

Case Number:	CM15-0005372		
Date Assigned:	01/20/2015	Date of Injury:	01/20/2011
Decision Date:	03/25/2015	UR Denial Date:	12/11/2014
Priority:	Standard	Application Received:	01/09/2015

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: Pennsylvania
 Certification(s)/Specialty: Internal 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 46 year old male who suffered an industrial related injury on 1/20/11. The injured worker had complaints of upper extremity pain. Intermittent pain in the cervical spine, left shoulder, and low back was also noted. Diagnoses included cervicgia status post C4-5 anterior cervical discectomy and fusion, lumbago status post L4-5 posterior lumbar interbody fusion, status post removal of lumbar spinal hardware, left wrist internal derangement, bilateral carpal tunnel syndrome, and shoulder impingement. The injured worker was treated with physical therapy, surgery as noted, and medications. The PR2 reports from December 2013 to November 2014 were submitted. Medications in March 2014 included naproxen, flexeril, omeprazole, tramadol, and ondansetron. In November 2014, the injured worker had ongoing pain; the physician documented that the medications were helping to relieve the injured worker's symptoms and improving activities of daily living and making it possible for him to continue working and/or maintain the activities of daily living, but specific activities of daily living were not discussed. Work status was noted as modified. Examination showed paravertebral tenderness and spasm in the cervical spine with negative Spruling's maneuver and normal sensation and strength, tenderness over the volar aspect of the wrist with positive Phalen's and Tinel's sign and diminished sensation in the radial digits, and paravertebral muscle tenderness and spasm in the lumbar spine with normal strength and sensation. The treating physician requested authorization for Fenoprofen calcium (Nalfon) 400mg #120, Omeprazole 2mg #120, Ondansetron 8mg #30, Cyclobenzaprine Hydrochloride 7.5mg #120, Tramadol 150mg #90, and Eszopiclone 1mg #30. Ondansetron was noted to be prescribed for nausea associated with headaches, omeprazole

was noted to be prescribed for GI symptoms and for prevention of gastrointestinal (GI) complications from pain and anti-inflammatory medications, eszopiclone was noted to be prescribed for treatment of insomnia related to pain condition, tramadol was noted to be prescribed for acute exacerbation of chronic pain, and fenoprofen was noted to be prescribed for inflammation and pain. On 12/11/14, Utilization Review (UR) noncertified requests for fenoprofen, omeprazole, ondansetron, tramadol, and eszopiclone, and modified the request for #120 cyclobenzaprine 7.5 mg to #60 cyclobenzaprine 7.5 mg, citing the MTUS and ODG. Regarding Fenoprofen calcium, UR noted the medical records failed to reveal a clear clinical rationale to support the use of this nonsteroidal anti-inflammatory agent (NSAID) as opposed to safer and more commonly prescribed NSAIDs. Regarding Omeprazole, UR noted the injured worker did not present with any of the risk factors that would warrant the use of a proton pump inhibitor. Regarding Ondansetron, UR noted the use of this medication is only warranted under specific indication with chemotherapy, immediate post-operative states, and radiation therapy. Regarding Cyclobenzaprine, UR noted the requested quantity of this medication exceeded guideline recommendations therefore the quantity was modified to certify a quantity of 60. Regarding Tramadol, UR noted due to the lack of evidence of functional improvement and the guideline recommendation that this medication is for short-term use. Regarding Eszopiclone, UR noted the most current medical report did not reveal subjective complaints of sleep disturbance or insomnia.

IMR ISSUES, DECISIONS AND RATIONALES

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

Fenoprofen calcium (Nalfon) #120 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): p. 67-73.

Decision rationale: Per the MTUS, nonsteroidal anti-inflammatory drugs (NSAIDs) are recommended as a second line treatment after acetaminophen for treatment of acute exacerbations of chronic back pain. NSAIDs are noted to have adverse effects including gastrointestinal side effects and increased cardiovascular risk; besides these well-documented side effects of NSAIDs, NSAIDs have been shown to possibly delay and hamper healing in all the soft tissues including muscles, ligaments, tendons, and cartilage. NSAIDs can increase blood pressure and may cause fluid retention, edema, and congestive heart failure; all NSAIDS are relatively contraindicated in patients with renal insufficiency, congestive heart failure, or volume excess. They are recommended at the lowest dose for the shortest possible period in patients with moderate to severe pain. The MTUS does not recommend chronic NSAIDs for low back pain, NSAIDs should be used for the short term only. Systemic toxicity is possible with NSAIDs. The FDA and MTUS recommend monitoring of blood tests and blood pressure. There is no evidence that the prescribing physician is monitoring blood tests for toxicity as recommended by the FDA and MTUS. NSAIDS have been prescribed for at least 9 months, along with multiple additional medications, without documentation of specific functional improvement related to use.

Ongoing back and neck pain were noted, and there was no change in work restrictions or decrease in the frequency of office visits or decrease in use of other medications. Due to long term use not in accordance with the guidelines, and lack of demonstration of functional improvement, the request for fenoprofen is not medically necessary.

Omeprazole 20mg #120: 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 (Chronic)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): p. 68.

Decision rationale: Co-therapy with a nonsteroidal anti-inflammatory medication (NSAID) and a proton pump inhibitor (PPI) is not indicated in patients other than those at intermediate or high risk for gastrointestinal events (including age > 65 years, history of peptic ulcer, gastrointestinal (GI) bleeding or perforation, concurrent use of aspirin, corticosteroids and/or an anticoagulant, or high dose/multiple NSAIDs such as NSAID plus low dose aspirin). Long term proton pump inhibitor (PPI) use (> 1 year) has been shown to increase the risk of hip fracture. The documentation indicates that omeprazole was prescribed for GI symptoms and for prevention of gastrointestinal (GI) complications from pain and anti-inflammatory medications. No GI symptoms were discussed and no abdominal examination was documented. The injured worker was not documented to have any of the risk factors for GI events noted above. Due to lack of indication in accordance with the guidelines, the request for omeprazole 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 Herr K, Bjoro K, Steffensmeier J, Rakel B. Acute pain management in older adults. Iowa City (IA): University of Iowa Gerontological Nursing Interventions Research Center, Research Translation and Dissemination Core; 2006 Jul. Tipton JM, McDaniel RQW, Barbour L, Johnston MP, Kayne M, Leroy P, Ripple ML. Putting evidence into practice: evidence-based interventions to prevent, manage, and treat chemotherapy-induced nausea and vomiting. Clin J Oncol Nurs 2007 Feb.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation chronic pain chapter: antiemetics

Decision rationale: The MTUS does not provide direction for the use of antiemetics. The Official Disability Guidelines recommends against their use for nausea presumed to be caused by chronic opioid intake. Ondansetron is FDA approved for nausea caused by chemotherapy and radiation treatment, postoperative use, and acute gastroenteritis. Ondansetron was currently noted to be prescribed for nausea associated with headaches. Previous documentation from March of 2014 noted that ondansetron was prescribed for nausea as a side effect of

cyclobenzaprine and other analgesic agents. This injured worker does not have an FDA-approved indication for use of ondansetron. The necessary indications are not present per the available guidelines and evidence and the request for ondansetron is not medically necessary.

Cyclobenzaprine Hydrochloride 7.5mg #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines cyclobenzaprine p. 41-42 muscle relaxants p. 63-66.

Decision rationale: The MTUS for chronic pain does not recommend muscle relaxants for chronic pain. Non-sedating muscle relaxants are an option for short-term exacerbations of chronic low back pain. The muscle relaxant prescribed in this case is sedating. The injured worker has chronic pain with no evidence of prescribing for flare-ups. Cyclobenzaprine has been prescribed for at least 9 months. The quantity prescribed implies long term use, not for a short period of use for acute pain. No reports show any specific and significant improvement in pain or function as a result of prescribing muscle relaxants. Per the MTUS chronic pain medical treatment guidelines, cyclobenzaprine (Flexeril, fexmid) is a skeletal muscle relaxant and a central nervous system depressant. It is recommended as an option for a short course of therapy, with greatest effect in the first four days of treatment. Guidelines state that treatment should be brief. The addition of cyclobenzaprine to other agents is not recommended. Limited, mixed evidence does not allow for a recommendation for chronic use. There was no documentation of functional improvement as a result of cyclobenzaprine use. Due to the length of use not in accordance with the guidelines, the request for cyclobenzaprine is not medically necessary.

Tramadol 150mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opioids p. 74-96 tramadol p. 93-94.

Decision rationale: Tramadol is a centrally acting synthetic opioid analgesic which is not recommended as a first line oral analgesic. Multiple side effects have been reported including increased risk of seizure especially in patients taking selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants (TCAs) and other opioids. It may also produce life-threatening serotonin syndrome. There is no evidence that the treating physician is prescribing opioids according to the MTUS, which recommends prescribing according to function, with specific functional goals, return to work, random drug testing, and opioid contract. There should be a prior failure of non-opioid therapy. None of these aspects of prescribing are in evidence. Per the MTUS, opioids are minimally indicated, if at all, for chronic non-specific pain, osteoarthritis, mechanical and compressive etiologies, and chronic back pain. Tramadol has been prescribed for at least 9 months. There is no evidence of significant pain relief or increased function from the

opioids used to date. The prescribing physician does not specifically address function with respect to prescribing opioids, and does not address the other recommendations in the MTUS. There is no evidence that the treating physician has utilized a treatment plan NOT using opioids, and that the patient 'has failed a trial of non-opioid analgesics.' Ongoing management should reflect four domains of monitoring, including analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors. The documentation does not reflect improvement in pain; specific change in activities of daily living, discussion of adverse side effects, and screening for aberrant drug-taking behaviors were not documented. The MTUS recommends urine drug screens for patients with poor pain control and to help manage patients at risk of abuse. There is no record of a urine drug screen program performed according to quality criteria in the MTUS and other guidelines. As currently prescribed, tramadol does not meet the criteria for long term opioids as elaborated in the MTUS and is therefore not medically necessary.

Eszopiclone 1mg #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), Mental Illness & Stress

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation chronic pain chapter: insomnia treatment

Decision rationale: Eszopiclone (Lunesta) is a nonbenzodiazepine hypnotic used for the treatment of insomnia. The MTUS does not address the use of hypnotics other than benzodiazepines. No physician reports describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of that in this case. For the treatment of insomnia, pharmacologic agents should only be used after careful evaluation of potential causes of sleep disturbance. Specific components of insomnia should be addressed. Eszopiclone was noted to be prescribed for treatment of insomnia related to pain condition. There was no documentation of evaluation of sleep disturbance in the injured worker, and components insomnia were not addressed. The treating physician has not addressed major issues affecting sleep in this patient, including the use of other psychoactive agents like opioids, which significantly impair sleep architecture, and depression. Due to lack of adequate evaluation for sleep disorder, Eszopiclone is not medically necessary.