

<b>Case Number:</b>	CM14-0132030		
<b>Date Assigned:</b>	08/22/2014	<b>Date of Injury:</b>	08/16/2001
<b>Decision Date:</b>	09/24/2014	<b>UR Denial Date:</b>	07/24/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/18/2014

### 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, has a subspecialty in Interventional Spine, 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 patient is a 51 year old female with an injury date of 08/16/01. The 02/10/14 and 02/03/14 progress reports by [REDACTED] state that the patient presents with neck pain that radiates "down bilateral upper extremity" and with lower back pain that radiates down the lateral lower extremities. She also presents with ongoing headaches. The pain is rated 6/10 with medications and 9/10 without. The patient remains temporarily totally disabled and reports ADL limitations. Examination of the cervical spine reveals a well-healed anterior scar with tenderness at the cervical paravertebral muscles and upper trapezial muscle with spasm. Examination of the lumbar spine reveals tenderness from the lumbar paravertebral muscle. Seated nerve root test is positive and there is dysesthesia at the L5 and S1 dermatomes. The patient's diagnoses include: 1. Status post C5-C6 anterior cervical discectomy and fusion (date unknown) 2. Lumbar discopathy. 3. Electrodiagnostic evidence of chronic right S1 radiculopathy. 4. Cervical disc degeneration. 5. Cervical failed back surgery. 6. Cervical radiculopathy. 7. Chronic pain. 8. Failed back surgery syndrome, lumbar. 9. Lumbar radiculopathy. Per the 02/30/14 report, medications are listed as Crestor, Fioricet and Flexeril. The utilization review being challenged is dated 07/24/14. Treatment reports were provided from 07/29/13 to 02/10/14.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**120 Diclofenac Sodium ER (Voltaren SR) 100mg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain Page(s): 60, 61.

**Decision rationale:** The patient presents with neck pain radiating down the bilateral upper extremity, lower back pain radiating down the lateral lower extremities and ongoing headaches. Pain is rated 6/10 with medications and 9/10 without. The treater requests for 120 Diclofenac Sodium ER (Voltaren SR) 100.mg. Per the reports provided it is unknown how long the patient has been taking this medication. The 06/27/14 utilization review references a 06/30/14 periodic report by [REDACTED]. The most recent report provided by the treater is dated 02/10/14. MTUS pages 60, 61 state, "Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity." The records provided do not indicate whether or not this patient is actually on this medication, for how long, and with what effect. Without any discussion regarding the medication, it cannot be considered. MTUS guidelines page 8 require that the treater provide monitoring of the patient's progress and make appropriate recommendations. Therefore, this request is not medically necessary recommendations. Recommendation is for denial.

**120 Omeprazole 20mg:** 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 NSAIDs, GI symptoms & cardiovascular risk Page(s): 68, 69.

**Decision rationale:** The patient presents with neck pain radiating down the bilateral upper extremity, lower back pain radiating down the lateral lower extremities and ongoing headaches. Pain is rated 6/10 with medications and 9/10 without. The treater requests for 120 Omeprazole 20 mg. It is not known how long the patient has been taking this medication as it is not listed on the treatment reports provided. The MTUS Guidelines state Omeprazole is recommended with precautions as indicated below. Clinician should weigh indications for NSAIDs against both GI and cardiovascular risk factors, determining if the patient is at risk for gastrointestinal events. 1. Age is more than 65 years. 2. History of peptic ulcers, GI bleeding, or perforations. 3. Concurrent use of ASA, corticosteroids, and/or anticoagulant. 4. High-dose multiple NSAIDs. MTUS also states, "Treatment of dyspepsia secondary to NSAID therapy: Stop the NSAID, switch to a different NSAID, or consider H2-receptor antagonists or a PPI." In this case, the reports provided show no discussion of GI complications and there is no discussion of the efficacy or use of this medication. Therefore, this request is not medically necessary. MTUS also states, "Treatment of dyspepsia secondary to NSAID therapy: Stop the NSAID, switch to a different NSAID, or consider H2-receptor antagonists or a PPI." In this case, the reports provided show no discussion of GI complications and there is no discussion of the efficacy or use of this medication. Therefore, recommendation is for denial.

### **30 Ondansetron 8mg: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. 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) ODG guidelines have the following regarding Zofran (Ondansetron): Not recommended for nausea and vomiting secondary to chronic opioid use. See Antiemetics (for opioid nausea). On Antiemetics for opioid nausea: 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). 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)

Promethazine (Phenergan®): This drug is a phenothiazine. It is recommended as a sedative and antiemetic in pre-operative and post-operative situations. Multiple central nervous system effects are noted with use including somnolence, confusion and sedation. Tardive dyskinesia is also associated with use. This is characterized by involuntary movements of the tongue, mouth, jaw, and/or face. Choreoathetoid movements of the extremities can also occur. Development appears to be associated with prolonged treatment and in some cases can be irreversible. Anticholinergic effects can occur (dry mouth, dry eyes, urinary retention and ileus).

Ondansetron (Zofran®): This drug is a serotonin 5-HT<sub>3</sub> 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. See also Nabilone (Cesamet®), for chemotherapy-induced nausea, but not pain.

**Decision rationale:** The patient presents with neck pain radiating down the bilateral upper extremity, lower back pain radiating down the lateral lower extremities and ongoing headaches. Pain is rated 6/10 with medications and 9/10 without. The treater requests for 30 Ondansetron 8 mg. ODG guidelines have the following regarding Ondansetron: Not recommended for nausea and vomiting secondary to chronic opioid use. It is recommended for chemo-induced or post-operative nausea. In this case, the reports provided show no discussion as to why this medication is being prescribed. There is no evidence of recent surgery or chemotherapy. Zofran is not indicated for opiate induced nausea. Therefore, this request is not medically necessary.

### **120 Cyclobenzaprine Hydrochloride tablets: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril, Amrix, Fexmid, generic available), Muscle relaxants Page(s): 63-64.

**Decision rationale:** The patient presents with neck pain radiating down the bilateral upper extremity, lower back pain radiating down the lateral lower extremities and ongoing headaches. Pain is rated 6/10 with medications and 9/10 without. The treater requests for 120 Cyclobenzaprine Hydrochloride tablets. MTUS guidelines for muscle relaxants state the following: "Recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use." MTUS guidelines for muscle relaxants for pain page 63 states the following: "Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP." MTUS does not recommend more than 2-3 weeks for use of this medication. The reports provided indicate the patient was taking this medication on 02/03/14 and 12/23/13. No medication lists have been provided since 02/03/14. In this case, it appears the patient has been taking this medication longer than the 2-3 weeks recommended. Therefore, this request is not medically necessary.

**90 Tramadol ER 150mg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 308, Chronic Pain Treatment Guidelines Opioids.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS Page(s): 88, 89, 78.

**Decision rationale:** The patient presents with neck pain radiating down the bilateral upper extremity, lower back pain radiating down the lateral lower extremities and ongoing headaches. Pain is rated 6/10 with medications and 9/10 without. The treater requests for 90 Tramadol ER 150 mg. The 07/24/14 utilization review modified the number to 14. It is unclear how long the patient has been taking this medication. Treatment reports provided show this as a listed medication 12/23/13 but not on 02/03/14. The utilization review notes Tramadol was last certified 09/03/13 and cites a 07/15/14 report that is not included in the reports provided. MTUS Guidelines pages 88 and 89 state, "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS page 78 also requires documentation of the 4As (analgesia, ADLs, adverse side effects, and adverse behavior), as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. In this case, the treater does not mention improvement in pain with this medication. There is no discussion of adverse side effects and adverse behavior. No specific ADLs are mentioned to show a significant change of use with this medication. The reports show no discussion of pain assessment or outcome measures as described above. Therefore, this request is not medically necessary.