

Case Number:	CM14-0134609		
Date Assigned:	08/27/2014	Date of Injury:	10/23/2012
Decision Date:	12/18/2014	UR Denial Date:	07/25/2014
Priority:	Standard	Application Received:	08/20/2014

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 Medicine 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 59-year-old male with cumulative dates of injury ending on October 23, 2012. A progress note from June 19, 2014 reports continued bilateral knee pain aggravated by activity on a scale of 8/10 and unchanged. The examination reveals a positive patellar grind test bilaterally, tenderness of the right knee anterior joint line, a positive right-sided McMurray's sign, and crepitus with range of motion of the right knee. The diagnoses include status post left knee arthroscopy with partial medial and lateral meniscectomy, degenerative joint disease, a Baker's cyst of the right knee. At issue are prescriptions for Diclofenac ER 100 mg #120 tablets, tramadol ER 150 mg #90 tablets, omeprazole 20 mg, Levaquin 750 mg #30 tablets, Zofran 8 mg #30 tablets, and cyclobenzaprine 7.5 mg #120 tablets. The injured worker was to have right knee surgery on June 27, 2014.

IMR ISSUES, DECISIONS AND RATIONALES

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

Diclofenac Sodium ER 100mg # 120: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM, Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines

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

Decision rationale: Diclofenac is not recommended as a first line NSAID 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. 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 this instance, there is no evidence that the injured worker has tried and failed a different NSAID. There is no discussion stating that the injured worker is at very low risk for cardiovascular disease. In fact, injured workers known to be overweight potentially elevating his cardiovascular risk. Additionally, there is no evidence provided that periodic monitoring of liver function is occurring given the known risk of liver injury with Diclofenac. Consequently, Diclofenac Sodium ER 100mg # 120 was not medically necessary.

Tramadol Hydrochloride ER 150mg # 90: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Official Disability Guidelines

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

Decision rationale: Those requiring chronic opioids should have ongoing assessment for pain relief, functionality, medication side effects, and any aberrant drug taking behavior. Typical questions regarding pain include how long it takes for analgesia, how long analgesia is provided with opioids, least amount of pain, greatest pain level, and the average pain scores. When an opioid is initiated with the anticipation that treatment will be chronic, the patient is to be seen by the physician every 2 weeks for the 1st 2 to 4 months of therapy to allow for reassessment. In this instance, questions regarding the effectiveness of the opioid medication are lacking as are questions regarding functionality as a consequence of taking the tramadol. Opioids may be continued when there is improvement in pain and functionality. If this is a new prescription for tramadol, it is unclear why a 90 day prescription was written as the physician's own form states that the tramadol ER 150 mg was to be taken once daily as needed. Consequently, medical necessity for continuing tramadol ER 150 mg was not established. Additionally, if the prescription for tramadol ER is in fact a new one, a 90 day prescription was not medically appropriate or necessary.

Omeprazole delayed release capsules 20mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Official Disability Guidelines

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

Decision rationale: Those requiring NSAID treatment should be assessed for risk for gastric ulceration. Those risks 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). Patients with one or more risk factors or history of gastric ulceration should be treated with a proton pump inhibitor like omeprazole to lessen the risk. In this instance, the NSAID the injured worker had been taking was found not to be medically necessary. Additionally, there are no documented risk factors otherwise for gastric ulceration. Consequently, Omeprazole delayed release capsules 20mg #120 was not medically necessary.

Levofloxacin 750mg # 30: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM, Chronic Pain Treatment Guidelines Official Disability Guidelines.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ASHP Therapeutic Guidelines, 1999, 56: 1839-88. Clinical Practice Guidelines for Antimicrobial Prophylaxis in Surgery

Decision rationale: The ASHP guidelines for peri-operative antibiotic prophylaxis recommend Cefazolin pre-operatively and either Vancomycin or Clindamycin for those who are penicillin allergic in cases of total joint replacements. Post-operative antimicrobial dosing is not necessary for most procedures. In this instance, the intent appears to be for pre-operative dosing of levofloxacin for 7 days to be continued another 3 weeks post-operatively. An extensive literature review failed to find support for such a regimen, especially for non-urologic procedures. Therefore, Levofloxacin 750mg # 30 was not medically necessary.

Ondansetron ODT tablets 8mg # 30: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM. Decision based on Non-MTUS Citation Official Disability Guidelines

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), Anti-emetics

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. Anti-emetics are not recommended for nausea and vomiting secondary to chronic opioid use. Recommended for acute use as noted below per FDA-approved indications. Nausea and vomiting is common with use of opioids. These side effects tend to diminish over days to weeks of continued exposure. 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. The differential diagnosis includes gastroparesis (primarily due to diabetes). In this instance, the only indication for rationale for use of Ondansetron comes from a pre-populated physician form. This form states that the Ondansetron was being prescribed for nausea associated with headaches from chronic neck pain. However, there is no indication of chronic neck pain, headaches, or nausea from the sole provided progress note. Therefore, Ondansetron ODT tablets 8mg # 30 was not medically necessary.

Cyclobenzaprine hydrochloride tablets 7.5mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM, Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41-42. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic), Muscle relaxants

Decision rationale: Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system (CNS) depressant that is marketed as Flexeril by [REDACTED]. It is recommended as an option, using a short course of therapy for pain. 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, there is no indication that the injured worker has muscle spasm. The intended duration of treatment is not brief as the quantity of cyclobenzaprine is sufficient to last 5 weeks of continuous dosing. Therefore, for Cyclobenzaprine hydrochloride tablets 7.5mg #120 was not medically necessary.