

<b>Case Number:</b>	CM14-0183076		
<b>Date Assigned:</b>	11/07/2014	<b>Date of Injury:</b>	01/07/2003
<b>Decision Date:</b>	12/30/2014	<b>UR Denial Date:</b>	10/08/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/03/2014

### 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 Internal Medicine, has a subspecialty in Nephrology, and is licensed to practice in California. 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 patient is a 59-year-old male who has submitted a claim for gastroesophageal reflux disease secondary to stress and medication, gastritis, hiatal hernia, constipation secondary to narcotic medication, hypertension, hyperlipidemia, glucose intolerance, chest pain, mild proteinuria, and sleep disorder associated with an industrial injury date of 1/7/2003. Medical records from 2014 were reviewed. The patient complained of exertional chest pain associated with tightness. He denied nausea, vomiting, or diaphoresis. The patient reported improvement from constipation and reflux symptoms with medication intake. He denied bloating. Vital signs were as follows: blood pressure 148/97 mmHg and heart rate 74 beats per minute. Lungs were clear to auscultation. Cardiovascular examination showed regular rate and rhythm, normal point of maximum impulse, normal carotid upstroke, and absence of rubs or gallops. Bipedal edema was not noted. Urine toxicology and other laboratory tests were performed on 9/10/2014. Treatment to date has included cervical surgery, and medications such as Nexium, Gaviscon, simethicone, and Sentra PM (since at least September 2014). The utilization review from 10/8/2014 denied the request for drug screen, qualitative because of no data concerning previous urine drug screen; denied Htn and GI profile testing because of nonspecific laboratory tests; denied SudoScan / autonomic nerve function test because of lack of evidence-based guidelines to support its use; denied Sentra AM, #60, 3 bottles and Sentra PM, #60, 3 bottles because of no documentation concerning nutritional deficiency; and denied Nexium 40mg, #30 because patient was not at intermediate risk for a gastrointestinal event.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Urine Toxicology screen:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78-80, 94.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, On-going Management Page(s): 78.

**Decision rationale:** Page 78 of the CA MTUS Chronic Pain Medical Treatment Guidelines state that urine drug screens are recommended as an option to assess order use or presence of illegal drugs and as ongoing management for continued opioid use. Screening is recommended randomly at least twice and up to 4 times a year. In this case, current medications include Nexium, Gaviscon, simethicone, and Sentra PM. It is unclear if patient is currently on opioids. Moreover, urine toxicology was performed on 9/10/2014 without disclosure of results. The medical necessity for a repeat testing has not been established due to insufficient information. Therefore, the request for urine toxicology screen is not medically necessary.

**SudoScan - autonomic nerve function test:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.ncbi.nlm.nih.gov/pubmed/23889506>, Casellini CM1, Parsons HK, Richardson MS, Nevoret ML, Vinik AI. 2013 Nov; 15(11): 948-53.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Diabetes Technology & Therapeutics: Sudoscan, a Noninvasive Tool for Detecting Diabetic Small Fiber Neuropathy and Autonomic Dysfunction (<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3817891/>)

**Decision rationale:** The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, Diabetes Technology & Therapeutics was used instead. According to the literature, Sudoscan measures electrochemical skin conductance (ESC) of hands and feet through reverse iontophoresis. It is a simple, noninvasive, easy-to-perform sudomotor test recently developed to allow the measurement of sweat gland function. Sudomotor dysfunction is one of the earliest detectable neurophysiologic abnormalities in distal small fiber neuropathies. Thus, sudomotor function represents an attractive tool to evaluate the peripheral autonomic system in people with diabetes mellitus. Moreover, the literature discussed that the course of a diabetic sensorimotor polyneuropathy is insidious, and up to 50% of patients with neuropathy may be asymptomatic--often resulting in delayed diagnosis, reduced quality of life, and increased morbidity, mortality, and economic burden. The patient is a known case of glucose intolerance. However, there are no subjective complaints or objective findings presented that may corroborate presence of diabetic neuropathy to warrant a Sudoscan. There is likewise no documented rationale for this request. The medical necessity cannot be established due to

insufficient information. Therefore, the request for Sudoscan - autonomic nerve function test is not medically necessary.

**Hypertension and GI labs profiles: 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 Other Medical Treatment Guideline or Medical Evidence: Laboratory Safety Monitoring of Chronic Medications in Ambulatory Care Settings <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1490088/>

**Decision rationale:** The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, the Journal of General Internal Medicine was used instead. Literature concludes that a large proportion of patients receiving selected chronic medications do not receive recommended laboratory monitoring in the outpatient setting. Further research is needed to determine to what degree these lapses in laboratory monitoring are associated with adverse clinical outcomes, to identify relevant methods to improve monitoring, and to clarify monitoring needs. The patient is a known case of gastroesophageal reflux disease secondary to stress and medication, gastritis, constipation secondary to narcotic medication, hypertension, hyperlipidemia and glucose intolerance. Current medications include Nexium, Gaviscon, simethicone, and Sentra PM. However, laboratory tests were already performed on 9/10/2014 without disclosure of results. The medical necessity for repeat testing could not be established due to insufficient information. Moreover, the present request as submitted failed to specify blood tests to be included. Therefore, the request for hypertension and GI labs profiles was not medically necessary.

**Nexium 40mg #30: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk; NSAIDs, specific drug l.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI Symptoms, and Cardiovascular Risk Page(s): 68.

**Decision rationale:** As stated on page 68 of CA MTUS Chronic Pain Medical Treatment Guidelines, clinicians should weigh the indications for NSAIDs against both GI and cardiovascular risk factors: age > 65 years, history of peptic ulcer, GI bleeding or perforation; concurrent use of ASA, corticosteroids, or anticoagulant; or on high-dose/multiple NSAIDs. Patients with intermediate risk factors should be prescribed proton pump inhibitors (PPI). In this case, patient has been on Nexium since September 2014 for gastritis and gastroesophageal reflux disease secondary to stress and medication. Patient reported symptom relief attributed to medication intake. The medical necessity for continuing PPI therapy has been established. Therefore, the request for Nexium 40mg, #30 is medically necessary.

**Sentra AM #60, QTY: 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), Pain, Medical food

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

**Decision rationale:** The CA MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, the Official Disability Guidelines (ODG), Pain Chapter was used instead. It states that Sentra is a medical food intended for use in management of sleep disorders associated with depression, which 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. Glutamic Acid is used for treatment of hypochlohydria and achlorhydria including those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. 5-hydroxytryptophan has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity, and sleep disorders. In this case, patient has been on Sentra AM since at least September 2014. However, there is no clear indication for Sentra due to lack evidence of insomnia and depression. Moreover, there is no evidence of nutritional deficiency that may warrant Sentra prescription. The medical necessity cannot be established due to insufficient information. Therefore, the request for Sentra AM #60, qty: 3 bottles is not medically necessary.

**Sentra PM, #60, QTY: 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), 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) Pain Chapter, Sentra

**Decision rationale:** The CA MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, the Official Disability Guidelines (ODG), Pain Chapter was used instead. It states that Sentra is a medical food intended for use in management of sleep disorders associated with depression, which 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. Glutamic Acid is used for treatment of hypochlohydria and achlorhydria

including those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. 5-hydroxytryptophan has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity, and sleep disorders. In this case, patient has been on Sentra PM since at least September 2014. However, there is no clear indication for Sentra due to lack evidence of insomnia and depression. Moreover, there is no evidence of nutritional deficiency that may warrant Sentra prescription. The medical necessity cannot be established due to insufficient information. Therefore, the request for Sentra PM #60, qty: 3 bottles is not medically necessary.