

Case Number:	CM14-0069627		
Date Assigned:	07/16/2014	Date of Injury:	08/13/2001
Decision Date:	08/27/2014	UR Denial Date:	04/14/2014
Priority:	Standard	Application Received:	05/14/2014

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 Interventional Spine 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 patient is a 50 year old male with an injury date on 08/13/2001. Based on the 04/09/2014 progress report provided by [REDACTED], the diagnoses are: 1. Lumbar radiculopathy 2. Failed back surgery syndrome 3. Spinal cord stimulator secondary to chronic pain 4. Depression - no suicide ideation 5. Long-term (current) use of medications 6. Encounter for therapeutic drug monitoring 7. Spasm of muscle 8. Anxiety NOS 9. Constipation - opioid induced According to this report, the patient complains of lower back pain radiating to both legs. The patient describes the pain as stiffness; spasms of back and left leg muscles, sharp, stabbing, shooting, burning with numbness and tingling. Lumbar range of motion is limited with pain. Decreased sensation of the bilateral lower extremities was noted with burning sensation. Heel walk and toe walk are positive. The patient also complains of insomnia, depression and anxiety. The symptoms are improved with medication. The pain is at 7-8/10 with medication and pain is at a 10/10 without medication. [REDACTED] is requesting: 1. Norco 10/325mg #30 #60 #75 #90 with 1 refill 2. Theramine #90 3. Sentra AM #60 4. Sentra PM #60. There were no other significant findings noted in this report. The utilization review denied the request on 04/14/2014. [REDACTED] is the requesting provider, and provided treatment reports from 01/16/2013 to 04/09/2014.

IMR ISSUES, DECISIONS AND RATIONALES

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

Norco 10/325mg #30 #60 #75 #90 with 1 refill: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Use of Opioids in musculoskeletal pain.

Decision rationale: According to the 04/09/2014 report by [REDACTED] this patient presents with low back pain, insomnia, depression and anxiety, which improved with medication. The treating physician is requesting Norco 10/325mg #30 #60 #75 #90 with 1 refill. Review of reports from 01/16/2013 to 04/09/2014 show that the patient has been taking Norco since 01/16/2013. The 11/20/2013 report mentions the combination of Norco, Flexeril and Opana help him to function and perform ADLs by decreasing pain and muscle tension. No other meaningful information is provided. For chronic opiate use, MTUS Guidelines page 88 and 89 require functioning documentation using a numerical scale or validated instrument at least once every 6 months. Documentation of 4 A's (analgesia, ADLs, adverse side effects, adverse behaviors) are also required. Furthermore, under outcome measures, MTUS recommends documentation of current pain, average pain, least pain, time it takes for medication to work, duration of pain relief with medications, et cetera. In this case, reports from 01/16/2013 to 04/09/2014 show documentation of pain assessment using a numerical scale describing the patient's pain. However, no outcome measures are provided. No specific ADL's or return to work are discussed. No discussions are provided regarding potential aberrant drug seeking behavior. Given the lack of sufficient documentation demonstrating efficacy of chronic opiate use, the patient should be slowly weaned as outlined in MTUS Guidelines. 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; 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) Medical Foods.

Decision rationale: According to the 04/09/2014 report by [REDACTED] this patient presents with low back pain, insomnia, depression and anxiety, which improved with medication. The treating physician is requesting Theramine, a medical food. The MTUS and ACOEM guidelines are silent with regards to this product. However, the ODG guidelines state that Theramine is a proprietary medication of [REDACTED] Its intended use is in the management of pain syndromes including acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. ODG further states for each ingredient, there is no high quality peer-reviewed literature that suggests that GABA is indicated, there is no known medical need for choline supplementation, L-Arginine is not indicated in current references for pain or inflammation & there is no indication for the use of L-Serine. It does not appear that there is any guideline to support this product in the management of chronic pain. Request is not medically necessary.

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; Pain (Acute & Chronic).

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

Decision rationale: According to the 04/09/2014 report by [REDACTED] this patient presents with low back pain, insomnia, depression and anxiety, which improved with medication. The treating physician is requesting Sentra AM, a medical food. Sentra AM is intended for use in the management of chronic and generalized fatigue, fibromyalgia, post-traumatic stress syndrome, and neurotoxicity-induced fatigue syndrome. Sentra AM is a patented blend of neurotransmitter and neurotransmitter precursors (choline bitartrate and glutamate); activators of precursor utilization (acetyl-Lcarnitine, glutamate, and cocoa powder). The MTUS and ACOEM guidelines are silent when it comes to this product. ODG on medical food states there is no known medical need for choline supplementation. MTUS also states any compounded product that contains at least one drug (or drug class) that is not recommended is then not recommended. In this case choline, an ingredient in Sentra is not supported by ODG guidelines. Therefore, Request is not medically necessary.

Sentra PM #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 (Acute & Chronic).

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

Decision rationale: According to the 04/09/2014 report by [REDACTED] this patient presents with low back pain, insomnia, depression and anxiety, which improved with medication. The treating physician is requesting Sentra PM, a medical food. The ODG guidelines states that, 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. ODG further states that for there is no known medical need for choline supplementation, glutamic acid is used for treatment of hypochlohydria 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. 5-hydroxytryptophan has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity and sleep disorders. It has been found to be effective for depression. MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is then not recommended. In this case choline an ingredient in Sentra PM is not supported by ODG guidelines. Therefore, Request is not medically necessary.

