

Case Number:	CM13-0001906		
Date Assigned:	10/08/2013	Date of Injury:	03/23/2004
Decision Date:	06/10/2014	UR Denial Date:	07/10/2013
Priority:	Standard	Application Received:	07/17/2013

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 and is licensed to practice in Virginia and District of Columbia. 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 56 year old female who sustained injury, on Mar 23 2004, to her hands , wrists, face and internal organs. She worked as a correctional officer for 2 years. Diagnoses include obesity, hypertension, hyperlipidemia, depression, anxiety and insomnia. The patient had gastric bypass in 2005. [REDACTED] saw the patient on June 4 2013 and she was noted to have swallowing difficulty. It was recommended that the patient follow up with her bariatric surgeon. She received a refill of her vitamin d supplementation. Labs were ordered and these included: CBC, CMP, lipid panel, hemoglobin A1c, vitamin d and TSH level. The patient was noted to be on several medications: Avapro, multivitamins, Glucosamine supplements, and Nexium.

IMR ISSUES, DECISIONS AND RATIONALES

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

GLUCOSAMINE-CHONDROITIN - QUANTITY: 3: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 50.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 50.

Decision rationale: The MTUS Chronic Pain Medical Treatment Guidelines, states that this is recommended as an option given its low risk, in patients with moderate arthritis pain, especially

for knee osteoarthritis. Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulphate (GS) on a number of outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride (GH). (Richy, 2003) (Ruane, 2002) (Towheed-Cochrane, 2001) (Braham, 2003) (Reginster, 2007) A randomized, doubleblind placebo controlled trial, with 212 patients, found that patients on placebo had progressive joint-space narrowing, but there was no significant joint-space loss in patients on glucosamine sulphate. (Reginster, 2001) Another RCT with 202 patients concluded that long-term treatment with glucosamine sulfate retarded the progression of knee osteoarthritis, possibly determining disease modification. (Pavelka, 2002) The Glucosamine Chondroitin Arthritis Intervention Trial (GAIT) funded by the National Institutes of Health concluded that "glucosamine hydrochloride (GH) and chondroitin sulfate were not effective in reducing knee pain in the study group overall; however, these may be effective in combination for patients with moderate-to-severe knee pain. [Note: The GAIT investigators did not use glucosamine sulfate (GS).] (Distler, 2006) Exploratory analyses suggest that the combination of glucosamine and chondroitin sulfate may be effective in the subgroup of patients with moderate-to-severe knee pain. (Clegg, 2006) In a recent meta-analysis, the authors found that the apparent benefits of chondroitin were largely confined to studies of poor methodological quality, such as those with small patient numbers or ones with unclear concealment of allocation. When the analysis was limited to the three best-designed studies with the largest sample sizes (40% of all patients), chondroitin offered virtually no relief from joint pain. While not particularly effective, chondroitin use did not appear to be harmful either, according to a meta-analysis of 12 of the studies. (Reichenbach, 2007) Despite multiple controlled clinical trials of glucosamine in osteoarthritis (mainly of the knee), controversy on efficacy related to symptomatic improvement continues. " Based on the documentation provided for review, there is no evidence to support that the patient has arthritis, including knee osteoarthritis. Therefore, the request for Glucosamine-Chondroitin, quantity 3 is not medically necessary and appropriate.

VITAMIN D SUPPLEMENTATION 800 UNITS - QUANTITY: 60 (#30, WITH 1 REFILL): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ACOEM: Evaluation And Management of Common Health Problems and Functional Recovery in Workers.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

Decision rationale: According to the California MTUS Guidelines, many interventions that might be classified as dietary supplements or as complementary or alternative treatments have been used to treat chronic pain conditions. A few of these interventions include homeopathic and naturopathic treatment, vitamins, herbal remedies (certain exceptions discussed below), spiritual healing, touch for healing, craniosacral therapy, aromatherapy, energy healing, and neural therapy. Most interventions do not have any quality evidence of efficacy and there is some controversy surrounding the issue of the value of placebo effects in healing. As there are many interventions shown to be efficacious for the treatment of acute and/or chronic pain, it is strongly recommended that patients be treated with therapies proven to be efficacious whether the intervention is considered complementary or not. In this case, the evidence supporting the use of

vitamin d supplement is weak and it is therefore not clinically indicated in this patient. The request for Vitamin D supplementation 800 units, quantity 60 (# 30 with 1 refill) is not medically necessary and appropriate.

LAB: CBC: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 23, 64, 70..

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 70.

Decision rationale: According to the MTUS Guidelines, for those taking NSAIDS, recommended with cautions below. "Disease-State Warnings for all NSAIDS: All NSAIDS have [U.S. Boxed Warning]: for associated risk of adverse cardiovascular events, including, MI, stroke, and new onset or worsening of pre-existing hypertension. NSAIDS should never be used right before or after a heart surgery (CABG - coronary artery bypass graft). NSAIDS can cause ulcers and bleeding in the stomach and intestines at any time during treatment (FDA Medication Guide). See NSAIDS, GI Symptoms and Cardiovascular Risks. Other disease-related concerns (non-boxed warnings): Hepatic: Use with caution in patients with moderate hepatic impairment and not recommended for patients with severe hepatic impairment. Borderline elevations of one or more liver enzymes may occur in up to 15% of patients taking NSAIDS. Renal: Use of NSAIDS may compromise renal function. FDA Medication Guide is provided by FDA mandate on all prescriptions dispensed for NSAIDS. Routine Suggested Monitoring: Package inserts for NSAIDS recommend periodic lab monitoring of a CBC and chemistry profile (including liver and renal function tests). There has been a recommendation to measure liver transaminases within 4 to 8 weeks after starting therapy, but the interval of repeating lab tests after this treatment duration has not been established. Routine blood pressure monitoring is recommended." In this case there is no evidence the patient was taking NSAIDS. Therefore, the request for Lab: CBC, is not medically necessary and appropriate.

LAB: CMP: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 23, 64, 70..

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 70.

Decision rationale: According to the California MTUS Guidelines, for those taking NSAIDS, "recommended with cautions below. Disease-State Warnings for all NSAIDS: All NSAIDS have [U.S. Boxed Warning]: for associated risk of adverse cardiovascular events, including, MI, stroke, and new onset or worsening of pre-existing hypertension. NSAIDS should never be used right before or after a heart surgery (CABG - coronary artery bypass graft). NSAIDS can cause ulcers and bleeding in the stomach and intestines at any time during treatment (FDA Medication Guide). See NSAIDS, GI Symptoms and Cardiovascular Risks. Other disease-related concerns

(non-boxed warnings): Hepatic: Use with caution in patients with moderate hepatic impairment and not recommended for patients with severe hepatic impairment. Borderline elevations of one or more liver enzymes may occur in up to 15% of patients taking NSAIDs. Renal: Use of NSAIDs may compromise renal function. FDA Medication Guide is provided by FDA mandate on all prescriptions dispensed for NSAIDs. Routine Suggested Monitoring: Package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile (including liver and renal function tests). There has been a recommendation to measure liver transaminases within 4 to 8 weeks after starting therapy, but the interval of repeating lab tests after this treatment duration has not been established. Routine blood pressure monitoring is recommended." In this case, there is no evidence the patient was taking NSAIDs. Therefore, the request for Lab: CMP is not medically necessary and appropriate.

LAB: LIPID PANEL: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 23, 64, 70..

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.uspreventiveservicestaskforce.org/uspstf08/lipid/lipidrs.htm>.

Decision rationale: The US Preventative Services Task Force Guidelines strongly recommends screening women aged 45 and older for lipid disorders if they are at increased risk for coronary heart disease. The optimal interval for screening is uncertain. On the basis of other guidelines and expert opinion, reasonable options include every 5 years, shorter intervals for people who have lipid levels close to those warranting therapy, and longer intervals for those not at increased risk who have had repeatedly normal lipid levels. Increased risk, for the purposes of this recommendation, is defined by the presence of any one of the risk factors listed below. The greatest risk for CHD is conferred by a combination of multiple listed factors. While the USPSTF did not use a specific numerical risk to bound this recommendation, the framework used by the USPSTF in making these recommendations relies on a 10-year risk of cardiovascular events: Diabetes; Previous personal history of CHD or non-coronary atherosclerosis (e.g., abdominal aortic aneurysm, peripheral artery disease, carotid artery stenosis); A family history of cardiovascular disease before age 50 in male relatives or age 60 in female relatives; Tobacco use; Hypertension; and Obesity (BMI ≥ 30). In this case, the patient has multiple risk factors requiring lipid screening and was being treated for hyperlipidemia. It is medically indicated. The request for Lab: Hemoglobin ALC is medically necessary and appropriate.

LAB: HEMOGLOBIN ALC: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 23, 64, 70..

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://laboratory->

manager.advanceweb.com/Archives/Article-Archives/New-ADA-Guidelines-for-Diagnosis-Screening-of-Diabetes.aspx.

Decision rationale: According to the American Diabetes Association, it is recommended A1c testing 2-4 times per year for patients with diabetes, and the recommended range is < 7.0% for individuals with diabetes, with an A1c of 8.0% and higher a cause for concern and re-evaluation of the patient's care. The American Diabetes Association believes that the use of an A1C test for screening will encourage more people to get tested for diabetes since this study does not require fasting. The A1C test represents an efficient and effective means to diagnose diabetes allowing for early intervention and treatment. In this case, the patient was diagnosed with obesity and underwent gastric bypass and is therefore considered to be suitable to screening. The request for Lab: Hemoglobin A1C is medically necessary and appropriate.

LAB: VITAMIN D LEVEL: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 23, 64, 70..

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://ods.od.nih.gov/factsheets/VitaminD-HealthProfessional/#h6>.

Decision rationale: According to the National Institutes of Health, "People who are obese or who have undergone gastric bypass surgery, A body mass index ≥ 30 is associated with lower serum 25(OH) D levels compared with non-obese individuals; people who are obese may need larger than usual intakes of vitamin D to achieve 25(OH) D levels comparable to those of normal weight. Obesity does not affect skin's capacity to synthesize vitamin D, but greater amounts of subcutaneous fat sequester more of the vitamin and alter its release into the circulation. Obese individuals who have undergone gastric bypass surgery may become vitamin D deficient over time without a sufficient intake of this nutrient from food or supplements, since part of the upper small intestine where vitamin D is absorbed is bypassed and vitamin D mobilized into the serum from fat stores may not compensate over time." In this case, the patient underwent gastric bypass and therefore had developed nutritional deficiencies. It is medically indicated to obtain this test. The request for Lab: Vitamin D level is medically necessary and appropriate.

LAB: TSH LEVEL: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 23, 64, 70..

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.uspreventiveservicestaskforce.org/3rduspstf/thyroid/thyr.rs.htm>.

Decision rationale: According to the US preventative services task force guidelines, "TSH screening is not routinely recommended. Rationale: The USPSTF found fair evidence that the

thyroid stimulating hormone (TSH) test can detect subclinical thyroid disease in people without symptoms of thyroid dysfunction, but poor evidence that treatment improves clinically important outcomes in adults with screen-detected thyroid disease. Although the yield of screening is greater in certain high-risk groups (e.g., postpartum women, people with Down syndrome, and the elderly), the USPSTF found poor evidence that screening these groups leads to clinically important benefits. There is the potential for harm caused by false positive screening tests; however, the magnitude of harm is not known. There is good evidence that over-treatment with levothyroxine occurs in a substantial proportion of patients, but the long-term harmful effects of over-treatment are not known. As a result, the USPSTF could not determine the balance of benefits and harms of screening asymptomatic adults for thyroid disease." Therefore, the request for Lab: TSH level, is not medically necessary and appropriate.