

Case Number:	CM14-0140412		
Date Assigned:	09/10/2014	Date of Injury:	08/15/2002
Decision Date:	11/03/2014	UR Denial Date:	08/20/2014
Priority:	Standard	Application Received:	08/29/2014

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert reviewer is Board Certified in Internal Medicine and is licensed to practice in California. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The patient is an injured worker with the diagnoses of cervicalgia, cervical spondylosis, chronic neck pain, history of disc herniation and spinal stenosis at C6-C7, status post cervical spine fusion surgery. Date of injury was 08/15/2002. Primary treating physician's progress report dated 8/4/2014 documented subjective complaints of neck pain, aggravated by physical activity and relieved by resting and medications. Patient rated her pain at 8/10. She is taking Norco 5/325, Galise, Pepcid, Lorzone, Voltaren gel, Naprelan, and Lunesta. Past treatments included aqua therapy, chiropractic care, TENS unit, acupuncture, massage therapy, homeopathic therapy, nutritional counseling and cranial-sacral reflexology. Surgery history included thyroidectomy and cervical fusions 2002 and 2003. Objective findings were documented. Physical examination findings included normal speech, judgment intact, cognitive function normal, and nerves intact bilateral grossly intact. Diagnoses included cervicalgia, cervical spondylosis, chronic neck pain, history of disc herniation and spinal stenosis at C6-C7, status post cervical spine fusion surgery. Treatment plan included medications and physical therapy. Agreed medical evaluation (AME) dated May 6, 2014 documented blood pressure 150/90. Laboratory tests dated 4/10/14 demonstrated hemoglobin 10.6. Utilization review determination date was 8/20/14.

IMR ISSUES, DECISIONS AND RATIONALES

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

Pepcid 20mg #30: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation PDR Reference 2014 and www.drugs.com

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation FDA Prescribing Information Pepcid (Famotidine) <http://www.drugs.com/pro/pepcid.html> American College of Gastroenterology. Guidelines for Prevention of NSAID-Related Ulcer Complications. Am J Gastroenterol 2009; 104:728 - 738; doi: 10.1038/ajg.2009.115; published online 24 February 2009. Frank L. Lanza , MD, FACP, Francis K.L. Chan, MD, FRCP, FACP, Eamonn M.M. Quigley , MD, FACP and the Practice Parameters Committee of the American College of Gastroent

Decision rationale: The Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address NSAIDs and gastrointestinal risk factors. Proton Pump Inhibitor (PPI), e.g. Omeprazole (Prilosec), is recommended for patients with gastrointestinal risk factors. MTUS does not address Pepcid (Famotidine). American College of Gastroenterology Guidelines for Prevention of NSAID-Related Ulcer Complications (2009) reported that systematic reviews have shown that H2RA histamine-2-receptor antagonist medications are effective in reducing the risk of NSAID-induced endoscopic gastric ulcers. Economic modeling suggests that co-therapy with an H2RA may be a cost-effective strategy for prevention of ulcer bleeding in NSAID users. FDA Prescribing Information states that Pepcid (Famotidine) is indicated for gastroesophageal reflux disease (GERD). Medical records document the use of prescription Naprelan (NSAID) which is a gastrointestinal risk factor. Primary treating physician's progress report dated 8/4/2014 documented GERD and heartburn symptoms controlled with Pepcid. Pepcid (Famotidine) is a histamine-2-receptor antagonist (H2RA). The use of Pepcid with NSAIDs is supported by the American College of Gastroenterology Guidelines for Prevention of NSAID-Related Ulcer Complications (2009). Pepcid has the FDA indication for GERD. The use of Pepcid is supported by FDA and clinical practice guidelines. Therefore, the request for Pepcid 20mg #30 is medically necessary.

Naprelan 500mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal antiinflammatory drugs) .

Decision rationale: The Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines addresses NSAIDs (non-steroidal anti-inflammatory drugs). All NSAIDs have the U.S. Boxed Warning for associated risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Use of NSAIDs may compromise renal function. FDA package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile including liver and renal function tests. Routine blood pressure monitoring is recommended. It is generally recommended that the lowest

effective dose be used for all NSAIDs for the shortest duration of time. All NSAIDs have the potential to raise blood pressure in susceptible patients. Medical records document that the patient had an elevated blood pressure 150/90 on May 6, 2014. Per MTUS, NSAIDs are associated with the risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. Laboratory tests dated 4/10/14 demonstrated anemia with hemoglobin 10.6. Per MTUS, NSAIDs can cause ulcers and bleeding in the stomach and intestines. Medical records indicate the long-term use of NSAIDs. Per MTUS, it is generally recommended that the lowest dose be used for NSAIDs for the shortest duration of time. Primary treating physician's progress report dated 8/4/2014 did not document a musculoskeletal examination. No tenderness or decreased range of motion was documented. The request for Naprelan (Naproxen) is not supported. Therefore, the request for Naprelan 500mg #60 is not medically necessary.

Lorzone 750mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxant.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47-49, Chronic Pain Treatment Guidelines Chlorzoxazone Muscle relaxants Page(s): 65 63-65. Decision based on Non-MTUS Citation FDA Prescribing Information Lorzone Chlorzoxazone <http://www.drugs.com/pro/lorzone-tablets.html>

Decision rationale: The Medical Treatment Utilization Schedule (MTUS) addresses muscle relaxants. The American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) states that muscle relaxants seem no more effective than NSAIDs for treating patients with musculoskeletal problems, and using them in combination with NSAIDs has no demonstrated benefit. Muscle relaxants may hinder return to function by reducing the patient's motivation or ability to increase activity. Table 3-1 states that muscle relaxants are not recommended. Chronic Pain Medical Treatment Guidelines (Page 63-66) address muscle relaxants. Muscle relaxants should be used with caution as a second-line option for short-term treatment. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. According to a review in American Family Physician, muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. Muscle relaxant drugs with the most limited published evidence in terms of clinical effectiveness include Chlorzoxazone. FDA guidelines state that Lorzone (Chlorzoxazone) is indicated for acute musculoskeletal conditions. The mode of action of this drug has not been clearly identified. Chlorzoxazone does not directly relax tense skeletal muscles in man. Medical records indicate the long-term use of Lorzone, which is not recommended by MTUS, ACOEM, and FDA guidelines. The patient's occupational injuries are chronic, not acute. FDA guidelines state that Lorzone is indicated for acute, not chronic, conditions. MTUS, ACOEM, and FDA guidelines do not support the use of Lorzone. Therefore, the request for Lorzone 750mg #60 is not medically necessary.

Voltaren Gel #5 Tubes AAA2g: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page 111-113 NSAIDs (non-steroidal anti-inflammatory drugs) Page(s).

Decision rationale: The Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address topical analgesics. Topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. All NSAIDs have the U.S. Boxed Warning for associated risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Use of NSAIDs may compromise renal function. FDA package inserts for NSAIDs recommend periodic lab monitoring of a CBC and chemistry profile including liver and renal function tests. Routine blood pressure monitoring is recommended. It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time. All NSAIDs have the potential to raise blood pressure in susceptible patients. Medical records document that the patient had an elevated blood pressure 150/90 on May 6, 2014. Per MTUS, NSAIDs are associated with the risk of adverse cardiovascular events, including, myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. Laboratory tests dated 4/10/14 demonstrated anemia with hemoglobin 10.6. Per MTUS, NSAIDs can cause ulcers and bleeding in the stomach and intestines. Medical records indicate the long-term use of NSAIDs. Per MTUS, it is generally recommended that the lowest dose be used for NSAIDs for the shortest duration of time. Primary treating physician's progress report dated 8/4/2014 did not document a musculoskeletal examination. No tenderness or decreased range of motion was documented. The request for Voltaren (Diclofenac) gel is not supported. Therefore, the request for Voltaren Gel #5 Tubes AAA2g is not medically necessary.