

<b>Case Number:</b>	CM14-0050055		
<b>Date Assigned:</b>	07/07/2014	<b>Date of Injury:</b>	05/27/2011
<b>Decision Date:</b>	08/25/2014	<b>UR Denial Date:</b>	03/31/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/17/2014

### 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 Family Medicine and is licensed to practice in California. 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 69 year-old male who was injured at work on 5/27/2011. The injuries were primarily to his knees, shoulders, and back. He is requesting review of denial for the following medications: Theramine, Simvastatin, Metformin, and Vicodin. Medical records corroborate the ongoing care of this patient for his chronic pain symptoms. Included are the Primary Treating Physician's Reports (PR-2s). Chronic diagnoses include: Right Shoulder Impingement Syndrome; Right Shoulder Labral Tear; Right Shoulder Rotator Cuff Syndrome; Right Shoulder/Upper Arm Sprain/Strain; Lumbar Spine Spondylosis. The secondary treating physician's progress reports includes the following additional diagnoses: Diabetes Mellitus, Triggered by Industrial Injury; Hyperlipidemia, Secondary to Diabetes Mellitus; Gastroesophageal Reflux; and Hypertension. Treatment has included the following medications: Prilosec, Vicodin, Metformin, Simvastatin, and Theramine.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Prospective request for 60 tablets of Theramine:** 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) - Treatment in Workers' Compensation (TWC), Online Edition, Chapter: Pain.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Chronic Pain, Theramine.

**Decision rationale:** The Official Disability Guidelines comment on the use of Theramine for patients with chronic pain. These guidelines state that Theramine is not recommended. Theramine is a medical food from [REDACTED], that is a proprietary blend of gamma-aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. See Medical food, Gamma-aminobutyric acid (GABA), where it says, "There is no high quality peer-reviewed literature that suggests that GABA is indicated"; Choline, where it says, "There is no known medical need for choline supplementation"; L-Arginine, where it says, "This medication is not indicated in current references for pain or inflammation"; & L-Serine, where it says, "There is no indication for the use of this product". In this manufacturer study comparing Theramine to Naproxen, Theramine appeared to be effective in relieving back pain without causing any significant side effects. Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. In summary, there is no evidence to support the use of Theramine in this patient. Therefore, this request is not medically necessary.

**Prospective request for 30 tablets of Simvastatin 20 mg: 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) - Treatment in Workers' Compensation (TWC), Chapter: Diabetes, Statins.

**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: American Diabetes Association. Standards of Medical Care in Diabetes-2014. Accessed through: <http://professional.diabetes.org/ResourcesForProfessionals.aspx?cid=84160>.

**Decision rationale:** In this case, there is no documentation provided in the medical records that relates the patient's hyperlipidemia to the work-related injury. It is unclear whether the patient's hyperlipidemia was a pre-existing condition and if there were efforts to establish relatedness and medical necessity as part of the worker's compensation claim. Without this documentation, the use of the medication, Simvastatin, cannot be substantiated. There is a strong link between type 2 diabetes and hyperlipidemia. Should there be evidence that relates the patient's diabetes and hyperlipidemia to his work-related injury, the American Diabetes Association Guidelines serve as the practice standards for the classification, diagnosis and management of diabetes; including the management of dyslipidemia. These guidelines state that patients with diabetes should have a fasting lipid profile at least annually. Treatment goals should include lifestyle modification. Statin therapy is recommended for diabetic patients with overt coronary vascular disease, or for those who are over age 40 years and have one or more risk factor (e.g. family history of coronary vascular disease, hypertension, smoking, or albuminuria). For lower risk patients, statin therapy should be considered if LDL cholesterol remains above 100mg/dL. The medical records provide

insufficient information to determine this patient's risk. Therefore, the request for 30 tablets of Simvastatin 20 mg is not medically necessary.

**Prospective request for 60 tablets of Metformin 500 mg: 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 Other Medical Treatment Guideline or Medical Evidence: American Diabetes Association. Standards of Medical Care in Diabetes-2014. Accessed through: <http://professional.diabetes.org/ResourcesForProfessionals.aspx?cid=84160>.

**Decision rationale:** In this case, there is no documentation provided in the medical records that relates the patient's diabetes to the work-related injury. It is unclear whether the patient's diabetes was a pre-existing condition and if there were efforts to establish relatedness and medical necessity as part of the worker's compensation claim. Without this documentation, the use of the medication, Metformin, cannot be substantiated. Should there be evidence that relates the patient's diabetes to his work-related injury, the American Diabetes Association Guidelines serve as the practice standards for the classification, diagnosis and management of diabetes. In these standards it is expected that there is evidence in the patient's medical records that meets the criteria for the diagnosis of diabetes. This typically would include a hemoglobin A1C level of greater than or equal to 6.5%. The hemoglobin A1C test is also used to monitor the level of glucose control. In reviewing the medical records, there is no evidence of a hemoglobin A1C test being done to establish the diagnosis or in monitoring the effects of treatment. As part of the management of type 2 diabetes, it is standard practice to document efforts towards diabetes self-management education and support. Typically, this includes medical nutrition therapy and guidance for physical activity. In reviewing the medical records, there is no evidence of efforts directed towards self-management education and support. Regarding pharmacologic therapy, metformin is the preferred initial agent for type 2 diabetes. However, there are contraindications for the use of this drug; e.g. chronic renal insufficiency. In reviewing the medical records, there is no evidence that the patient was screened for the presence of chronic renal insufficiency as a contraindication to the use of this drug. In summary, there is insufficient documentation to establish the relatedness of diabetes to this patient's injury and there is insufficient documentation to suggest that the patient's diabetes is being managed according to established national guidelines. Under these conditions, Metformin is not considered medically necessary.

**Prospective request for 30 tablets of Vicodin 5/500 mg: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids.

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

**Decision rationale:** The MTUS/Chronic Pain Medical Treatment Guidelines comment on the long-term use of opioids. These guidelines have established criteria of the use of opioids for the

ongoing management of pain. Actions should include: prescriptions from a single practitioner and from a single pharmacy. The lowest possible dose should be prescribed to improve pain and function. There should be an ongoing review and documentation of pain relief, functional status, appropriate medication use and side effects. Pain assessment should include: current pain, the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. There should be evidence of documentation of the 4 A's for Ongoing Monitoring. These four domains include: pain relief, side effects, physical and psychological functioning, and the occurrence of any potentially aberrant drug-related behaviors. Further, there should be consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain that does not improve on opioids in 3 months. There should be consideration of an addiction medicine consult if there is evidence of substance misuse (Pages 76-78). Finally, the guidelines indicate that for chronic back pain, the long-term efficacy of opioids is unclear. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy (Page 80). Based on the review of the medical records, there is insufficient documentation in support of these stated MTUS/Chronic Pain Medical Treatment Guidelines for the ongoing use of opioids. There is insufficient documentation of the 4 A's for Ongoing Monitoring. The treatment course of opioids in this patient has extended well beyond the timeframe required for a reassessment of therapy. In summary, there is insufficient documentation to support the chronic use of an opioid in this patient. Therefore, the request for 30 tablets of Vicodin 5/500 mg is not considered as medically necessary.