

Case Number:	CM15-0123822		
Date Assigned:	07/08/2015	Date of Injury:	08/27/2009
Decision Date:	09/21/2015	UR Denial Date:	06/10/2015
Priority:	Standard	Application Received:	06/26/2015

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 44-year-old female who sustained a work related injury August 27, 2009. Past history included lumbar surgery and fibroid surgery. A consulting physician's progress report, dated January 26, 2015, found the injured worker dealing with a medical issue, bleeding due to fibroids in the uterus. Her back continued to be painful and she continues with pain management and avoidance of activities. Physical examination revealed a well-healed midline lumbar incision with swelling in the area. There was diffuse tenderness in the lower back with deep palpation and limited lumbar range of motion due to pain. There is tightness in the hamstrings at 70 degrees bilaterally but not a frank straight leg sign and no motor or sensory deficits. Diagnosis is documented as lumbar psuedoarthrosis at L4-5 and L5-S1 with lumbar flat back deformity. According to a primary treating physician's progress report, June 4, 2015, after surgery the injured worker had a lot of pain and did not get a patch from the surgeon. She is near being out of Fentanyl. Current medication besides Fentanyl included Norco, Cymbalta, Xanax, Soma, and Prevacid. Objective findings stated gait remains slow and using a rolling walker. There is a continued area of pain in the back. Diagnoses are degeneration lumbar/lumbosacral; post-laminectomy syndrome, lumbar; chronic pain syndrome; dysthymic disorder. Treatment plan included a request for Cymbalta, Xanax, Soma, Prevacid, Fentanyl patch, and Norco.

IMR ISSUES, DECISIONS AND RATIONALES

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

Cymbalta 30mg, qty 90 with 2 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain interventions and treatments Page(s): 15-16.

Decision rationale: MTUS state regarding antidepressants for pain, "Recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. (Feuerstein, 1997) (Perrot, 2006) Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Analgesia generally occurs within a few days to a week, whereas antidepressant effect takes longer to occur". The treating physician does not indicate failure of first-line agents and does not indicate how a first line agent is ineffective, poorly tolerated, or contraindicated. MTUS states regarding Cymbalta: "Selective serotonin and norepinephrine reuptake inhibitors (SNRIs): Duloxetine (Cymbalta): FDA-approved for anxiety, depression, diabetic neuropathy, and fibromyalgia. Used off-label for neuropathic pain and radiculopathy; Duloxetine is recommended as a first-line option for diabetic neuropathy. (Dworkin, 2007) No high quality evidence is reported to support the use of duloxetine for lumbar radiculopathy. (Dworkin, 2007) More studies are needed to determine the efficacy of duloxetine for other types of neuropathic pain. Side effects: CNS: dizziness, fatigue, somnolence, drowsiness, anxiety (3% vs. 2% for placebo), insomnia (8-13% vs. 6-7% for placebo). GI: nausea and vomiting (5-30%), weight loss (2%). Trial period: Some relief may occur in first two weeks; full benefit may not occur until six weeks. Withdrawal effects can be severe. Abrupt discontinuation should be avoided and tapering is recommended before discontinuation". Cymbalta is FDA approved for the treatment of depression and requires continued monitoring for effectiveness per MTUS guidelines. Thus 2 refills would indicate 90 days without additional interim reevaluation. As such, the request for Cymbalta 30mg #30 with 2 refills is not medically necessary.

Xanax 0. 5mg qty 120 with 2 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness, Benzodiazepines.

Decision rationale: MTUS and ODG states that benzodiazepine (i.e. Lorazepam) is "Not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks". ODG further states regarding Lorazepam "Not recommended". The requested amount is in excess of the guidelines. The medical record does not provide any extenuating circumstances to recommend exceeding the guideline recommendations. As such, the request is not medical necessary.

Soma 350mg qty 90 with 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Carisoprodol (Soma).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants; Soma Page(s): 29, 63-66. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, Soma (Carisoprodol).

Decision rationale: MTUS states regarding Carisoprodol, "Not recommended. This medication is not indicated for long-term use. Carisoprodol is a commonly prescribed, centrally acting skeletal muscle relaxant whose primary active metabolite is meprobamate (a schedule-IV controlled substance). Carisoprodol is now scheduled in several states but not on a federal level. It has been suggested that the main effect is due to generalized sedation and treatment of anxiety. Abuse has been noted for sedative and relaxant effects. In regular abusers the main concern is the accumulation of meprobamate. Carisoprodol abuse has also been noted in order to augment or alter effects of other drugs". ODG States that Soma is "Not recommended. This medication is FDA-approved for symptomatic relief of discomfort associated with acute pain in musculoskeletal conditions as an adjunct to rest and physical therapy (AHFS, 2008). This medication is not indicated for long-term use". Guidelines do not recommend long term usage of SOMA. Treating physician does not detail circumstances that would warrant extended usage. The requested amount is in excess of the guidelines. As such, the request is not medically necessary.

Prevacid 30mg qty 30 with 2 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG-TWC, Proton pump inhibitors (PPI's).

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 (200g 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.

Fentanyl patch 75mg qty 20 with 2 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Fentanyl; opioids Page(s): 44, 79. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Opioids, Specific drug list.

Decision rationale: CA MTUS states and ODG agrees: "Not recommended as a first-line therapy. Duragesic is the trade name of a fentanyl transdermal therapeutic system, which releases fentanyl, a potent opioid, slowly through the skin . . . The FDA-approved product labeling states that Duragesic is indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by other means". ODG does not recommend the use of opioids "except for short use for severe cases, not to exceed 2 weeks". The patient has exceeded the 2 week recommended treatment length for opioid usage. MTUS does not discourage use of opioids past 2 weeks, but does state 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 include pain assessments and includes current, least, and average. The treatment notes indicate consistent pain rating between 7-10 and patient cites an average of 10 out of 10 on the pain scale. It is clear that the current treatment regimen is not beneficial to the patient. With the multiple pain medications, there is serious risk of opioid dependence. Weaning from this regimen should occur. As such, the request is not medically necessary.

Norco 10/325mg qty 180: Upheld

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

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) Neck and Upper Back (Acute and Chronic), Low Back - Lumbar & Thoracic (Acute & Chronic), Opioids, Pain.

Decision rationale: ODG does not recommend the use of opioids for neck and low back pain "except for short use for severe cases, not to exceed 2 weeks". The patient has exceeded the 2 week recommended treatment length for opioid usage. MTUS does not discourage use of opioids past 2 weeks, but does state 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 Norco 325/10mg # 180 is not medically necessary.