

<b>Case Number:</b>	CM14-0208310		
<b>Date Assigned:</b>	12/19/2014	<b>Date of Injury:</b>	07/21/2007
<b>Decision Date:</b>	02/18/2015	<b>UR Denial Date:</b>	11/11/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/11/2014

### 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. 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: Physical Medicine & Rehabn

### 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 31-year-old female with a date of injury of 07/21/2007. The medical file provided for review includes 1 secondary treating physician's re-evaluation report dated 07/08/2014. According to this report, the patient presents with continued symptoms in the lumbar spine as it relates to the retained symptomatic lumbar spinal hardware. The patient also complains of constant cervical spine pain and associated headaches that are migrainous in nature as well as tension between the shoulder blades. Physical examination of the cervical spine revealed palpable paravertebral muscle tenderness with spasm. There is positive axial loading compression test and positive Spurling's maneuver test. There is pain with terminal motion. Examination of the right shoulder revealed positive Hawkins' impingement sign. There is tenderness around the anterior glenohumeral region and subacromial space. Range of motion is restricted by approximately 20% of normal when compared to the left shoulder. Examination of the lumbar spine revealed well-healed midline scar. There is pain and tenderness over the top of palpable hardware, most pronounced on the right side. There is tenderness noted and standing flexion and extension are guarded and restricted. The patient was given a hardware block in the lumbar spine using 3 mL of Celestone, 7 mL of lidocaine, and 7 mL of Marcaine. Flexion and extension radiographs of the lumbar spine were obtained on this date which revealed rod and screw fixation of the levels of L5-S1 with solid bone incorporation, with some osteolysis around the screws. The listed diagnoses are: 1. Cervical discopathy with radiculitis. 2. Status Right shoulder impingement syndrome. 3. Positive L5-S1 discogram. 4. Retained symptomatic lumbar spine hardware. 5. post posterior lumbar fusion at L5-S1.

The treating physician states that the retained symptomatic lumbar hardware is causing the majority of the patient's symptomatology, and recommendation is made for surgical intervention in the form of removal of the L5-S1 hardware with inspection of fusion and possible re-grafting of screw holes and nerve root exploration. This is a request for fenoprofen calcium, omeprazole 20 mg, ondansetron 8 mg, cyclobenzaprine 7.5 mg, and tramadol ER 150 mg. The utilization review denied the request for medications on 11/11/2014. The medical file provided for review includes one report dated 07/08/2014, lumbar discogram report dated 10/04/2013, and MRI of the lumbar spine dated 06/02/2014.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **120 Fenoprofen calcium (Nalfon) 400mg: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-inflammatories Page(s): 22.

**Decision rationale:** This patient presents with continued symptoms of the lumbar spine as it relates to the retained symptomatic lumbar spinal hardware. The treating physician has made a request for surgical intervention in the form of removal of the L5-S1 hardware with inspection of fusion and possible re-grafting of screw holes and nerve root exploration. The request is for #120 fenoprofen calcium (Nalfon) 400 mg. The one progress report provided for review does not provide any discussion regarding this medication. The utilization review denied the request stating that the patient has been taking NSAIDs since at least June of 2013. For anti-inflammatory medications, the MTUS Guidelines page 22 states, "Anti-inflammatories are the traditional first line of treatment to reduce pain, so activity and functional restoration can resume, but long-term use may not be warranted." The utilization review notes that the patient has been taking anti-inflammatories as early as June of 2013. The treating physician has provided no discussion regarding any improvement in pain or functional changes with taking Fenoprofen. MTUS page 60 requires documentation of pain assessment and functional changes when medications are used for chronic pain. Given the lack of discussion regarding efficacy, the requested fenoprofen calcium is not medically necessary.

#### **120 Omeprazole 20mg: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Omeprazole Page(s): 68 and 69.

**Decision rationale:** This patient presents with continued symptoms of the lumbar spine as it relates to the retained symptomatic lumbar spinal hardware. The treating physician has made a

request for surgical intervention in the form of removal of the L5-S1 hardware with inspection of fusion and possible re-grafting of screw holes and nerve root exploration. The current request is for #120 omeprazole 20 mg. The MTUS Guidelines page 68 and 69 states that Omeprazole is recommended with precaution for patients at risk for gastrointestinal events: (1) Age is greater than 65, (2) History of peptic ulcer disease and GI bleeding or perforation, (3) Concurrent use of ASA or corticosteroid and/or anticoagulant, (4) High dose/multiple NSAID. It appears the patient has been utilizing anti-inflammatories on a long-term basis, but the treating physician does not document dyspepsia or GI issues. Routine prophylactic use of PPI without documentation of gastric issues is not supported by the guidelines without GI-risk assessment. This request is not medically necessary.

### **30 Ondansetron ODT 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 (ODG), Pain (Chronic)

**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, Antiemetic

**Decision rationale:** This patient presents with continued symptoms of the lumbar spine as it relates to the retained symptomatic lumbar spinal hardware. The treating physician has made a request for surgical intervention in the form of removal of the L5-S1 hardware with inspection of fusion and possible re-grafting of screw holes and nerve root exploration. The current request is for #30 ondansetron ODT 8 mg. The MTUS and ACOEM Guidelines do not discuss Ondansetron. The ODG Guidelines has the following regarding Antiemetic under the Pain Chapter, ""Not recommended for nausea and vomiting secondary to chronic opioid use. Recommended for acute use as noted below per FDA-approved indications." ODG further states "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." It appears the treating physician is requesting this medication for postoperative use. However, there is no indication that the patient has been approved for surgery. The ODG Guidelines do not support the use of Ondansetron other than for nausea following chemotherapy, acute gastroenteritis, or for postoperative use. The patient currently does not meet the indication for this medication. The requested Zofran is not medically necessary.

### **120 Cyclobenzaprine Hydrochloride 7.5mg: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines muscle relaxants Page(s): 63, 64.

**Decision rationale:** This patient presents with continued symptoms of the lumbar spine as it relates to the retained symptomatic lumbar spinal hardware. The treating physician has made a request for surgical intervention in the form of removal of the L5-S1 hardware with inspection of fusion and possible re-grafting of screw holes and nerve root exploration. The current request is for #120 cyclobenzaprine hydrochloride 7.5 mg. The MTUS Guidelines page 63 regarding muscle relaxants states, "Recommended non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. Muscle relaxants may be effective in reducing pain and muscle tension and increasing mobility; however, in most LBP cases, they showed no benefit beyond NSAIDs and pain with overall improvement. Efficacy appears to diminish over time, and prolonged use of some medication in this class may lead to dependence." It is unclear when the patient was first prescribed this medication. The current request is for cyclobenzaprine 7.5 mg #120. The MTUS Guidelines support the usages of cyclobenzaprine for short course of therapy, not longer than 2 to 3 weeks. The requested cyclobenzaprine #120 is not medically necessary.

**90 Tramadol ER 150mg:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines CRITERIA FOR USE OF OPIOIDS; medication for chronic pain Page(s): 88 and 89, 76-78; 60-61.

**Decision rationale:** This patient presents with continued symptoms of the lumbar spine as it relates to the retained symptomatic lumbar spinal hardware. The treating physician has made a request for surgical intervention in the form of removal of the L5-S1 hardware with inspection of fusion and possible re-grafting of screw holes and nerve root exploration. The current request is for tramadol ER 150 mg. The medical file provided for review includes one progress report dated 07/08/2014. There is no discussion regarding this medication. The utilization review denied the request stating that patient has been utilizing opioids since at least June of 2013. For chronic opioid use, the 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. Recommendation for Tramadol cannot be made as there is no documentation of analgesia or specific functional improvement as required by MTUS for opiate management. There was no discussion of possible adverse side effects and aberrant behavior such as urine drug screens or CURES reports are not provided. The MTUS criteria for long term use of opiates have not been met. The continued use of Tramadol is not medically necessary and recommendation for slow weaning per MTUS Guidelines.