

Case Number:	CM15-0147279		
Date Assigned:	08/11/2015	Date of Injury:	01/09/1991
Decision Date:	09/23/2015	UR Denial Date:	06/30/2015
Priority:	Standard	Application Received:	07/28/2015

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 61 year old male, who sustained an industrial injury on 1-3-91. It is noted the injured worker suffered a heart attack during one of this back surgeries. The injured worker was diagnosed as having degeneration of lumbar intervertebral disc, lumbosacral radiculitis, congestive heart failure and atrial fibrillation. Treatment to date has included multiple lumbar surgeries, oral medications including Amitiza 24mcg, Aripiprazole 10mg, Atorvastatin 80mg, Baclofen 20mg, Carvedilol 25mg, Cephalexin 500mg, Chlorhexidine gluconate mouthwash, Doxycycline 100mg, Effexor XR 75mg, Furosemide 40 mg, Hydromorphone 4mg, Hydromorphone 8mg, Latuda 20mg, Latuda 80mg, Lisinopril 10mg, Nexium 40mg, Oxybutynin chloride ER 10mg, Oxybutynin chloride ER 15mg, Potassium chloride ER 20 mEq, Spironolactone 25mg, Tamsulosin ER 0.4mg, Tikosyn 500mcg, Wellbutrin XL 150mg and Xarelto 20mg, intrathecal pump, psychotherapy, activity modifications. Currently on 6-16-15, the injured worker complains of bilateral low back pain rated 5-7 out of 10 which is constant, but variable in intensity and associated with lower extremity weakness and numbness in the bilateral lower extremities. He also complains of constipation. Physical exam performed on 6-16-15 revealed tenderness to palpation over the paraspinal muscles with muscle spasm over lower paraspinal and limited range of motion of lumbar spine with a normal gait. The treatment plan included continuation of medications: Amitiza 24mcg, Aripiprazole 10mg, Atorvastatin 80mg, Baclofen 20mg, Carvedilol 25mg, Cephalexin 500mg, Chlorhexidine gluconate mouthwash, Doxycycline 100mg, Effexor XR 75mg, Furosemide 40 mg, Hydromorphone 4mg, Hydromorphone 8mg, Latuda 20mg, Latuda 80mg, Lisinopril 10mg, Nexium 40mg, Oxybutynin chloride ER 10mg, Oxybutynin chloride ER 15mg, Potassium chloride ER 20 mEq, Spironolactone 25mg, Tamsulosin ER 0.4mg, Tikosyn 500mcg, Wellbutrin XL 150mg and Xarelto 20mg.

IMR ISSUES, DECISIONS AND RATIONALES

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

Amitiza 24mcg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 76-80.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Federal Drug Administration (FDA), Amitiza Indications Use and Prescribing Information
http://www.accessdata.fda.gov/drugsatfda_docs/label/2008/021908s0051bl.pdf.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of Amitiza prescription for this patient. Amitiza is the name brand equivalent of generic Lubiprostone. The clinical records submitted do support the fact that this patient has opioid induced constipation. However, the records do not support the use of this medication for that indication. The California MTUS guidelines, Occupational Disability Guidelines and the ACOEM Guidelines do not address the topic of Amitiza prescription. Per the Federal Drug Administration's (FDA) prescribing guidelines for Amitiza use, the medication is only indicated for idiopathic constipation and/or irritable bowel syndrome. This patient has opioid induced constipation; Amitiza is not approved by the FDA for that indication. Therefore, based on the submitted medical documentation, the request for Amitiza prescription is not-medically necessary.

Chlorhexidine Gluconate 0.12% mouthwash: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Federal Drug Administration (FDA), Peridex Indications Use and Prescribing Information
http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/019028s0201bl.pdf.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of a Chlorhexidine Gluconate 0.12% Mouthwash prescription for this patient. The clinical records submitted do not support the fact that this patient has periodontal gingivitis. The medical records do not support the use of this medication for that indication. The California MTUS guidelines, Occupational Disability Guidelines and the ACOEM Guidelines do not address the topic of Chlorhexidine Gluconate 0.12% Mouthwash prescription. Per the Federal Drug Administration's (FDA) prescribing guidelines for Peridex use, the medication is only indicated for Peridex is indicated for use between dental visits as part of a of a professional program for the treatment of gingivitis as characterized by redness and swelling of the gingivae, including gingival bleeding upon probing. This patient has no documentation that they are part of a professional program for the treatment of gingivitis between dental visits. Therefore, based on the submitted medical documentation, the request for Chlorhexidine Gluconate 0.12% Mouthwash prescription is not-medically necessary.

Furosemide 40mg: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mosby's Drug Consult.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Federal Drug Administration (FDA), Lasix Indications Use and Prescribing Information
http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/016273s0611bl.pdf.

Decision rationale: There is sufficient clinical information provided to justify the medical necessity of a Lasix prescription for this patient. Lasix is the name brand equivalent of generic, furosemide. The clinical records submitted do support the fact that this patient has coronary artery disease and hypertension. The California MTUS guidelines, Occupational Disability Guidelines and the ACOEM Guidelines do not address the topic of Lasix prescription. Per the Federal Drug Administration's (FDA) prescribing guidelines for Lasix use, the medication is only indicated for hypertension and edema. Specifically, Oral Lasix may be used in adults for the treatment of hypertension alone or in combination with other antihypertensive agents. This patient's medical records support that he has refractory hypertension which is not associated with congestive heart failure. Use of Lasix for treatment of this patient's hypertension is clinically appropriate. Therefore, based on the submitted medical documentation, the request for Lasix prescription is medically necessary.

Oxybutynin ER 10mg: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mosby's Drug Consult.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Federal Drug Administration (FDA) Oxybutynin Indications Use and Prescribing Information
http://www.accessdata.fda.gov/drugsatfda_docs/label/2008/017577s034,018211s017,020897s0118bl.pdf.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of an Oxybutynin prescription for this patient. Oxybutynin is the generic equivalent of the name brand medication, Ditropan. The clinical records submitted do support the fact that this patient has neurogenic bladder as demonstrated on urodynamics with high post-void residuals. However, the records indicate that this medication was prescribed Oxybutynin 10mg ER for a 3-month supply on June 30th of 2015. The California MTUS guidelines, Occupational Disability Guidelines and the ACOEM Guidelines do not address the topic of Oxybutynin prescription. Per the Federal Drug Administration's (FDA) prescribing guidelines for Oxybutynin use, the medication is only indicated for neurogenic bladder dysfunction. This patient has neurogenic bladder dysfunction, but the medical records fail to support the need for why a second refill is necessary. Therefore, based on the submitted medical documentation, the request for Oxybutynin prescription is not-medically necessary.

Baclofen 20mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants for pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants: Antispasticity/Antispasmodic Drugs Page(s): 97 and 100.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of a Baclofen prescription for this patient. The clinical records submitted do support the fact that this patient has chronic lower back pain. However, the records indicate that this patient has been on the medication for longer than 2 weeks with no documentation of muscle spasms. The California MTUS guidelines address the topic of muscle relaxant prescription. In accordance with the California MTUS guidelines, Baclofen is a muscle relaxant and muscle relaxants are not recommended for the treatment of chronic pain. From the MTUS guidelines: Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. There is no indication in the documentation Baclofen is being prescribed for this patient's chronic pain. The presence of muscle spasms is not documented in this patient's recent clinical records. Documentation of the continued need for Baclofen prescription is not supported. Therefore, based on the submitted medical documentation, the request for Baclofen prescription is not-medically necessary.

Carvedilol 25mg: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mosby's Drug Consult.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Federal Drug Administration (FDA), Carvedilol Indications Use and Prescribing Information https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020297s013lbl.pdf.

Decision rationale: There is sufficient clinical information provided to justify the medical necessity of a Carvedilol prescription for this patient. The clinical records submitted do support the fact that this patient has coronary artery disease and hypertension. The California MTUS guidelines, Occupational Disability Guidelines and the ACOEM Guidelines do not address the topic of Carvedilol prescription. Per the Federal Drug Administration's (FDA) prescribing guidelines for Carvedilol use, the medication is indicated for hypertension, left Ventricular Dysfunction Following Myocardial Infarction and congestive heart failure. This patient's medical records support that he has refractory hypertension which is not associated with congestive heart failure. However, the patient has a past medical history significant for post-operative myocardial infarction after spinal surgery. Use of Carvedilol for treatment of this patient's hypertension is clinically appropriate. Therefore, based on the submitted medical documentation, the request for Carvedilol prescription is medically necessary.

Lisinopril 10mg: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mosby's Drug Consult.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Federal Drug Administration (FDA) Lisinopril Indications Use and Prescribing Information http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/019777s054lbl.pdf.

Decision rationale: There is sufficient clinical information provided to justify the medical necessity of a Lisinopril prescription for this patient. The clinical records submitted do support the fact that this patient has coronary artery disease and hypertension. The California MTUS guidelines, Occupational Disability Guidelines and the ACOEM Guidelines do not address the topic of Lisinopril prescription. Per the Federal Drug Administration's (FDA) prescribing guidelines for Lisinopril use, the medication is indicated for hypertension, acute Myocardial Infarction and congestive heart failure. This patient's medical records support that he has refractory hypertension which is not associated with congestive heart failure. However, the patient has a past medical history significant for post-operative myocardial infarction after spinal surgery. Use of Lisinopril for treatment of this patient's hypertension is clinically appropriate. Therefore, based on the submitted medical documentation, the request for Lisinopril prescription is medically necessary.

Nexium 40mg DR: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68 and 69.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of a Nexium prescription for this patient. Nexium is the name brand equivalent of generic, esomeprazole. The clinical records submitted do not support the fact that this patient has refractory GERD resistant to H2 blocker therapy or an active h. pylori infection. The California MTUS guidelines address the topic of proton pump prescription. In accordance with California MTUS guidelines, PPI's (Proton Pump Inhibitors) can be utilized if the patient is concomitantly on NSAIDs and if the patient has gastrointestinal risk factors. This patient is not on NSAIDs. Additionally, per the Federal Drug Administration's (FDA) prescribing guidelines for Nexium use, the medication is only indicated for hypertension and edema. Chronic use of a proton pump inhibitor is not recommended due to the risk of developing atrophic gastritis. Short-term GERD symptoms may be controlled effectively with an H2 blocker unless a specific indication for a proton pump inhibitor exists. This patient's medical records support that he has GERD. However, the patient has no documentation of why chronic PPI therapy is necessary. His GERD is not documented to be refractory to H2 blocker therapy and he has not records that indicate an active h. pylori infection. Therefore, based on the submitted medical documentation, the request for Nexium prescription is not medically necessary.

Potassium chloride ER 20 MEQ ER: 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 Federal Drug Administration (FDA) Potassium Chloride Indications Use and Prescribing Information

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM270390.pdf>.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of a Potassium Chloride prescription for this patient. The clinical records submitted do not support the fact that this patient has hypokalemia. The California MTUS guidelines, Occupational Disability Guidelines and the ACOEM Guidelines do not address the topic of Potassium Chloride prescription. Per the Federal Drug Administration's (FDA) prescribing guidelines for Potassium Chloride use, the medication is only indicated for treatment of hypokalemia. Although this patient takes Lasix for refractory hypertension, his medical records do not support that he has hypokalemia. Lab testing for potassium wasting has not been clinically documented. Without confirmation of hypokalemia, a potassium prescription is not appropriate. Therefore, based on the submitted medical documentation, the request for potassium chloride prescription is not medically necessary.

Spironalactone 25mg: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Federal Drug Administration (FDA) Spironolactone Indications Use and Prescribing Information http://www.accessdata.fda.gov/drugsatfda_docs/label/2008/012151s062lbl.pdf.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of a spironolactone prescription for this patient. The clinical records submitted do not support the fact that this patient has edema with uncontrolled hypertension refractory to other medications. The California MTUS guidelines, Occupational Disability Guidelines and the ACOEM Guidelines do not address the topic of spironolactone prescription. Per the Federal Drug Administration's (FDA) prescribing guidelines for spironolactone, the medication is indicated for Edematous conditions associated with essential hypertension. Usually in combination with other drugs, spironolactone is indicated for patients who cannot be treated adequately with other agents or for whom other agents are considered inappropriate. This patient's medical records support that he has refractory hypertension, which is not associated with congestive heart failure. However, lab testing for potassium wasting has not been clinically documented. Without confirmation or concern for hypokalemia, a potassium-sparing agent is not appropriate. The medical records also fail to document that this patient has edematous disease or nephrotic syndrome to support its use. Therefore, based on the submitted medical documentation, the request for spironolactone prescription is not-medically necessary.

Tikosyn 500mcg capsule: 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 Federal Drug Administration (FDA) Tikosyn Indications Use and Prescribing Information <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM266277.pdf>.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of a Tikosyn prescription for this patient. Tikosyn is the name brand equivalent of generic Dofetilide. The clinical records submitted do not support the fact that this patient has been receiving lab testing every three months to support the drug's use as an antiarrhythmic. The California MTUS guidelines, Occupational Disability Guidelines and the ACOEM Guidelines do not address the topic of Tikosyn prescription. Per the Federal Drug Administration's (FDA) prescribing guidelines for Tikosyn, providers must ensure that patient's lab measures and ECG should be re-evaluated every 3 months due to risk of primary arrhythmias while on the medication. The clinical records do not support that this patient has been receiving q3month testing to safely receive Tikosyn. Therefore, based on the submitted medical documentation, the request for Tikosyn prescription is not-medically necessary.

Xarelto 20mg: Overturned

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Federal Drug Administration (FDA) Xarelto Indications Use and Prescribing Information <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM280333.pdf>.

Decision rationale: There is sufficient clinical information provided to justify the medical necessity of a Xarelto prescription for this patient. The clinical records submitted do support the fact that this patient has coronary artery disease, atrial fibrillation and hypertension. The California MTUS guidelines, Occupational Disability Guidelines and the ACOEM Guidelines do not address the topic of Xarelto prescription. Per the Federal Drug Administration's (FDA) prescribing guidelines for Xarelto use, the medication is indicated for anticoagulation in the setting of atrial fibrillation. This patient's medical records support that he has coronary artery disease, hypertension atrial fibrillation. Anticoagulation in the setting of atrial fibrillation is recommended by the American College of Cardiologists to prevent extracardiac thrombotic events. Therefore, use of Xarelto for treatment of this patient's atrial fibrillation is clinically appropriate. Therefore, based on the submitted medical documentation, the request for Xarelto prescription is medically necessary.

Wellbutrin XL 150mg ER: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Mental Illness and Stress.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 15 Stress Related Conditions Page(s): 402.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of a Wellbutrin prescription for this patient. Wellbutrin is the name brand equivalent of generic bupropion. The clinical records submitted do support the fact that this patient has chronic depression. However, the medical records do not support that this patient has a refractory major depressive disorder with supervision by a specialist. The California MTUS guidelines do address the topic of Wellbutrin prescription. Specifically, per MTUS, Wellbutrin is an atypical antidepressant that acts as a norepinephrine and dopamine reuptake inhibitor. Antidepressants have many side effects and can result in decreased work performance or mania in some people. Wellbutrin is an atypical antipsychotic. Antidepressant or antipsychotic medication may be prescribed for major depression or psychosis; however, this is best done in conjunction with specialty referral. This patient has been diagnosed with depression; however, the clinical records indicate that he continues to have severe depression despite multiple medications. Management of clinical depression is best done with a specialist. Despite his persistent depression, there is no evidence this patient is being treated by a specialist. Therefore, based on the submitted medical documentation, the request for Wellbutrin prescription is not-medically necessary.

Effexor XR 75mg: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Mental Illness and Stress.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants, Effexor Page(s): 123.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of an Effexor prescription for this patient. Effexor is the name brand equivalent of generic Venlafaxine. The clinical records submitted do support the fact that this patient has chronic depression. However, the medical records do not support that this patient has a refractory major depressive disorder with supervision by a specialist. The California MTUS guidelines do address the topic of Effexor prescription. Specifically, per MTUS, Effexor is a member of the selective-serotonin and norepinephrine reuptake inhibitor (SNRIs) class of antidepressants. It has FDA approval for treatment of depression and anxiety disorders. Additionally, Antidepressant or antipsychotic medication may be prescribed for major depression or psychosis; however, this is best done in conjunction with specialty referral. This patient has been diagnosed with depression; however, the clinical records indicate that he continues to have severe depression despite multiple medications. Management of clinical depression is best done with a specialist. Despite his persistent depression, there is no evidence this patient is being treated by a specialist. Therefore, based on the submitted medical documentation, the request for Effexor prescription is not-medically necessary.

Atorvastatin 80mg: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mosby's Drug Consult.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Federal Drug Administration (FDA) Lipitor Indications Use and Prescribing Information http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020702s0571bl.pdf.

Decision rationale: There is sufficient clinical information provided to justify the medical necessity of an Atorvastatin prescription for this patient. Lipitor is the name brand equivalent of generic Atorvastatin. The clinical records submitted do support the fact that this patient has a coronary artery disease, hypertension and a history of myocardial infarction. The California MTUS guidelines, Occupational Disability Guidelines and the ACOEM Guidelines do not address the topic of Lipitor prescription. Per the Federal Drug Administration's (FDA) prescribing guidelines, In patients with clinically evident coronary heart disease, LIPITOR is indicated to: 1) Reduce the risk of non-fatal myocardial infarction 2) Reduce the risk of fatal and non-fatal stroke 3) Reduce the risk for revascularization procedures 4) Reduce the risk of hospitalization for CHF 5) Reduce the risk of angina. This patient has been diagnosed with a history of myocardial supported after spinal surgery. The patient has atrial fibrillation, coronary artery disease and hypertension. Use of a plaque stabilizing HMG-coA reductase inhibitor is supported by current peer-reviewed literature. Therefore, based on the submitted medical documentation, the request for atorvastatin prescription is medically necessary.