

Case Number:	CM15-0071185		
Date Assigned:	05/22/2015	Date of Injury:	04/20/2008
Decision Date:	07/09/2015	UR Denial Date:	03/18/2015
Priority:	Standard	Application Received:	04/15/2015

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: Indiana

Certification(s)/Specialty: Preventive Medicine, Occupational 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 (IW) is a 62 year old female who sustained an industrial injury on 04/20/2008. She reported musculoskeletal complaints. The injured worker was diagnosed as status post lumbar fusion at L4 through S1 in 2011, revision of fusion at L4 through S1 in January 2013, lumbar radiculopathy, and chronic pain. Other diagnoses include sleep disorder, history of hypertension, abdominal pain, constipation, blurred vision, bilateral (more frequent in left eye), glucose intolerance, and hypertriglyceridemia. Treatment to date has included the above mentioned surgeries, injections at the hardware sites, Pain Management, use of oral pain medications, non-steroidal anti-inflammatory medications and narcotics. Currently, the injured worker complains of ongoing abdominal signs and symptoms of bloating, but notes improvement in her cramping. She denies constipation and fatigue and her glucose intolerance is resolving. She states her average fasting blood glucose is 110. According to provider notes, the worker's fasting blood sugars had remained stable, her abdomen was soft and non-tender and there was no guarding during the exam. She was advised to avoid non-steroidal anti-inflammatories, and requests were submitted for the following: 30 Prilosec 20mg, 60 Probiotics, 60 Sentra Am 3 Bottles, 60 Sentra Pm 3 Bottles, 1 Accu-Chek blood glucose test, 60 Simethicone 80mg and H. Pylori Stool Test.

IMR ISSUES, DECISIONS AND RATIONALES

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

30 Prilosec 20mg: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs; GI discomfort Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: MTUS states "Determine if the patient is at risk for gastrointestinal events: (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)." And "Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 ‚ g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44)." The medical documents provided do not establish the patient has having documented GI bleeding/perforation/peptic ulcer or other GI risk factors as outlined in MTUS. Additionally, there is no evidence provided to indicate the patient suffers from dyspepsia because of the present medication regimen. As such, the request for Omeprazole is not medically necessary.

60 Probiotics: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation First Line Therapy's.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental, Psychobiotics Other Medical Treatment Guideline or Medical Evidence: www.uptodate.com, Probiotics for gastrointestinal diseases.

Decision rationale: MTUS is silent specifically with regards to probiotics. ODG states, under study. Psychobiotics are live organisms (probiotics) that when ingested may produce health benefits in patients suffering from mental illness. The term psychobiotic was created as recent studies have begun to explore a possible link between probiotics and behavior. Several preclinical studies showed a link between specific probiotics and beneficial behavioral effects. Preclinical studies suggest that depression is associated with an alteration in the microbiota. Psychobiotics are good bacteria that have the potential to increase microbial diversity and treat the symptoms of depression. Human studies are still largely lacking, but one study showed that healthy volunteers who received *Lactobacillus helveticus* R0052 plus *B longum* for 30 days reported significantly lower stress levels than those who received placebo, as well as significantly reduced urinary free cortisol levels. Up-to-date states, several probiotic preparations have promise in preventing or treating various conditions. However, most studies have been small, and many have important methodologic limitations, making it difficult to make unequivocal conclusions regarding efficacy, especially when compared with proven

therapies. Furthermore, considerable differences exist in composition, doses, and biologic activity between various commercial preparations, so that results with one preparation cannot be applied to all probiotic preparations. Medical documents do not detail what mental illness the requested probiotics meant for. Medical records do not detail why exception to the guidelines are necessary. As such, the request for Probiotics is not medically necessary at this time.

60 Sentra Am 3 Bottles: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disabilities Guidelines.

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

Decision rationale: Sentra AM is a medical food that contains choline and acetylcarnitine as in intended to maintain production of acetylcholine in the central and peripheral nervous system. MTUS and ODG are silent specifically regarding Sentra AM. In addition ODG states that a medical food is Definition: Defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3)) as a food which is formulated to be consumed or administered eternally 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. To be considered the product must, at a minimum, meet the following criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. ODG specifically states 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. Medical records do not indicate that the patient meets these criteria. The medical records do not indicate the specific dietary disease or condition for which there is a distinctive nutritional requirement that the medication would be used for. Additionally, there is a component of this medication that is not recommended per guidelines. As such, the request for is not medically necessary.

60 Sentra Pm 3 Bottles: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disabilities Guidelines.

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

Decision rationale: MTUS is silent regarding Sentra PM. ODG states that Sentra PM is a medical food from Targeted Medical Pharma Inc., Los Angeles, CA, intended for use in management of sleep disorders associated with depression that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. In addition ODG states that a medical food is Definition: Defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) as a food which is formulated to be consumed or administered eternally 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. To be considered the product must, at a minimum, meet the following criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. ODG specifically states 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. Medical records do not indicate that the patient meets these criteria. The medical records do not indicate the specific dietary disease or condition for which there is a distinctive nutritional requirement that the medication would be used for. Additionally, there is a component of this medication that is not recommended per guidelines. As such, the request for Sentra PM is not medically necessary.

1 Accu-Chek blood glucose test: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disabilities Guidelines.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines; Diabetes; Glucose monitoring.

Decision rationale: MTUS is silent on Accu-check blood glucose testing, but ODG states the following: "Recommend self-monitoring of blood glucose (SMBG) for people with type 1 diabetes as well as for those with type 2 diabetes who use insulin therapy, plus long-term assessment, but not continuous glucose monitoring (CGM) for routine use. Current glucose monitoring strategies can be classified into 2 categories: patient self-monitoring, which would allow patients to change behavior (diet or exercise) or medication dose (most often insulin), or long-term assessment, which allows both the patient and the clinician to evaluate overall glucose control and risk for complications over weeks or months. Although some form of glucose self-monitoring has long been available, current-day forms of self-monitoring include self-monitoring of blood glucose (SMBG) and continuous glucose monitoring (CGM), while long-term assessment is most often by A1C. Accuracy of the current generation of CGM devices is not yet deemed sufficient by the FDA to recommend them for routine use. A1C should be measured at least twice yearly in all patients with DM and at least 4 times yearly in patients not at target. SMBG should be performed by all patients using insulin (minimum of twice daily and ideally at least before any injection of insulin). More frequent SMBG after meals or in the middle of the night may be required for insulin-taking patients with frequent hypoglycemia, patients not at A1C targets, or those with symptoms. Patients not requiring insulin therapy may benefit from

SMBG, especially to provide feedback about the effects of their lifestyle and pharmacologic therapy; testing frequency must be personalized. Although still early in its development, continuous glucose monitoring (CGM) can be useful for many patients to improve A1C levels and reduce hypoglycemia. (Handelsman, 2011) Self-monitoring of blood glucose (SMBG) has a small effect on glycemic control in patients with type 2 diabetes who are not using insulin, according to this Cochrane review. Any effect on A1C levels was found to occur only in the first 6 months, during which time the A1C level decreased by 0.26%, and the effect of SMBG was no longer significant at 12 months follow-up, with a decrease in A1C levels of only 0.1%. SMBG has been shown to be an effective tool for people with type 1 diabetes as well as for those with type 2 diabetes who use insulin therapy, because patients use the glucose levels to adjust insulin doses. This systemic review suggests that patients with type 2 diabetes are not using SMBG to adjust their diet and lifestyle. (Malanda, 2012) Clinical practice guidelines that advise self-monitoring of blood glucose (SMBG) for patients with diabetes who do not use insulin are generally more positive about the practice than the evidence cited to back them up, according to an analysis of 18 clinical practice guidelines, 15 systematic reviews, and 14 randomized controlled trials. The findings question the benefit of SMBG among patients with type 2 diabetes who do not use insulin (or insulin secretagogues such as sulfonylureas) and who are therefore not at increased risk for hypoglycemia. SMBG has its greatest benefit as a safety tool for patients on insulin, to know about and avoid hypoglycemia. When it is used as a therapeutic tool, the evidence is less robust. SMBG doesn't lower blood sugar levels; only lifestyle changes and medicine do, so SMBG only helps when it is coupled to these other interventions. (Aakre, 2012)." The employee has type 2 diabetes and has had some challenges in keeping her blood glucose levels in the normal range. Therefore, the request for an Accu-check glucose monitor is medically necessary.