

Case Number:	CM15-0120248		
Date Assigned:	06/30/2015	Date of Injury:	10/09/2014
Decision Date:	09/21/2015	UR Denial Date:	05/27/2015
Priority:	Standard	Application Received:	06/22/2015

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: Indiana

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

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 62-year-old female who sustained an industrial injury on 10/09/2014. Mechanism of injury was cumulative. Diagnoses include cervical/lumbo discopathy, cervicgia, carpal tunnel/double crush syndrome, and rule out internal derangement of the bilateral shoulders. Treatment to date has included diagnostic studies, medications, and she is awaiting cervical epidural steroid injection. The injured worker continues to work light duty. Electromyography and Nerve conduction studies done on 03/03/2015 showed a normal finding. Magnetic Resonance Imaging of the cervical spine done on 01/13/2015 revealed multilevel disc changes, with facet joint arthropathy on the right and left at C4-C5 and C5-C6. There is compromise of exiting nerve roots at C3-C4, C4-C5, C5-C6 and C6-C7 on the left and C5-C6 on the right. A physician progress note dated 03/31/2015 documents the injured worker has constant pain in the cervical spine and it is aggravated by her heavy case load at work the pain is sharp a radiates to the upper back and into the upper extremities, right greater than left, with associated tingling and numbness. Cervical range of motion is restricted and painful. She has tenderness to palpation. She has tingling and numbness into the anterolateral shoulder and arm, lateral forearm and hand, greatest over the thumb and the middle finger which correlates with a C5-6, C6-7 dermatomal pattern. She also has headaches that are migrainous in nature as well as tension in between the shoulder blades. She rates her pain as 8 out of 10 on the pain scale. There is tenderness in the upper extremities which is consistent with a possible double crush, right side greater than left. There is a positive palmar compression test subsequent to Phalen's maneuver, and positive Tinel's. She has constant low back pain that radiates to the upper back

and rates her pain as 8 out of 10 on the pain scale. The lumbar spine range of motion is restricted and painful. She has tingling and numbness in the lateral thigh, anterolateral and posterior leg as well as the foot, which correlates with an L5 and S1 dermatomal pattern. She has right greater than left shoulder pain that is characterized as throbbing and burning and rates it as 8 out of 10. She has positive Hawking and impingement sign with the right shoulder being greater than the left shoulder pain. The injured worker has right elbow pain that is associated with tingling and numbness and rates it as 7 out of 10. She has frequent right wrist, hand, and finger pain that are throbbing and there is swelling present. This pain is rated as 7 out of 10. Treatment requested is for Cyclobenzaprine hydrochloride 7.5 mg Qty 120, Fenoprofen calcium (Nalfon) 400 mg Qty 120, Lansoprazole (Prevacid) 30 mg Qty 120, Ondansetron 8 mg ODT (orally disintegrating tablet) Qty 30, Sumatriptan succinate 25 mg Qty 9 (x2), and Tramadol ER (extended release) 150 mg Qty 90.

IMR ISSUES, DECISIONS AND RATIONALES

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

Fenoprofen calcium (Nalfon) 400 mg Qty 120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non steroidal anti inflammatory drugs).

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 Fenoprofen Calcium 400mg #120 is not medically necessary.

Lansoprazole (Prevacid) 30 mg Qty 120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs; GI 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 is not medically necessary.

Ondanestron 8 mg ODT (orally disintegrating tablet) Qty 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: Pain - Antiemetics, Zofran.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, Antiemetics (for opioid nausea).

Decision rationale: Odansteron (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 anti-emetic 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 post-operative. 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, odansteron is not a proton pump inhibitor and is not considered first line treatment. As such the request is not medically necessary.

Cyclobenzaprine hydrochloride 7.5 mg Qty 120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine; antispasmodics Page(s): 41-66. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Cyclobenzaprine (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 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 anti-depressants 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. Therefore, the request is not medically necessary.

Tramadol ER (extended release) 150 mg Qty 90: 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 Page(s): 74-110. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) - Medications for acute pain (analgesics), Tramadol (Ultram®).

Decision rationale: Ultram is the brand name version of tramadol, which is classified as 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. As such, the request is not medically necessary.

Sumatriptan succinate 25 mg Qty 9 (x2): Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Head, Triptans.

Decision rationale: MTUS and ACOEM are silent with regards to sumatriptan (immitrex). Other guidelines were utilized. ODG states regarding sumatriptan, "Recommended for migraine sufferers." The records presented for review indicate the prescription of sumatriptan was for the treatment of migraines but they do not document the diagnosis of migraines. They indicate that the headaches are directly related to cervical pain and increase with an increase of that pain. This would indicate that the headaches are cervicogenic in nature and would not require the use of, nor benefit from, a serotonin 5-HT 1 receptor agonist. Therefore, the request for sumatriptan is deemed not medically necessary.