

Case Number:	CM14-0043187		
Date Assigned:	08/08/2014	Date of Injury:	02/22/2011
Decision Date:	09/11/2014	UR Denial Date:	03/05/2014
Priority:	Standard	Application Received:	03/17/2014

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 Occupational 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:

This is a 55-year-old female with a 2/22/11 date of injury. The mechanism of injury was not noted. According to a progress report dated 2/5/14, the patient has not received her insulin for the past 2 months. While on insulin, her morning fasting sugar is 100-168 and her evening fasting sugar is in the 180's. Without insulin, her morning and evening fasting sugar is 250-350. She also complained of right upper extremity pain. Objective findings: limited to vital signs. Diagnostic impression: orthopaedic injury, GERD/gastritis, irritable bowel syndrome, diabetes mellitus. Treatment to date: medication management, activity modification. A UR decision dated 3/5/14 denied the requests for Dexilant, Helidac, Lantus, Metformin, Glipizide, Lisinopril, and Citrucel. Regarding Dexilant, there is no documentation regarding gastric symptoms, NSAID usage, or increased risk for gastrointestinal events. Regarding Helidac, there is no mention in the documentation of any sort of ulcer, of abdominal pain, gastric symptoms, infection, or of any condition relating to the gastrointestinal system. Regarding Lantus, Metformin, and Glipizide, there is no documentation regarding a diabetic diagnosis, with supporting laboratory values, symptoms, and the need for diabetic medication and care. Regarding Lisinopril, there is no documentation regarding hypertension, heart failure, or of diabetic related high blood pressure or renal failure. Regarding Citrucel, there is no documentation describing gastric symptoms, constipation, or diarrhea.

IMR ISSUES, DECISIONS AND RATIONALES

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

DEXILANT (unspecified): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disabilities guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792.24.2 Page(s): 68. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: FDA (Dexilant).

Decision rationale: CA MTUS and the FDA support proton pump inhibitors in the treatment of patients with GI disorders such as gastric/duodenal ulcers, GERD, erosive esophagitis, or patients utilizing chronic NSAID therapy. According to the reports reviewed, it is documented that the patient has a diagnosis of GERD and gastritis. An RFA dated 12/19/13 shows that this request is for Dexilant 60 mg. However, the quantity of the medication requested was not noted. Therefore, the request for Dexilant (unspecified), as submitted, was not medically necessary.

HELIDAC-TETRACYCLINE, METRONIZADOLE, BUSMUTH SUBSALICYLATE (unspecified): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disabilities guidelines.

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: FDA (Helidac).

Decision rationale: CA MTUS and ODG do not address this issue. HELIDAC Therapy consists of 112 bismuth subsalicylate 262.4-mg chewable tablets, 56 metronidazole 250-mg tablets, USP, and 56 tetracycline hydrochloride 500-mg capsules, USP, for oral administration. The components of the HELIDAC Therapy (bismuth subsalicylate, metronidazole, and tetracycline hydrochloride), in combination with an H2 antagonist, are indicated for the eradication of H. pylori for treatment of patients with H. pylori infection and duodenal ulcer disease (active or a history of duodenal ulcer). Appropriate doses of H2 antagonists for the treatment of active duodenal ulcers should be prescribed in all patients. The eradication of H. pylori has been demonstrated to reduce the risk of duodenal ulcer recurrence in patients with active duodenal ulcer disease. There was no documentation of H. pylori infection or duodenal ulcer in the reports reviewed. There was no rationale provided as to why the patient requires this medication. Therefore, the request for HELIDAC-TETRACYCLINE, METRONIZADOLE, BUSMUTH SUBSALICYLATE (unspecified) was not medically necessary.

LANTIS INSULIN (unspecified): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disabilities guidelines.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Diabetes Chapter Other Medical Treatment Guideline or Medical Evidence: FDA (Lantus).

Decision rationale: CA MTUS does not address this issue. According to ODG Diabetes guidelines, insulin is recommended for the treatment of type 1 diabetes, or for type 2 diabetes if glycemic 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 naive or not, has symptomatic hyperglycemia. Lantus is indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus. Lantus is a recombinant human insulin analog for once daily subcutaneous administration with potency that is approximately the same as the potency of human insulin. Lantus exhibits a relatively constant glucose-lowering profile over 24 hours that permits once-daily dosing. There is no documentation as to what type of diabetes the patient has. There are no supporting laboratory values, such as A1C level, or symptoms provided to determine the patient's medication needs. In addition, there is no documentation as to whether or not the patient is utilizing diet and exercise as an adjunct to her medications. Furthermore, the dosage and quantity were not provided in this request. Therefore, the request for Lantus insulin (unspecified) was not medically necessary.

METROMIN (unspecified): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disabilities guidelines.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Diabetes Chapter Other Medical Treatment Guideline or Medical Evidence: FDA (Metformin).

Decision rationale: CA MTUS does not address this issue. According to 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. There are no laboratory values provided in the reports reviewed such as pre-prandial values, post-prandial values, or A1C values. In addition, there was no mention of the role of diet and exercise in the treatment of the patient's diabetes. Furthermore, it is unknown if the patient has type 1 diabetes or type 2 diabetes. Therefore, the request for Metformin (unspecified) was not medically necessary.

GLIPIZIDE (unspecified): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disabilities guidelines.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Diabetes Chapter Other Medical Treatment Guideline or Medical Evidence: FDA (Glipizide).

Decision rationale: CA MTUS does not address this issue. Glipizide is an oral blood-glucose-lowering drug of the sulfonylurea class that helps control blood sugar levels by helping the pancreas produce insulin. According to ODG guidelines, sulfonylureas 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. 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. According to the reports reviewed, there is no documentation of a trial of a first-line agent. There are no laboratory values provided in the reports reviewed such as pre-prandial values, post-prandial values, or A1C values. In addition, there was no mention of the role of diet and exercise in the treatment of the patient's diabetes. Furthermore, it is unknown if the patient has type 1 diabetes or type 2 diabetes. Therefore, the request for Glipizide (unspecified) was not medically necessary.

LISINOPRIL (unspecified): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disabilities guidelines.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Diabetes Chapter Other Medical Treatment Guideline or Medical Evidence: FDA (Lisinopril).

Decision rationale: CA MTUS does not address this issue. ODG guidelines 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. Lisinopril is in a group of drugs called ACE inhibitors. ACE stands for angiotensin converting enzyme. Lisinopril is used to treat high blood pressure (hypertension), congestive heart failure, and to improve survival after a heart attack. It is also used for preventing kidney failure due to high blood pressure and diabetes. According to the reports reviewed, there is no documentation regarding hypertension, heart failure, or diabetic related high blood pressure, or renal failure. Without clear cut documentation of diagnosis, symptoms, medication need, and efficacy with prior use, medical necessity cannot be established. In addition, blood pressure values were not provided for review. Therefore, the request for Lisinopril (unspecified) was not medically necessary.

CITRUCEL (unspecified): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disabilities guidelines.

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: <http://www.webmd.com/drugs/2/drug-6149/citrucel-oral/details>.

Decision rationale: CA MTUS and ODG do not address this issue. According to an online search, Citrucel is a bulk-forming fiber laxative, containing methylcellulose, used to treat constipation. It increases the bulk in your stool, an effect that helps to cause movement of the intestines. It also works by increasing the amount of water in the stool, making the stool softer and easier to pass. Citrucel has also been used along with a proper diet to treat high cholesterol and for constipation associated with other bowel disorders like IBS. According to the reports reviewed, the patient has been diagnosed with irritable bowel syndrome. However, the quantity was not noted in this request. Therefore, the request for Citrucel (unspecified), as submitted, was not medically necessary.