

Case Number:	CM15-0115919		
Date Assigned:	06/24/2015	Date of Injury:	11/15/2011
Decision Date:	09/18/2015	UR Denial Date:	05/28/2015
Priority:	Standard	Application Received:	06/16/2015

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: Maryland, Texas, Virginia

Certification(s)/Specialty: Internal Medicine, Allergy and Immunology, Rheumatology

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 47-year-old male, who sustained an industrial injury on 11/15/11. He reported initial complaints of cumulative type injures to left shoulder and low back. The injured worker was diagnosed as having cervical discopathy; status post left shoulder surgery; shoulder impingement left greater than right; lumbar discopathy. Treatment to date has included status post left shoulder surgery; left shoulder injections (3/31/15) medications. Currently, the PR-2 notes dated 3/31/15 indicated the injured worker came to this office on this date for an orthopedic re-evaluation. The injured worker reports frequent flare-ups of left shoulder pain. The pain is reported as frequent and aggravated by forward reaching, lifting, pushing, pulling and working at or above the left shoulder level. It is characterized as throbbing and recently worsening with pain level 5/10. He reports frequent cervical spine pain that is aggravated by repetitive motions of the neck, pushing, pulling, lifting, forward reaching and working above his shoulder level. The pain is characterized as sharp and radiating to the upper extremities and can be associated with migrainous headaches as well as tension between the shoulder blades. The pain is unchanged and rates 5/10. He has constant pain in the right shoulder that is also aggravated by forward reaching, lifting, pushing, pulling and working at or above the right shoulder level. It is characterized as throbbing with pain level 7/10. On physical examination of the cervical spine there is palpable paravertebral muscle tenderness with spasm. A positive axial loading compression test is noted and Spurling's is found to be positive. He has limited range of motions due to pain. The left shoulder notes a well-healed scar with tenderness at the left shoulder anteriorly. His range of motion notes pain with terminal motion. There is no swelling or

instability on exam. The right shoulder notes tenderness around the anterior glenohumeral region and subacromial space. Hawkin's and impingement signs are positive. His rotator cuff function appears intact albeit painful. There is reproducible symptomology with internal rotation and forward flexion and no evidence of instability on exam and no swelling. The lumbar spine notes palpable paravertebral muscle tenderness with spasm. Seated nerve root test is positive. Standing flexion and extension are guarded and restricted with no clinical evidence of instability on examination. There is tingling and numbness in the lateral thigh, anterolateral leg and foot and L5 dermatomal pattern. The injured worker reports a giving way of his legs and dragging of his feet which is further proof of progression of neurologic deficit noted by this provider. On this date, the provider administered an injection of Celestone, Lidocaine and Marcaine into the left shoulder. The provider has requested authorization of: Cyclobenzaprine hydrochloride 7.5mg #120; Fenopropfen calcium (Nalfon) 400mg #120; Lansoprazole (Prevacid) delayed-release 30mg #120; Ondansetron 8mg #30 and Tramadol ER 150mg #90.

IMR ISSUES, DECISIONS AND RATIONALES

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

Cyclobenzaprine Hydrochloride 7.5mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain), Antispasmodics, Cyclobenzaprine, Weaning of Medications Page(s): 64, 124.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Medications for chronic pain, Antispasmodics Page(s): 41-42, 60-61, 64-66. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Cyclobenzaprine (Flexeril®) and Other Medical Treatment Guidelines UpToDate, Flexeril.

Decision rationale: MTUS Chronic Pain Medical Treatment states for Cyclobenzaprine, "Recommended as an option, using a short course of therapy. . . The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. (Browning, 2001) Treatment should be brief." "The medication is not recommended to be used for longer than 2-3 weeks." The medical documents indicate that patient is far in excess of the initial treatment window and period. Additionally, MTUS outlines that "Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity. Before prescribing any medication for pain the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) Uptodate "flexeril" also recommends "Do not use longer than 2-3 weeks". Medical documents do not fully detail the components outlined in the guidelines above and do not establish the need for long term/chronic usage of cyclobenzaprine. ODG states regarding cyclobenzaprine, "Recommended as an option, using a short course of therapy . . . The addition of cyclobenzaprine to other agents is not recommended." Several other pain medications are being requested, along with cyclobenzaprine, which ODG recommends against. As such, the request for Cyclobenzaprine hydrochloride 7.5mg #120 is not medically necessary.

Tramadol ER 150mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Tramadol, Criteria for use, On-Going management, Weaning of Medications Page(s): 93-94, 78-80, 124.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Tramadol, Ultram Page(s): 74-96, 113, 123. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) - Medications for acute pain (analgesics), Tramadol (Ultram®).

Decision rationale: Tramadol is classified as a central acting synthetic opioids. MTUS states regarding tramadol that "A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals." ODG further states, "Tramadol is not recommended as a first-line oral analgesic because of its inferior efficacy to a combination of Hydrocodone/ acetaminophen." The treating physician did not provide sufficient documentation that the patient has failed a trial of non-opioid analgesics at the time of prescription or in subsequent medical notes. Additionally, no documentation was provided which discussed the setting of goals for the use of tramadol prior to the initiation of this medication. MTUS states that "ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." The treating physician does not fully document the least reported pain over the period since last assessment, intensity of pain after taking opioid, pain relief, increased level of function, or improved quality of life. As such, the request for Tramadol ER 150mg #90 is not medically necessary.

Fenoprofen calcium (Nalfon) 400mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs), Fenoprofen Page(s): 67-68, 72.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67-72. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Fenoprofen (Nalfon®).

Decision rationale: Tramadol is classified as a central acting synthetic opioids. MTUS states regarding tramadol that "A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals." ODG further states, "Tramadol is not recommended as a first-line oral analgesic because of its inferior efficacy to a combination of Hydrocodone/ acetaminophen." The treating physician did not provide sufficient documentation that the patient has failed a trial of non-opioid analgesics at the time of prescription or in subsequent medical notes. Additionally, no documentation was provided which discussed the setting of goals for the use of tramadol prior to the initiation of this medication. MTUS states that "ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current

pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." The treating physician does not fully document the least reported pain over the period since last assessment, intensity of pain after taking opioid, pain relief, increased level of function, or improved quality of life. As such, the request for Tramadol ER 150mg #90 is not medically necessary.

Lansoprazole (Prevacid) delayed-release 30mg #120: Upheld

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

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 Official Disability Guidelines (ODG) Pain (Chronic), NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: MTUS states "Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA)." And "Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44)." ODG states "If a PPI is used, omeprazole OTC tablets or lansoprazole 24HR OTC are recommended for an equivalent clinical efficacy and significant cost savings. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi, 2008) A trial of omeprazole or lansoprazole is recommended before Nexium therapy. The other PPIs, Protonix, Dexilant, and Aciphex, should also be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. (AHRQ, 2011)" The medical documents fail to demonstrate any of the above indications. As such, the request for Lansoprazole (Prevacid) delayed-release 30mg #120 is not medically necessary.

Ondansetron 8mg #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Antiemetics (for opioid nausea), Ondansetron (Zofran).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants, NSAIDs, GI symptoms, opioids Page(s): 68-69, 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, Antiemetics (for opioid nausea).

Decision rationale: Ondansetron (Zofran) is an antiemetic used to decrease nausea and vomiting. Nausea is a known side effect of chronic opioid use and some Serotonin norepinephrine reuptake inhibitors (SNRIs). ODG does not recommend use of antiemetic for

"nausea and vomiting secondary to chronic opioid use. Additionally, "This drug is a serotonin 5-HT3 receptor antagonist. It is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also FDA-approved for postoperative use." There is no evidence that patient is undergoing chemotherapy/radiation treatment or postoperative. MTUS is specific regarding the gastrointestinal symptoms related to NSAID usage. If criteria are met, the first line treatment is to discontinue usage of NSAID, switch NSAID, or consider usage of proton pump inhibitor. There is no documentation provided that indicated the discontinuation of NSAID or switching of NSAID occurred. Additionally, ondansetron is not a proton pump inhibitor and is not considered first line treatment. As such the request for Ondansetron 8mg #30 is not medically necessary.