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| Case Number: | CM15-0144410 | | |
| Date Assigned: | 08/05/2015 | Date of Injury: | 03/25/2014 |
| Decision Date: | 09/02/2015 | UR Denial Date: | 07/14/2015 |
| Priority: | Standard | Application Received: | 07/24/2015 |

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: Iowa, Illinois, Hawaii

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Public Health & General Preventive 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 57 year old female who sustained an industrial/work injury on 3-25-14. She reported an initial complaint of low back and shoulder pain. The injured worker was diagnosed as having cervical discopathy, lumbar discopathy, and internal derangement of right shoulder. Treatment to date includes medication and diagnostics. MRI results were reported on 5-5-15 of the shoulder noted full thickness and complete tear of the supraspinatus tendon with retraction to the level of the glenohumeral joint measuring 4 cm. Currently, the injured worker complained of constant pain in the low back with radiation into the right extremity with pain of 9 out of 10. There was also right shoulder pain characterized by throbbing rated 8 out of 10. Per the primary physician's report (PR-2) on 6-11-15, palpable paravertebral muscle tenderness with spasm, positive seated nerve root, range of motion was guarded and restricted. Shoulder tenderness around the anterior glenohumeral region and subacromial space, and positive Hawkin's. The requested treatments include Nabumetone (Relafen) 750mg, Lansoprazole (Prevacid) Delayed-Release capsules 30mg, and Ondansetron 8mg ODT (oral disintegrating tablet).

IMR ISSUES, DECISIONS AND RATIONALES

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

Nabumetone (Relafen) 750mg 1 pill TID #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS; Relafen Page(s): 67-72.

Decision rationale: MTUS recommends the use of NSAIDS for the acute exacerbation of back pain at the lowest effective dose for the shortest amount of time due to the increased cardiovascular risk, renal, hepatic and GI side effects associated with long term use. MTUS states "Nabumetone (Relafen, generic available): 500, 750 mg. Dosing: Osteoarthritis: The recommended starting dose is 1000 mg PO. The dose can be divided into 500 mg PO twice a day. Additional relief may be obtained with a dose of 1500 mg to 2000 mg per day. The maximum dose is 2000 mg/day. Patients weighing less than 50 kg may be less likely to require doses greater than 1000 mg/day. The lowest effective dose of nabumetone should be sought for each patient. Use for moderate pain is off-label. (Relafen Package Insert)." The patient has been prescribed Relafen without any significant improvement in pain, quality of life, or functionality. The treating physician has not provided any justification to exceed MTUS guidelines. As such, the request for Nabumetone (Relafen) 750mg 1 pill TID #120 is not medically necessary.

Lansoprazole (Prevacid) Delayed-Release capsules 30mg 1 by mouth 12H PRN #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 & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: MTUS states "Determine if the 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)." And "Patients at intermediate risk for gastrointestinal events and no cardiovascular disease : (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44)." ODG states "If a PPI is used, omeprazole OTC tablets or lansoprazole 24HR OTC are recommended for an equivalent clinical efficacy and significant cost savings. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi, 2008) A trial of omeprazole or lansoprazole is recommended before Nexium therapy. The other PPIs, Protonix, Dexilant, and Aciphex, should also be second-line. According

to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. (AHRQ, 2011)." The medical documents provided do not establish the patient has having documented GI bleeding/perforation/peptic ulcer or other GI risk factors as outlined in MTUS. As such, the request for Lansoprazole (Prevacid) Delayed-Release capsules 30mg 1 by mouth 12H PRN #120 is not medically necessary.

Ondansetron 8mg ODT 1 prn no more than 2/day #30: 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, opioids. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, Antiemetics (for opioid nausea).

Decision rationale: Ondansetron (Zofran) is an antiemetic used to decrease nausea and vomiting. Nausea is a known side effect of chronic opioid use and some Serotonin norepinephrine reuptake inhibitors (SNRIs). ODG does not recommend use of antiemetic for "nausea and vomiting secondary to chronic opioid use." Additionally, "This drug 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." There is no evidence that patient is undergoing chemotherapy/radiation treatment or postoperative. MTUS is specific regarding the gastrointestinal symptoms related to NSAID usage. If criteria are met, the first line treatment is to discontinue usage of NSAID, switch NSAID, or consider usage of proton pump inhibitor. There is no documentation provided that indicated the discontinuation of NSAID or switching of NSAID occurred. Additionally, Ondansetron is not a proton pump inhibitor and is not considered first line treatment. As such the request for Ondansetron 8mg ODT 1 prn no more than 2/day #30 is not medically necessary.