

<b>Case Number:</b>	CM15-0194336		
<b>Date Assigned:</b>	10/08/2015	<b>Date of Injury:</b>	10/14/2002
<b>Decision Date:</b>	12/16/2015	<b>UR Denial Date:</b>	10/01/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/02/2015

### 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 is a 61 year old male, who sustained an industrial injury on 10-14-2002. The injured worker is being treated for diabetes mellitus and dyslipidemia. Treatment to date has modified work, included diagnostics and medications. Per the handwritten Primary Treating Physician's Progress Report dated 8-06-2015 the injured worker reported no chest pain and good glycemic control. He reported left knee pain. Objective findings are documented as 112-76 and 76. The notes from the provider do not document efficacy of the prescribed medications. Work status was modified. The plan of care included, and authorization was requested on 9-21-2015 for Glyburide 5mg #90, Invokana 300mg #30, Apidra 100u-mL 10 units 2 bottles, contour test strips #100, Lantus insulin 100u-mL 2 bottles and Metformin 500mg #90. On 10-01-2015, Utilization Review non-certified the request for Lantus insulin 100u-mL 2 bottles and Metformin 500mg #90.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Glyburide 5mg quantity 90 with six 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, Treatment Index, Diabetes Chapter, Glyburide (DiaBeta).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Diabetes (Type 1, 2, and Gestational) Chapter-Sulfonylurea.

**Decision rationale:** Sulfonylurea are not recommended as a first-line choice, 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. Glyburide has been part of the medical management for diabetes in this injured worker. Medical necessity of Glyburide 5mg has been established. The requested treatment is medically necessary.

**Metformin 500mg quantity 90 with six 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, Treatment Index, Diabetes Chapter, Metformin (Glucophage).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Diabetes (Type 1, 2, and Gestational) Chapter-Metformin.

**Decision rationale:** This prescription for Metformin is evaluated in light of the Official Disability Guidelines (ODG) Official Disability Guidelines (ODG) recommend Metformin 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. The documentation indicates the injured worker has been maintained on Metformin and review of Medical Records do show that previous use of this medication has been effective in diabetes management in this injured worker. Based on the currently available information, the medical necessity for this medication has been established. The requested treatment is medically necessary.

**Invokane 300mg quantity 30 with six 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, Treatment Index, Diabetes Chapter, Canagliflozin (Invokana).

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

**Decision rationale:** CA MTUS and ODG do not address this, therefore alternate guidelines, including Uptodate were reviewed. Invokana is Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitor. The SGLT2 is expressed in the proximal tubule and mediates reabsorption of approximately 90 percent of the filtered glucose load. SGLT2 inhibitors promote the renal excretion of glucose and thereby modestly lower elevated blood glucose levels in patients with type 2 diabetes. The ability to lower blood glucose and A1C levels is limited by the filtered load of glucose and the osmotic diuresis that is caused by this therapy. The glucose-lowering effect is independent of insulin (beta cell function and insulin sensitivity). Thus, they do not usually cause hypoglycemia in the absence of therapies that otherwise cause hypoglycemia. Sodium-glucose co-transporter 2 (SGLT2) inhibitors are not recommended for routine use in patients with type 2 diabetes. SGLT2 inhibitors may play a role as a third-line agent in patients with inadequate glycemic control on two oral agents (eg, Metformin and sulfonylurea) if for some reason combination Metformin and insulin is not a therapeutic option. Review of submitted records provide no clear rationale about the prescription for Invokana in this injured worker. The requested treatment: Invokana 300mg quantity 30 with six refills is not medically necessary.

**Lantus Insulin 100u/ml 2 bottles with six 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, Treatment Index, Diabetes Chapter, Insulin.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Diabetes (Type 1, 2, and Gestational), Insulin and Other Medical Treatment Guidelines Uptodate.

**Decision rationale:** Insulin is recommended for treatment of type 1 diabetes, or for type 2 diabetes if glycaemic goals are not reached by oral antidiabetics. Insulin is required in all patients with T1DM, and it should be considered for patients with T2DM when noninsulin antihyperglycemic therapy fails to achieve target glycemic control or when a patient, whether drug nave or not, has symptomatic hyperglycemia. Also recommended for metabolic deterioration, co-morbidities, surgery, pregnancy or contradictions against oral antidiabetics. Review of submitted medical records do indicate that the injured worker has diabetes and insulin has been part of treatment regime. Medical necessity of the requested item Lantus Insulin has been established. The requested treatment is medically necessary.

**Apidra 100 units/ml 10 units two bottles with six 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, Treatment Index, Diabetes Chapter, Insulin.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Diabetes (Type 1, 2, and Gestational)?Insulin and Other Medical Treatment Guidelines Uptodate.

**Decision rationale:** Insulin is recommended for treatment of type 1 diabetes, or for type 2 diabetes if glycaemic goals are not reached by oral antidiabetics. Insulin is required in all patients with T1DM, and it should be considered for patients with T2DM when noninsulin antihyperglycemic therapy fails to achieve target glycemic control or when a patient, whether drug nave or not, has symptomatic hyperglycemia. Also recommended for metabolic deterioration, co-morbidities, surgery, pregnancy or contradictions against oral antidiabetics. Review of submitted medical records do indicate that the injured worker has diabetes and insulin has been part of treatment regime. Medical necessity of the requested treatment: Apidra 100 units/ml has been established. The requested treatment is medically necessary.

**Contour Test Strips quantity 100:** Overturned

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Treatment Index, Diabetes Chapter, Glucose Monitoring.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG--Diabetes (Type 1, 2, and Gestational)--Glucose monitoring.

**Decision rationale:** As per Official Disability Guidelines (ODG) self-monitoring of blood glucose (SMBG) is recommended for people with type 1 diabetes as well as for those with type 2 diabetes who use insulin therapy, plus long-term assessment, but not continuous glucose monitoring (CGM) for routine use. Current glucose monitoring strategies can be classified into 2 categories: patient self-monitoring, which would allow patients to change behavior (diet or exercise) or medication dose (most often insulin), or long-term assessment, which allows both the patient and the clinician to evaluate overall glucose control and risk for complications over weeks or months. Review of submitted medical records do indicate that the injured worker has diabetes and his A1C is not at goal. Medical necessity of the requested treatment: Contour Test Strips has been established. The requested treatment is medically necessary.