

<b>Case Number:</b>	CM14-0174704		
<b>Date Assigned:</b>	10/27/2014	<b>Date of Injury:</b>	08/31/2010
<b>Decision Date:</b>	12/03/2014	<b>UR Denial Date:</b>	09/23/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/21/2014

### 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 Internal Medicine 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 an injured worker with lumbosacral spine conditions. Date of injury was 08-31-2010. Primary treating physician's progress report dated July 15, 2014 documented low back pain. The patient had completed physical therapy sessions. Surgical intervention to the lumbar spine from the levels of L3 to S1 was recommended. MRI magnetic resonance imaging of the lumbar spine performed on June 5, 2014 demonstrated evidence of instability with a Grade I spondylolisthesis in the distal lumbar spine. There is moderate to severe narrowing of the neural foramina from L3 to S1 resulting in significant compromise of the nerve roots throughout. There are large disc extrusions measuring from 4 mm to 7 mm from L3 to S1 in both posterior and anterior approaches. There is moderate to severe facet hypertrophy as well. Physical examination was documented. There is palpable paravertebral muscle tenderness with spasm. Standing flexion and extension are guarded and restricted. Diagnosis was lumbar discopathy with segmental instability. The progress report dated 8/26/14 documented subjective complaints of sharp, constant low back pain rated at a severity of 8 out of 10 that was aggravated with bending, lifting, twisting, pushing, pulling, prolonged sitting and standing, and walking multiple blocks. The pain radiated to the lower extremities and the patient reported his symptoms were worsening. Upon physical examination, there was tenderness and muscle spasm in the lumbar spine, positive nerve root testing, guarded and restricted lumbar range of motion, no evidence of instability, paresthesia and muscle weakness consistent with L5 and SI dermatomal and myotomal patterns, and asymmetrical ankle jerk reflexes. Lumbar x-rays revealed decreased disc space height from L3 to S1 and instability at L4/5. The diagnoses included lumbago and lumbar disc disorder. The patient was to return to full work duty with no limitations or restrictions. Utilization review determination date was 9/23/14.

## IMR ISSUES, DECISIONS AND RATIONALES

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

### **120 Fenopufen Calcium 400mg: Overturned**

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

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 308.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) addresses NSAIDs. American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) states that NSAIDs are recommended for back conditions. Medical records document the diagnoses of lumbago and lumbar disc disorder. Objective evidence of pathology was demonstrated on physical examination and imaging studies. ACOEM guidelines support the use of Fenopufen, which is an NSAID, for low back conditions. Therefore, the request for 120 Fenopufen Calcium 400mg is medically necessary.

### **120 Omeprazole 20mg: Overturned**

**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 rationale:** Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines addresses NSAIDs and gastrointestinal risk factors. Proton Pump Inhibitor (PPI), e.g. Omeprazole, is recommended for patients with gastrointestinal risk factors. High dose NSAID use is a gastrointestinal risk factor. Medical records document the prescription of Fenopufen, which is an NSAID. NSAID use is a gastrointestinal risk factor. MTUS guidelines support the use of a proton pump inhibitor such as Omeprazole in patients with gastrointestinal risk factors. MTUS guidelines and medical records support the medical necessity of Omeprazole. Therefore, the request for 120 Omeprazole 20mg is medically necessary.

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

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Ondansetron (Zofran®) FDA Prescribing Information Zofran (Ondansetron) <http://www.drugs.com/pro/zofran.html>

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) does not address Zofran (Ondansetron). Official Disability Guidelines (ODG) states that Ondansetron (Zofran) is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment, and for postoperative use. Medical records do not document symptoms of nausea or vomiting associated with chemotherapy or radiation treatment or postoperative use. No cancer chemotherapy or radiotherapy was documented. Ondansetron was not being prescribed for postoperative use. The medical records do not support the use of Ondansetron (Zofran). Therefore, the request for 30 Ondansetron 8 mg is not medically necessary.

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

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

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, 49, Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril); Muscle relaxants Page(s): 41-42; 63-66. Decision based on Non-MTUS Citation FDA Prescribing Information Flexeril Cyclobenzaprine <http://www.drugs.com/pro/flexeril.html>

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) addresses muscle relaxants. American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) states that muscle relaxants seem no more effective than NSAIDs for treating patients with musculoskeletal problems, and using them in combination with NSAIDs has no demonstrated benefit. Muscle relaxants may hinder return to function by reducing the patient's motivation or ability to increase activity. Table 3-1 states that muscle relaxants are not recommended. Chronic Pain Medical Treatment Guidelines addresses muscle relaxants. Muscle relaxants should be used with caution as a second-line option for short-term treatment. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. According to a review in American Family Physician, muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. Chronic Pain Medical Treatment Guidelines state that Cyclobenzaprine (Flexeril) is an option for a short course of therapy. Treatment should be brief. The addition of Cyclobenzaprine to other agents is not recommended. FDA guidelines state that Cyclobenzaprine is indicated for acute musculoskeletal conditions. Cyclobenzaprine should be used only for short periods (up to two or three weeks) because adequate evidence of effectiveness for more prolonged use is not available. Medical records document that the patient's occupational injuries are chronic. MTUS, ACOEM, and FDA guidelines do not support the use of Cyclobenzaprine (Flexeril) for chronic conditions. The patient has been prescribed NSAIDs. Per MTUS, using muscle relaxants in combination with NSAIDs has no demonstrated benefit. The use of Cyclobenzaprine (Flexeril) is not supported by MTUS and ACOEM guidelines. Therefore, the request for 120 Cyclobenzaprine Hydrochloride Tablets 7.5 mg is not medically necessary.

### **90 Tramadol ER 150mg: Overturned**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol (Ultram); Opioids Page(s): 93-94, 113, 123; 74-96.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address Ultram (Tramadol). Ultram is a centrally acting synthetic opioid analgesic. Ultram is indicated for the management of moderate to moderately severe pain. MTUS Chronic Pain Medical Treatment Guidelines (Page 89) present the strategy for maintenance for long-term users of opioids. "Do not attempt to lower the dose if it is working." Supplemental doses of break-through medication may be required for incidental pain, end-of-dose pain, and pain that occurs with predictable situations. The standard increase in dose is 25 to 50% for mild pain and 50 to 100% for severe pain. Medical records document the diagnoses of lumbago and lumbar disc disorder. Objective evidence of pathology was demonstrated on physical examination and imaging studies. Ultram (Tramadol) is indicated for the management of moderate to moderately severe pain. Medical records and MTUS guidelines support the prescription of Tramadol (Ultram). Therefore, the request for 90 Tramadol ER 150 mg is medically necessary.