MAXIMUS Federal Services

Case Number:	CM15-0177692		
Date Assigned:	09/18/2015	Date of Injury:	10/07/2009
Decision Date:	11/18/2015	UR Denial Date:	08/20/2015
Priority:	Standard	Application Received:	09/09/2015

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: Tennessee, Florida, Ohio
Certification(s)/Specialty: Surgery, Surgical Critical Care

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 58-year-old male who sustained an industrial injury October 7, 2009. Diagnoses include lumbar sprain, radiculitis, bilateral knee sprain, malignant hypertension, hyperlipidemia, and diabetes. Documented treatment related to this request for authorization includes medication. The treating physician's plan of care includes: Lantus insulin, 8 mm needles, Omega 3 ethyl esters, B-D insulin syringes, Hydrochlorothiazide, Atorvastatin, Lisinopril, Aspirin 81 mg., Metroprolol tartrate, Clonidine, Nifedipine, Glipizide, Metformin, and Byetta. There is no documentation provided regarding the symptoms related to this request or response to treatment. These were denied August 20, 2015.

IMR ISSUES, DECISIONS AND RATIONALES

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

Lantus insulin 100/U ml inject 40 units, ten count: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://www.drugs.com/pro/lantus.com.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation US FDA Clinical Indications and Prescribing Guidelines: Lantus Insulin.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. The California MTUS/ACOEM guidelines and the Official Disability Guidelines do not address the requested medication. Lantus insulin is a long-acting insulin which is required for insulin dependent diabetes. The medical records fail to document this patient's glucose log, recent A1C or current serum glucose levels. This injured work had a lumbar and bilateral knee sprain in 2009. He suffers from multiple medical conditions. However, the patient's most recent medical records provided are dated more than 1 year ago (11/2014). The most recent note is hand written, incomplete and partially illegible. The clinical documentation fails to address the patient's current clinical status in regards to his comorbid medical conditions and concurrent need for medications. Without a recent physical examination, assessment and lab work, the requested medication is not indicated. Therefore, based on the submitted medical documentation, the request for lantus insulin is not medically necessary.

Unifine pentip 8 mm needle, 100 count: 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 Official Disability Guidelines (ODG) Diabetes, Insulin Durable Medical Equipment.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. The California MTUS/ACOEM guidelines do not address the requested medical equipment. The Official Disability Guidelines state that durable medical equipment is necessary for a medically supported diagnosis. This injured work had a lumbar and bilateral knee sprain in 2009. He suffers from multiple medical conditions. However, the patient's most recent medical records provided are dated more than 1 year ago (11/2014). The most recent note is hand written, incomplete and partially illegible. The clinical documentation fails to address the patient's current clinical status in regards to his comorbid medical conditions and concurrent need for medications. Without a recent physical examination, assessment and lab work supporting this patient's diagnosis of insulin dependent diabetes, the requested DME is not indicated. Therefore, based on the submitted medical documentation, the request for Unifine pentip needles are not medically necessary.

Omega 3 ethyl esters 1 gram, 120 count: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://www.drugs.com/monograph/omega-3-acid-ethyl-esters.html.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation US FDA Clinical Indications and Prescribing Guidelines: Omega 3 ethyl Esters (Lovaza).

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. The California MTUS guidelines, the ACOEM Guidelines and the Official Disability Guidelines do not address this topic. Therefore, outside sources were sought. The FDA Lovaza Indications for Use note that Lovaza is generically known as omega 3 ethyl esters which are a lipid regulating agent supplied as a liquid filled gel capsule oral administration. Lovaza is a lipid regulating agent supplied as a liquid filled gel capsule oral administration. The initial treatment for dyslipidemia is dietary therapy specific for the type of lipoprotein abnormality. Excess body weight and excess alcohol intake may be important factors in hypertriglyceridemia and should be managed prior to any drug therapy. Physical exercise can be an important ancillary measure, and has been associated with rises in HDL-cholesterol. Diseases contributory to hyperlipidemia such as hypothyroidism or diabetes mellitus should be looked for and adequately treated. The use of drugs should be considered only when reasonable attempts have been made to obtain satisfactory results with non-drug methods. If the decision is made to use drugs, the patient should be instructed that this does not reduce the importance of adhering to diet. This injured work had a lumbar and bilateral knee sprain in 2009. He suffers from multiple medical conditions. However, the patient's most recent medical records provided are dated more than 1 year ago (11/2014). The most recent note is hand written, incomplete and partially illegible. The clinical documentation fails to address the patient's current clinical status in regards to his comorbid medical conditions and concurrent need for medications. Without a recent physical examination, assessment and lab work, the requested medication is not indicated. Therefore, based on the submitted medical documentation, the request for Omega 3 ethyl esters is not medically necessary.

B-D ins U100 1 ml ultra syr, 100 count: 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 Official Disability Guidelines (ODG) Diabetes, Insulin Durable medical Equipment.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. The California MTUS/ACOEM guidelines do not address the requested medication. The Official Disability Guidelines state that durable medical equipment is necessary for a medically diagnosed condition. B-D insulin U100 ultra syringes are necessary for poorly controlled diabetes which requires short acting, highly potent insulin regulation. This injured work had a lumbar and bilateral knee sprain in 2009. He suffers from multiple medical conditions. However, the patient's most recent medical records provided are dated more than 1 year ago (11/2014). The most recent note is hand written, incomplete and partially illegible. The clinical documentation fails to address the patient's current clinical status in regards to his comorbid medical conditions and concurrent need for medications. Without a

recent physical examination, assessment and lab work, the requested medication is not indicated. Therefore, based on the submitted medical documentation, the request for BD insulin U100 ultra syringes is not medically necessary.

Hydrochlorothiazide 25 mg, thirty count: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://www.drugs.com/hydrochlorothiazide.html.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation US FDA Clinical Indications and Prescribing Guidelines: Hydrochlorothiazide.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. The California MTUS/ACOEM guidelines and the Official Disability Guidelines do not address the requested medication. Hydrochlorothiazide is a diuretic medication which is used to control primary and secondary hypertension. This injured work had a lumbar and bilateral knee sprain in 2009. He suffers from multiple medical conditions. However, the patient's most recent medical records provided are dated more than 1 year ago (11/2014). The most recent note is hand written, incomplete and partially illegible. The clinical documentation fails to address the patient's current clinical status in regards to his comorbid medical conditions and concurrent need for medications. Without a recent physical examination, assessment and lab work, the requested medication is not indicated. Therefore, based on the submitted medical documentation, the request for hydrochlorothiazide is not medically necessary.

Atorvastatin 40 mg, thirty count: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://www.drugs.com/pro/atorvastatin.html.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation US FDA Clinical Indications and Prescribing Guidelines: Atorvastatin.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. The California MTUS/ACOEM guidelines and the Official Disability Guidelines do not address the requested medication. Atorvastatin is a HMG-co-A reductase inhibitor which is used to control hyperlipidemia in patients who are at risk for development of early cardiovascular disease. This injured work had a lumbar and bilateral knee sprain in 2009. He suffers from multiple medical conditions. However, the patient's most recent medical records provided are dated more than 1 year ago (11/2014). The most recent note is hand written, incomplete and partially illegible. The clinical documentation fails to address the patient's current clinical status in regards to his comorbid medical conditions and concurrent need for medications. Without a recent physical examination, assessment and lab work, the

requested medication is not indicated. Therefore, based on the submitted medical documentation, the request for atorvastatin is not medically necessary.

Lisinopril 40 mg, thirty count: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://www.drugs.com/pro/lisinopril.html.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation US FDA Clinical Indications and Prescribing Guidelines: Lisinopril.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. The California MTUS/ACOEM guidelines and the Official Disability Guidelines do not address the requested medication. Lisinopril is classified as an ACE inhibitor to control primary and secondary hypertension. It is deemed cardioprotective in patients with acute congestive heart failure. This injured work had a lumbar and bilateral knee sprain in 2009. He suffers from multiple medical conditions. However, the patient's most recent medical records provided are dated more than 1 year ago (11/2014). The most recent note is hand written, incomplete and partially illegible. The clinical documentation fails to address the patient's current clinical status in regards to his comorbid medical conditions and concurrent need for medications. Without a recent physical examination, assessment and lab work, the requested medication is not indicated. Therefore, based on the submitted medical documentation, the request for Lisinopril is not medically necessary.

Aspirin 81 mg, thirty count: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://www.drugs.com/ppa/aspirin-acetylsalicylic-acid-asa.html.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) US FDA Clinical Indications and Prescribing Guidelines: Aspirin.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. The California MTUS/ACOEM guidelines and the Official Disability Guidelines do not address the requested medication. Aspirin is an antiplatelet agent which has been indicated to treat local musculoskeletal pain as well as provide cardioprotection for patients at high risk of cardiovascular disease. This injured work had a lumbar and bilateral knee sprain in 2009. He suffers from multiple medical conditions. However, the patient's most recent medical records provided are dated more than 1 year ago (11/2014). The most recent note is hand written, incomplete and partially illegible. The clinical documentation fails to address the patient's current clinical status in regards to his comorbid medical conditions and concurrent need for medications. Without a recent physical examination,

assessment and lab work, the requested medication is not indicated. Therefore, based on the submitted medical documentation, the request for Aspirin is not medically necessary.

Metroprolol tartrate 50 mg, six count: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.ncbi.nim.nih.gov/medlineplus/druginfo/meds/a682864.html.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation FDA Prescribing Guidelines and Indications for Lopressorhttp://www.accessdata.fda.gov/drugsatfda_docs/label/2012/017963s067lbl.pdf.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. The California MTUS guidelines, the ACOEM Guidelines and the Official Disability Guidelines (ODG) do not address this topic. Lopressor is a beta1-selective receptor blocker. Clinical pharmacology studies have demonstrated the beta-blocking activity of metoprolol, as shown by (1) reduction in heart rate and cardiac output at rest and upon exercise, (2) reduction of systolic blood pressure upon exercise, (3) inhibition of isoproterenol-induced tachycardia, and (4) reduction of reflex orthostatic tachycardia. The FDA prescribing guidelines state that metoprolol is indicated for the treatment of hypertension. This injured work had a lumbar and bilateral knee sprain in 2009. He suffers from multiple medical conditions. However, the patient's most recent medical records provided are dated more than 1 year ago (11/2014). The most recent note is hand written, incomplete and partially illegible. The clinical documentation fails to address the patient's current clinical status in regards to his comorbid medical conditions and concurrent need for medications. Without a recent physical examination, assessment and lab work, the requested medication is not indicated. Therefore, based on the submitted medical documentation, the request for metroprolol is not medically necessary.

Clonidine 0.2 mg, four count: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://www.drugs.com/pro/clonidine-tablets.html.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation US FDA Clinical Indications and Prescribing Guidelines: Clonidine.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. The California MTUS/ACOEM guidelines and the Official Disability Guidelines do not address the requested medication. Clonidine is a centrally acting alpha agonist which is used for the primary treatment of essential hypertension. This injured work had a lumbar and bilateral knee sprain in 2009. He suffers from multiple medical conditions. However, the patient's most recent medical records provided are dated more than 1

year ago (11/2014). The most recent note is hand written, incomplete and partially illegible. The clinical documentation fails to address the patient's current clinical status in regards to his comorbid medical conditions and concurrent need for medications. Without a recent physical examination, assessment and lab work, the requested medication is not indicated. Therefore, based on the submitted medical documentation, the request for Clonidine is not medically necessary.

Nifedipine 90 mg, thirty count: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://www.drugs.com/pro/nifedipine-capsules.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation US FDA Clinical Indications and Prescribing Guidelines: Nifedipine.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. The California MTUS/ACOEM guidelines and the Official Disability Guidelines do not address the requested medication. Nifedipine is a calcium channel blocker which has been approved by the FDA to treat essential hypertension. This injured work had a lumbar and bilateral knee sprain in 2009. He suffers from multiple medical conditions. However, the patient's most recent medical records provided are dated more than 1 year ago (11/2014). The most recent note is hand written, incomplete and partially illegible. The clinical documentation fails to address the patient's current clinical status in regards to his comorbid medical conditions and concurrent need for medications. Without a recent physical examination, assessment and lab work, the requested medication is not indicated. Therefore, based on the submitted medical documentation, the request for Nifedipine is not medically necessary.

Glipizide 10 mg, 120 count: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://www.drugs.com/pro/glipizide.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation US FDA Clinical Indications and Prescribing Guidelines: Glipizide.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. The California MTUS/ACOEM guidelines and the Official Disability Guidelines do not address the requested medication. Glipizide is an antiglycemic medication which is used adjunctively in diabetes to treat poorly controlled diabetes mellitus. This injured work had a lumbar and bilateral knee sprain in 2009. He suffers from multiple medical conditions. However, the patient's most recent medical records provided are dated more than 1 year ago (11/2014). The most recent note is hand written, incomplete and partially illegible. The clinical documentation fails to address the patient's current clinical status

in regards to his comorbid medical conditions and concurrent need for medications. Without a recent physical examination, assessment and lab work, the requested medication is not indicated. Therefore, based on the submitted medical documentation, the request for Glipizide is not medically necessary.

Metformin HCL 850 mg, ninety count: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://www.drugs.com/pro/metformin.html.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Federal Drug Administration (FDA) Metformin Indications Use and Prescribing Informationhttp://www.fda.gov/ohrms/dockets/dailys/02/May02/053102/800471e6.pdf.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. The California MTUS/ACOEM guidelines and the Official Disability Guidelines do not address the requested medication. Glucophage is a antiglycemic medication which is taken orally to control diabetes mellitus. It may result in metabolic acidosis and hyperchloremia is routine lab monitoring is not performed. This injured work had a lumbar and bilateral knee sprain in 2009. He suffers from multiple medical conditions. However, the patient's most recent medical records provided are dated more than 1 year ago (11/2014). The most recent note is hand written, incomplete and partially illegible. The clinical documentation fails to address the patient's current clinical status in regards to his comorbid medical conditions and concurrent need for medications. Without a recent physical examination, assessment and lab work, the requested medication is not indicated. Therefore, based on the submitted medical documentation, the request for Metformin is not medically necessary.

Byetta 10 mcg/0.04 ml, #2.40: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation http://www.drugs.com/pro/byetta.html.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation US FDA Clinical Indications and Prescribing Guidelines: Byetta.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this request for this patient. The California MTUS/ACOEM guidelines and the Official Disability Guidelines do not address the requested medication. Byetta is a GLP-1 Receptor Agonist which is used as an antiglycemic in the treatment of poorly controlled type II diabetes. This injured work had a lumbar and bilateral knee sprain in 2009. He suffers from multiple medical conditions. However, the patient's most recent medical records provided are dated more than 1 year ago (11/2014). The most recent note is hand written, incomplete and partially illegible. The clinical documentation fails to address the patient's current clinical status

in regards to his comorbid medical conditions and concurrent need for medications. Without a recent physical examination, assessment and lab work, the requested medication is not indicated. Therefore, based on the submitted medical documentation, the request for Byetta is not medically necessary.