

<b>Case Number:</b>	CM15-0035268		
<b>Date Assigned:</b>	03/03/2015	<b>Date of Injury:</b>	08/02/2007
<b>Decision Date:</b>	06/23/2015	<b>UR Denial Date:</b>	01/28/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/25/2015

### 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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials: State(s) of Licensure: New York  
Certification(s)/Specialty: Pediatrics, Internal Medicine

### 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 60 year old male, who sustained an industrial injury reported on 8/2/2007. He reported constant, moderate lower back pain. The diagnoses were noted to include displacement of the cervical and lumbar intervertebral discs without myelopathy; lumbar spine herniated nucleus pulposus with right radiculopathy; lateral epicondylitis; aggravated periodontal disease; and nocturnal obstruction of airway. Treatments to date have included consultations; diagnostic imaging studies; ultrasonic Doppler auscultation analysis; polysomnogram respiratory studies; functional capacity evaluation report (7/11/14); and medication management. The work status classification for this injured worker (IW) was noted to be temporarily totally disabled and was to return to full duty work on 1/20/2015. The 5/16/2014 primary treating physician, initial comprehensive medical evaluation report notes the accepted body parts to be the neck and low back. No subjective complaints, only the description of the accident and the objective findings were noted; and he was given temporary total disability status. The 5/16/2014 doctor's first report of occupational injury notes subjective complaints of pain to the cervical spine and left elbow that now radiates to the lower back and down the right leg, to the foot; and with numbness and tingling to the right toes. The chief complaint noted on the 7/11/2014 functional capacity report is constant and moderate lower back pain; and that he was working unrestricted, full time duty, on unspecified pain medications. The 8/16/2014 PR-2 is hand written and mostly illegible, but does not note any subjective complaints. The 9/23/2014 PR-2 is also hand written, mostly illegible, and notes the chief complaint to be "LSS 7/10, CSP 7/10 and left elb 6/10", along with a diagnosis of bilateral edema and to refer to the Urgent Care notes. Aside from the 8/29/2014 nocturnal obstruction of airway report and 10/6/2014 request for authorization of periodontal treatments,

no other progress notes are available for my review. On 1/28/2015, Utilization Review (UR) modified, for medical necessity, the request, made on 1/19/2014, for Protonix - Pantoprazole 20mg, twice a day, #60; Flexeril - Cyclobenzaprine 7.5mg, twice a day, #60; Medical foods: Theramine #60, Senta PM #60, Senta AM #60, and Gabadone #60. The Medical Treatment Utilization Schedule, chronic pain medical treatment guidelines, non-steroidal anti-inflammatory drugs - gastrointestinal and cardiovascular risks, anti-spasmodic / muscle relaxer; and the Official Disability Guidelines, pain chapter, medical foods, chronic pain, Theramine, Senta AM and PM, GABA done, were cited.

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

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

#### **Protonix-Pantoprazole 20mg BID #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): 68-69.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69.

**Decision rationale:** According to MTUS guidelines it is necessary to determine if the patient is at risk for gastrointestinal events. Risk factors are: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). A history of ulcer complications is the most important predictor of future ulcer complications associated with NSAID use. Progress notes state that the IW was started on pantoprazole for GI upset with NSAID use. Pantoprazole is FDA approved for treatment of erosive esophagitis and hypersecretory conditions neither of which is present in the IW. This request is not medically necessary and appropriate

#### **Flexeril-Cyclobenzaprine 7.5mg BID #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antispasmodics, Cyclobenzaprine Page(s): 64.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 63-65.

**Decision rationale:** Cyclobenzaprine is recommended as an option for muscle spasms using a short course of therapy. Treatment should be brief, no longer than 2-3 weeks. There is no clear evidence in the notes provided that the IW has benefit from the muscle relaxer and at this time frame routine use of these medications is not indicated. The request is not medically necessary.

#### **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, Pain, Theramine.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Medications - Medical Food.

**Decision rationale:** MTUS guidelines do not comment on the use of Theramine. ODG states that Theramine is not recommended for the treatment of chronic pain. See Medical food. Under this entry discussions of the various components of this product are given. The entries for 5-hydroxytryptophan, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine and GABA are given and all indicate there is no role for these supplements as treatment for chronic pain. This request is not medically necessary and appropriate.

**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, Pain, Sentra PM.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Medications - Medical Food.

**Decision rationale:** MTUS guidelines do not comment on the use of Sentra. ODG states that Sentra is not recommended. Sentra PM is intended for use in management of sleep disorders associated with depression. Sentra PM is a proprietary blend of neurotransmitter precursors (choline bitartrate, glutamate, and 5-hydroxytryptophan); polyphenolic antioxidants (hawthorn berry, cocoa); an amino acid uptake stimulator (gingko biloba); activators of amino acid utilization (acetyl-L-carnitine, glutamate, cocoa powder); and an adenosine antagonist (cocoa powder). Choline is a precursor of acetylcholine. 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. This is a precursor of gamma-aminobutyric acid (GABA). This supplement is used for treatment of gastric hydrochloric acid deficiency. This is the intermediate metabolite between biosynthesis of L-tryptophan to serotonin. In alternative medicine it has been used for insomnia, obesity, aggressive behavior, eating disorders, fibromyalgia, chronic headaches and various pain disorders (postulated to inhibit inflammation). Current peer-reviewed evidence is inconclusive to support these claims. This request is not medically necessary and appropriate.

**Sentra AM #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, Pain, Medical food and Administration of an Amino Acid-Based Regimen for the Management of Autonomic Nervous System Dysfunction related to Combat-Induced Illness - J Cent Nerv Syst Dis. 2014 Oct 8;6:93-8. doi: 10.4137/JCNSD.S13793.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Medications - Medical Food.

**Decision rationale:** MTUS guidelines do not comment on the use of Sentra. ODG states that Sentra is not recommended. Sentra AM is a medical food from Targeted Medical Pharma Inc., Los Angeles, CA, intended for use in management of fatigue and cognitive disorders. It is a

proprietary blend of Choline Bitartrate, Cocoa Extract, L-Glutamic Acid, Acetyl L-Carnitine, Dextrose, Ginkgo Biloba, and Hawthorn Berry. See Medical food, Choline & Glutamic Acid. This request is not medically necessary and appropriate.

**Gabadone #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, Pain, GABAdone.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Medications - Medical Food.

**Decision rationale:** MTUS guidelines do not comment on the use of GABAdone. ODG states that GABAdone is not recommended. GABAdone is a Medical food from Physician Therapeutics, Los Angeles, CA, that is a proprietary blend of choline bitartrate, glutamic acid, 5-hydroxytryptophan, GABA, grape seed extract, griffonia extract, whey protein, valerian extract, ginkgo biloba and cocoa. It is intended to meet the nutritional requirements for sleep disorders and sleep disorders associated with insomnia. This request is not medically necessary and appropriate.