

Case Number:	CM14-0107334		
Date Assigned:	08/01/2014	Date of Injury:	02/29/2012
Decision Date:	10/28/2014	UR Denial Date:	06/17/2014
Priority:	Standard	Application Received:	07/10/2014

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 cervicgia and cervical disc disorder. Date of injury was 02/29/12. Right shoulder arthroscopy was performed 6/28/13. The progress report dated 03/18/14 indicated that the patient complained of neck pain with radicular symptoms. Examination revealed tenderness at the cervical spine and trapezius muscles with spasms. Decreased range of motion was noted. The provider recommended to physical therapy and conservative treatment for the cervical spine. The progress report dated 04/29/14 indicated that the patient complained of constant cervical spine pain with radiation to the shoulders. Examination revealed tenderness at the cervical spine with spasms. Decreased range of motion was noted. Treatment plan included cervical spine epidural injection, physical therapy, and medications. Requested treatments were Naproxen, Ondansetron, Omeprazole, Orphenadrine, Tramadol, and Terocin Patch. The progress report dated 6/10/14 documented cervical spine and upper extremities pain and headaches. Diagnoses were cervical disc disorder and cervicgia. Pain medicine evaluation report dated June 24, 2014 documented that the patient has a history of hypertension controlled with medications. Subjective complaints included neck pain and low back pain. Pain was rated as 6/10 in intensity with medications. Pain was rated as 9/10 in intensity without medications. Cervical spasm and tenderness was noted. The range of motion was limited. Deep tendon reflexes in the upper extremities are within normal limits bilaterally. Utilization review determination date was 6/16/14.

IMR ISSUES, DECISIONS AND RATIONALES

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

Naproxen Na 550mg #120: 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 anti-inflammatory drugs) Page(s): 67-73.

Decision rationale: 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. 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. NSAIDs can increase blood pressure in patients with hypertension. They may cause fluid retention, edema, and congestive heart failure. Medical records document the long-term use of NSAID medications, which is not recommended by MTUS guidelines. No laboratory tests were present in the medical records. MTUS guidelines recommend monitoring of laboratory tests for patients prescribed NSAIDs. Medical records document a history of hypertension. MTUS guidelines warn against the use of NSAIDs in patients with hypertension. MTUS guidelines and medical records do not support the use of the NSAID Naproxen. Therefore, the request for Naproxen Na 550mg #120 is not medically necessary.

Ondansetron ODT 8mg 360: Upheld

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

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) Ondansetron (Zofran®) FDA Prescribing Information Zofran (Ondansetron) <http://www.drugs.com/pro/zofran.html>

Decision rationale: Medical Treatment Utilization Schedule (MTUS) does not address Zofran (Ondansetron). Official Disability Guidelines (ODG) state that Ondansetron (Zofran) is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment, and for postoperative use. Medical records do not document symptoms of nausea or vomiting associated with chemotherapy or radiation treatment or postoperative use. No cancer chemotherapy or radiotherapy was documented. Zofran was not being prescribed for postoperative use. The medical records do not support the use of Zofran (Ondansetron). Therefore, the request for Ondansetron ODT 8mg 360 is not medically necessary.

Omeprazole DR 20mg #120: Upheld

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

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

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines addresses NSAIDs and gastrointestinal risk factors. Proton Pump Inhibitor (PPI), e.g. Omeprazole, is recommended for patients with gastrointestinal risk factors. The progress report dated 6/10/14 did not document gastrointestinal symptoms. Pain medicine evaluation report dated June 24, 2014 did not document gastrointestinal symptoms. The NSAID Naproxen was determined to be not medically necessary. Therefore, Omeprazole is not medically necessary. Therefore, the request for Omeprazole DR 20mg #120 is not medically necessary.

Orphenadrine Citrate ER 100mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants for Pain. Decision based on Non-MTUS Citation Official Disability Guidelines: Muscle Relaxants

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

Decision rationale: Medical Treatment Utilization Schedule (MTUS) addresses muscle relaxants. 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. 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) addresses 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. Orphenadrine Citrate (Norflex) has been reported in case studies to be abused for euphoria and to have mood elevating effects. FDA Prescribing Information states that Orphenadrine Citrate (Norflex) is indicated for acute musculoskeletal conditions. Orphenadrine has been chronically abused for its euphoric effects. The mood elevating effects may occur at therapeutic doses of orphenadrine. Medical records indicate the long-term use of muscle relaxants for chronic conditions. MTUS and ACOEM guidelines do not recommend the long-term use of muscle relaxants. FDA guidelines states that Orphenadrine Citrate (Norflex) is indicated for

acute conditions. The medical records and MTUS, ACOEM, and FDA guidelines do not support the use of Orphenadrine Citrate (Norflex). Therefore, the request for Orphenadrine Citrate ER 100mg #120 is not medically necessary.

Tramedol HCL ER 150mg #90: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic Pain Medical Treatment Guidelines Tramadol (Ultram) Opioids Page(s): 74-96 9.

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address Ultram (Tramadol). Ultram is a centrally acting synthetic opioid analgesic. Ultram is indicated for the management of moderate to moderately severe pain. MTUS Chronic Pain Medical Treatment Guidelines (Page 89) present the strategy for maintenance for long-term users of opioids. "Do not attempt to lower the dose if it is working." Supplemental doses of break-through medication may be required for incidental pain, end-of-dose pain, and pain that occurs with predictable situations. The standard increase in dose is 25 to 50% for mild pain and 50 to 100% for severe pain. The progress report dated 6/10/14 documented cervical spine and upper extremities pain. Pain medicine evaluation report dated 6/24/14 documented subjective complaints including neck pain. Pain was rated as 6/10 in intensity with medications. Pain was rated as 9/10 in intensity without medications. Cervical spasm and tenderness was noted. The range of motion was limited. Right shoulder arthroscopy was performed 6/28/13. The medical records document significant pathology. Ultram (Tramadol) is indicated for the management of moderate to moderately severe pain. Medical records document analgesia and benefit from medications. Medical records document the stable use of Tramadol and regular clinic visits. Medical records support the maintenance of the Tramadol prescription. Medical records and MTUS guidelines support the prescription of Tramadol (Ultram). Therefore, the request for Tramadol HCL ER 150mg #90 is medically necessary.

Terocin Patch #30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Capsaicin, topical NSAIDs Terocin <http://www.drugs.com/pro/teroc>. Decision based on Non-MTUS Citation Terocin <http://www.drugs.com/pro/terocin.html>

Decision rationale: Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines addresses 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. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Capsaicin is only an option in patients who have not responded or are intolerant to other treatments. Besides

Lidoderm, no other commercially approved topical formulation of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Further research is needed to recommend topical Lidocaine for chronic neuropathic pain disorders other than post-herpetic neuralgia. Topical Lidocaine is not recommended for non-neuropathic pain. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. The efficacy in clinical trials of topical NSAIDs has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be either not superior to placebo after two weeks, or with a diminishing effect after two weeks. For osteoarthritis of the knee, topical NSAID effect appeared to diminish over time. There are no long-term studies of their effectiveness or safety for chronic musculoskeletal pain. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Topical NSAIDs are not recommended for neuropathic pain as there is no evidence to support use. All NSAIDs have the U.S. Boxed Warning for associated risk of adverse cardiovascular events, including, MI, 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 (FDA Medication Guide). Use of NSAIDs may compromise renal function. FDA medication guide recommends 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. Terocin is a topical analgesic, containing methyl salicylate, capsaicin, menthol and lidocaine hydrochloride. Medical records document the long-term use of NSAID medications, which is not recommended by MTUS guidelines. No laboratory tests were present in the medical records. MTUS guidelines recommend monitoring of laboratory tests for patients prescribed NSAIDs. Medical records document a history of hypertension. MTUS guidelines warn against the use of NSAIDs in patients with hypertension. MTUS guidelines and medical records do not support the use of the NSAIDs. Methyl salicylate is a NSAID. There is no documentation that the patient has not responded or is intolerant to other treatments. This is a requirement for the use of topical Capsaicin. There was no documentation of post-herpetic neuralgia. Further research is needed to recommend topical Lidocaine for chronic neuropathic pain disorders other than post-herpetic neuralgia. Topical Lidocaine is not recommended for non-neuropathic pain. Per MTUS guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. MTUS guidelines and medical records do not support the medical necessity of topical Lidocaine, Capsaicin, or Methyl Salicylate, which are active ingredients in Terocin. Therefore, the request for Terocin Patch #30 is not medically necessary.