

<b>Case Number:</b>	CM15-0023509		
<b>Date Assigned:</b>	03/24/2015	<b>Date of Injury:</b>	12/18/2007
<b>Decision Date:</b>	06/22/2015	<b>UR Denial Date:</b>	01/08/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/09/2015

### 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: New York

Certification(s)/Specialty: Internal 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 61-year-old male who sustained an industrial injury on 12/18/2007. He suffered a gunshot wound to the face; many body regions were affected. Diagnoses include left-sided facial neuralgia, post-traumatic headache, diabetes mellitus, hypertension with atrial enlargement and left ventricular hypertrophy, hyperlipidemia (uncontrolled), proteinuria, sleep disorder; rule out sleep apnea, diabetic retinopathy and/or hypertensive/arteriosclerotic retinopathy and status post H. pylori treatment. Treatment to date has included medications. Diagnostics performed to date included laboratory tests and a sleep study. According to the progress notes dated 6/18/14, the IW reported his blood pressure and blood sugar were under control, but he eats a high salt and high sugar diet. Blood pressure on the date of service was 148/78, heart rate 62 bpm and blood glucose was 207 mg/dl. His weight was 215 pounds. The requested medications were part of the provider's treatment plan for control of blood pressure, blood glucose levels, cholesterol levels and weight.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Amlopidine 10 Mg, Thirty Count With Two Refills: 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).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Not addressed. Decision based on Non-MTUS Citation <http://www.nlm.nih.gov/medlineplus/>.

**Decision rationale:** Amlodipine is in a class of medications called calcium channel blockers. This medication is used alone or in combination with other medications to treat high blood pressure and chest pain (angina). Documentation provided reveals that the injured worker is diagnosed with Hypertension, which at the time of the requested service, is not well controlled. The recommendation for ongoing use of Amlodipine is clinically appropriate. The request for Amlodipine 10 mg, thirty counts with two refills is medically necessary.

**Metoprolol 25 Mg, Sixty Count With Two Refills: 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).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Not addressed. Decision based on Non-MTUS Citation <http://www.nlm.nih.gov/medlineplus/>.

**Decision rationale:** Metoprolol is in a class of medications called beta-blockers, used alone or in combination with other medications to treat high blood pressure and heart failure. It also is used to prevent angina (chest pain) and to improve survival after a heart attack. Documentation provided reveals that the injured worker is diagnosed with Hypertension, which at the time of the requested service, is not well controlled. The recommendation for ongoing use of Metoprolol is clinically appropriate. The request for Metoprolol 25 mg, sixty counts with two refills is medically necessary.

**Lisinopril 40 Mg, Sixty Count With Two Refills: 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).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Not addressed. Decision based on Non-MTUS Citation <http://www.nlm.nih.gov/medlineplus/>.

**Decision rationale:** Lisinopril is an Angiotensin-converting enzyme inhibitors (ACE inhibitor) used to treat Hypertension and Heart disease. ACE-inhibitors are also used in Diabetic patients to treat Kidney problems and to lower, the risk of developing complications of Diabetes related Kidney disease. Documentation provided reveals that the injured worker is diagnosed with Hypertension and Diabetes, which at the time of the requested service, are at suboptimal control. The recommendation for ongoing use of Lisinopril is clinically appropriate. The request for Lisinopril 40 mg, sixty counts with two refills is medically necessary by guidelines.

**Gemfibrozil 60 Mg, Sixty Count With Two Refills: Overturned**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Task Force for Management of Dyslipidemia and Prevention of Atherosclerosis, American Association of Clinical Endocrinologists' Guidelines for Management of Dyslipidemia and Prevention of Atherosclerosis.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Not addressed. Decision based on Non-MTUS Citation <http://www.nlm.nih.gov/medlineplus/>.

**Decision rationale:** Gemfibrozil is in a class of lipid-regulating medications called fibrates, used together with lifestyle changes (diet, weight-loss, exercise) to reduce the amount of triglycerides (a fat-like substance) in the blood in people with very high triglycerides. Gemfibrozil is also used in people with a combination of low high-density lipoprotein (HDL; 'good cholesterol') levels and high low-density lipoprotein (LDL; 'bad cholesterol') and triglyceride levels to reduce the risk of heart disease. Documentation provided reveals that the injured worker is diagnosed with Hyperlipidemia that is not well controlled. The recommendation for ongoing use of Gemfibrozil is clinically appropriate. The request for Gemfibrozil 60 mg, sixty counts with two refills is medically necessary.

#### **Lovanza 4 Grams With Two Refills: Overturned**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation American Diabetic Association, Disorders of Lipid Metabolism, Evidence-Based Nutrition Practice Guideline, Chicago, IL.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Not addressed. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Omega-3 fatty acids (EPA/DHA) and Other Medical Treatment Guidelines <http://www.nlm.nih.gov/medlineplus/>.

**Decision rationale:** Lovaza is a prescription Omega-3 fatty acid used together with lifestyle changes (diet, weight-loss, exercise) to treat severe hypertriglyceridemia (high levels of a fat-like substance) and for secondary prevention of myocardial infarction (heart attack). Documentation provided reveals that the injured worker is diagnosed with Hyperlipidemia that is not well controlled. The recommendation for ongoing use of Lovanza is clinically appropriate. The request for Lovanza 4 grams with two refills is medically necessary.

#### **Crestor 10 Mg, Thirty Count With Two Refills: 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).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG: Diabetes, Statins.

**Decision rationale:** ODG does not recommend Statins as a first-line treatment for Diabetics, because recent FDA-approved labeling change states that taking a statin can raise blood sugar

and Hemoglobin A1C levels. The new American College of Cardiology (ACC) and American Heart Association (AHA) guidelines do not generally recommend high-intensity statin therapy, such as Rosuvastatin (Crestor) or atorvastatin for Diabetics. Documentation provided reveals that the injured worker is diagnosed with Diabetes and Hyperlipidemia, both uncontrolled on current medication regimen. The medical necessity for ongoing use of this high-intensity statin therapy in the setting of poorly controlled Diabetes when other treatment options are available is not supported. The request for Crestor 10 mg, thirty counts with two refills is not medically necessary per guidelines.

### **Metformin 850 Mg, Ninety Count With Two Refills: 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).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Not addressed. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Diabetes, Metformin (Glucophage).

**Decision rationale:** ODG recommends Metformin as first-line treatment of type 2 diabetes to decrease insulin resistance, used either alone or in combination with other antidiabetic drugs. Metformin often has beneficial effects on components of the metabolic syndrome, including mild to moderate weight loss, improvement of the lipid profile, and improved fibrinolysis. Because of its safety and efficacy, ODG states that Metformin should also be the cornerstone of dual therapy for most patients. Physician report at the time of the requested service under review indicates the injured worker has poorly controlled Diabetes, supporting the medical necessity to optimize medication management. The request for Metformin 850 mg, ninety counts with two refills is appropriate and medically necessary per guideline.

### **Glipizide 10 Mg, Sixty Count With Two Refills: 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).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Not addressed. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Diabetes, Sulfonylurea.

**Decision rationale:** Per ODG, Sulfonylureas are not recommended as a first-line choice in the treatment of Diabetes, but may be recommended as a safe alternative to thiazolidinedione treatment. Some authors report that sulfonylureas are safer compared to thiazolidinediones, because they give a better and faster improvement of glycated hemoglobin without giving the adverse effects reported with the use of thiazolidinediones. Physician report at the time of the requested service under review indicates the injured worker has poorly controlled Diabetes, supporting the medical necessity to optimize medication management. The request for Glipizide 10 mg, sixty counts with two refills is appropriate and medically necessary per guideline.

**Victoza With Needles, 1.8 Mg With Two Refills: 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).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Not addressed. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Diabetes, Glucagon-like peptide-1 (GLP-1) agonists, Liraglutide (Victoza).

**Decision rationale:** ODG recommends Victoza as second-line treatment of type 2 diabetes, specifically in patients having inadequate glucose control or with hypoglycemia inadequately controlled with diet, exercise, and/or Metformin alone. Documentation shows that the injured worker is prescribed multiple oral agents to treat the diagnosis of Diabetes. Physician report at the time of the requested service under review indicates poorly controlled Diabetes, supporting the medical necessity to optimize medication management. The request for Victoza with needles, 1.8 mg with two refills is appropriate and medically necessary per guideline.

**ASA EC 81 Mg, Thirty Count With Two Refills: 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).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Not addressed. Decision based on Non-MTUS Citation <http://www.uptodate.com/>.

**Decision rationale:** Aspirin is in a group of medications called salicylates that may be used prevent heart attacks and ischemic strokes in people who are at risk or have had this type of stroke or mini-stroke in the past. The 2012 American College of Chest Physicians Antithrombotic Therapy and Prevention of Thrombosis guideline on the Primary and secondary prevention of cardiovascular (Heart) disease recommend low-dose aspirin (as opposed to no aspirin) for primary prevention in all persons over the age of 50 years. Guidelines stress the importance of individual clinical judgment, which should include an assessment of the absolute benefits and risks of Aspirin use. Documentation reveals that the injured worker is diagnosed with Hypertension and Diabetes, which may increase cardiovascular risk. The ongoing use of Aspirin prophylaxis is clinically appropriate. The request for ASA EC 81 mg, thirty counts with two refills is medically necessary per guidelines.

**Sentra PM, Sixty Count: 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).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Not addressed. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Medical Food, Medications, Sentra PM.

**Decision rationale:** Sentra PM is a medical food for use in management of sleep disorders associated with depression. It is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan, hawthorn berry, cocoa, ginkgo biloba, and acetyl L-carnitine. Per ODG, medical foods are not recommended for treatment of chronic pain, as they have not been shown to produce meaningful benefits or improvements in functional outcomes. There is no objective evidence provided to support the medical necessity for a medical food in the presence of established treatment guidelines utilizing prescription medications. The request for Sentra PM, sixty counts is not medically necessary.

**Theramine #60, Three Bottles:** 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).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Not addressed. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Medical food.

**Decision rationale:** Theramine is a medical food that contains 5-hydroxytryptophan 95%, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine, gamma-aminobutyric acid (GABA), whey protein concentrates, grape seed extract 85%, cinnamon, and cocoa (theobromine 6%). Per ODG, medical foods are not recommended for treatment of chronic pain, as they have not been shown to produce meaningful benefits or improvements in functional outcomes. Documentation fails to show objective evidence supporting the medical necessity for a medical food in the treatment of this injured worker. The request for Theramine #60, three bottles is not medically necessary.

**Apprim-D #120, Three Bottles:** 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).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Not addressed. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Medical food and Other Medical Treatment Guidelines [CincinnatiHealthInstitute.com](http://CincinnatiHealthInstitute.com).

**Decision rationale:** Apprim-D is a medical food formulated to treat obesity, morbid obesity and metabolic syndrome. Per ODG, medical foods are not recommended for treatment of chronic pain, as they have not been shown to produce meaningful benefits or improvements in functional outcomes. Documentation fails to show objective evidence supporting the medical necessity for a medical food in the treatment of this injured worker. The request for Apprim-D #120 three bottles is not medically necessary.

**Hypertensa #60, Three Bottles:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Not addressed. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Medical food and Other Medical Treatment Guidelines Cincinnatihealthinstitute.com.

**Decision rationale:** Hypertensa is an FDA approved medical food prescribed for the nutritional management of the metabolic process associated with Hypertension. The injured worker is diagnosed with Hypertension, being treated appropriately with prescription medication. Documentation fails to show evidence supporting the clinical use of a medical food. The request Hypertense #60 three bottles is not medically necessary.