

<b>Case Number:</b>	CM14-0189236		
<b>Date Assigned:</b>	11/17/2014	<b>Date of Injury:</b>	01/27/2013
<b>Decision Date:</b>	01/07/2015	<b>UR Denial Date:</b>	10/21/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/10/2014

### 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 Family Medicine and is licensed to practice in Ohio. 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 injured worker is a 44-year-old male with a date of injury of January 27, 2013. He developed pain and numbness in both hands and later developed neck pain. It appears he was treated initially with acupuncture, chiropractic care, physical therapy, and topical analgesics. He continues to complain of pain, weakness, and numbness to both hands, increasing neck pain, and right shoulder and trapezius pain. It was noted to have sleeping difficulty as a consequence of the pain. The physical exam reveals diminished light touch sensation to the right-sided deltoid, biceps, and triceps region. There is diminished sensation to both hands. Tinel's and Phalen's signs are positive bilaterally. A cervical spine MRI scan revealed multilevel facet hypertrophy and disc protrusions without central spinal canal or neural foraminal stenosis. The diagnoses include cervical disc herniation, myospasm, bilateral carpal tunnel syndrome, sprain/strain of the wrists and hands, and cervical brachial syndrome. At issue is a request for numerous medications that apparently were prescribed on October 10, 2014.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Anaprox (naproxen 550mg #60):** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67.

**Decision rationale:** NSAIDs like Anaprox are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In this instance, the injured worker is described pain between 7-10/10 which certainly seems to qualify as moderate to severe pain. He evidently failed topical analgesics. Therefore, Anaprox (naproxen 550mg #60) was medically necessary.

**Omeprazole 20mg #60:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Protonic pump inhibitors (PPI). Decision based on Non-MTUS Citation ODG, PPIs

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms, and cardiovascular risk Page(s): 68.

**Decision rationale:** Those prescribed NSAIDs should have assessment for risk for gastric ulceration. Risk factors for gastric ulceration include age greater than 65, history of peptic ulcer, GI bleeding or perforation; concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). In this instance, the injured worker was prescribed a high dose NSAID. Those with one or more risk factors for gastric ulceration may also be prescribed a proton pump inhibitor such as omeprazole to diminish the risk. Therefore, Omeprazole 20mg #60 was medically necessary.

**Tramadol 150mg #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 76-77.

**Decision rationale:** Steps to take before initiating a therapeutic trial of opioids: (a) Attempt to determine if the pain is nociceptive or neuropathic. Also attempt to determine if there are underlying contributing psychological issues. Neuropathic pain may require higher doses of opioids, and opioids are not generally recommended as a first-line therapy for some neuropathic pain. (b) A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. (c) Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals. (d) Baseline pain and functional assessments should be made. Function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale. (e) Pain related assessment should include history of pain treatment and effect of

pain and function.(f) Assess the likelihood that the patient could be weaned from opioids if there is no improvement in pain and function. (g) The patient should have at least one physical and psychosocial assessment by the treating doctor (and a possible second opinion by a specialist) to assess whether a trial of opioids should occur. When subjective complaints do not correlate with imaging studies and/or physical findings and/or when psychosocial issue concerns exist, a second opinion with a pain specialist and a psychological assessment should be obtained. (h) The physician and surgeon should discuss the risks and benefits of the use of controlled substances and other treatment modalities with the patient, caregiver or guardian. (i) A written consent or pain agreement for chronic use is not required but may make it easier for the physician and surgeon to document patient education, the treatment plan, influence the patient's use of medications for relief from pain. This should include the consequences of non-adherence. (j) Consider the use of a urine drug screen to assess for the use or the presence of illegal drugs. In this instance, Anaprox 550 mg appears to be prescribed at the same time as tramadol 150 mg. These medications appear to originate from the date of entry October 10, 2014. It does not appear that the injured worker has failed a non-opioid pain medication prior to this date although it is possible that there are some medical records out there that were not submitted. The medical record does not reflect that the injured worker has set goals in terms of the opioids. It does not appear that a baseline functional assessment has been done. Lastly, does not appear that risks and benefits of the use of the opioids were discussed. Consequently, the requirements for a therapeutic trial of opioids have not been met and therefore Tramadol 150mg #60 was not medically necessary.

**Theramine #90 (2 bottles): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Pain, medical foods

**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), Medical food

**Decision rationale:** Theramine is a medical food that consists of: choline bitartrate, L-arginine, L-histidine HCL, L-glutamine, L-serine, GABA, griffonia seed (95% 5HTP), whey protein hydrolysate, grape seed extract (85% polyphenols), cinnamon, and cocoa extract (6% theobromine). Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. FDA defines a medical food as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. Because medical foods are not recommended for the treatment of chronic pain, Theramine #90 (2 bottles) was not medically necessary.

**Sentra PM #60 (1bottle): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Pain, medical foods

**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), Medical food and Insomnia Treatment

**Decision rationale:** Sentra PM is a medical food which contains amino acid precursors for acetylcholine and serotonin. Those with certain sleep disorders are found to be deficient in these neurotransmitters. However, medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. FDA defines a medical food as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. The cited guidelines do not address the use of medical food to treat insomnia associated with chronic pain. Therefore, Sentra PM #60 (1 bottle) was not medically necessary.

**Sentra AM #60 (1 bottle):** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Pain, medical foods

**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), Medical Food

**Decision rationale:** Sentra AM is a Medical Food designed to increase and maintain the production of acetylcholine by peripheral neurons and brain cells. Sentra AM contains choline and acetylcarnitine as precursors to acetylcholine production. Choline is an essential amino acid and choline deficiency leads to a number of disease states. The FDA allows a health claim for choline in the prevention of certain forms of liver disease. It is well recognized that defects of acetylcholine function are part of a number of disease states including Alzheimer's disease, vascular dementia, chronic fatigue, memory disorders, neurotoxicity related to pesticides and other environmental toxins. Sentra AM is designed to support the production of acetylcholine. Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. FDA defines a medical food as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. Therefore, Sentra AM #60 (1 bottle) was not medically necessary.