

Case Number:	CM14-0030285		
Date Assigned:	06/20/2014	Date of Injury:	10/11/2003
Decision Date:	09/10/2014	UR Denial Date:	02/07/2014
Priority:	Standard	Application Received:	03/10/2014

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 Physical Medicine and Rehabilitation 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 injured worker is a 55-year-old female who reported injury on 10/11/2003 reportedly in a motorcycle accident. The accident was a low speed accident. She had slowed down, hit some wet grass, and the motorcycle turned to its side. She fell onto her left shoulder having blunt trauma without fracture of the left shoulder but at the same time raised herself with the right wrist, broke her right thumb, and injured her right wrist as well. The injured worker's treatment history included surgery, medications, injection, and physical therapy. The injured worker was evaluated on 08/12/2014 and it was documented the injured worker complained of bilateral knee pain, she requested a referral back to the surgeon who did her right knee replacement surgery. It noted she was walking with a limp, but was not using any narcotic pain medications. Current pain level was 8/10. Medications included Metformin HCl 1000 mg, Simvastatin 20 mg, Benicar 20 mg, Estradiol 0.05 mg, Actos 45 mg, Tramadol - Acetaminophen 3.7/325 mg, Quinapril-Hydrochlorothiazide 20/25 mg, Glimepiride 4 mg, aspirin 325 mg, and Neurontin 40 mg. Diagnoses included hypertension, diabetes, joint disease, obese, hypercholesterolemia, RSD of right hand and arm, chronic pain syndrome, and diabetic peripheral neuropathy. The request dated 02/12/2014 was for Celebrex 200 mg, and Pepcid 10 mg and Ultram 3.75/325 mg; however, the rationale was not submitted for this review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Prescription of Metformin HCL 1000mg: 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), Diabetic Medications.

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

Decision rationale: According to Official Disability Guidelines (ODG) Metformin is recommended as first line treatment of type 2 diabetes to decrease insulin resistance. As a result of its safety and efficacy, Metformin should also be the cornerstone of dual therapy for most patients. Metformin is effective in decreasing both fasting and postprandial glucose concentrations. 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. Metformin is also effective as monotherapy and in combination with other anti-diabetic agents, including sulfonylureas, TZDs, AGIs, DPP-4 inhibitors, GLP-1 agonists, and Pramlintide. It can also be used in combination with insulin. Because of its relatively short duration of action, it is usually administered 2 to 3 times daily and is best tolerated if taken with meals. A long acting, once daily formulation is also available. The maximal recommended dosage is 2,500 mg daily, although little additional benefit is seen with dosages exceeding 2,000 mg daily. When used as monotherapy, metformin has a very low risk of hypoglycemia. When Metformin is used in combination with an insulin secretagogue or insulin, however, hypoglycemia may occur. Evidence supports metformin as a first-line agent to treat type 2 diabetes. Researchers found that the older diabetes drug metformin is just as good, if not better, than newer classes of medications. In addition, any two-drug combination produces similar diabetes control, but they have different adverse events. Overall, most of the diabetes medications used alone decreased HbA1c by about 1 percentage point. Similar results were obtained with various 2 drug combinations. Metformin performed better than several other classes by not increasing body weight and by lowering LDL-cholesterol. There was also a better safety profile with Metformin in terms of risk for low blood sugar. For example, sulfonylureas had a fourfold higher risk for mild or moderate hypoglycemia compared with Metformin. The documents submitted indicated the injured worker having diabetes however; there were no lab results submitted indicated the injured worker blood sugar levels. In addition the request lacked frequency and duration of medication. Given the above, the request for Metformin HCl is not medically necessary.

Prescription of Simvastatin 20mg: 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), Diabetic Medications, Statins.

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

Decision rationale: According to Official Disability Guidelines (ODG) do not recommend Simvastatin as a first line treatment for diabetics. Patients with DM should be screened for dyslipidemia, and therapeutic recommendations should include lifestyle changes and, as needed, consultation with a registered dietitian. Statins may be a treatment in the absence of contraindications, but recent studies have associated increased risk of DM with use of all types of statins. Statin use in postmenopausal women is associated with a significantly increased risk of diabetes mellitus, according to data from the Women's Health Initiative, with a 48% increased risk of diabetes among the women taking these lipid lowering medications. At baseline, 7% of women were taking statins, with 30% of women taking Simvastatin, 27% taking Lovastatin, 22% taking Pravastatin, 12.5% taking Fluvastatin, and 8% taking Atorvastatin. In an unadjusted risk model, statin use at baseline was associated with a 71% increased risk of diabetes. After adjusting for potential confounding variables, the risk of diabetes associated with statin therapy declined to 48%. The association was observed for all types of statins. The document s submitted the provider noted the injured worker having diabetes. Per the guidelines Simvastatin is not recommended for patients with diabetes as a first line treatment. In addition, the request submitted failed to indicate frequency, duration and quantity of medication. Given the above, the request for Simvastatin 20 mg is not medically necessary.

Prescription of Benicar 20mg: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Institutes of Health, Benicar.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Diabetes, Hypertension Treatment.

Decision rationale: According to Official Disability Guidelines (ODG) Benicar is the first-line choice of hypertension treatment. The guideline also recommend that blood pressure in DM be controlled to levels of 140/80, but 130 may be appropriate for younger patients if it can be achieved without undue treatment burden. Over 88% of patients with type 2 DM either have uncontrolled hypertension or are being treated for elevated blood pressure. Hypertension is not only more prevalent in type 2 DM than in the general population, but it also predicts progression to DM. Once hypertension is diagnosed, an individual is 2.5 times more likely to receive a DM diagnosis within the next 5 years, and the combination of hypertension and DM magnifies the risk of DM-related complications. It is recommended that blood pressure in DM be controlled to levels of 130/80 mm Hg, starting with lifestyle modification and diet, and including medications. The issue as to whether any one class is superior to another is no longer part of the decision-making process because most patients with DM need at least 2 to 4 drugs to achieve target blood pressure. Agents such as angiotensin-converting enzyme inhibitors and angiotensin II receptor blockers are preferred given their renal and/or CVD benefits. Other agents such as vasodilating b-adrenergic blockers, calcium channel blockers, diuretics, and centrally-acting agents should be used as necessary. The documents submitted indicated the injured worker having diagnoses of hypertension and her blood pressure was 134/81 on 08/12/2014, however, the request submitted failed to indicate frequency, duration or quantity of medication. Given the above, the request for Benicar 20 mg is not medically necessary.

Prescription of Pepcid AC10mg: 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), Pain Chapter, Proton Pump Inhibitors (PPI).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Proton Pump Inhibitors Page(s): 68-69.

Decision rationale: Prilosec is recommended for patients taking NSAIDs who are at risk of gastrointestinal events. The documentation did not indicate that the injured worker having gastrointestinal events however, the provider failed to indicate the frequency, duration and quantity of medication on the request that was submitted. Their lack of documentation of conservative care measures such as, home exercise regimen and the provider failed to indicate long-term functional goals, medication pain management outcome measurements for the injured worker. Given the above, the request for Pepcid AC 10 mg is not medically necessary.

Prescription of Estradiol 0.05mg/24 hour patch: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Institutes of Health, Estrogen.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline: Drugs.com.

Decision rationale: According to Drugs.com estradiol patches are for treatment of moderate to severe vasomotor symptoms due to menopause. Treatment of moderate to severe symptoms of Vulvar atrophy due to menopause limitation of use when prescribed solely for the treatment of vulvar and vagina atrophy due to menopause, topical vaginal products should be considered. Therapy should be started at the lowest effective dosage and the shortest duration consistent with the treatment goals. Attempts to taper or discontinue the medication should be made at 3 to 6 months intervals. The documents submitted failed to indicate the rationale for the request for Estradiol Patches. It was no clear how this medication is helpful in the overall treatment plan to the injured worker specific work injury, as there e were no documentation submitted for the medical necessity for the requested medication. In addition the request lacked quantity of medication. As such, the request for Estradiol 0.05mg/24 hour patch is not medically necessary.

Prescription of Celebrex 200mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-inflammatory.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (Non-steroidal anti-anti-inflammatory drugs) Page(s): 67.

Decision rationale: The Chronic Pain Medical Treatment Guidelines recommend that Celebrex is used as a second line treatment after Acetaminophen; there is conflicting evidence that NSAIDs are more effective than Acetaminophen for acute LBP. For acute low back pain with sciatica a recent Cochrane review (included 3 heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs versus a placebo. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low back pain and that acetaminophen have fewer side effects. The provider failed to indicate long-term functional goals for the injured worker. There was lack of documentation stating the efficiency of the Celebrex for the injured worker. There was a lack of documentation regarding average pain, intensity of the pain and longevity of the pain after the Celebrex is taken by the injured worker. In addition, the request for Celebrex did not include the frequency. Given the above, the request for is not medically necessary.

Prescription of Actos 45mg: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Institutes of Health, Diabetes Medication, Actos.

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

Decision rationale: According to Official Disability Guidelines (ODG) Actos is not recommended as a first-line choice. Studies have associated thiazolidinedione (TZD) treatment with cardiovascular disease. At present, there are two available TZDs: Pioglitazone and Rosiglitazone. According to one study, pioglitazone has a beneficial effect on cardiovascular disease while it seems that rosiglitazone increases cardiovascular risk. Some authors have reported that the improved glycemic control obtained with thiazolidinedione use is associated with an increase in body weight and a worsening of lipid profile. When metformin is contraindicated, a thiazolidinedione (TZD) may be used as the foundation of dual therapy for most patients. The first approved TZD, Troglitazone, was associated with rare cases of liver damage, leading to liver failure and death; therefore, its use was discontinued approximately 10 years ago. The currently available TZDs, pioglitazone and rosiglitazone, are effective insulin-sensitizing agents. When used as monotherapy or in combination with other anti-diabetic agents (including insulin), TZDs are effective in decreasing both fasting and postprandial glucose concentrations. When used as monotherapy, they do not cause hypoglycemia. When TZDs are used with insulin secretagogues or insulin, however, hypoglycemia can occur. The major side effect of the TZDs is weight gain, due to both increased adipose tissue mass and fluid retention. In patients with New York Heart Association class III or class IV congestive heart failure, TZDs are contraindicated. Weight gain can be a major problem for patients who are overweight or obese. A 1.5- to 2.5-fold increased risk of bone fractures has been documented in both men and women using TZDs. In light of the potential ischemic risk of rosiglitazone and the multiple other available medications to treat diabetes, clinicians will need to determine when the benefits of rosiglitazone outweigh the potential risk for individual patients, in keeping with FDA warnings. Thiazolidinediones are associated with higher rates of edema and congestive heart failure

compared with other oral medications to treat type 2 diabetes. According to ACP, thiazolidinediones are associated with an increased risk for heart failure, and both rosiglitazone and pioglitazone are contraindicated in patients with serious heart failure. The documents submitted for review indicated the injured worker having diagnoses of obesity. The guidelines do not recommend this medication as a first-line choice. In addition, the request submitted failed to indicate frequency, duration and quantity of medication. Given the above the request for Actos 45 mg is not medically necessary.

Prescription of Tramadol/Acetaminophen 37.5/325mg: 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), Pain Chapter, Ultracet.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol, Opioids for Neuropathic Pain Page(s): 82, 113.

Decision rationale: The chronic pain medication treatment guidelines do not recommend Ultracet as a first line oral analgesic. The guidelines also states that for analgesics and Tramadol have been suggested as a second line treatment (alone or in combination with first line drugs). A recent consensus guideline stated that opioids could be considered first line therapy for the following circumstances, prompt pain relief while titrating a first line drug, treatment of episodic exacerbations of severe pain and treatment of neuropathic cancer pain. The documents submitted indicated the injured worker having conservative care however, the outcome measurements were not provided. The request did not include frequency or duration of medication. In addition, the provider failed to indicate injured worker longevity of pain relief after medication is taken. As such, the request is not medically necessary.

Prescription of Quinapril/Hydrochlorothiazide 20/25mg: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Institutes of Health, Quinapril/Hydrochlorothiazide.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Diabetes, Hypertension Treatment.

Decision rationale: According to Official Disability Guidelines (ODG) Quinapril /Hydrochlorothiazide is a third- line choice of hypertension treatment. The guidelines also recommend that blood pressure in DM be controlled to levels of 140/80, but 130 may be appropriate for younger patients if it can be achieved without undue treatment burden. Over 88% of patients with type 2 DM either have uncontrolled hypertension or are being treated for elevated blood pressure. Hypertension is not only more prevalent in type 2 DM than in the general population, but it also predicts progression to DM. Once hypertension is diagnosed, an individual is 2.5 times more likely to receive a DM diagnosis within the next 5 years, and the

combination of hypertension and DM magnifies the risk of DM-related complications. It is recommended that blood pressure in DM be controlled to levels of 130/80 mm Hg, starting with lifestyle modification and diet, and including medications. The issue as to whether any one class is superior to another is no longer part of the decision-making process because most patients with DM need at least 2 to 4 drugs to achieve target blood pressure. Agents such as angiotensin-converting enzyme inhibitors and angiotensin II receptor blockers are preferred given their renal and/or CVD benefits. Other agents such as vasodilating b-adrenergic blockers, calcium channel blockers, diuretics, and centrally-acting agents should be used as necessary. The documents submitted indicated the injured worker having diagnoses of hypertension and her blood pressure was 134/81 on 08/12/2014, however, the request submitted failed to indicate frequency, duration or quantity of medication. Given the above, the request for Quinapril/Hydrochlorothiazide 20/25mg is not medically necessary.

Prescription of Glimepiride 4mg: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Institutes of Health, Diabetes Medication, Glimepiride.

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

Decision rationale: According to Official Disability Guidelines (ODG) Glimepiride is the first-line choice for Diabetes. But it may be recommended as a safe alternative to thiazolidinedione treatment. Some authors report that sulfonylureas are safer compared to thiazolidinedione's because they give a better and faster improvement of glycated hemoglobin without giving the adverse effects reported with the use of thiazolidinediones. Sulfonylureas should have much less priority because use of these agents is associated with hypoglycemia, weight gain, and limited duration of effectiveness after initiation of therapy. GLP-1 agonists and DPP-4 inhibitors are increasingly preferred for most patients in place of sulfonylureas and glinides. Sulfonylureas consistently increased the risk for hypoglycemia more than monotherapy with Metformin, thiazolidinediones, DPP-4 inhibitors, or liraglutide did. Sulfonylureas compared with Metformin alone had greater than a 4-fold higher risk for hypoglycemia, and Metformin plus a sulfonylurea compared with Metformin plus a thiazolidinedione had almost a 6-fold higher risk. The DPP-4 inhibitors had a lower risk for hypoglycemia than sulfonylureas that was similar to that of Metformin. Conclusions on comparative risk for adverse events were clearest for sulfonylureas and meglitinides, which increased the risk for hypoglycemia. This case control study suggests that use of anti-diabetics such as sulfonylureas and insulin were associated with an increased risk for pancreatic cancer. High-quality evidence showed that risk for dangerous levels of hypoglycemia was higher with sulfonylureas than with Metformin or thiazolidinediones. In addition, the combination of Metformin plus sulfonylureas is associated with 6-fold greater risk for hypoglycemia than the combination of Metformin plus thiazolidinediones. When used as monotherapy, the risk for hypoglycemia with Metformin and thiazolidinediones was similar, based on moderate-quality evidence. Compared to Metformin, oral anti-diabetic drug treatment with sulfonylureas increased the risk of a decline in kidney function or death. Use of sulfonylureas compared with Metformin for initial treatment of diabetes was associated with an

increased hazard of CVD events or death. Among 253,690 patients initiating treatment (98,665 with sulfonylurea therapy and 155,025 with Metformin therapy), crude rates of the composite outcome were 18.2 per 1000 person-years in sulfonylurea users and 10.4 per 1000 person-years in Metformin users (adjusted incidence rate difference, 2.2 more CVD events with sulfonylureas per 1000 person-years; adjusted hazard ratio, 1.21). Results were consistent for both glyburide and glipizide. First-line therapy with sulfonylureas significantly increases the risk for death in patients with type 2 diabetes when compared with treatment with Metformin. Additional research showed that the combination of Metformin and a sulfonylurea was also associated with a significantly increased risk for death when compared with combination therapy with Metformin and a DPP-4 inhibitor. According to the author, people should avoid using a drug where the balance of evidence demonstrates that it kills people. The decimation submitted indicated the injured worker was prescribed Metformin HCL as well as Glimepiride, however the guidelines does not recommend the two drugs to be taken in combination with each other. In addition, the request submitted failed to indicate frequency duration and quantity of medication. As such, the request for Glimepiride is not medically necessary.

Prescription of Aspirin 325mg: 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), Nonprescription Medications.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Nonprescription Medications Page(s): 67.

Decision rationale: The Chronic Pain Medical Treatment Guidelines recommend Acetaminophen (safest); NSAIDs (Aspirin, Ibuprofen). There should be caution about daily doses of Acetaminophen and liver disease if over 4 g/day or in combination with other NSAIDs. The documents submitted for review lacked rationale why injured worker needs Aspirin. In addition the request for Aspirin lacked frequency, quantity of medication. Given the above, the request for Aspirin 325mg is not medically necessary.