MAXIMUS Federal Services

Case Number:	CM15-0125895		
Date Assigned:	07/16/2015	Date of Injury:	05/29/1990
Decision Date:	10/19/2015	UR Denial Date:	06/11/2015
Priority:	Standard	Application Received:	06/29/2015

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: California
Certification(s)/Specialty: Emergency 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 female, who sustained an industrial injury on 5/29/1990. The medical records submitted for this review did not include the details regarding the initial injury or the prior treatments to date. Diagnoses include diabetes mellitus, hyperlipidemia, diabetic neuropathy, and low back pain. Currently, she was evaluated for chronic pain and medication management. On 4/21/15, the physical examination documented decreased sensation in bilateral lower extremities. The plan of care included Freestyle Lite Test Strips, used four times a day, #120; Zoloft 100mg tablets, one tablet twice a day #60; Humulin 70/30, 10 unit twice a day, 100 unit/ML #6; Peri-colace 8.6/50mg two tablets daily #60: 240 with five refills; Hydroxyzine 25mg every four hour #120 with five refills; Tena Ultra Brief, large, one four times a day #120 with five refills; Lasix 40mg, one twice a day #60 with five refills; ASA EC 82mg, one daily #30; Gemifibrozil 600mg one tablets twice a day #60; Sucralfate 1GM/10ML suspension, 10ML twice a day 600ML with five refills; and Pantoprazole sodium ER 40mg, one tablet twice a day #60 with five refills.

IMR ISSUES, DECISIONS AND RATIONALES

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

Freestyle lite test strips #120 with 5 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); Diabetes Chapter (Online Version), Glucose Monitoring.

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

Decision rationale: The request is for the blood sugar test strips. The official disability guidelines state the following regarding this topic: 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 detoriation, co-morbidities, surgery, pregnancy or contradictions against oral antidiabetics (Lechleitner, 2011). The amount of insulin must be balanced with food intake and daily activities. Not recommend regular human insulin (Humulin R, Novolin R) because onset of action is too slow and persistence of effect is too long to mimic a normal prandial physiologic profile; the result is impaired efficacy and increased risk of delayed hypoglycemia. Not recommend NPH insulin (Humulin N, Novolin N) because it does not provide a sufficiently flat peakless basal insulin; highly variable absorption even within individuals; increased risk of hypoglycemia compared with the long-acting insulin analogues. Recommend rapid-acting insulin analogues; premixed insulin/protamine; and long-acting insulin analogues. (Rodbard, 2009) (Davis, 2010) The addition of premixed insulin to metformin seemed to produce greater reduction in HbA1c level, slightly greater weight gain, and higher risk for hypoglycemia compared with metformin plus a basal insulin. (Bennett, 2011) (Misso, 2010) (Phung, 2010) This case control study suggests that use of antidiabetics such as sulfonylureas and insulin were associated with an increased risk for pancreatic cancer. One analysis found that patients with diabetes who relied on insulin alone faced as much as 4.5 times the estimated risk for pancreatic cancer, as measured in cancer events per 1000 patient years. In addition, diabetes mellitus appears to be both a cause of and a risk factor for pancreatic cancer. (Bodmer, 2012) The addition of insulin as a second-line agent after metformin in patients with type 2 diabetes is associated with increased cardiovascular risk compared with adding a sulfonylurea. Therefore, it may be better to use 2 oral medications before progressing to insulin use in type 2 diabetes. Over 14 months, patients who received insulin as second-line treatment after metformin had statistically significant increased risks of 30% for nonfatal cardiovascular outcomes and a 44% increase in all-cause mortality. (AHRQ, 2014)As stated above, the use of insulin for glucose control is essential in preventing systemic illness both acute and chronic. In this case, the issue is the number of refills requested. There is poor documentation of screening measures needed in order to prevent complications of use. This includes daily glucose readings, which should be recorded in order to alter the dosage need for proper glucose control. Due to the critical nature of daily blood sugar control, the refills are not medically necessary.

Zoloft 100mg #60 with 5 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

Decision rationale: Medications in the class of antidepressants are recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. (Feuerstein, 1997) (Perrot, 2006) They are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Analgesia generally occurs within a few days to a week, whereas antidepressant effect usually takes longer to occur. (Saarto-Cochrane, 2005) Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality/duration, and psychological assessment. Side effects can include excessive sedation and should be assessed. It is recommended that these outcome measurements should be initiated at one week of treatment with a recommended trial of at a minimum of 4 weeks. It has been suggested that if pain is in remission for 3-6 months, a gradual tapering of anti-depressants can be undertaken. In this case, the use of this medication is not certified for use based on the lack of documented assessment of screening measures for ongoing use. Pending submission of the required treatment efficacy and evaluation of function as well as psychological assessment, the request is not medically necessary.

Humulin 70/30 100 unit/ml #6 with 5 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); Diabetes Chapter (Online Version).

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

Decision rationale: The request is for the medication insulin. The official disability guidelines state the following regarding this topic: 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 detoriation, co-morbidities, surgery, pregnancy or contradictions against oral antidiabetics (Lechleitner, 2011). The amount of insulin must be balanced with food intake and daily activities. Not recommend regular human insulin (Humulin R, Novolin R) because onset of action is too slow and persistence of effect is too long to mimic a normal prandial physiologic profile; the result is impaired efficacy and increased risk of delayed hypoglycemia. Not recommend NPH insulin (Humulin N, Novolin N) because it does not provide a sufficiently flat peakless basal insulin; highly variable absorption even within individuals; increased risk of hypoglycemia compared with the long-acting insulin analogues. Recommend rapid-acting insulin analogues; premixed insulin/protamine; and long-acting insulin analogues. (Rodbard, 2009) (Davis, 2010) The addition of premixed insulin to metformin seemed to produce greater reduction in HbA1c level,

slightly greater weight gain, and higher risk for hypoglycemia compared with metformin plus a basal insulin. (Bennett, 2011) (Misso, 2010) (Phung, 2010) This case control study suggests that use of antidiabetics such as sulfonylureas and insulin were associated with an increased risk for pancreatic cancer. One analysis found that patients with diabetes who relied on insulin alone faced as much as 4.5 times the estimated risk for pancreatic cancer, as measured in cancer events per 1000 patient years. In addition, diabetes mellitus appears to be both a cause of and a risk factor for pancreatic cancer. (Bodmer, 2012) The addition of insulin as a second-line agent after metformin in patients with type 2 diabetes is associated with increased cardiovascular risk compared with adding a sulfonylurea. Therefore, it may be better to use 2 oral medications before progressing to insulin use in type 2 diabetes. Over 14 months, patients who received insulin as second-line treatment after metformin had statistically significant increased risks of 30% for nonfatal cardiovascular outcomes and a 44% increase in all-cause mortality. (AHRQ, 2014) As stated above, the use of insulin for glucose control is essential in preventing systemic illness both acute and chronic. In this case, the issue is the number of refills requested. There is poor documentation of screening measures needed in order to prevent complications of use. This includes daily glucose readings, which should be recorded in order to alter the dosage need for proper glucose control. Due to the critical nature of daily blood sugar control, the refills are not medically necessary.

Peri-colace 8.6-50gm #240 with 5 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Roberts Pharmaceuticals (2004) Colace Oral, Colace Dialose, DSS, Surfak (docusate sodium).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2780140/.

Decision rationale: The request is for the use of peri-colace which is a product usually used for constipation. Its active ingredient is ducusate sodium, which is a surface-active agent laxative. The MTUS and ODG guidelines are silent regarding this topic and as such, an alternative source was used. Ducusate is an effective agent and can be used safely for chronic constipation. In this case, there is inadequate documentation of a full evaluation delineating the etiology of the patient's symptoms as well as non-pharmacologic dietary treatment rendered. As such, the request is not medically necessary.

Hydroxazine 25mg #120 with 5 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pfizer (October 2004) Atarax (hydroxazine).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation https://www.pfizermedicalinformation.com/en-us/vistaril.

Decision rationale: The request is for the medication hydroxazine. The MTUS and ODG are silent regarding this issue. Alternative sources were use. Per the manufacturer, the indications for use are as follows: For symptomatic relief of anxiety and tension associated with psychoneurosis and as an adjunct in organic disease states in which anxiety is manifested. Useful in the management of pruritus due to allergic conditions such as chronic urticaria and atopic and contact dermatoses, and in histamine-mediated pruritus. As a sedative when used as premedication and following general anesthesia, Hydroxyzine may potentiate meperidine (Demerol) and barbiturates, so their use in pre-anesthetic adjunctive therapy should be modified on an individual basis. Atropine and other belladonna alkaloids are not affected by the drug. Hydroxyzine is not known to interfere with the action of digitalis in any way and it may be used concurrently with this agent. The effectiveness of hydroxyzine as an antianxiety agent for long-term use, that is, more than 4 months, has not been assessed by systematic clinical studies. The physician should reassess periodically the usefulness of the drug for the individual patient. In this case, there is inadequate documentation of the above-mentioned indications. As such, the request is not medically necessary.

Tena Ultra Brief-large #120 with 5 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.tena.us/stretch-ultra-brief/6780267803,en_US.pd.html.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation https://www.tena.us/ultra-briefs/6725267200-P,en_US,pd.html.

Decision rationale: The request is for Tena Ultra briefs. This is a moisture-protecting incontinence garment. In this case, there is insufficient documentation to suggest why the patient requires this product. As such, the request is not medically necessary.

Lasix 40mg #60 with 5 refills: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.rxlist.com/lasix-drug.htm.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://www.webmd.com/drugs/2/drug-5512-8043/furosemide-oral/furosemide-oral/details.

Decision rationale: The request is for the medication furosemide. This is usually used for patients with edema or congestive heart failure. It can also be used for hypertension. In this case, there is documentation of edema, which would benefit from this mediation. As such, the request is medically necessary.

ASA EC 81mg #30 with 5 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), Pain Chapter (Online Version), Aspirin.

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

Decision rationale: The request is for the use of the medication aspirin. The official disability guidelines state the following regarding its use in diabetics: Under study. The use of aspirin for primary prevention has become controversial due to recent data showing little benefit. Several recent meta-analyses show no statistically significant benefit on either total cardiovascular outcomes or the individual events such as death, myocardial infarction, or stroke. The controversial findings of the different studies may reflect the results of studies showing that patients with DM have an increased resistance to the effects of aspirin, linked in part to an effect of hyperglycemia. Some studies, but not all, support the use of low-dosage aspirin in the secondary prevention of CVD in patients with DM. (Zhang, 2010) (Younis, 2010) (Handelsman, 2011) (Gerstein, 2011) In this case, the use of this mediation is reasonable. This is secondary to data showing prevention of cardiovascular disease in diabetics. As such, the request is medically necessary.

Gemfibrozil 600mg #60 with 5 refills: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation MedicineNet.com.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://www.webmd.com/drugs/2/drug-11423/gemfibrozil-oral/details.

Decision rationale: The request is for the medication gemfibrozil. This is typically used for patients with dyslipidemia. Specifically, it helps reduce triglyceride levels and increases HDL. In this case, there is documentation supporting the use of this medication. As such, the request is medically necessary.

Sucralfate 1gm/10ml susp, 10ml 600 with 5 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation WebMD.com.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic)/ NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: The request is for an antacid medication to aid in gastrointestinal symptoms likely related to the use of NSAIDs. The Official Disability Guidelines state the following

regarding this topic: Recommend with precautions as indicated below. Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). A history of ulcer complications is the most important predictor of future ulcer complications associated with NSAID use. (Garcia Rodriguez, 1994) (Malfertheiner, 2009) Recommendations Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g., ibuprofen, naproxen, etc.) Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg Omeprazole daily) or misoprostol (200 g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxyn plus low-dose aspirin plus a PPI. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007) Treatment of dyspepsia secondary to NSAID therapy: Stop the NSAID, switch to a different NSAID, or consider H2-receptor antagonists or a PPI. A recent systematic review concluded that slow-release formulations of NSAIDs are associated with a greater risk of upper GI bleeding/perforation, and should be used with care. The RR of upper GI bleeding/perforation was 4.50 for traditional NSAIDs, 2.69 for ibuprofen, and 1.88 for coxibs. Estimated RRs were 5.63 for naproxen immediate release, but as much as 14.54 for some slow-release formulations. In this case, the use of this medication is not indicated based on the guidelines. This is secondary to poor evidence of efficacy for the patient's condition. As such, the request is not medically necessary.

Pantoprazole Sod Dr 40mg #60 with 5 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG); Pain Chapter, (Online Version), Proton Pump Inhibitors (PPIs).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic)/ NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: The request is for an antacid medication to aid in gastrointestinal symptoms likely related to the use of NSAIDs. The Official Disability Guidelines state the following regarding this topic: Recommend with precautions as indicated below. Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). A history of ulcer complications is the most important predictor of future ulcer complications associated with NSAID use. (Garcia Rodriguez, 1994) (Malfertheiner, 2009) Recommendations Patients with no risk factor and no

cardiovascular disease: Non-selective NSAIDs OK (e.g., ibuprofen, naproxen, etc.). Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg Omeprazole daily) or misoprostol (200 g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxyn plus low-dose aspirin plus a PPI. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007) Treatment of dyspepsia secondary to NSAID therapy: Stop the NSAID, switch to a different NSAID, or consider H2-receptor antagonists or a PPI. A recent systematic review concluded that slow-release formulations of NSAIDs are associated with a greater risk of upper GI bleeding/perforation, and should be used with care. The RR of upper GI bleeding/perforation was 4.50 for traditional NSAIDs, 2.69 for ibuprofen, and 1.88 for coxibs. Estimated RRs were 5.63 for naproxen immediate release, but as much as 14.54 for some slow-release formulations. In this case, the use of an antacid is not indicated based on the guidelines. This is secondary to inadequate qualifying criteria. As such, the request is not medically necessary.