

<b>Case Number:</b>	CM14-0043986		
<b>Date Assigned:</b>	07/02/2014	<b>Date of Injury:</b>	11/27/2012
<b>Decision Date:</b>	09/10/2014	<b>UR Denial Date:</b>	03/24/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/10/2014

### 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 Medicine and is licensed to practice in Massachusetts. 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:

According to the documents available for review, the patient is a 45-year-old female. The date of injury is 11/27/12. Per the patient, she experienced sexual harassment from her supervisor and subsequently developed headaches, anxiety and depression. The patient also developed neck pain, left shoulder pain, jaw pain, low back pain and left arm pain. Additionally she did develop a sleep disturbance secondary to the pain. Her current diagnoses include cervico - brachial syndrome, thoracalgia, lumbar facet syndrome, left elbow tenosynovitis, posttraumatic anxiety and depression, post-traumatic gastritis, posttraumatic headache. The patient has been treated with the multimodal pain treatment regimen consisting of traction, hot lamps, chiropractic adjustments, and pain indications. She is currently being treated with Theramine, Sentra PM and Zanaflex for her pain complaints. Your request for Theramine, Sentra PM and Zanaflex was denied.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Theramine one month supply:** Upheld

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

**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.

**Decision rationale:** According to the official disability guidelines, Theramine is not recommended. Theramine is a medical food from Physician Therapeutics, Los Angeles, CA, that is a 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. See Medical food, Gamma-aminobutyric acid (GABA), where it says, There is no high quality peer-reviewed literature that suggests that GABA is indicated; Choline, where it says, There is no known medical need for choline supplementation; L-Arginine, where it says, This medication is not indicated in current references for pain or inflammation; & L-Serine, where it says, There is no indication for the use of this product. In this manufacturer study comparing Theramine to Naproxen; Theramine appeared to be effective in relieving back pain without causing any significant side effects. (Shell, 2012) Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. Therefore, at this time, the request of Theramine for one month supply is not medically necessary and appropriate.

**Sentra PM one (1) month supply:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Official Disability Guidelines, Mental Illness and Stress, Sentra PM and Pain (Chronic), Sentra PM.

**Decision rationale:** According to the Official Disability Guidelines, 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. Under study for insomnia. Preliminary results are promising, from a single study sponsored by the manufacturer, but independent unbiased studies are necessary for a recommendation. Therefore, the request of Sentra PM one (1) month supply is not medically necessary and appropriate.

**Zanaflex 4mg #90:** 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 Antispasticity / Antispasmodic Drugs, Zanaflex Page(s): 66.

**Decision rationale:** According to the MTUS, Tizanidine (Zanaflex, generic available) is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity;

unlabeled use for low back pain. (Malanga,2008) Eight studies have demonstrated efficacy for low back pain. (Chou, 2007) One study (conducted only in females) demonstrated a significant decrease in pain associated with chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain. (Malanga, 2002) May also provide benefit as an adjunct treatment for fibromyalgia. (ICSI, 2007) Side effects: somnolence, dizziness, dry mouth, hypotension, weakness, hepatotoxicity (LFTs (Liver Function Tests) should be monitored baseline, 1, 3, and 6 months). (See, 2008) Dosing: 4 mg initial dose; titrate gradually by 2 - 4 mg every 6 - 8 hours until therapeutic effect with tolerable side-effects; maximum 36 mg per day. (See, 2008) Use with caution in renal impairment; should be avoided in hepatic impairment. Tizanidine use has been associated with hepatic amino transaminase elevations that are usually asymptomatic and reversible with discontinuation. Zanaflex is recommended as a first-line agent for myofascial pain and additionally, the patient is currently receiving good analgesia from his agent at less than the maximum recommended dose. Therefore, at this time, the requirements for treatment have been met and medical necessity has been established, so that the request of Zanaflex 4mg #90 is medically necessary and appropriate.