

Case Number:	CM15-0075311		
Date Assigned:	05/14/2015	Date of Injury:	11/29/2011
Decision Date:	06/17/2015	UR Denial Date:	04/01/2015
Priority:	Standard	Application Received:	04/20/2015

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:

This 60-year-old woman sustained an industrial injury on 11/29/2011. The mechanism of injury is not detailed. Diagnoses include cervical discopathy, lumbar discopathy, carpal tunnel/double crush syndrome, tear of the triangular fibrocartilage and scapholunate advanced collapse of the left wrist, De Quervain's syndrome, and sleep difficulty. Treatment has included medications and cognitive behavioral psychotherapy. A psychologic report from November 2014 notes that the injured worker had anxiety, depression, and sleep issues, with difficulty falling asleep and staying asleep due to depression. Prilosec (omeprazole), zofran (ondansetron), and flexeril (cyclobenzaprine) were prescribed in May 2012. Anaprox was prescribed in June 2012. Gastropathy secondary to medication was noted in July 2012. Physician notes dated 1/27/2015 show complaints of increasing pain in the bilateral hands and wrists with swelling and deformity rated 8/10, cervical spine pain with radiation to the bilateral upper extremities rated 7/10, low back pain with radiation to the bilateral lower extremities rated 7/10, bilateral shoulder pain rated 7/10, headaches, and difficulty sleeping. Examination showed cervical paravertebral tenderness with spasm, positive Spurling's maneuver, and dysesthesia at the C5-7 dermatomes, tenderness of the shoulder with positive Hawkin's and impingement signs, wrist tenderness with positive palmar compression test, Phalen's maneuver, and Tine's sign, lumbar paravertebral tenderness with spasm, positive seated nerve root test, and dysesthesia at the L4-5 dermatome. Work status was noted as permanently partially disabled/retired. Recommendations include physical therapy, Fenopren Calcium, Omeprazole, Ondansetron, Cyclobenzaprine, Tramadol, Eszopiclone, and follow up in several weeks. The treating physician noted that omeprazole was

being prescribed for gastrointestinal (GI) symptoms and to protect the stomach from pain an anti-inflammatory medication, as the injured worker described a history of some epigastric pain and stomach upset while using NSAIDS in the past. Ondansetron was noted to be prescribed for nausea associated with headaches associated with chronic cervical spine pain. Cyclobenzaprine was noted to be prescribed for muscle spasm. Eszopiclone was noted to be prescribed for insomnia related to pain condition. On 4/1/15, Utilization Review (UR) non-certified requests for the items currently under Independent Medical Review, citing the MTUS, ODG, and PubMed.

IMR ISSUES, DECISIONS AND RATIONALES

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

Fenoprofen Calcium (Nalfon) 400mg #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 67-73.

Decision rationale: This injured worker has chronic neck, back, and hand/wrist pain. NSAIDs were noted to be prescribed in June of 2012, with documentation of GI side effects including gastropathy, epigastric pain, and stomach upset. Per the MTUS, non-steroidal anti-inflammatory drugs (NSAIDs) are recommended as a second line treatment after acetaminophen for treatment of acute exacerbations of chronic back pain. The MTUS does not specifically reference the use of NSAIDs for long term treatment of chronic pain in other specific body parts. 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 adequately monitoring for toxicity as recommended by the FDA and MTUS. NSAIDS were continued in spite of documentation of ongoing GI issues. There was no documentation of functional improvement as a result of use of NSAIDS. Work status was noted as permanently partially disabled/retired, and there was no discussion of improvement in activities of daily living. The injured worker was noted to have chronic pain, rather than an acute flare-up of pain. The quantity prescribed implies long-term use, not for a short period of use for acute pain. Due to chronic use not in accordance with the guidelines, documented GI side effects of NSAIDS, and lack of functional improvement, the request for fenoprofen is not medically necessary.

Omeprazole 20mg #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI symptoms and cardiovascular risk Page(s): 68-69.

Decision rationale: This injured worker has been prescribed fenoprofen, a nonsteroidal anti-inflammatory medication (NSAID), and omeprazole, a proton pump inhibitor (PPI). She was previously treated with anaprox, with documentation of gastropathy secondary to medication, and epigastric pain and GI upset while using NSAIDS in the past. Non-specific GI symptoms were noted, without further discussion. Omeprazole was first prescribed in May of 2012. Per the MTUS, 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). None of these risk factors was present for this injured worker. Long-term proton pump inhibitor (PPI) use (> 1 year) has been shown to increase the risk of hip fracture. The MTUS, FDA, and recent medical literature have described a significantly increased risk of hip, wrist, and spine fractures, pneumonia, Clostridium-difficile-associated diarrhea, and hypomagnesemia in patients on proton pump inhibitors. There are no medical reports, which adequately describe signs and symptoms of possible GI (gastrointestinal) disease. There is no examination of the abdomen on record. There are many possible etiologies for GI symptoms; the available reports do not provide adequate consideration of these possibilities. Empiric treatment after minimal evaluation is not indicated. If one were to presume that a medication were to be the cause of the undescribed gastrointestinal symptoms, the treating physician would be expected to change the medication regime accordingly, at least on a trial basis to help determine causation. Note the MTUS recommendation regarding the options for NSAID-induced dyspepsia, which include stopping the NSAID, switching to a different NSAID, or consideration of H2 receptor antagonists or a PPI. In this case, there is no evidence of any attempts to determine the cause of symptoms, including minimal attempts to adjust medications. The associated NSAID has been determined to be not medically necessary. Due to lack of specific indication, and potential for toxicity, the request for Omeprazole is not medically necessary.

Ondansetron 8mg ODT #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.pubmed.com.

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

Decision rationale: The MTUS does not provide direction for the use of antiemetics. Ondansetron (Zofran) is FDA approved for nausea caused by chemotherapy and radiation treatment, postoperative use, and acute gastroenteritis. The documentation indicates that

ondansetron was prescribed for nausea associated with headaches. This injured worker does not have an FDA-approved indication. The treating physician has not provided an adequate evaluation of any condition causing nausea. 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 Page(s): 41-42, 63-66.

Decision rationale: This injured worker has chronic multifocal pain with muscle spasms. Flexeril (cyclobenzaprine) was first prescribed in 2012. 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. 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. Work status was noted as permanently partially disabled/retired, and there was no discussion of improvement in activities of daily living. Per the MTUS chronic pain medical treatment guidelines, cyclobenzaprine (Flexeril, Fexmid, Amrix) 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. Cyclobenzaprine is not recommended to be used for longer than 2-3 weeks. The addition of cyclobenzaprine to other agents is not recommended. In this case, multiple other agents were also prescribed. Limited, mixed evidence does not allow for a recommendation for chronic use. Due to length of use in excess of the guidelines, the request for cyclobenzaprine is not medically necessary.

Tramadol ER 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: Initiating opioids Page(s): 76-77.

Decision rationale: This injured worker has chronic neck, back, and hand/wrist pain. Tramadol was prescribed for pain. 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. The documentation submitted does not discuss prior use of opioids, and this request is consistent with an initial request. The MTUS criteria for use of opioids includes

establishment of a treatment plan, including trial of reasonable alternatives to treatment and assessment of likelihood of abuse or adverse outcome, attempt to determine if the pain is nociceptive or neuropathic, attempt to determine if there are underlying contributing psychological issues, failure of trial of non-opioid analgesics, baseline pain and functional assessment, setting of goals before the initiation of therapy, a pain related assessment and assessment of likelihood of weaning from opioids, at least one physical and psychological assessment, discussion of risks and benefits of use of controlled substances, consideration of a written consent or pain agreement for chronic use, and consideration of the use of a urine drug screen to assess for the use of illegal drugs. In this case, there was no discussion of a treatment plan, risk assessment for adverse outcome, discussion of goals/risk/benefits, presence of a pain agreement, or urine drug screen. As currently prescribed, Tramadol does not meet the criteria for use of 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 <http://www.odg-twc.com>.

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

Decision rationale: This injured worker was noted to have insomnia. Lunesta (eszopiclone) is a nonbenzodiazepine hypnotic agent indicated for the treatment of insomnia. It is recommended for short term use only. 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. There was no documentation of evaluation of sleep disturbance in the injured worker, and components insomnia was not addressed. The number prescribed is not consistent with short-term use. Due to lack of sufficient evaluation of sleep disturbance, and quantity prescribed consistent with length of use in excess of the guideline recommendations, the request for Eszopiclone is not medically necessary.