

Case Number:	CM15-0115639		
Date Assigned:	06/23/2015	Date of Injury:	08/14/2013
Decision Date:	09/17/2015	UR Denial Date:	05/26/2015
Priority:	Standard	Application Received:	06/15/2015

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 (IW) is a 46 year old male who sustained an industrial injury on 08/14/2013. He reported neck pain, left shoulder pain, low back pain, and right ankle pain. The injured worker was diagnosed as having right ankle pain, rule out internal derangement; cervical/lumbar discopathy; cervicgia; rule out internal derangement left shoulder; and rule out internal derangement right ankle. Treatment to date has included medications, MRI of the lumbar, cervical spine, and MRI of the right ankle. Currently, the injured worker complains of neck pain rated at 8/10 with radiation into the left upper extremity with numbness and tingling; throbbing left shoulder pain rated 7/10 that is aggravated by forward reaching, pushing, pulling, and working at or above the shoulder level, low back pain rated 5/10 that is characterized as sharp, and is aggravated by pushing, pulling, prolonged sitting, prolonged standing, and walking multiple blocks, and right ankle pain rated 8/10 that is aggravated by ascending and descending stairs and is characterized as dull/burning. These complaints were unchanged from prior examinations. On examination the cervical spine has palpable paravertebral muscle tenderness with spasm, a positive Spurling's maneuver, and positive axial loading compression. There is extension of symptomology in the upper extremities with signs and symptoms consistent with double crush and carpal tunnel syndrome. Range of motion is limited by pain. There is tingling and numbness correlating with a C6-C7 dermatomal pattern. The left shoulder has tenderness around the anterior glenohumeral region and subacromial space. Rotator cuff function appears intact but painful. Hawkins and impingement signs are positive. The lumbar spine has palpable paravertebral muscle tenderness with spasm. Seated nerve root test is positive. Range of motion

is guarded and restricted. Coordination and balance are intact. There is tenderness over the anterior portion of the ankle. Range of motion is full but painful. The strength and stability are normal and there is no apparent swelling. The treatment plan includes upper and lower extremity Electromyogram/Nerve conduction velocity testing, and medications. A request for authorization is made for: 1. 120 Nalfon 400mg, 2, 120 Lansoprazole 30mg, 3. 30 Ondansetron 8mg, 4. 120 Cyclobenzaprine 7.5mg, 5. 90 Tramadol ER 150mg.

IMR ISSUES, DECISIONS AND RATIONALES

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

120 Nalfon 400mg: Upheld

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

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: MTUS recommends the use of NSAIDS for the acute exacerbation of back pain at the lowest effective dose for the shortest amount of time due to the increased cardiovascular risk, renal, hepatic and GI side effects associated with long-term use. Fenoprofen (Nalfon, generic available): 200, 600 mg. Dosing: osteoarthritis; (off-label use for ankylosing spondylitis); 300- 600mg PO 3 to 4 times per day (Max daily dose is 3200mg). Improvement may take as long as 2 to 3 weeks. Mild to moderate pain (off-label use for bone pain): 200mg PO every 4 to 6 hours as needed. The patient does have documented back pain. Medical records do indicate that the patient has been on NSAID for several years and would not be considered shortest amount of treatment time. Additionally, the medical records do not subjectively define the pain well and does not subjectively or objectively annotate improvement. As such, the request for 120 Nalfon 400mg is not medically necessary.

120 Iansoprazole 30mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Proton pump inhibitors (PPI).

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 provided do not establish the patient has having documented GI bleeding/perforation/peptic ulcer or other GI risk factors as outlined in MTUS. Additionally, there is no evidence provided to indicate the patient suffers from dyspepsia because of the present medication regimen. As such, the request for 120 lansoprazole 30mg is not medically necessary.

30 Ondansetron 8mg: Upheld

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

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 30 ondansetron 8mg is not medically necessary.

120 Cyclobenzaprine 7.5mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril).

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 120 cyclobenzaprine 7.5mg is not medically necessary.

90 Tramadol ER 150mg: Upheld

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

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: TrTramadol 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 90 Tramadol ER 150mg is not medically necessary. 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 90 Tramadol ER 150mg is not medically necessary.