

Case Number:	CM14-0061539		
Date Assigned:	07/09/2014	Date of Injury:	01/21/1997
Decision Date:	09/08/2014	UR Denial Date:	04/17/2014
Priority:	Standard	Application Received:	05/02/2014

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 Anesthesiology, has a subspecialty in Pain Management; and is licensed to practice in Tennessee. 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:

Patient is a 52-year-old male who has submitted a claim for lumbar radiculopathy associated with an industrial injury date of 01/21/1997. Medical records from 2013 to 2014 were reviewed. Patient complained of low back pain associated with spasms, radiating to bilateral lower extremities. Physical examination showed tenderness and muscle spasm at the paralumbar muscles. Range of motion was restricted. FABER sign was positive. Sensation was diminished at left lateral leg and right posterior leg. Treatment to date has included acupuncture, exercise program, and medications such as Soma, Lortab, ketoprofen cream, Theramine, Sentra AM, and Sentra PM. Utilization review from 04/17/2014 denied the requests for Sentra AM #60 and Sentra PM #60 because of no indication that patient had been complaining of difficulty sleeping; denied Ketoprofen cream 20% #2 2 refills because of limited published studies concerning its efficacy and safety; denied Theramine #90 because it was not identified as a superior product in comparison with standard first-line medications; modified the request for Soma 350mg #60 into Soma 35mg #60 for the purpose of weaning; and denied Norco 10/325mg #180 because long-term use was not recommended given its lack of substantial clinical efficacy in this case.

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 Healthouch Online.

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

Decision rationale: The CA MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, the Official Disability Guidelines (ODG), Pain Chapter was used instead. It states that Sentra is a medical food intended for use in management of sleep disorders associated with depression, which is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. 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. Glutamic Acid is used for treatment of hypochlohydria and achlorhydria including those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. 5-hydroxytryptophan has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity, and sleep disorders. In this case, patient has been on Sentra AM since March 2014 and reported beneficial effects from its use with resultant diminishing need for Tylenol. However, there was no clear indication for Sentra due to lack evidence of insomnia and depression. The medical necessity cannot be established due to insufficient information. Therefore, the request for Sentra AM, #60 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 Healthouch Online.

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

Decision rationale: The CA MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, the Official Disability Guidelines (ODG), Pain Chapter was used instead. It states that Sentra is a medical food intended for use in management of sleep disorders associated with depression, which is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. 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. Glutamic Acid is used for treatment of hypochlohydria and achlorhydria including those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. 5-hydroxytryptophan has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity, and sleep disorders. In this case, patient has been on Sentra PM since March 2014 and reported beneficial effects from its use with resultant diminishing need for Tylenol. However, there was no clear indication for Sentra due to lack evidence of insomnia and depression. The medical necessity cannot be established due to insufficient information. Therefore, the request for Sentra PM, #60 is not medically necessary.

Ketoprofen cream 20% #2 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, NSAID. Decision based on Non-MTUS Citation Official Disability Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. Ketoprofen is not recommended for topical use as there is a high incidence of photo contact dermatitis. In this case, patient has been on ketoprofen cream since February 2014 and noted pain relief during flare-ups upon its use. However, guidelines do not recommend its use as stated above. There is no compelling rationale presented for continuing its management. Therefore, the request for Ketoprofen cream 20% #2 2 refills 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, Pain Chapter, Theramine.

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) Section, Theramine.

Decision rationale: The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, Official Disability Guidelines, Pain section was used instead. ODG states that Theramine is a medical food that is a proprietary blend of GABA (gamma-aminobutyric acid) and choline bitartrate, L-arginine and L-serine that is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain and inflammatory pain. However, it remains not recommended by the guidelines. In this case, patient has been on Theramine since March 2014 and reported beneficial effects from its use with resultant diminishing need for Tylenol. However, this medication is not recommended by the guidelines. Therefore, the request for Theramine, #90 is not medically necessary.

Soma 350mg #60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792.20 - 9792.26, Carisoprodol (Soma) Page(s): 29.

Decision rationale: As stated on page 29 of CA MTUS Chronic Pain Medical Treatment Guidelines, carisoprodol (Soma) is a centrally acting skeletal muscle relaxant that is not indicated for long-term use. Carisoprodol abuse has been noted in order to augment or alter effects of other drugs such as hydrocodone, tramadol, benzodiazepine and codeine. In this case, patient has been on carisoprodol since 2013. Although the most recent physical examination still showed evidence of muscle spasm, long-term use of Soma is not recommended. Furthermore, this medication is being requested together with opioids, which is not recommended by the guidelines due to high potential of abuse. Therefore, the request for Soma 350mg #60 is not medically necessary.

Norco 10/325mg #180: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792.20 - 9792.26, Opioids Page(s): 78.

Decision rationale: As stated on page 78 of CA MTUS Chronic Pain Medical Treatment Guidelines, there are 4 A's for ongoing monitoring of opioid use: pain relief, side effects, physical and psychosocial functioning and the occurrence of any potentially aberrant drug-related 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. In this case, patient has been on opioids since 2013. However, the medical records do not clearly reflect continued analgesia, continued functional benefit, or a lack of adverse side effects. MTUS Guidelines require clear and concise documentation for ongoing management. Therefore, the request for Norco 10/325mg #180 is not medically necessary.