

<b>Case Number:</b>	CM13-0024981		
<b>Date Assigned:</b>	11/20/2013	<b>Date of Injury:</b>	02/06/2009
<b>Decision Date:</b>	01/17/2014	<b>UR Denial Date:</b>	09/06/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/16/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Family Practice and is licensed to practice in Texas. 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 physician 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 a 60-year-old male with a reported date of injury on February 06, 2009. The patient presented with fatigue, numbness, weakness, sore muscles, limited neck range of motion, pain in the shoulders, a positive Speed's test, and weakened grip strength on the right secondary to pain. The patient had normal range of motion in the shoulders, normal range of motion of the wrists, and no deltoid atrophy or supraspinatus atrophy. The patient had diagnoses including apophysitis/spondylosis of the cervical spine, C7 compressive neuropathy, multilevel cervical spine stenosis of the facet joint from C4-7, status post failed radial nerve tunnel release, compression neuropathy of the right radial nerve, status post lumbar laminectomy at L4-5, right shoulder rotator cuff tendinitis, and subacromial bursitis, as well as acromioclavicular arthritis, lateral humeral epicondylitis, status post coronary artery angioplasty with stents x2, hypertension, and diabetes mellitus. The physician's treatment plan included request for Anaprox (Naproxen Sodium) 550mg, Neurontin (Gabapentin) 600mg, Prilosec (Omeprazole) 20mg, Tramadol (Ultram) 50mg, Flurbiprofen 6gm, Cyclobenzaprine and Neurontin 3gm, Theramine, and Sentra.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Anaprox (Naproxen Sodium) 550mg: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs Page(s): 67-68.

**Decision rationale:** The California MTUS Guidelines recommend the use of NSAIDs for patients with osteoarthritis (including knee and hip) and patients with acute exacerbations of chronic low back pain. The guidelines recommended NSAIDs 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. In patients with acute exacerbations of chronic low back pain, the guidelines recommend NSAIDs as an option for short-term symptomatic relief. Within the provided documentation, the requesting physician did not include adequate documentation of the efficacy of the medication as evidenced by objective functional improvement with the use of the medication. Therefore, the request for Anaprox (Naproxen Sodium) 550mg is neither medically necessary, nor appropriate.

**Neurontin (Gabapentin) 600mg:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs) Page(s): 16-22, 49.

**Decision rationale:** The California MTUS Guidelines note Gabapentin is an anti-epilepsy drug (AEDs - also referred to as anti-convulsants), which has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. The guidelines recommend Gabapentin for patients with spinal cord injury as a trial for chronic neuropathic pain that is associated with this condition. The guidelines also recommend a trial of Gabapentin for patients with fibromyalgia and patients with lumbar spinal stenosis. Within the provided documentation it did not appear the patient had a diagnosis of diabetic painful neuropathy or postherpetic neuralgia. Additionally, within the provided documentation, the requesting physician did not include adequate documentation of objective functional improvement with the use of the medication. Therefore, the request for Neurontin (Gabapentin) 600mg is neither medically necessary, nor appropriate.

**Prilosec (Omeprazole) 20mg:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 68-69.

**Decision rationale:** The California MTUS Guidelines recommend the use of a proton pump inhibitor (such as Omeprazole) for patients at intermediate risk for gastrointestinal events with

no cardiovascular disease and patient at high risk for gastrointestinal events with no cardiovascular disease. The guidelines note to determine if the patient is at risk for gastrointestinal (GI) events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of Aspirin (ASA), corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Within the provided documentation, the requesting physician did not include adequate documentation that the patient was at risk for gastrointestinal events. The patient is not over 65 years of age and it was not indicated if the patient has a history of peptic ulcer, GI bleeding, or perforation. Therefore, the request for Prilosec (Omeprazole) 20mg is neither medically necessary, nor appropriate.

### **Tramadol (Ultram) 50mg: Upheld**

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

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

**Decision rationale:** The California MTUS Guidelines recommend patients utilizing opioid medication should obtain prescriptions from a single practitioner, medications should be taken as directed, and all prescriptions should come from a single pharmacy. Providers should prescribe the lowest possible dose should be prescribed to improve pain and function. Provider should conduct ongoing review with documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. Within the provided documentation, the requesting physician did not include adequate documentation of significant improvement in functional status with the use of the medication. It was not noted if the patient was utilizing medications properly. Additionally, within the provided documentation, the requesting physician did not include an adequate and full assessment of the patient's pain including the least reported pain over the period since the last assessment, average pain, intensity of pain after taking the opioid, how long it takes for pain relief, and how long pain relief lasts. Therefore, the request for Tramadol (Ultram) 50mg is neither medically necessary, nor appropriate.

### **Cyclobenzaprine and Neurontin 3gms: Upheld**

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

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

**Decision rationale:** The California MTUS Guidelines state, any compounded product that contains at least 1 drug or drug class that is not recommended is not recommended. The guidelines note the topical use of gabapentin is not recommended as there is no peer-reviewed literature to support use. The guidelines also note there is no evidence for use of any other muscle relaxant as a topical product. The use of Gabapentin and Cyclobenzaprine topically are not recommended within the guidelines. Therefore, the request for Cyclobenzaprine and Neurontin 3gms is neither medically necessary, nor appropriate.

**Theramine:** 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

**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:** Theramine is comprised of Choline Bitartrate, L-Arginine, L-Histidine, L-Glutamine, L-Serine, GABA, Griffonia Seed (20% 5HTP), Whey Protein, Grape Seed Extract, Ginkgo Biloba, Cinnamon, and Cocoa. The ODG note 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. There is no high quality peer-reviewed literature that suggests that GABA is indicated. There is no known medical need for choline supplementation. L-Arginine is not indicated in current references for pain or inflammation. There is no indication for the use of L-Serine. Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. The use of Theramine is not recommended per the guidelines. Therefore, the request for Theramine is neither medically necessary, nor appropriate.

**Sentra:** 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

**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), Sentra PM® & Medical food.

**Decision rationale:** Sentra PM® is a medical food intended for use in management of sleep disorders associated with depression that 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 and there is inconclusive evidence that this product is indicated for an endurance aid, memory, seizures, and transient ischemic attacks. Glutamic Acid is used for

treatment of hypochlorhydria and achlorhydria; treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses and it is generally used for digestive disorders in complementary medicine. 5-hydroxytryptophan has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity and sleep disorders as well as for depression. In alternative medicine it has been used for depression, anxiety, insomnia, obesity, aggressive behavior, eating disorders, fibromyalgia, chronic headaches and various pain disorders. Within the provided documentation, it did not appear the patient had a diagnosis that would be supported within the guidelines for the use of Sentra. Within the provided documentation, the requesting physician did not include adequate documentation of sleep disturbance or anxiety disorders in order to demonstrate the patient's need for Sentra at this time. Therefore, the request for Sentra is neither medically necessary, nor appropriate.