

Case Number:	CM15-0136741		
Date Assigned:	07/24/2015	Date of Injury:	10/30/2012
Decision Date:	09/29/2015	UR Denial Date:	06/24/2015
Priority:	Standard	Application Received:	07/14/2015

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: New York, 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 53 year old male who sustained an industrial injury on 10/30/2012. According to a progress report dated 05/12/2015, the injured worker was in constant pain in the cervical spine that was characterized as sharp. There was radiation of pain into the upper extremities. There were associated headaches that were migrainous in nature as well as tension between the shoulder blades. The provider noted that the injured worker's pain was improving. Pain was rated 4 on a scale of 1-10. There was constant pain in the low back that was characterized as sharp. There was radiation of pain into the lower extremities. Pain was improving and was rated 4. The injured worker had 1 lumbar epidural steroid injection that was helping. Physical examination of the cervical spine demonstrated palpable paravertebral muscle tenderness with spasm. A positive loading compression test was noted. Spurling maneuver was positive. Range of motion was limited with pain. There was no clinical evidence of stability on exam. Examination of the lumbar spine demonstrated palpable paravertebral muscle tenderness with spasm. Seated nerve root test was positive. Standing flexion and extension were guarded and restricted. No clinical evidence of stability was noted on exam. There was tingling and numbness in the lateral thigh, anterolateral and posterior leg as well as foot, L5 and S1 dermatomal patterns. Strength was 4 in the extensor hallucis longus and ankle plantar flexors, L5 and S1 innervated muscles. Ankle reflexes were asymmetric. Diagnoses included disc disorder cervical and disc disorder lumbar. Medication regimen was not listed in the progress report. Medications were ordered under a separate cover letter. Acupuncture treatment was requested for the cervical and lumbar spine. Work status included modified work. An authorization request dated 06/18/2015 was submitted for review. The requested services

included Relafen 750 mg #120 1 pill three times a day, Lansoprazole (Prevacid) delayed release 30 mg #120 1 by mouth every 12 hours as needed for upset stomach, Ondansetron 8 mg ODT #30 1 as needed for upset stomach/cramping and nausea, Cyclobenzaprine Hydrochloride 7.5 mg #120 1 by mouth every 8 hours as needed for spasm and Tramadol ER 150 mg #90 once a day as needed for severe pain. The request stated that meds were not yet dispensed and the progress report from 05/12/2015 was referenced. According to an agreed medical examination dated 04/22/2015, the injured worker's medication regimen included Norflex, Tramadol, Naproxen, Fenoprofen, Cyclobenzaprine, Ondansetron, Metformin, Glipizide and Omeprazole. Currently under review is the request for Lansoprazole (Prevacid) delayed release 30 mg #120, Ondansetron 8 mg ODT #30, Cyclobenzaprine Hydrochloride 7.5 mg #120 and Tramadol ER 150 mg #90.

IMR ISSUES, DECISIONS AND RATIONALES

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

Lansoprazole (Prevacid) delayed release 30 mg #120: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, gastrointestinal symptoms & cardiovascular risk Page(s): 68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter-Proton Pump Inhibitors.

Decision rationale: CA MTUS states that proton pump inhibitors, such as Omeprazole (Prilosec), are recommended for patients taking NSAIDs with documented GI distress symptoms or specific GI risk factors. Risk factors include, age >65, history of peptic ulcer disease, GI bleeding, concurrent use of aspirin, corticosteroids, and/or anticoagulants or high-dose/multiple NSAIDs. There is no documentation indicating the patient has any GI symptoms or GI risk factors. Official Disability Guidelines (ODG) states that proton pump inhibitors are recommended for patients at risk for gastrointestinal events. Decision to use proton pump inhibitors long-term must be weighed against the risks. The potential adverse effects of long-term proton pump inhibitor use included B12 deficiency, iron deficiency, hypomagnesemia, increased susceptibility to pneumonia, enteric infection and fractures, hypergastrinemia and cancer and more recently adverse cardiovascular effects. Proton pump inhibitors have a negative effect on vascular function, increasing the risk for myocardial infarction. Patients with gastroesophageal reflux disease on proton pump inhibitors had a 1.16 greater risk of myocardial infarction and a 2.00 risk for cardiovascular mortality. Proton pump usage may be serving as a marker for a sicker population, but this is unlikely, given the lack of increased risk seen in patients taking H2 blockers. (Shah, 2015) In this study proton pump inhibitor use was associated with a 1.58 fold greater risk of myocardial infarction and in the case-crossover study, adjusted odds ratios of proton pump inhibitor for myocardial risk were 4.61 for the 7 day window and 3.47 for the 14 day window. However, the benefits of proton pump inhibitors may greatly outweigh the risks of adverse cardiovascular effects, with number needed to harm of 4357. (Shih, 2014) Outpatient proton pump use is associated with a 1.5 fold increased risk of community-acquired pneumonia, with the highest risk within the first 30 days after initiation of therapy.

(Lamber, 2015) The updated Beers Criteria, which help prevent adverse drug events in older adults, added a recommendation to avoid the use of proton pump inhibitors for more than 8 weeks, except for long-term NSAID users and patients with erosive esophagitis, Barrett's esophagitis, pathologic hypersecretory condition, or a demonstrated need for maintenance therapy. There are many studies demonstrating, in elderly patients, an increased risk for Clostridium difficile infection and bone loss and fractures with the long-term use of proton pump inhibitors. (AGS, 2015) Medical necessity for the requested treatment has not been established. The requested medication is not medically necessary

Ondansetron 8 mg ODT #30: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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-Ondansetron-Anti-emetics.

Decision rationale: CA MTUS Guidelines do not address Ondansetron. Ondansetron (Zofran) is used to prevent nausea and vomiting that may be caused by anesthesia/surgery, or chemotherapy or radiation therapy. It is also approved for use acutely with gastroenteritis. Ondansetron is not used and is ineffective for nausea associated with narcotic analgesics. In this case, the treating provider did not document that the injured worker had complaints of nausea or suffered from acute gastroenteritis or was being treated postoperatively. Medical necessity for the requested treatment is not established. The requested treatment is not necessary. Medical necessity for the requested treatment is not established. The requested treatment is not medically necessary.

Cyclobenzaprine Hydrochloride 7.5 mg #120: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63-64.

Decision rationale: CA MTUS Chronic Pain Medical Treatment Guidelines state that all therapies are focused on the goal of functional restoration rather than merely the elimination of pain and assessment of treatment efficacy is accomplished by reporting functional improvement. MTUS guidelines recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbation in patients with chronic low back pain. Muscle relaxants may be effective in reducing pain and muscle tension and increasing mobility. However, in most low back pain cases, they show no benefit beyond NSAIDs (non-steroidal anti-inflammatory drugs) in pain and overall improvement. Also there was no additional benefit shown in combination with NSAIDs. Efficacy appeared to diminish over time and prolonged use of some medications in this class may lead to dependence. Per MTUS guidelines, Cyclobenzaprine is not recommended to be used longer than 2-3 weeks. In this case, records dated 04/22/2015 shows that the injured worker's medication regimen included Cyclobenzaprine. A physical examination dated 05/12/2015 continued to reveal muscle spasms. Long term use is not recommended. The provider's request of #120 Cyclobenzaprine exceeds the recommended guidelines of 2-3 weeks. There is no documentation indicating that this is an acute exacerbation of pain. In addition, there is a lack of

functional improvement with the treatment already provided. The treating physician did not provide sufficient evidence of improvement in the work status, activities of daily living, and dependency on continued medical care. Medical necessity for the requested treatment is not established. The requested treatment is not medically necessary.

Tramadol ER 150 mg #90: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Functional Restoration Approach to Chronic Pain Management, Opioids, Long-term users of opioids Page(s): 9, 78, 88.

Decision rationale: CA MTUS Chronic Pain Medical Treatment Guidelines state that all therapies are focused on the goal of functional restoration rather than merely the elimination of pain and assessment of treatment efficacy is accomplished by reporting functional improvement. MTUS guidelines state that on-going management of opioid therapy should include ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include current pain, the least reported pain over the period since the last assessment, average pain, the intensity of pain after taking the opioid, how long it takes for pain relief, and how long pain relief lasts. Information from family members or other caregivers should be considered in determining the patient's response to treatment. In addition to pain relief, the practitioner should monitor side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. Pain and functional improvement should be documented and compared to baseline. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function or improved quality of life. Pain should be assessed at each visit and functioning should be measured at 6 month intervals using a numerical scale or validated instrument. In this case, the injured worker has been utilizing opioids long term. The treating provider does not document the least reported pain over the period since the last assessment, average pain, the intensity of pain after taking the opioid, how long it takes for pain relief, and how long pain relief lasts. There is a lack of functional improvement with the treatment already provided. The treating physician did not provide sufficient evidence of improvement in the work status, activities of daily living, and dependency on continued medical care. Medical necessity for the requested treatment is not established. The requested treatment is not medically necessary.