

<b>Case Number:</b>	CM14-0110719		
<b>Date Assigned:</b>	08/01/2014	<b>Date of Injury:</b>	10/29/2002
<b>Decision Date:</b>	09/12/2014	<b>UR Denial Date:</b>	06/16/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/16/2014

### 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 Orthopaedic Surgery, 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:

This 56-year-old female sustained an industrial injury on 10/29/02. The mechanism of injury was not documented. Records indicated that the patient had been diagnosed with sleep disturbance, depression and gastrointestinal discomfort, in addition to musculoskeletal pain involving the neck, left shoulder, and bilateral wrists. The patient was prescribed Theramine, Trepadone and Sentra on 1/27/14. The 4/30/14 internal medicine and pain medicine report indicated that there was no change in the patient's abdominal pain, acid reflux or constipation with medication. Additional complaints included musculoskeletal pain and poor sleep quality. The diagnosis was abdominal pain, acid reflux, constipation, history of elevated blood pressure, and sleep disorder, rule out obstructive sleep apnea. The 6/16/14 utilization review denied the requests for Sentra PM, Theramine, Trepadone, and topical creams based on an absence of guideline support or indications. There is no documentation in the record of any benefit to the use of Sentra PM, Theramine, or Trepadone relative to sleep disorders or gastrointestinal symptoms.

### IMR ISSUES, DECISIONS AND RATIONALES

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

#### **1 Prescription of 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 (ODG): Pain (Chronic) Official Disability Guidelines (ODG): Mental Stress & Illness, 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) Mental Illness and Stress, Pain (Chronic), Sentra PM®ç, Medical Food.

**Decision rationale:** The California MTUS does not provide recommendations for the use of Sentra PM. The Official Disability Guidelines describe Sentra PM as a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan intended for use in management of sleep disorders associated with depression. Guidelines state that Sentra PM is under study for insomnia with no independent unbiased studies supporting use at this time. 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. There is no documentation that the patient suffers from a choline deficiency. Guidelines do not support all of the individual components of Sentra PM. Therefore, this request for one prescription of Sentra PM #60 is not medically necessary.

### **1 Prescription of Theramine #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 (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), Theramine®ç, Medical Food.

**Decision rationale:** The California MTUS do not address the use of Theramine. Theramine is a medical food and proprietary blend of gamma-aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. The Official Disability Guidelines state that Theramine is not recommended as there are no high quality studies of the individual ingredients. Additionally, adverse reactions associated with GABA include hypertension which is a current diagnosis. Therefore, lacking guideline support for all of the individual ingredients in this compound product, this request for Theramine #60 is not medically necessary.

### **1 Prescription of Trepadone #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 (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) Trepadone®ç, Medical Food.

**Decision rationale:** The California MTUS do not address the use of Trepadone. Trepadone is a medical food and a proprietary blend of L-arginine, L-glutamine, choline bitartrate, L-serine and gamma aminobutyric acid [GABA]. It is intended for use in the management of joint disorders associated with pain and inflammation. The Official Disability Guidelines state there is no high quality peer-reviewed literature that suggests that GABA is indicated for treatment of insomnia and hypertension is reported as a side effect. Guidelines state 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. There is no documentation that the patient suffers from a choline deficiency. Therefore, lacking guideline support for all of the individual ingredients in this compound product, this request for one prescription of Trepadone #90 is not medically necessary.

**1 Prescription of Fluriprofen 20%, Tramadol 20% in Mediderm base 210gm #1: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic), NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) Flurbiprofen.

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

**Decision rationale:** The California MTUS state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Guidelines indicate that topical analgesics in general are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There are no high-quality literary studies or guidelines which support the safety or efficacy of Tramadol utilized topically. Flurbiprofen is not on the list of approved topical non-steroidal anti-inflammatory drugs. Given the absence of guideline support for all components of this product, this product is not recommended by guidelines. Therefore, this request for one prescription of Flurbiprofen 20%, Tramadol 20% in Mediderm base 210 gm, #1 is not medically necessary.

**1 Prescription of Gabapentin 10%, Amitriptyline 10%, Dextromethopan 10% in Mediderm base 210gm: Upheld**

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

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

**Decision rationale:** The California MTUS state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Guidelines indicate that topical analgesics in general are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Topical Gabapentin is not recommended by the guidelines. There is no evidence based medical guidance relative to the safety or efficacy of topical amitriptyline. Dextromethorphan is an NMDA-receptor antagonist like Ketamine. Ketamine is

under study and only recommended for treatment of neuropathic pain in refractory cases where all primary and secondary treatment has been exhausted. Given the absence of guideline support for all components of this product, this product is not recommended by guidelines. Therefore, this request for one prescription of Gabapentin 10%, Amitriptyline 10%, Dextromethorphan 10% in Mediderm base 210 gm is not medically necessary.