

Case Number:	CM14-0118397		
Date Assigned:	08/06/2014	Date of Injury:	11/15/2011
Decision Date:	10/09/2014	UR Denial Date:	07/01/2014
Priority:	Standard	Application Received:	07/28/2014

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 Physical Medicine and Rehabilitation and is licensed to practice in California. 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 53 year-old male with a date of injury of 11/15/2011. The patient's industrially related diagnoses include lumbar discopathy, lumbar radiculopathy, cervical discopathy and shoulder pain. The disputed issues are Diclofenac Sodium ER 100mg #120 once a day with food as needed, Omeprazole 20mg #120 one by mouth 12 hours as need for upset stomach, and Ondansetron 8mg (ODT) #30 one as need for upset stomach, cramping, and nausea. A utilization review determination on 7/1/2014 had noncertified these requests. The stated rationale for the denial of Diclofenac Sodium ER 100mg was "NSAIDs are recommended as an option for short-term symptomatic relief and they are indicated for acute mild to moderate pain. The request is not reasonable as patient has been on long-term NSAID without any documentation of significant derived benefit through prior long term use." The stated rationale for the denial of Omeprazole 20mg was that "this patient is not at intermediate risk of GI events and NSAID use is not recommended any longer, therefore the request is not reasonable." Lastly, Ondansetron was denied because the guidelines state anti-emetics are not recommended for nausea and vomiting secondary to chronic opioid use. It is recommended for acute use for FDA-approved indications.

IMR ISSUES, DECISIONS AND RATIONALES

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

Omeprazole 20mg quantity: 120, 1 by mouth every 12 hours as needed: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 68-69.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs and GI & Cardiovascular Risk Page(s): 68-69.

Decision rationale: Omeprazole is a proton pump inhibitor (PPI). The Chronic Pain Medical Treatment Guidelines recommend that if a patient is at intermediate risk for gastrointestinal events and has no cardiovascular disease, then a non-selective NSAID with a PPI (Proton Pump Inhibitor, for example, 20 mg Omeprazole daily) can be used. The following is used to determine if a 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)." However, it should be noted that long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44). The Utilization Review report states: "this patient is not at intermediate risk of GI events and NSAID use is not recommended any longer, therefore the request is not reasonable." However, in the progress report dated 5/9/2014, the treating physician prescribed Naproxen Sodium tablets 550mg #100 1 every 12 hours for pain along with Omeprazole 20mg for GI symptoms because the patient described a history of some epigastric pain and stomach upset while using NSAIDs in the past for chronic pain. Therefore, based on the guidelines referenced above and the patient's risk for gastrointestinal events, Omeprazole 20mg #60 is medically necessary at this time.

Ondansetron 8mg ODT quantity: 30 1 as needed: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Anti-emetics

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, Anti-Emetics

Decision rationale: The California Medical Treatment Utilization Schedule does not specifically address the antiemetic Ondansetron. Therefore the Official Disability Guidelines Pain chapter was consulted. Ondansetron 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. According to the guidelines, Ondansetron is not recommended for nausea and vomiting secondary to chronic opioid use but is recommended for acute use of FDA-approved indications. In the progress report dated 5/9/2014, the treating physician stated that Ondansetron (ODT) 8mg was prescribed for nausea associated with the headaches that were present from chronic cervical spine pain. This is not an FDA-approved indication and is therefore not recommended. Therefore, Ondansetron (ODT) 8mg #30 1 PRN for upset stomach/cramping/nausea is not medical necessary.

Diclofenac Sodium ER (Voltaren SR) 100mg Quantity: 120 Once A Day with Food as Needed.: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 71.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 67-68, 70-71.

Decision rationale: In the progress reports dated 5/9/2014 and 5/30/2014, the treating physician prescribed Naproxen Sodium tablets 550mg #100 1 Q12H. However, on the RFA form dated 6/27/2014, the request was for Diclofenac Sodium ER (Voltaren SR) 100mg #120 once a day with food as needed. There is no documentation stating the reason for the change or if the injured worker is currently taking Naproxen. There is documentation that the injured worker was previously treated with NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) for the management of his pain symptoms but the specific drug names were not provided and there was no documentation of how the injured worker responded to the treatment. According to the Chronic Pain Medical Treatment Guidelines, Diclofenac Sodium ER 100mg should only be used for chronic maintenance therapy. The guidelines generally recommend that the lowest effective dose be used for all NSAIDs for the shortest duration of time consistent with the individual patient treatment goals. For chronic low back pain, NSAIDs are recommended as an option for short-term symptomatic relief. The prescription for Diclofenac ER 100mg is written for #120 tablets, which is a four-month supply if taken as prescribed. While Diclofenac Sodium ER is indicated for the treatment of chronic low back pain, it should be prescribed for a short period of time with re-evaluation of treatment response. Therefore Diclofenac Sodium 100mg ER #120 is not medically necessary at this time.