

Case Number:	CM15-0195424		
Date Assigned:	10/09/2015	Date of Injury:	02/17/2006
Decision Date:	12/15/2015	UR Denial Date:	09/16/2015
Priority:	Standard	Application Received:	10/05/2015

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: California

Certification(s)/Specialty: Emergency 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 63 year old male who sustained an industrial injury February 17, 2006. Diagnoses are constipation; internal-external hemorrhoids secondary to constipation; vertigo positional secondary to headaches; sleep disorder; diabetes mellitus; metabolic syndrome. According to a secondary treating physician's progress report dated June 16, 2015, the injured worker presented for evaluation and reported stable gastroesophageal reflux with medication, unchanged blurred vision, and no changes to his constipation or headaches. He is sleeping seven hours nightly, waking 4-5 times per night. His sleeping difficulty, internal hemorrhoids and vertigo, are reported as improved. The physician documented labs from March 16, 2015 as creatinine 3.3, lipase 132 and amylase 239. Physical examination revealed; 5'3" and 146 pounds; blood glucose 124; lungs are clear to auscultation; regular heart rate and rhythm; abdomen is soft with normoactive bowel sounds. The physician documented his constipation is controlled with laxatives and deferred diagnoses to appropriate treating physicians are; psychiatric complaints; nocturia; vitamin D deficiency. A body composition study was performed in the office at this visit. Treatment plan included re-education on dietary measures to better control his blood sugar and recommendations for weight loss. At issue, is the request for authorization dated June 16, 2015 for Sentra AM and Sentra PM, Body Composition study, EKG (electrocardiogram), abdominal ultrasound, and Sudoscan. According to utilization review dated September 16, 2015, the requests for Prilosec 20mg #30 + 2 refills, Citrucel #120 + 2 refills, Colace 250mg #60 + 2 refills, Anusol HC Suppositories #1 + 2 refills, Meclizine 12.5mg #60, Metformin 500mg #30, and Diabetic Test Strips-Lancets-Alcohol Swabs 3 month supply, all with a date of service of

June 16, 2015, were all certified. The requests for Sentra AM #60 + 3 refills, Sentra PM #60 + 3 refills, Body Composition Study, EKG, Abdominal Ultrasound, and Sudoscan, all with a service date of June 16, 2015, were non-certified.

IMR ISSUES, DECISIONS AND RATIONALES

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

Sentra AM Qty 60 with 3 refills (retrospective DOS 06/16/2015): 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.

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

Decision rationale: The request is for the use of Sentra, which is a blend of multiple supplements. The Official Disability Guidelines state the following regarding this topic: Not recommended. Sentra PM is a medical food from [REDACTED], 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. See Medical food, Choline, Glutamic Acid, & 5-hydroxytryptophan. In this case, the use of this medication is not indicated. As stated above, there is limited evidence to support its effectiveness. As such, the request is not medically necessary.

Sentra PM Qty 60 with 3 refills (retrospective DOS 06/16/2015): 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; 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/Sentra.

Decision rationale: The request is for the use of Sentra which is a blend of multiple supplements. The Official Disability Guidelines state the following regarding this topic: Not recommended. Sentra PM is a medical food from [REDACTED], 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. See Medical food, Choline, Glutamic Acid, & 5-hydroxytryptophan. In this case, the use of this medication is not indicated. As stated above, there is limited evidence to support its effectiveness. As such, the request is not medically necessary.

Body composition study (retrospective DOS 06/16/2015): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation URL [www.sudoscan-usa.com].

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.ncbi.nlm.nih.gov/pubmed/24090645>.

Decision rationale: The request is for a whole body composition scan. This is a measure of lean muscle and fat by using dual-energy X-ray absorptiometry. The MTUS and ODG are silent regarding this topic and an alternative source was referenced. In this case, this test is not supported. This is secondary to a lack of specific interventions that would be affected by the results or a change in the clinical management of the patient. As such, the request is not medically necessary.

EKG (electrocardiogram), (retrospective DOS 06/16/2015): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Centers for Medicare & Medicaid Services, url [www.cms.gov/MCD/viewicd.asp?icd_id=28255&icd_version=19&show=all].

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low back - Lumbar & Thoracic (Acute & Chronic)/Preoperative electrocardiogram (ECG).

Decision rationale: The request is for an electrocardiogram. The official disability guidelines state the following regarding this topic: Recommended for patients undergoing high-risk surgery and those undergoing intermediate-risk surgery who have additional risk factors. Patients undergoing low-risk surgery do not require electrocardiography. Patients with signs or symptoms of active cardiovascular disease should be evaluated with appropriate testing, regardless of their preoperative status. Preoperative ECGs in patients without known risk factors for coronary disease, regardless of age, may not be necessary. Preoperative and postoperative resting 12-lead ECGs are not indicated in asymptomatic persons undergoing low-risk surgical procedures. Low risk procedures (with reported cardiac risk generally less than 1%) include endoscopic procedures; superficial procedures; cataract surgery; breast surgery; & ambulatory surgery. An ECG within 30 days of surgery is adequate for those with stable disease in whom a preoperative ECG is indicated. (Fleisher, 2008) (Feely, 2013) (Sousa, 2013) Criteria for Preoperative electrocardiogram (ECG): High Risk Surgical Procedures: These are defined as all vascular surgical procedures (with reported cardiac risk often more than 5%, which is the combined incidence of cardiac death and nonfatal myocardial infarction), and they include: Aortic and other major vascular surgery; & Peripheral vascular surgery. Preoperative ECG is recommended for vascular surgical procedures. Intermediate Risk Surgical Procedures: These are defined as procedures with intermediate risk (with reported cardiac risk generally 1-5%), and they include: Intraperitoneal and intrathoracic surgery; Carotid endarterectomy; Head and neck surgery; & Orthopedic surgery, not including endoscopic procedures or ambulatory surgery. Preoperative ECG is recommended for patients with known CHD, peripheral arterial disease, or cerebrovascular disease. Preoperative ECG may be reasonable in patients with at least 1

clinical risk factor: History of ischemic heart disease; History of compensated or prior HF; History of cerebrovascular disease, diabetes mellitus, or renal insufficiency. Low Risk Surgical Procedures: These are defined as procedures with low risk (with reported cardiac risk generally less than 1%), and they include endoscopic procedures; Superficial procedures; Cataract surgery; Breast surgery; & Ambulatory surgery. ECGs are not indicated for low risk procedures. In this case, there is inadequate documentation of the reasoning for this test. There is no indication that the patient is pending a surgical procedure and no records revealing concern regarding cardiac disease. There is also no indication that this is requested as a screening measure. As such, pending further information, the request is not medically necessary.

Abdominal ultrasound, (retrospective DOS 06/16/2015): 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 <http://www.medscape.com/medline/abstract/1006277>.

Decision rationale: The request is for an abdominal ultrasound. The MTUS and ODG are silent regarding this issue. An alternate source was utilized. Clinical indications for ultrasonography in diseases of the abdominal organs include Aortic Aneurysm, Cholelithiasis, Cysts, Hepatomegaly, Hodgkin Disease, Kidney Neoplasms, Liver Abscess, Liver Neoplasms, Pancreatic Neoplasms, Pancreatitis. In this case, there is inadequate documentation of the reasoning for the study. The patient does appear to have chronic renal insufficiency and diabetes but the intent of the study is not addressed. Pending further information, the request is not medically necessary.

Sudoscans (retrospective DOS 06/06/2015): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.sudoscans-usa.com>.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Diabetes/SudoScan.

Decision rationale: The request is for a Sudo scan. The official disability guidelines state the following regarding this topic: Not recommended, as there is a lack of evidence showing that this device improves patient management. See also Autonomic nervous system function testing in the Pain Chapter. The Sudoscans is an autonomic nervous system function test for sudomotor function. The autonomic nervous system regulates blood pressure, heart rate, temperature, respiration, gastrointestinal, bladder and sexual function. Autonomic nervous system testing can be grouped into three categories, sudomotor, cardiovagal innervation, and vasomotor adrenergic innervation. The tests for sudomotor function can include QSART, TST, SSR, Silasticsweat imprint, Sudoscans and QDIRT. The Sudoscans is a non-invasive method to measure sweat gland

function. The device evaluates sweat gland function by obtaining electrochemical reaction between sweat chlorides and stainless-steel electrodes, and it measures electrochemical skin conductance of hands and feet through reverse iontophoresis. A study on the use of Sudoscan as a screening tool for microvascular complications in type-2 diabetes found that the sensitivity was 82% and the specificity was 61%, and for detection of peripheral neuropathy, sensitivity was 82% and specificity was 55%. The study had many limitations and there should be a follow-up study. Much of the literature is limited to small case series. In comparing Sudoscan to conventional measures of peripheral and cardiac neuropathy, authors conclude that the Sudoscan is not a substitute for conventional neuropathy testing. There is a paucity of evidence documenting how these autonomic tests change management or impact treatment in clinical disorders associated with autonomic nervous systems dysfunction. (Calvet, 2013) (Casellini, 2013) (Eranki, 2013) (Nvoret, 2015) (Raisanen, 2014) (Smith, 2014) As indicated above, this test would not be supported by the guidelines. This is secondary to poor clinical evidence revealing how the results impact the treatment rendered. As such, the request is not medically necessary.