

<b>Case Number:</b>	CM15-0065826		
<b>Date Assigned:</b>	05/18/2015	<b>Date of Injury:</b>	02/13/2012
<b>Decision Date:</b>	07/16/2015	<b>UR Denial Date:</b>	03/06/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/07/2015

### 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: Pennsylvania  
 Certification(s)/Specialty: 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 61 year old female, who sustained an industrial injury on 2/13/12. The injured worker was diagnosed as having left carpal tunnel syndrome, status post right carpal tunnel release, right middle finger trigger release, right shoulder subacromial impingement syndrome, erosive gastritis, constipation rule out irritable bowel syndrome, Barrett's metaplasia, hypertension, diabetes, hyperlipidemia, weight loss, and sleep disorder. Treatment to date has included medications. Laboratory studies in August 2014 included hemoglobin A1C and glucose. A report from the primary treating physician in October 2014 notes use of anaprox, prilosec, and tylenol #3. At a visit on 11/4/14, the injured worker reported blood pressure at home was 120's/70's and morning blood sugar is 150-160. Examination showed height of 5'1", weight of 155 pounds, blood pressure of 125/76. Lungs were clear, heart was regular, abdomen was soft and nontender without hepatosplenomegaly. Medications were noted to include amlodipine, atenolol, dexilant, simvastatin, metformin, novolog, victoza, probiotics, sentra am, sentra pm, apptrim-D, and theramine. Currently, the injured worker complains of right shoulder pain. The treating physician requested authorization for Dexilant 60mg #30, Sentra AM #60 3 bottles, Sentra PM #60 3 bottles, Apptrim-D #120 3 bottles, Theramine #60 3 bottles, a urine toxicology screen, a urinalysis profile, labs for gastrointestinal profile, labs for hypertension profile, and labs for a diabetes mellitus profile. On 3/5/15, Utilization Review non-certified requests for the items currently under Independent Medical Review.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Dexilant 60mg #30: 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).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI symptoms and cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation UpToDate: Medical management of gastroesophageal reflux disease in adults. Overview and comparison of the proton pump inhibitors for the treatment of acid related disorders. In UpToDate, edited by Ted W. Post, published by UpToDate in Waltham, MA, 2015.

**Decision rationale:** Per the MTUS, co-therapy with a nonsteroidal anti-inflammatory medication (NSAID) and a proton pump inhibitor (PPI) is not indicated in patients other than those at intermediate or high risk for gastrointestinal events (including age > 65 years, history of peptic ulcer, gastrointestinal (GI) bleeding or perforation, concurrent use of aspirin, corticosteroids and/or an anticoagulant, or high dose/multiple NSAIDS such as NSAID plus low dose aspirin). None of these risk factors were documented for this injured worker. In this case, anaprox (a NSAID) was noted to be prescribed in October 2014. It was unclear from the most recent progress note if this medication was still in use. The UpToDate reference cited states that PPIs should be used in patients who fail twice-daily histamine 2-receptor antagonist therapy, and in patients with erosive esophagitis and/or frequent (two or more episodes per week) or severe symptoms of GERD that impair quality of life. Diagnoses did include erosive gastritis and Barrett's metaplasia, but there was no documentation as to whether there were any current active GI issues or symptoms. Proton pump inhibitors are frequently used in patients with Barrett's metaplasia, although no studies have shown unequivocal regression of Barrett's esophagus or a decrease in the risk of esophageal malignancy with any medical or surgical therapy. In this case, there was no documentation of current symptoms of GERD. Duration and outcome of treatment with PPIs was not discussed. Dates and findings of any GI endoscopy procedures were not submitted. Due to lack of documentation of current symptoms and GI findings, the request for dexilant is not medically necessary.

**Sentra AM #60, 3 bottles: 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).

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

**Decision rationale:** Sentra AM is a medical food intended for use in the management of chronic and generalized fatigue, fibromyalgia, post-traumatic stress syndrome (PTSD), neurotoxicity-induced fatigue syndrome, and cognitive impairment involving arousal, alertness, and memory. The 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. There is no documentation of a specific nutritional deficiency which would be expected to be improved with this medical food. The ODG states that 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. Due to lack of recommendation by the guidelines, the request for sentra am is not medically necessary.

**Sentra PM #60, 3 bottles:** 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).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) chronic pain chapter: Medical food, insomnia treatment, Sentra PM.

**Decision rationale:** Sentra PM is a medical food intended for use in management of sleep disorders associated with depression. It is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan, hawthorn berry, cocoa, ginkgo biloba, and acetyl L-carnitine. The MTUS does not address the use of hypnotics other than benzodiazepines. The ODG states that medical food is not recommended for the treatment of chronic pain. The ODG specifies that pharmacologic agents for the treatment of insomnia should only be used after careful evaluation of potential causes of sleep disturbance. There was no discussion of insomnia or sleep disturbance. No physician reports describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of that in this case. Per the ODG, Sentra PM is not recommended. As such, the request for sentra pm is not medically necessary.

**Apptrim-D #120, 3 bottles:** 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).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) chronic pain chapter: Medical fooddiabetes chapter: obesity and Other Medical Treatment Guidelines AppTrim Product Information.

**Decision rationale:** Sentra PM is a medical food intended for use in management of sleep disorders associated with depression. It is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan, hawthorn berry, cocoa, ginkgo biloba, and acetyl L-carnitine. The MTUS does not address the use of hypnotics other than benzodiazepines. The ODG states that medical food is not recommended for the treatment of chronic pain. The ODG specifies that

pharmacologic agents for the treatment of insomnia should only be used after careful evaluation of potential causes of sleep disturbance. There was no discussion of insomnia or sleep disturbance. No physician reports describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of that in this case. Per the ODG, Sentra PM is not recommended. As such, the request for sentra pm is not medically necessary.

**Theramine #60, 3 bottles:** 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).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) chronic pain chapter: Medical food, theramine.

**Decision rationale:** Theramine is medical food intended for use in the management of chronic pain syndromes which contains 5-hydroxytryptophan 95%, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine, gamma-aminobutyric acid (GABA), whey protein concentrates, grape seed extract 85%, cinnamon, and cocoa (theobromine 6%). Per the ODG, theramine is not recommended for the treatment of chronic pain. The 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. There is no documentation of a specific nutritional deficiency which would be expected to be improved with this medical food. As such, the request for theramine is not medically necessary.

**Urine toxicology screen:** Upheld

**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 drug testing p. 43, opioids p. 77- 78, p. 89, p. 94 Page(s): 43, 77-78, 89, 94. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) chronic pain chapter: urine drug testing, opioids, screening tests for risk of addiction and misuse.

**Decision rationale:** Per MTUS chronic pain medical treatment guidelines, urine drug screens are recommended as an option to assess for the use or the presence of illegal drugs, in accordance with a treatment plan for use of opioid medication, and as a part of a pain treatment agreement for opioids. Per the ODG, urine drug testing is recommended as a tool to monitor compliance with prescribed substances, identify use of undisclosed substances, and uncover diversion of prescribed substances. Urine drug testing is recommended at the onset of treatment when chronic opioid management is considered, if the patient is considered to be at risk on

addiction screening, or if aberrant behavior or misuse is suspected or detected. Ongoing monitoring is recommended if a patient has evidence of high risk of addiction and with certain clinical circumstances. Frequency of urine drug testing should be based on risk stratification. Patients with low risk of addiction/aberrant behavior should be tested within six months of initiation of therapy and on a yearly basis thereafter. Patients at moderate risk for addiction/aberrant behavior should be tested 2-3 times per year. Patients at high risk of adverse outcomes may require testing as often as once a month. Random collection is recommended. Results of testing should be documented and addressed. In this case, the documentation indicates that tylenol #3 was prescribed in October 2014, but there was no documentation that this medication was still currently in use. There was no risk stratification for aberrant behavior discussed, which would be required to determine necessary frequency of urine drug testing. No prior urine drug testing was submitted. Due to insufficient documentation of current use of opioids and lack of risk stratification for aberrant behavior, the request for urine toxicology screen is not medically necessary.

**Urinalysis profile:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medical Practice Standard of Care.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) UpToDate: Wald, Ron: Urinalysis in the diagnosis of kidney disease. Overview of medical care in adults with diabetes mellitus. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

**Decision rationale:** The urinalysis is used in evaluating acute and chronic kidney disease, and can be used to monitor the course of kidney diseases in some patients. It may be used in patients with suspected kidney disease (on the basis of clinical findings or concurrent illness) or kidney stones. In this case, there was no documentation of presence of suspicion of kidney disease. This injured worker has a diagnosis of diabetes. Measurement of the urine albumin to creatinine ratio in an untimed urinary sample is the preferred screening strategy for moderately increased albuminuria in all patients with diabetes, and should be repeated yearly. In this case, the request for urinalysis profile is not a specific request for urine testing for microalbuminuria. The date and results of any prior urine testing for this injured worker were not submitted. Due to lack of specific indication, the request for urinalysis profile is not medically necessary.

**Labs for GI profile:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medical Practice Standard of Care.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI symptoms and cardiovascular risk Page(s): 68-70.

**Decision rationale:** This injured worker has diagnoses of erosive gastritis and Barrett's metaplasia. The documentation indicates treatment in the recent past with nonsteroidal anti-inflammatory agents. Package inserts for NSAIDS recommend periodic monitoring of a CBC and chemistry profile (including liver and renal function tests). It is possible that this request is related to the GI diagnoses noted, or to the use of NSAIDS, but this was not discussed. The treating physician has provided no specific indications for a gastrointestinal (GI) profile, and has not listed the specific laboratory tests to be included in this profile. Tests should not be performed without specific indications. There are many possible laboratory tests related to gastrointestinal issues, and the documentation does not indicate the specific tests to be performed. Due to lack of specific indication and lack of a sufficiently specific prescription, the request for gastrointestinal profile is not medically necessary.

**Labs for HTN profile:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medical Practice Standard of Care.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Overview of hypertension in adults. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

**Decision rationale:** This injured worker has a diagnosis of hypertension. The treating physician has provided no specific indications for a hypertension profile, and has not listed the specific laboratory tests to be included in this profile. Tests should not be performed without specific indications. There are many possible laboratory tests related to the diagnosis of hypertension, and the documentation does not indicate the specific tests to be performed. Due to lack of specific indication and lack of a sufficiently specific prescription, the request for hypertension profile is not medically necessary.

**Labs for DM profile:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medical Practice Standard of Care.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) diabetes chapter: fasting plasma glucose test, glucose monitoring.

**Decision rationale:** The ODG diabetes chapter recommends testing of the fasting plasma glucose for the diagnosis of diabetes, and self-monitoring of blood glucose for those with type 2 diabetes who use insulin therapy. Hemoglobin A1C should be measured at least twice yearly in all patients with diabetes and at least four times yearly in patients not at target. This injured worker has a diagnosis of diabetes. Hemoglobin A1C was noted from August 2014. The specific tests to be performed included in the request for diabetes profile were not discussed. Due to lack of sufficiently specific prescription, the request for diabetes profile is not medically necessary.