

<b>Case Number:</b>	CM15-0100031		
<b>Date Assigned:</b>	06/04/2015	<b>Date of Injury:</b>	01/24/1994
<b>Decision Date:</b>	09/28/2015	<b>UR Denial Date:</b>	05/08/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/26/2015

### 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 (IW) is a 67-year-old female who sustained an industrial injury on 01/24/1994. The original report and mechanism of injury are not included in the medical records provided. The injured worker was diagnosed as having cervical facet arthropathy, cervical radiculopathy, lumbar facet arthropathy, lumbar radiculopathy, and bilateral hip pain. Other diagnoses include asthma unspecified, unspecified chest pain, and malignant hypertension. She has diagnosis of a major depressive disorder of a moderate single episode 03/31/2015. Treatment to date has included oral and topical medications for her pain, psychotherapy, and psychiatric consultations to maintain medications. According to the provider notes of 03/31/2015, the IW is taking Xanax, Nortriptyline, Lexapro and Ritalin. All known medications listed 04/13/2015 included Celebrex capsule, Percocet, Ambien, Lidocaine 5% ointment, and Tramadol for pain. The IW had a lumbar epidural steroid injection on 04/17/2015 for lumbar pain. Currently the injured worker complains of having problems sleeping, and being depressed. (03/07/2015). She also complains of back pain (04/13/2015). In the visit of 04/08/2015, the IW has objective findings of hypertension, chest pain and asthma. The treatment plan includes requests for authorizations for the following refills: Atorvastatin 80mg, #120; Felodipine ER 10mg, #120; Fenofibrate 145mg, #120; Hydrochlorothiazide 25mg, #160; Lactulose 10gm/15ml Solution, #1892; Omeprazole 20mg, #360; Potassium CL ER 10meq, #480; and Benefiber SF PWD, #944.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Atorvastatin 80mg, #120: 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 Federal Drug Administration (FDA) Lipitor Indications Use and Prescribing Information [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/020702s057lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020702s057lbl.pdf).

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of an Atorvastatin prescription for this patient. Lipitor is the name brand equivalent of generic Atorvastatin. The clinical records submitted do support the fact that this patient has a coronary artery disease or a history of myocardial infarction. The California MTUS guidelines, Occupational Disability Guidelines and the ACOEM Guidelines do not address the topic of Lipitor prescription. Per the Federal Drug Administration's (FDA) prescribing guidelines, "In patients with clinically evident coronary heart disease, LIPITOR is indicated to: 1) Reduce the risk of non-fatal myocardial infarction. 2) Reduce the risk of fatal and non-fatal stroke. 3) Reduce the risk for revascularization procedures. 4) Reduce the risk of hospitalization for CHF. 5) Reduce the risk of angina." This patient has been diagnosed with a hyperlipidemia and hypertriglyceridemia. The patient's current medical provider report does not demonstrate that serial lipid assessment is being used to monitor this patient's lipid profile. Use of a plaque stabilizing HMG-coA reductase inhibitor is supported by current peer-reviewed literature only if concurrent lipid monitoring is performed to demonstrate efficacy of the medication. Therefore, based on the submitted medical documentation, the request for atorvastatin prescription is not medically necessary.

**Felodipine ER 10mg, #120: 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 Felodipine Indications Use and Prescribing Information [http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/98/19834S009\\_PLENDIL\\_PRN\\_TLBL.PDF](http://www.accessdata.fda.gov/drugsatfda_docs/nda/98/19834S009_PLENDIL_PRN_TLBL.PDF).

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of a Felodipine prescription for this patient. The clinical records submitted do not support the fact that this patient has uncontrolled hypertension monitored and refractory to other medications. The California MTUS guidelines, Occupational Disability Guidelines and the ACOEM Guidelines do not address the topic of Felodipine prescription. Per the Federal Drug Administration's (FDA) prescribing guidelines for Felodipine, the medication is indicated for: "the treatment of hypertension." This patient's medical records do not support that they have

refractory hypertension, which is actively being managed by their treating physician. The patient's most recent medical records fail to address the patient's hypertension management or monitoring. Therefore, based on the submitted medical documentation, the request for Felodipine prescription is not-medically necessary.

**Fenoibrate 145mg, #120: 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 Federal Drug Administration (FDA) Fenofibrate Indications Use and Prescribing Information [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2008/021350s0081bl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021350s0081bl.pdf).

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of a Fenofibrate prescription for this patient. The clinical records submitted do not support the fact that this patient has uncontrolled hypertriglyceridemia monitored and refractory to other medications. The California MTUS guidelines, Occupational Disability Guidelines and the ACOEM Guidelines do not address the topic of Fenofibrate prescription. Per the Federal Drug Administration's (FDA) prescribing guidelines for Fenofibrate, the medication is indicated for "adjunctive therapy to diet for the reduction of LDL-C, Total-C, Triglycerides and Apo B in adult patients with primary hypercholesterolemia or mixed dyslipidemia. (Fredrickson Types IIa and IIb)" This patient's medical records do not support that they have hypertriglyceridemia, which is actively being managed by their treating physician. The patient's most recent medical records fail to address the patient's triglyceride management or monitoring. Furthermore, there is no evidence that the patient is using the medication as an adjunctive therapy to diet and exercise. Therefore, based on the submitted medical documentation, the request for Fenofibrate prescription is not-medically necessary.

**Hydrochlorothiazide 25mg, #160: 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.accessdata.fda.gov/drugsatfda\\_docs/label/2010/016042s0771bl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/016042s0771bl.pdf).

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of a hydrochlorothiazide prescription for this patient. The clinical records submitted do not support that this patient's hypertension is being monitored or controlled. The California MTUS guidelines the ACOEM Guidelines and the Occupational Disability Guidelines (ODG) guidelines do not address the topic of antihypertensive therapy. Hydrochlorothiazide blocks the reabsorption of sodium and chloride ions, and thereby increases the quantity of sodium traversing the distal tubule and the volume of water excreted. The FDA prescribing information

for Hydrochlorothiazine states that it should be used in-patient for the indication of hypertension or edema. This patient has a history of hypertension and hyperlipidemia. However, the most recent clinical records do not reflect that the patient's medical provider is actively monitoring and controlling the patient's blood pressure. Therefore, based on the submitted medical documentation, the request for hydrochlorothiazide prescription is not medically necessary.

**Lactulose 10gm/15ml Solution, #1892: 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 Federal Drug Administration (FDA) Lactulose Indications Use and Prescribing Information <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchAction&SearchType=BasicSearch&SearchTerm=LACTULOSE>.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of a lactulose prescription for this patient. The clinical records submitted do support the fact that this patient has opioid induced constipation. However, the records do not support the use of this medication for that indication. The California MTUS guidelines, Occupational Disability Guidelines and the ACOEM Guidelines do not address the topic of lactulose prescription. Per the Federal Drug Administration's (FDA) prescribing guidelines for Amitiza use, the medication is only indicated for chronic idiopathic constipation. This patient has opioid induced constipation; the FDA for that indication does not approve lactulose. Therefore, based on the submitted medical documentation, the request for lactulose prescription is not-medically necessary.

**Omeprazole 20mg, #360: 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.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm152692.htm>.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of a Prilosec prescription for this patient. Prilosec is the name brand equivalent of generic, Omeprazole. 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 Prilosec

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 they have a history of GERD. However, the patient has no documentation of why chronic PPI therapy is necessary. Their GERD is not documented to be refractory to H2 blocker therapy and there are no records that indicate an active h. pylori infection. Therefore, based on the submitted medical documentation, the request for Omeprazole prescription is not medically necessary.

**Potassium CL ER 10meq, #480:** 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 Federal Drug Administration (FDA) Potassium Chloride Indications Use and Prescribing Information <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM270390.pdf>.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of a Potassium Chloride prescription for this patient. The clinical records submitted do not support the fact that this patient has hypokalemia. The California MTUS guidelines, Occupational Disability Guidelines and the ACOEM Guidelines do not address the topic of Potassium Chloride prescription. Per the Federal Drug Administration's (FDA) prescribing guidelines for Potassium Chloride use, the medication is only indicated for treatment of hypokalemia. Although this patient takes potassium wasting medications for essential hypertension, his medical records do not support that he has hypokalemia. Lab testing for potassium wasting has not been recently clinically documented. Without confirmation of active hypokalemia, a potassium prescription is not appropriate. Therefore, based on the submitted medical documentation, the request for potassium chloride prescription is not medically necessary.

**Benefiber SF PWD, #944:** 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 National Fiber Council [http://www.nationalfiberCouncil.org/supplement\\_chart.shtml](http://www.nationalfiberCouncil.org/supplement_chart.shtml) Fiber Supplement amounts and dosing indications.

**Decision rationale:** There is not sufficient clinical information provided to justify the medical necessity of a benefiter prescription for this patient. The clinical records submitted do support the fact that this patient has opioid induced constipation. However, the records do not support the

use of this medication for that indication. The California MTUS guidelines, Occupational Disability Guidelines and the ACOEM Guidelines do not address the topic of this prescription. Per the Federal Drug Administration's (FDA) and the National Fiber Council, the medication is only indicated for increasing dietary fiber as a stool bulking agent. This patient has opioid induced constipation; the FDA for that indication does not approve benefiter. Therefore, based on the submitted medical documentation, the request for benefiter prescription is not-medically necessary.