

| | | | |
|-----------------------|--------------|------------------------------|------------|
| Case Number: | CM15-0080195 | | |
| Date Assigned: | 05/01/2015 | Date of Injury: | 07/10/2013 |
| Decision Date: | 08/28/2015 | UR Denial Date: | 04/09/2015 |
| Priority: | Standard | Application Received: | 04/27/2015 |

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: California
Certification(s)/Specialty: Emergency 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 injury on 7/10/13. The injured worker reported symptoms in the cervical spine and upper extremities. The injured worker was diagnosed as having cervicgia, joint derangement and carpal tunnel syndrome. Treatments to date have included nonsteroidal anti-inflammatory drugs, proton pump inhibitor, and oral opioid analgesics. Currently, the injured worker complains of discomfort in the cervical spine and upper extremities. The plan of care was for medication prescriptions and a follow up appointment at a later date.

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 non-steroidal anti-inflammatory drugs (NSAIDs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 67-68 of 127.

Decision rationale: The request is for the use of NSAIDS to aid in pain relief. NSAIDS are usually used to aid in pain and inflammation reduction. The MTUS guidelines states that for osteoarthritis NSAIS are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDS appear to be superior to acetaminophen especially for patients with moderate to severe pain. There is no evidence to support one drug in this class over another based on efficacy. In particular, there appears to be no difference between NSAIDS and COX-2 NSAIDS in terms of pain relief. The main concern of selection is based on adverse effects, with COX-2 NSAIDS having fewer GI side effects at the risk of increased cardiovascular side effects. The FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDS and is a class effect (with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain and function. (Chen, 2008) (Laine, 2008) For back pain, NSAIDS are recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDS are more effective that acetaminophen for acute LBP. (van Tulder, 2006) (Hancock, 2007) For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDS vs. placebo. In patients with axial low back pain this same review found that NSAIDS were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. (Roelofs-Cochrane, 2008) The addition of NSAIDS or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician. (Hancock, 2007) In this case, there is inadequate documentation of functional improvement to justify continued use, as the guidelines recommend the lowest dose for the shortest period of time. The significant side effect profile of medications in this class put the patient at risk when used chronically. As such, the request is not medically necessary.

Omeprazole 20mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Proton Pump Inhibitors (PPIs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68 of 127.

Decision rationale: The request is for the use of a medication in the class of a proton pump inhibitor. This is usually given as an acid reducing medication for patients with esophageal reflux, gastritis, or peptic ulcer disease. It can also be used as a preventative measure in patients taking non-steroidal anti-inflammatories for chronic pain. Unfortunately, they do have certain side effects including gastrointestinal disease. The MTUS guidelines states that patients who are classified as intermediate or high risk, should be treated prophylactically. Criteria for risk are as follows: "(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)." Due to the fact the patient does not meet to above stated criteria, the request for use is not medically necessary.

Ondansetron 8mg #30: 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 regarding Antiemetics (for opioid nausea).

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

Decision rationale: The request is for the use of Zofran. The MTUS and ACOEM guidelines are silent regarding this topic. The ODG guidelines states that this medication is not recommended for nausea and vomiting secondary to chronic opioid use. It is 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). Current research for treatment of nausea and vomiting as related to opioid use primarily addresses the use of antiemetics in patients with cancer pain or those utilizing opioids for acute/postoperative therapy. Recommendations based on these studies cannot be extrapolated to chronic non-malignant pain patients. There is no high-quality literature to support any one treatment for opioid-induced nausea in chronic non-malignant pain patients. (Moore 2005) Ondansetron (Zofran): 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. Acute use is FDA-approved for gastroenteritis. In this case, the use of Zofran is not indicated. As stated above, it is not to be use for nausea and vomiting related to chronic opioid use. As such, the request is not medically necessary.

Cyclobenzaprine hydrochloride tablets 7.5mg #120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 41-42 of 127.

Decision rationale: The request is for the use of Cyclobenzaprine. This medication is classified as a muscle relaxant and central nervous system depressant with side effects including drowsiness and dizziness. The MTUS guidelines states that it is indicated for short term use for low back pain. The effect seems to be greatest the first 4 days of use which suggests that treatment should be brief. In this case, due to the duration of treatment, further use would not be indicated. As such, the request would not be medically necessary.

Tramadol ER 150mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 80-83 of 127.

Decision rationale: Tramadol is a pain medication in the category of a centrally acting analgesic. They exhibit opioid activity and a mechanism of action that inhibits the reuptake of serotonin and norepinephrine. Centrally acting drugs are reported to be effective in managing neuropathic type pain although it is not recommended as first line therapy. The side effect profile is similar to opioids. For chronic back pain, it appears to be efficacious for short term pain relief, but long term (>16 weeks) results are limited. It also did not appear to improve function. The use of tramadol for osteoarthritis is indicated for short term use only (<3 months) with poor long-term benefit. In this case, the patient does not meet the qualifying criteria or indications. As such, the request is not medically necessary.

Sumatriptan succinate 20mg #9 x2: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Head chapter, Triptans.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Imitrex (Sumatriptan)-Head/Triptans.

Decision rationale: The request is for the use of Imitrex which is a medication for migraine sufferers. The MTUS and ACOEM guidelines are silent regarding its use. The ODG states at marketed doses, all oral triptans (e.g., sumatriptan, brand name Imitrex) are effective and well tolerated. Differences among them are in general relatively small, but clinically relevant for individual patients. A poor response to one triptan does not predict a poor response to other agents in that class. In this case there is inadequate documentation of a neurologic evaluation revealing migraine-type headaches with symptomatic and functional improvement seen with use. As such, the request is not medically necessary.