

Case Number:	CM15-0135390		
Date Assigned:	07/23/2015	Date of Injury:	08/08/2008
Decision Date:	09/18/2015	UR Denial Date:	06/26/2015
Priority:	Standard	Application Received:	07/13/2015

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 61 year old male who sustained an industrial injury on 8-8-08. Diagnoses are cervical radiculopathy , cervical disk disease, status post C5-C7 anterior cervical fusion with retained removal of painful hardware and dysphagia, status post removal of painful hardware 5-8-15. In an agreed medical reevaluation dated 2-27-14, the physician notes that the injured worker states that following his 11-9-10 revision fusion of the cervical spine anterior cervical interbody fusion C5 through C7, he has had substantial issues swallowing and he was recommended to see a specialist. On 10-26-11, he was a referred to see an otolaryngologist who provided him with trials of Reglan and Zantac. Due to spinal complaints, he reports at times he was only sleeping one hour at a time and also notes he chokes on his saliva and has difficulty swallowing food. He notes severe dry mouth and as a consequence of prolonged medication intake, and he has lost 2 teeth. An operative report notes removal of painful hardware on 5-8-15. Previous treatment includes medication, physical therapy, home exercise, cervical steroid epidural injection 4-27-15, and surgery. The requested treatment is Nabumetone 750mg #120, Lansoprazole DR 30mg #120, Cyclobenzaprine 7.5mg #120, Acetaminophen-Codeine #4- #60, Tramadol HCL ER 150mg #90.

IMR ISSUES, DECISIONS AND RATIONALES

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

Nabumetone 750mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs), NSAIDs, GI symptoms & cardiovascular risk, Nabumetone.

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, NSAIDs.

Decision rationale: MTUS and ODG state regarding NSAIDs for osteoarthritis, "Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy." For acute back pain, "Recommended as a second-line treatment after acetaminophen." For chronic back pain, "Recommended as an option for short-term symptomatic relief." For neuropathic pain, "There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in with neuropathic pain." MTUS states "Nabumetone (Relafen, generic available): 500, 750 mg. Dosing: Osteoarthritis: The recommended starting dose is 1000 mg PO. The dose can be divided into 500 mg PO twice a day. Additional relief may be obtained with a dose of 1500 mg to 2000 mg per day. The maximum dose is 2000 mg/day. Patients weighing less than 50 kg may be less likely to require doses greater than 1000 mg/day. The lowest effective dose of nabumetone should be sought for each patient. Use for moderate pain is off-label. (Relafen Package Insert)." While guidelines do not specifically state the use of Nabumetone in regards to synovitis or wrist pain, it does state that Tylenol is preferred in many cases as first line. The medical documents state that multiple other pain medications were attempted, however, the names of the medications were not included nor were the results. Additionally, medical records do not indicate any significant improvement in pain, quality of life, or functionality. The patient has been prescribed Relafen for a period of time that would no longer be considered short-term therapy. The treating physician has not provided justification to exceed MTUS guidelines. As such, the request for Nabumetone 750 MG is not medically necessary.

Lansoprazole Dr 30mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Prilosec, Proton pump inhibitors.

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 ug 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 24 HR 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.

Cyclobenzaprine 7.5mg #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Flexeril, anti-spasmodics 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 antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) Up-to-date "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 is not medically necessary.

Acetaminophen-Codeine #4 #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Codeine, On-Going Management of Opioid Use.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Codeine Page(s): 35. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, (Tylenol with Codeine®).

Decision rationale: MTUS and ODG state regarding codeine, "Recommended as an option for mild to moderate pain, as indicated below. Codeine is a schedule C-II controlled substance. It is similar to morphine. 60 mg of codeine is similar in potency to 600 mg of acetaminophen. It is widely used as a cough suppressant. It is used as a single agent or in combination with acetaminophen (Tylenol with Codeine) and other products for treatment of mild to moderate pain." ODG further states regarding opioid usage, "Not recommended as a first-line treatment for chronic non-malignant pain, and not recommended in patients at high risk for misuse, diversion, or substance abuse. Opioids may be recommended as a 2nd or 3rd line treatment option for chronic non-malignant pain, with caution, especially at doses over 100 mg morphine equivalent dosage/day (MED)." The medical records do not indicate what first-line treatment was tried and failed. Additionally, medical records do not detail how the patient's pain and functional level with Tylenol with Codeine has improved. As such, the request for Tylenol with Codeine is not medically necessary.

Tramadol HCL ER 150mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids; Tramadol Page(s): 74-123. 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. The original utilization review recommended weaning and modified the request, which is appropriate. As such, the request for tramadol is not medically necessary.