

Case Number:	CM14-0140228		
Date Assigned:	09/10/2014	Date of Injury:	06/21/2002
Decision Date:	12/18/2014	UR Denial Date:	08/18/2014
Priority:	Standard	Application Received:	08/29/2014

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. The expert reviewer is Board Certified in Family Practice and is licensed to practice in Ohio. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 48-year-old female with a date of injury of June 21, 2002. The mechanism of injury was not given. On July 24, 2014 she complained of constant 9/10 pain of the cervical spine radiating into the upper extremities and 7/10 pain of the low back radiating into the lower extremities. The physical exam revealed diminish the cervical range of motion, a positive Spurling's test, tenderness and spasm of the paravertebral cervical muscles and diminished sensation in the region of the C-5 dermatome. The lumbar spine revealed diminished range of motion, tenderness and spasm of the paravertebral muscles, a positive seeded root nerve test, and diminished sensation in the region of the L5 and S1 dermatome. The diagnoses include chondromalacia patella, lumbosacral neuritis, and cervicalgia. The request is for previously denied Diclofenac Sodium 100mg #120, Omeprazole 20mg #120, Ondansetron 8mg #30, Cyclobenzaprine Hydrochloride 7.5mg #120, and Tramadol ER 150mg #90

IMR ISSUES, DECISIONS AND RATIONALES

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

Diclofenac Sodium 100mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Diclofenac Sodium (Voltaren, Voltaren-XR) Page(s): 71.

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

Decision rationale: Diclofenac is not recommended as a first line non-steroidal anti-inflammatory drug due to increased risk profile. A large systematic review of available evidence on NSAIDs confirms that Diclofenac, a widely used NSAID, poses an equivalent risk of cardiovascular events to patients as did Rofecoxib (Vioxx), which was taken off the market. According to the authors, this is a significant issue and doctors should avoid Diclofenac because it increases the risk by about 40%. For a patient who has a 5% to 10% risk of having a heart attack that is a significant increase in absolute risk, particularly if there are other drugs that don't seem to have that risk. For people at very low risk, it may be an option. Another meta-analysis supported the substantially increased risk of stroke with Diclofenac, further suggesting it not be a first-line NSAID. In this nationwide cohort study the traditional NSAID Diclofenac was associated with the highest increased risk of death or recurrent myocardial infarction (hazard ratio, 3.26; 95% confidence interval, 2.57 to 3.86 for death/MI at day 1 to 7 of treatment) in patients with prior MI, an even higher cardiovascular risk than the selective COX-2 inhibitor Rofecoxib, which was withdrawn from the market due to its unfavorable cardiovascular risk profile. According to FDA MedWatch, post marketing surveillance of topical Diclofenac has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure. Some of these reported cases resulted in fatalities or liver transplantation. If using Diclofenac then consider discontinuing as it should only be used for the shortest duration possible in the lowest effective dose due to reported serious adverse events. Post marketing surveillance has revealed that treatment with all oral and topical Diclofenac products may increase liver dysfunction, and use has resulted in liver failure and death. Physicians should measure transaminases periodically in patients receiving long-term therapy with Diclofenac. In 2009 the FDA issued warnings about the potential for elevation in liver function tests during treatment with all products containing Diclofenac sodium. With the lack of data to support superiority of Diclofenac over other NSAIDs and the possible increased hepatic and cardiovascular risk associated with its use, alternative analgesics and/or non-pharmacological therapy should be considered. In this instance, there is no evidence provided that NSAIDs other than Diclofenac have been tried and failed. There appear to be no assessments from the treating physician that the injured worker is at very low risk for cardiovascular disease. There appear to be no measurements of liver function to ensure hepatic safety with Diclofenac. Consequently, Diclofenac Sodium 100mg #120 was not medically necessary per the cited guidelines

Omeprazole 20mg #120: Upheld

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

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

Decision rationale: Those who require treatment with NSAIDs should have a risk assessment for gastrointestinal events such as gastric ulcers. Those risk factors include (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). Those with one or more risk factors should be treated with a proton pump inhibitor such as omeprazole to lessen the chance of gastric ulceration. In this instance, the injured worker was prescribed high dose Diclofenac but that has been said to be not medically necessary. She otherwise does not appear to have risk factors for gastric ulceration. Therefore, Omeprazole 20mg #120 was not medically necessary.

Ondansetron 8mg #30:

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 Chapter (updated 07/10/14)

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

Decision rationale: Ondansetron 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. Acute use is FDA-approved for gastroenteritis. Not recommended for nausea and vomiting secondary to chronic opioid use. Studies of opioid adverse effects including nausea and vomiting are limited to short-term duration (less than four weeks) and have limited application to long-term use. If nausea and vomiting remains prolonged, other etiologies of these symptoms should be evaluated for. In this instance, the provider has checked a standardized form that the Ondansetron is being prescribed for nausea associated with the headaches found with chronic neck pain. The sole provided progress note for review makes no mention of this issue. Therefore, Ondansetron 8mg #30 was not medically necessary.

Cyclobenzaprine Hydrochloride 7.5mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 64.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic), Muscle relaxants for pain

Decision rationale: Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system (CNS) depressant that is marketed as Flexeril by [REDACTED]. Cyclobenzaprine is recommended as an option, using a short course of therapy for pain. Cyclobenzaprine (Flexeril) is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. Treatment should be brief. The Official

Disability Guidelines recommend non-sedating muscle relaxants with caution as a second-line option for short-term (less than two weeks) treatment of acute LBP and for short-term treatment of acute exacerbations in patients with chronic LBP. In this instance, the quantity of cyclobenzaprine requested provides enough medication for 5 weeks of continuous use if dosed every 8 hours. That period of time exceeds what is generally considered a short course of therapy. Therefore, Cyclobenzaprine Hydrochloride 7.5mg #120 was not medically necessary.

Tramadol ER 150mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, specific drug list, Tramadol Page(s): 93-94.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96.

Decision rationale: Those prescribed opioids require ongoing assessment of pain relief, functionality, adverse side effects, and any aberrant drug taking behavior. Those prescribed opioids for the first time should be seen by the physician every 2 weeks for the first 2-4 months. If the requested prescription of tramadol is for continuation, there should be an indication in the progress notes of least pain, most pain, and average pain on a numerical scale. There should be mention of functionality with and without the medication. There should be inquiries about side effects and mention of [REDACTED] reports and/or periodic urine drug screening. None of these can be found in the records provided. If the tramadol requested is for a new prescription, the quantity requested would provide enough medication for 3 months of continuous use, dosed once a day as needed. The guidelines call for reassessment 2 weeks after starting opioids. Therefore, Tramadol ER 150mg #90 was not medically necessary per the referenced guidelines.