings to support need for narcotics and no treatment plan with goals was documented. This patient has already taken extended course of opioids in the past with little to no improvement and with evidence of serious non-adherence / misuse. (Patient's urine drug testing has been negative for prescribed substances on more than 2 occasions, suggesting possible diversion, and urine drug testing has been positive for opioids not prescribed by the treating physician on at least 3 occasions, suggesting outside and/or illicit procurement of opioids.) Given patient's history of lack of improvement with opioids, her exhibited non-adherence / misuse with opioids, and her failure to try non-opioid options, Norco is not medically indicated for this patient.

Urine Drug Screen: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (acute & chronic)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Part 2 - Pain Interventions and Treatments Page(s): 77-78.

Decision rationale: Per the MTUS Guidelines, urine drug testing is indicated to monitor opioid use and check for illicit substances that could interfere or interact with the opioids. As opioids are not indicated / not approved in this patient, the urine drug testing would not be medically necessary.

Prednisone 10mg #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Low Back (acute & chronic)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Medline literature review: Drug therapy for back pain. Which drugs help which patients? Deyo RA. Spine (Phila Pa 1976). 1996 Dec 15; 21(24):2840-9; discussion 2849-50.

Decision rationale: California MTUS Guidelines do not address Prednisone, or steroid class, so review of available research / analysis in Medline was conducted for evidence-based recommendations. Per Medline search, there is insufficient evidence in the literature to support use of systemic corticosteroids for acute or chronic low back pain. No large scales, quality research studies in human trials have shown improvement in back pain when compared to placebo, local steroids, and/or non-steroidal anti-inflammatory drugs. The request for Prednisone is not medically necessary as no recommendation exists to support its use in this patient.

Percura #120. unknown strength: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (acute & chronic)

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence Medscape Drug Database Medline literature review: Amino acids in human and animal nutrition. Karau A, Grayson I. Adv Biochem Eng. Biotechnol. 2014; 143:189-228. DOI: 10.1007/10_2014_269. Review. FDA Orphan Drug Act and Amendments FDA Nutrition Labeling and Education Act.

Decision rationale: California MTUS Guidelines do not address Percura or other medical foods, so MEDLINE literature review was conducted, and Medscape drug database accessed for composition of Percura. No research articles available on Medline for Percura, though a general article on amino acid supplementation and possible advantages in improving athlete performance was identified. Percura is a proprietary blend of amino acids, categorized as a medical food. No strong evidence exists to support the use of Percura or its components for pain or patient's secondary complaint of insomnia. Percura is classified as a medical food and in Amendment to the FDA Orphan Drug Act, medical food is defined as "a food which is formulated to be consumed or administered orally or by tube feedings, 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 definition and established criteria for use. It is unclear from the records supplied for review, exactly what the treating physician intended to manage with Percura. However, there is no literature support for use of Percura in pain or insomnia, and little information on the use of Percura or its components in any nutritional deficiency state that may be present. (There is also no evidence that patient has any nutritional deficiencies) Therefore, as no evidence-based literature or guideline supports its use, Percura is not medically indicated.

MRI of the lumbar spine: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (acute & chronic)

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 287-290, 296.

Decision rationale: While patient has longstanding low back pain, the radicular symptoms with which she presented August 2014 are new for her in recent weeks. No "red flags" (symptoms or conditions that warrant urgent consultation or imaging) were identified by the treating physician and no physical findings to corroborate patient stated complaints were noted either by treating physician. Per the ACOEM Guidelines, the primary goals for evaluating and managing patients with Low back complaints are as follows: Identify any possible "red flags" which could be indicative of serious disease or injury. "Red flags" per the Guidelines, include fever / evidence of infection, cauda equina, fracture, signs or symptoms of dissecting abdominal aortic aneurysm and / or progressive numbness / tingling / weakness in legs. If no "red flags" are identified, then imaging, including MRI, would still not be recommended until 4-6 weeks after treatment initiated. If at that time, interventions have not resolved symptoms, MRI could be ordered. For initial treatment, the guidelines recommend non-steroidal anti-inflammatory drug or over the counter pain relievers, and ice or heat as tolerated, and regular activities as tolerated. Early stabilizing stretches have been shown to help prevent further limitation of motion and can be done without exacerbating symptoms. However, returning to normal activities as tolerated results in recovery faster than bed rest or exercises. As patient has no "red flags" noted or identified on exam, MRI not medically indicated at the time requested.