

Case Number:	CM15-0090423		
Date Assigned:	05/18/2015	Date of Injury:	08/12/1979
Decision Date:	09/29/2015	UR Denial Date:	04/20/2015
Priority:	Standard	Application Received:	05/13/2015

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 73 year old male, who sustained an industrial injury on 8/12/79. He reported the initial crush injury to the chest and spinal cord T11 and T12. The injured worker was diagnosed as having lumbago, cervical radiculitis; pain in limb; cervicgia; mild dyspepsia; syringomyelia at thoracic level above original spinal cord injury; severe lower extremity spasticity; dysphagia; neurogenic bladder and bowel with megacolon; chronic neck/back/left hip pain; status post left arm blood clot; recurrent pneumonia; visual disturbances; left arm pain, weakness, numbness; left shoulder rotator cuff tear; erectile dysfunction; balanitis; penile foreskin stenosis; end stage urinary bladder; BPH; recurrent urinary tract infections; fractured right proximal tibia; open sores on right leg.. Treatment to date has included spinal cyst removed and shunted (12/2005); status post again cyst removed from spine and shunt replaced (12/2007); asymmetric yoked prism rehabilitation lenses to compensate for vertical phoria/abnormal egocentric localization. Currently, the PR-2 notes dated 1/12/15 indicated the injured worker returns on this date requesting refill of medications and supplies. He has exhausted his supply and pain levels have increased. He describes relief with medications usage and notes he was hospitalized the week before for hyperkalemia and has since discontinued the potassium. On examination he remains in a motorized wheel chair. There is tenderness in the cervical musculature moving into the trapezius bilaterally. There is mild to moderate muscle spasms that are palpable. His cervical range of motion remains decreased in all fields due to increased pain with movements. His right shoulder remains tender to palpation throughout the shoulder girdle. His left hand remains hypersensitive to touch. He is permanent and stationary. All subsequent PR-2's appear to have the same to similar treatment plan. The

provider is requesting: Alcohol Wipes (in boxes) QTY 2; Body Wash 1 gallon QTY 1; Distilled Water for CPAP (in gallons) QTY 3; Skin Lotion x 3 QTY 1; Baclofen 5mg #120; Celebrex 200mg QTY 30; Coumadin 4mg #30; Creon 24,000 units #90; Dexilant DR 60mg QTY 30; Eliquis 5mg #60; Flomax 0.4mg QTY 30; Fluticasone nasal spray 16 grams QTY 1; Lasix 40mg #60; Loratadine 10mg # #30; Nitrofurantoin MCR 100mg QTY 30; Norco 10/325mg #90; Vitamin B-12 injection weekly QTY 1; Vitamin C 250mg #60.

IMR ISSUES, DECISIONS AND RATIONALES

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

Norco 10/325mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): s 47, 83, and 95.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for the use of opioids Page(s): s 77-79.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of Norco for this patient. The clinical records submitted do not support the fact that this patient has a dose, which does not exceed 120 mg oral morphine equivalents per day. In accordance with California MTUS guidelines, narcotics for chronic pain management should be continued if, (a) If the patient has returned to work, (b) If the patient has improved functioning and pain. MTUS guidelines also recommends that dosing not exceed 120 mg oral morphine equivalents per day, and for patients taking more than one opioid, the morphine equivalent doses of the different opioids must be added together to determine the cumulative dose. This patient currently takes Norco for chronic pain management. The cumulative dose of opioids prescribed this patient exceeds that of 120mg oral morphine equivalents per day. Therefore, based on the submitted medical documentation, the request for Norco is not-medically necessary.

Baclofen 5mg #120: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants, Antispasticity/Antispasmodic Drugs Page(s): 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 indication in the medical documentation that 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.

Eliquis 5mg #60: 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 ELIQUIS FDA Prescribing Guidelines <http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm384790.htm>.

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. According to its FDA prescribing recommendations, Eliquis is a blood thinner which be associated with urinary and gastrointestinal bleeding. Its use is not recommended with other anticoagulants or in patients with a known history of bleeding. This patient has a history of ER visits for blood in the stool and urine. The patient also takes Coumadin therapy with no evidence of recent INR testing to indicate therapeutic levels. Therefore, based on the submitted medical documentation, the request for Eliquis is not-medically necessary.

Flomax 0.4mg QTY 30: 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) Flomax Indications Use and Prescribing Information http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/200603s0001bl.pdf.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of a Flomax prescription for this patient. Flomax is the name brand equivalent of generic Tamsulosin. The clinical records submitted do support the fact that this patient has bowel and bladder incontinence. However, the medical records do not support that this patient has benign prosthetic hypertrophy. The California MTUS guidelines, Occupational Disability Guidelines and the ACOEM Guidelines do not address the topic of Flomax prescription. Per the Federal Drug Administration's (FDA) prescribing guidelines, Flomax is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). This patient has been diagnosed with urinary and bowel incontinence; however, the clinical records do not indicate that he has benign prosthetic hypertrophy. Use of Flomax without BPH is off-label and not supported by current peer-reviewed literature. Therefore, based on the submitted medical documentation, the request for Flomax prescription is not-medically necessary.

Celebrex 200mg QTY 30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, specific drug list & adverse effects Page(s): 63.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 64, 66, and 102-105.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of treatment of Celebrex for this patient. The California MTUS guidelines address the topic of NSAID prescriptions by stating, A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. The MTUS guidelines do not recommend routine use of NSAIDS due to the potential for adverse side effects (GI bleeding, ulcers, renal failure, etc). This patient has a history of GI and urinary bleeding. The medical records do not support that the patient has a contraindication to other non-opioid analgesics. In fact, the patient currently takes opioids with a reported stable pain level. Therefore, medical necessity for Celebrex prescription has not been established. The request is not medically necessary.

Lasix 40mg #60: 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) Lasix Indications Use and Prescribing Information http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/016273s061lbl.pdf.

Decision rationale: There is not 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 not support the fact that this patient has congestive heart failure or uncontrolled hypertension with edema. 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 hypertension which is not associated with congestive heart failure. A recent cardiac echo demonstrated normal cardiac ejection function. Use of Lasix for treatment in this patient is not supported by the medical documentation. Therefore, based on the submitted medical documentation, the request for Lasix prescription is not medically necessary.

Loratadine 10mg # #30: 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 <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=SearchDrugDetails>.

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. According to its FDA prescribing recommendations, Loratadine is approved for the treatment of hay fever and other allergies. This patient has a history of neuropathy and chronic lower back pain after spinal cyst excision. The medical records do not support that this patient has a history of uncontrolled allergies. Therefore, based on the submitted medical documentation, the request for Loratadine is not-medically necessary.

Nitrofurantoin MCR 100mg QTY 30: 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) Nitrofurantoin Indications Use and Prescribing Information.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of a nitrofurantoin prescription for this patient. The clinical records submitted do not support the fact that this patient has an active soft tissue or urinary tract infection. The California MTUS guidelines, Occupational Disability Guidelines and the ACOEM Guidelines do not address the topic of nitrofurantoin prescription. Per the Federal Drug Administration's (FDA) prescribing guidelines for nitrofurantoin, "Culture and susceptibility tests should be initiated prior to and during therapy." Additionally, "To reduce the development of drug-resistant bacteria and maintain the effectiveness of nitrofurantoin and other antibacterial drugs, nitrofurantoin should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria." Although this patient has had urinary tract infections in the remote past, there is no indication that he currently has an active infection. Chronic use of unnecessary antibiotics can lead to diarrhea and antibiotic drug resistance. Therefore, based on the submitted medical documentation, the request for nitrofurantoin MCR 100mg prescription is not-medically necessary.

Dexilant DR 60mg QTY 30: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of a Dexilant DR prescription for this patient. 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 Dexilant DR, use 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 Dexilant DR prescription is not medically necessary.

Coumadin 4mg #30: 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 FDA Prescribing Guidelines and Indications for Coumadin <http://www.fda.gov/downloads/Drugs/DrugSafety/ucm088578.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. According to its FDA prescribing recommendations, Coumadin is a blood thinner which is associated with urinary and gastrointestinal bleeding. Its use is not recommended with other anticoagulants or in patients with a known history of bleeding. This patient has a history of ER visits for blood in the stool and urine. The patient also takes Eliquis with no evidence of recent INR testing to indicate therapeutic levels. Therefore, based on the submitted medical documentation, the request for Coumadin is not-medically necessary.

Vitamin C 250mg #60: 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) Wrist, Vitamin C.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. The California MTUS guidelines and the ACOEM do not address this topic. Per Occupational Disability Guidelines (ODG), Vitamin C is: "Vitamin C was associated with a lower risk of reflex sympathetic dystrophy" after acute fracture. This patient has a history of neuropathy and chronic lower back pain after spinal cyst excision. The patient has not had any recent acute fractures or demonstrates a vitamin C deficiency on recent labwork. Therefore, based on the submitted medical documentation, the request for Vitamin C is not-medically necessary.

Vitamin B-12 injection weekly QTY 1: 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) Pain, Chronic, B vitamins & vitamin B complex.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. The California MTUS guidelines and the ACOEM do not address this topic. Per Occupational Disability Guidelines (ODG), Vitamin B12 is: "Not recommended for the treatment of chronic pain unless this is associated with documented vitamin deficiency." This patient has a history of neuropathy and chronic lower back pain after spinal cyst excision. The patient has not had any recent blood work which demonstrates a B12 deficiency. Vitamin B12 is not indicated for chronic pain or depression treatment. Therefore, based on the submitted medical documentation, the request for Vitamin B12 weekly injections are not-medically necessary.

Creon 24,000 units #90: 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

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm149334.htm>.

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. According to its FDA prescribing recommendations, Creon is approved pancrelipase for adult and pediatric patients with exocrine pancreatic insufficiency (EPI) due to cystic fibrosis (CF) and chronic pancreatitis. This patient has a history of neuropathy and chronic lower back pain after spinal cyst excision. The patient has not had any recent blood work that demonstrates a deficiency of pancrelipase. Therefore, based on the submitted medical documentation, the request for Creon is not-medically necessary.

Fluticasone nasal spray 16 grams QTY 1: 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 fluticasone FDA Prescribing Guidelines

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/UCM235282.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. According to its FDA prescribing recommendations, fluticasone is approved for "Maintenance treatment of asthma as prophylactic therapy in patients aged 4 years and older." The medication is not approved for the treatment of non-asthma related bronchospasm. This patient has a history of neuropathy and chronic lower back pain after spinal cyst excision. The medical records do not support that this patient has a history of uncontrolled asthma. Therefore, based on the submitted medical documentation, the request for Fluticasone is not-medically necessary.

Body Wash 1 gallon QTY 1: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids & other medications Page(s): 123.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this prescription for this patient. The clinical records submitted do not support prescription of a recommended dose or frequency for use of this medication. The California MTUS guidelines address the topic of prescriptions. Per the guidelines, "There will be a limit of number of medications, and dose of specific medications." The body wash prescription requested does not have a brand name, quantity, dose or dispensing instructions provided. Therefore, based on the submitted medical documentation, the request for body wash prescription is not medically necessary.