

Case Number:	CM15-0178913		
Date Assigned:	09/21/2015	Date of Injury:	03/11/2009
Decision Date:	10/27/2015	UR Denial Date:	08/05/2015
Priority:	Standard	Application Received:	09/11/2015

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: Tennessee, Florida, Ohio
 Certification(s)/Specialty: Surgery, Surgical Critical Care

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 49 year old female, who sustained an industrial injury on March 11, 2009. The injured worker was diagnosed as having hypertension, abdominal pain, acid reflux, diarrhea, and sleep disorder. Treatment and diagnostic studies to date has included medication regimen, sleep disorder breathing respiratory diagnostic study, x-rays of the hand and wrist, psychological evaluation, laboratory studies, transthoracic echocardiogram, overnight electroencephalogram, ultrasound of the abdomen, and ultrasound of the bilateral carotid arteries. In a progress note dated July 08, 2015 the treating physician reports an examination revealing for a blood pressure of 126-87mmHG, a heart rate of 81bpm, and plus one epigastric tenderness. In a progress note dated June 01, 2015 the treating physician reports an examination revealing of blood pressure readings of 163-99mmHG, 160-108mmHG, and 145-99mmHG, a heart rate of 59 bpm, and plus one epigastric tenderness. On June 01, 2015 the progress note included the requests for the medications of Hydrochlorothiazide, Prilosec, Gemfibrozil, Lovaza, and Crestor. The progress notes from June 01, 2015 and July 08, 2015 did not include prior laboratory studies of cholesterol screening with triglyceride and cholesterol levels. Transthoracic echocardiogram performed on March 17, 2015 was revealing for an estimated ejection fraction of 55%, with "trivial" mitral valve regurgitation, "trivial" tricuspid valve regurgitation, and "normal" left ventricular systolic function. The documentation from June 11, 2015 noted prior testing of ultrasound of the abdomen performed on June 01, 2015 that was unrevealing for acute cholecystitis and an ultrasound of the bilateral carotid arteries performed on June 01, 2015 that was revealing for a "normal" duplex examination of the carotid bifurcations. On July 08, 2015

the treating physician requested the medications of Gemfibrozil 600mg twice a day for the quantity of 60, Crestor 5mg at bedtime with a quantity of 30, and Lovaza 4 grams daily for a one month supply with a quantity of 30, noting prior prescriptions of these medications. The treating physician also requested the medications of Ranitidine 150mg with a quantity of 30, Dexilant 60mg with a quantity of 30, and Lisinopril 20mg daily with a quantity of 30, but the progress noted did not indicate the specific reason of these requested medications. On August 05, 2015 the Utilization Review determined the requests for Ranitidine 150mg with a quantity of 30, Gemfibrozil 600mg twice a day for the quantity of 60, Dexilant 60mg with a quantity of 30, Crestor 5mg at bedtime with a quantity of 30, Lisinopril 20mg daily with a quantity of 30, and Lovaza 4 grams daily for a one month supply with a quantity of 30 to be non-approved.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ranitidine 150mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk, NSAIDs (non-steroidal anti-inflammatory drugs).

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. Regarding the request for ranitidine, California MTUS states that H2 receptor antagonists are appropriate for the treatment of dyspepsia secondary to NSAID therapy. Within the documentation available for review, there is no indication that the patient has complaints of recent dyspepsia secondary to NSAID use or another indication for this medication. The patient's most recent abdominal exam notes that the patient had mild epigastric tenderness with a normal abdominal ultrasound. Therefore, based on the submitted medical documentation, the request for ranitidine 150mg is not medically necessary.

Gemfibrozil 600mg BID #60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.ncbi.nlm.nih.gov/pubmed/2245435.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Drugs.com: Gemfibrozil <http://www.rxlist.com/lopid-drug/indications-dosage.htm>, <http://www.drugs.com/pro/gemfibrozil.html>.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. The California MTUS guidelines, the ACOEM Guidelines and the Official Disability Guidelines do not address this topic. Therefore, outside sources were sought. Drugs.com indicates that Gemfibrozil is a lipid regulating medication. It goes on to state the initial treatment for dyslipidemia is dietary therapy specific for the type of

lipoprotein abnormality. Excess body weight and excess alcohol intake may be important factors in hypertriglyceridemia and should be managed prior to any drug therapy. Physical exercise can be an important ancillary measure, and has been associated with rises in HDL-cholesterol. Diseases contributory to hyperlipidemia such as hypothyroidism or diabetes mellitus should be looked for and adequately treated. The use of drugs should be considered only when reasonable attempts have been made to obtain satisfactory results with non-drug methods. If the decision is made to use drugs, the patient should be instructed that this does not reduce the importance of adhering to diet. However, there is no indication that the patient has tried lifestyle changes prior to the initiation of medication for the treatment of dyslipidemia. Finally, in the documentation available for review there are no laboratory data to verify the diagnosis or benchmark a baseline of dyslipidemia before initiating therapy. Therefore, based on the submitted medical documentation, the request for Gemfibrozil is not medically necessary.

Dexilant 60mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs), NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of the requested prescription for this patient. The clinical records submitted do not support the fact that this patient has refractory GERD resistant to H2 blocker therapy or an active h- pylori infection. The California MTUS guidelines address the topic of proton pump prescription. In accordance with California MTUS guidelines, PPI's (Proton Pump Inhibitors) can be utilized if the patient is concomitantly on NSAIDS and if the patient has gastrointestinal risk factors. This patient is not on NSAIDS. Additionally, per the Federal Drug Administration's (FDA) prescribing guidelines for Nexium use, chronic use of a proton pump inhibitor is not recommended due to the risk of developing atrophic gastritis. Short-term GERD symptoms may be controlled effectively with an H2 blocker unless a specific indication for a proton pump inhibitor exists. This patient's medical records support that he has epigastric pain. However, the patient has no documentation of why chronic PPI therapy is necessary, especially with a name brand, third generation PPI medication. The patient has no history of known gastric surgery or any clear evidence to indicate an active h- pylori infection. Therefore, based on the submitted medical documentation, the request for Dexilant 60mg prescription is not medically necessary.

Crestor 5mg at bedtime #30: 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), Diabetes, Statins.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation FDA Crestor Clinical Indications for Use: <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm109095.htm>.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. The California MTUS guidelines, the ACOEM Guidelines and the Official Disability Guidelines do not address this topic. Therefore, outside sources were sought. The FDA Crestor Indications for Use note that Crestor belongs to a group of drugs called HMG CoA reductase inhibitors, or statins. Rosuvastatin reduces levels of bad cholesterol (low-density lipoprotein, or LDL) and triglycerides in the blood, while increasing levels of good cholesterol. The initial treatment for dyslipidemia is dietary therapy specific for the type of lipoprotein abnormality. Excess body weight and excess alcohol intake may be important factors in hypertriglyceridemia and should be managed prior to any drug therapy. Physical exercise can be an important ancillary measure, and has been associated with rises in HDL-cholesterol. Diseases contributory to hyperlipidemia such as hypothyroidism or diabetes mellitus should be looked for and adequately treated. The use of drugs should be considered only when reasonable attempts have been made to obtain satisfactory results with non-drug methods. If the decision is made to use drugs, the patient should be instructed that this does not reduce the importance of adhering to diet. However, there is no indication that the patient has tried lifestyle changes prior to the initiation of medication for the treatment of dyslipidemia. Finally, in the documentation available for review, there is no recent laboratory data to verify the diagnosis or benchmark a baseline of dyslipidemia before initiating therapy. Therefore, based on the submitted medical documentation, the request for Crestor is not medically necessary.

Lisinopril 20mg QD #30: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Diabetes, Hypertension treatment.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Federal Drug Administration (FDA) Lisinopril Indications Use and Prescribing Information http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/019777s054lbl.pdf.

Decision rationale: There is sufficient clinical information provided to justify the medical necessity of a Lisinopril prescription for this patient. The clinical records submitted do support the fact that this patient has coronary artery disease and hypertension. The California MTUS guidelines, Occupational Disability Guidelines and the ACOEM Guidelines do not address the topic of Lisinopril prescription. Per the Federal Drug Administration's (FDA) prescribing guidelines for Lisinopril use, the medication is indicated for primary and refractory hypertension, acute Myocardial Infarction and congestive heart failure. This patient's medical records support that she has refractory hypertension which is not associated with congestive heart failure. On multiple occasions, the patient has been demonstrated to have hypertension in the clinical setting. Use of Lisinopril for treatment of this patient's primary hypertension is

clinically appropriate and cardio-renal protective. Therefore, based on the submitted medical documentation, the request for Lisinopril prescription is medically necessary.

Lovaza 4 grams QD 1 month supply #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.ncbi.nlm.gov/pmc/articles/PMC2683599; Title: Omega-3-acid Ethyl Esters (Lovaza) for Severe Hypertriglyceridemia.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation FDA Lovaza Clinical Indications for Use:http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021654s023lbl.pdf.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. The California MTUS guidelines, the ACOEM Guidelines and the Official Disability Guidelines do not address this topic. Therefore, outside sources were sought. The FDA Lovaza Indications for Use note that Lovaza is a lipid regulating agent supplied as a liquid filled gel capsule oral administration. Lovaza is a lipid regulating agent supplied as a liquid filled gel capsule oral administration. The initial treatment for dyslipidemia is dietary therapy specific for the type of lipoprotein abnormality. Excess body weight and excess alcohol intake may be important factors in hypertriglyceridemia and should be managed prior to any drug therapy. Physical exercise can be an important ancillary measure, and has been associated with rises in HDL-cholesterol. Diseases contributory to hyperlipidemia such as hypothyroidism or diabetes mellitus should be looked for and adequately treated. The use of drugs should be considered only when reasonable attempts have been made to obtain satisfactory results with non-drug methods. If the decision is made to use drugs, the patient should be instructed that this does not reduce the importance of adhering to diet. However, there is no indication that the patient has tried lifestyle changes prior to the initiation of medication for the treatment of dyslipidemia. Finally, in the documentation available for review, there is no recent laboratory data to verify the diagnosis or benchmark a baseline of dyslipidemia before initiating therapy. Therefore, based on the submitted medical documentation, the request for lovaza is not medically necessary.