

<b>Case Number:</b>	CM13-0038404		
<b>Date Assigned:</b>	01/03/2014	<b>Date of Injury:</b>	01/25/1993
<b>Decision Date:</b>	06/19/2014	<b>UR Denial Date:</b>	10/03/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/25/2013

### 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 Occupational 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 patient is an employee of [REDACTED] and has submitted a claim for lumbar degenerative disc disease, fibromyalgia, TMJ disorder, and depression associated with an industrial injury date of 01/25/1993. Treatment to date has included lumbar spine fusion at L4-L5 in 1994, L5-S1 foraminotomy in 1999, lumbar epidural steroid injection, physical therapy, aquatic therapy, Toradol injection, acupuncture, and home exercise program. Current medications include morphine, Percocet, Theramine, Sentra PM, Sentra AM, Lexapro, Ambien, Provigil, and Soma. Medical records from 1994 to 2013 were reviewed showing that the patient complained of generalized pain especially at the low back, graded 10/10 in severity, and relieved to 4/10 with medications. Physical examination revealed tenderness over the bilateral temporomandibular joints, and paralumbar muscles. Range of motion of the thoracolumbar spine was restricted on all planes. There were 18 trigger points. Motor testing revealed 5-/5 at right anterior tibialis, and right extensor hallucis longus. Deep tendon reflexes were equal and symmetric. Sensation was diminished at the right L4 and L5 dermatomes. Patient had an antalgic gait. Utilization review from 10/03/2013 denied the requests for Sentra AM, #60, with 2 refills; and Sentra PM, #60, with 2 refills because it contains Choline which is not recommended unless there is a clinical deficiency of Choline. The request has been likewise denied for Theramine, #90, with 2 refills because it is not recommended. Modified certifications were determined for the following: MS Contin, 30 mg, #90, with 2 refills into 1 refill; and Percocet, 10/325mg #180, with 2 refills into #135 with 1 refill for weaning purposes since there was no pain relief observed; Soma 350mg #90 with 2 refills into #30, 1 refill for tapering purposes since muscle spasm was not documented; Lexapro 20mg, #30, with 2 refills into 1 refill for tapering purposes since there was no psychological assessment, evaluation of function, pain outcomes,

etc. associated with its use; and Provigil 200mg,#30, with 2 refills into Provigil 200mg, #30 with 0 refill because it is appropriate since the opiates and muscle relaxant will be tapered.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **1 PRESCRIPTION OF MS CONTIN 30MG #90 2 REFILLS: Overturned**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78.

**Decision rationale:** As stated on page 78 of the CA MTUS Chronic Pain Medical Treatment Guidelines, 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 potential aberrant (or non-adherent) 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 MS Contin since 2005. She reported relief of symptoms from 10/10 to 6-7/10 with noted improvement in functional status upon its use. Patient reported constipation, however, Senokot was already prescribed. The guideline criteria for continuing opioid management have been met. Therefore, the request for MS Contin, 30 mg, #90, with 2 refills is medically necessary and appropriate.

#### **1 PRESCRIPTION OF PERCOCET 10/325MG #180 2 REFILLS: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids. Decision based on Non-MTUS Citation University of Michigan Health System; 2011 Jan. pg. 36.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78.

**Decision rationale:** As stated on page 78 of the CA MTUS Chronic Pain Medical Treatment Guidelines, 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 potential aberrant (or non-adherent) 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 Percocet since 2005. Currently it is being prescribed as Percocet 1 tablet po every 4 - 6 hours for breakthrough pain only. She reported relief of symptoms from 10/10 to 6-7/10 with noted improvement in functional status upon its use. Patient reported constipation, however, Senokot was already prescribed. The guideline criteria for continuing opioid management have

been met. Therefore, the request for Percocet, 10/325mg #180, with 2 refills is medically necessary and appropriate.

**1 PRESCRIPTION OF SOMA 350MG #90 WITH 2 REFILLS: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Soma (Carisoprodol).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 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 Soma since 1993. Furthermore, this medication is being prescribed together with opioids which is not recommended by the guidelines due to high potential of abuse. In addition, there are no muscle spasms noted in the most recent progress reports. Long-term use is likewise not recommended. Therefore, the request for Soma 350mg, #90 with 2 refills is not medically necessary.

**1 PRESCRIPTION OF LEXAPRO 20MG #30 W/ 2 REFILLS: Overturned**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 13 and 16.

**Decision rationale:** As stated on pages 13 and 16 of CA MTUS Chronic Pain Medical Treatment Guidelines, antidepressants are recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. Escitalopram (Lexapro) is a selective serotonin reuptake inhibitor (SSRI), which is considered controversial based on controlled trials. It has been suggested that the main role of SSRIs may be in addressing psychological symptoms associated with chronic pain. In this case, patient has been on Lexapro since 2000. She had previous lumbar surgery, which did not provide relief of symptoms. She likewise has fibromyalgia and concomitant depression secondary to pain. Prescribing antidepressants in this case may provide relief with her chronic pain. Therefore, the request for Lexapro 20mg, #30, with 2 refills is medically necessary.

**1 PRESCRIPTION OF SENTRA AM #60 W/ 2 REFILLS: 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 (Chronic).

**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.

**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 2012 for her fibromyalgia. She reported beneficial effects with its use. However, the report failed to indicate the specific improvement derived from it. Although Sentra may be used since the patient has concomitant depression, there was no evidence suggesting that the patient has nutritional requirements or amino acid deficiency that would necessitate this medication. Therefore, the request for Sentra AM, #60, with 2 refills is not medically necessary.

**1 PRESCRIPTION OF SENTRA PM #60 W/ 2 REFILLS:** 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 (Chronic).

**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.

**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 2012 for her fibromyalgia. She reported beneficial effects with its use. However, the report failed to indicate the specific improvement derived from it. Although Sentra may be used since the patient has concomitant depression, there was no evidence suggesting that the patient has nutritional requirements or amino acid deficiency that would necessitate this medication. Therefore, the request for Sentra PM, #60, with 2 refills is not medically necessary.

## **1 PRESCRIPTION OF THERAMINE #90 W/ 2 REFILLS: 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 (Chronic).

**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.

**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 2012 for her chronic pain. She reported beneficial effects with its use. However, the report failed to indicate the specific improvement derived from it. Furthermore, this medication is not recommended by the guidelines, therefore, the request for Theramine, #90, with 2 refills is not medically necessary.

## **1 PRESCRIPTION OF PROVIGIL 200MG #30 W/ 2 REFILLS: Overturned**

**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 (Chronic).

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

**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 Section was used instead. It states that Modafinil (Provigil) is not recommended solely to counteract sedation effects of narcotics until after first considering reducing excessive narcotic prescribing. In this case, patient has been on Provigil since 2012 to maintain wakefulness and subsequently, enabling her to function. The patient has decreased opioid intake of Percocet 10/325 mg to an as needed basis. Given the reduction of opioid use, the request for Provigil 200mg #30, with 2 refills is medically necessary.