

Case Number:	CM14-0028651		
Date Assigned:	06/16/2014	Date of Injury:	02/21/1997
Decision Date:	07/30/2014	UR Denial Date:	02/06/2014
Priority:	Standard	Application Received:	03/06/2014

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 and is licensed to practice in Virginia and the 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:

This is a 71 year old patient who sustained injury on Feb 21 1997. The patient was seen by [REDACTED] on Jan 8 2014 for follow up. He was noted to have hospitalization in the recent time period for atrial fibrillation. He was continued on omeprazole for gerd and metformin for diabetes. He was continued on lisinopril for hypertension. He was continued on simvastatin and fenofibrate for hyperlipidemia. He was also noted to have other medical conditions which included atrial flutter and congestive heart failure.

IMR ISSUES, DECISIONS AND RATIONALES

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

Omeprazole 20mg twice daily: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms and Cardiovascular Risk Section.

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

Decision rationale: This patient was noted GERD was being treated with omeprazole and dietary modification. The use of omeprazole is medically indicated. Per MTUS, Recommend with precautions as indicated below. Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. 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). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastroduodenal lesions. Recommendations Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g, ibuprofen, naproxen, etc.) 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). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardio-protection) and a PPI. The request is not medically necessary.

Metformin 500mg twice daily: Overturned

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: <http://www.uptodate.com/contents/diabetes-mellitus-type-2-treatment-beyond-the-basics>.

Decision rationale: This patient was diagnosed with diabetes and metformin would be medically indicated for treatment. Per guidelines cited, TYPE 2 DIABETES MEDICINES -- A number of oral medicines (pills) are available to treat type 2 diabetes. Patients with certain types of kidney, liver, and heart disease, and those who drink alcohol excessively should not take metformin. You should stop taking metformin 48 hours before any test that uses iodine-based contrast dye (like a computed tomography [CT] scan with contrast), and you should stop it before any type of surgery. The request is medically necessary.

Fenofibrate 145mg daily: Overturned

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: <http://emedicine.medscape.com/article/126568-medication>.

Decision rationale: This patient had multiple coronary conditions, which include CHF, and diabetes. Standard of care dictates that cholesterol levels be treated to reduce risk. Fenofibrate is a medication used to treat elevated triglycerides and would be indicated to optimize this patient's cholesterol goals. Fibrates raise HDL, and they may increase LDL, particularly if the triglyceride level is greater than 400 mg/dL. Because LDL particles change from being small and dense to

being large and buoyant, they may be less atherogenic. Fibrates activate peroxisome proliferator activated receptor (PPAR) alpha, increasing the activity of lipoprotein lipase, which causes a decrease in triglyceride levels. LDL changes from small, dense morphology to large, buoyant particles that are more rapidly cleared by liver. PPARalpha activation also increases HDL production. Four fibrates are used clinically: 2 are available in the United States, both in generic formulations: gemfibrozil (Lopid) and fenofibrate (multiple brand names); the other 2 agents, bezafibrate and ciprofibrate, are available in Europe and elsewhere but have not been approved by the US Food and Drug Administration (FDA). Fenofibrate is available in micronized and nonmicronized formulations; no convincing data suggest that one has greater efficacy than the other. Some formulations are better absorbed with food. Relatively recently, the FDA approved a new fenofibrate formulation known as fenofibric acid (Trilipix) with a specific indication for use with a statin in patients with mixed dyslipidemia. The request is medically necessary.

Simvastatin 40mg at bedtime: Overturned

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: <http://www.rxlist.com/zocor-drug/indications-dosage.htm>.

Decision rationale: This patient was found to have elevated cholesterol and lipid lowering therapy was prescribed, in addition to dietary modifications. This is medically indicated. ZOCOR is indicated to reduce elevated total cholesterol (total-C), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), and triglycerides (TG), and to increase high-density lipoprotein cholesterol (HDL-C) in patients with primary hyperlipidemia (Fredrickson type IIa, heterozygous familial and nonfamilial) or mixed dyslipidemia (Fredrickson type IIb). The request is medically necessary.

Lisinopril 2.5mg daily: Overturned

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: <http://care.diabetesjournals.org/content/26/8/2421.long>.
<http://www.uptodate.com/contents/diabetic-kidney-disease-diabetic-nephropathy-beyond-the-basics>.

Decision rationale: This patient was found to have diabetes and had high blood pressure. He was prescribed lisinopril, an ACE inhibitor. This is medically appropriate. The benefits of ACE inhibitor therapy in reducing cardiovascular end points in patients with myocardial infarction (MI) or left ventricular (LV) dysfunction have been demonstrated in many studies e.g. the SAVE (Survival And Ventricular Enlargement), AIRE (Acute Infarction Ramipril Efficacy) and ISIS-4

(Fourth International Study of Infarct Survival) studies, including post-hoc subgroup analyses in diabetic patients.[5-7] The HOPE (Heart Outcomes Prevention Evaluation) study examined the potential benefits of ramipril in a wider population of patients with vascular disease but no history of LV systolic dysfunction.[8] Patients with diabetes and at least one other cardiovascular risk factor were also eligible. Analysis of the diabetic cohort of the 3,577 patients (38% of total) enrolled in the HOPE study demonstrated a statistically significant 25% relative risk reduction in the combined primary end point of MI, stroke and cardiovascular death ($p=0.0004$). These reductions were seen regardless of whether the patients had type 1 or type 2 diabetes (although the vast majority of patients had type 2 diabetes), previous cardiovascular events, hypertension or microalbuminuria. The reduction in the primary end point remained significant after adjustment for the slight reduction in blood pressure seen in the treatment group. The request is thus medically necessary.