

<b>Case Number:</b>	CM15-0202393		
<b>Date Assigned:</b>	10/21/2015	<b>Date of Injury:</b>	10/20/2010
<b>Decision Date:</b>	12/23/2015	<b>UR Denial Date:</b>	09/12/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/14/2015

### 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: 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 46 year old female, who sustained an industrial injury on 10-20-2010. A review of the medical records indicates that the injured worker (IW) is undergoing treatment for diabetes, lumbar degenerative disc disease, lumbar radiculopathy, neck pain, left shoulder pain, headaches and previous carpal tunnel syndrome. Medical records (03-19-2015) indicate ongoing radiating low back pain, radiating neck pain, headaches and bilateral shoulder pain. Pain levels were rated 6-9 out of 10 in severity on a visual analog scale (VAS). Records also indicate no changes in activity levels or level of function. Per the treating physician's progress report (PR), the IW could work with restrictions. The physical exam, dated 08-26-2015, revealed restricted range of motion (ROM) in the left shoulder, tenderness over the left rotator cuff, the acromioclavicular (AC) joint, biceps, tendons and posterior capsule, and positive impingement sign, Hawkin's test and Speed's test. Relevant treatments have included: lumbar laminectomy, decompression and discectomy, physical therapy (PT), electrical stimulation, work restrictions, and medications. The treating physician indicates that Celebrex, Ultracet, Flexeril, tramadol, and Trazodone have been prescribed since at least 03-2015. The request for authorization (08-26-2015 and 09-23-2015) shows that the following medications and testing were requested: retrospective Celebrex 200mg #30 (08-26-2015), retrospective Ultracet 37.5mg #60 (08-26-2015), retrospective Flexeril #60 (08-26-2015), retrospective Celebrex 200mg #30 (09-23-2015), retrospective Aciphex 20mg #30 (09-23-2015), retrospective tramadol ER 150mg #30 (09-23-2015), Cymbalta 200mg #30 (09-23-2015), Norflex ER 100mg #60 (09-23-2015), Trazodone 50mg #60 (09-23-2015), and a MRI. The original utilization review (09-11-2015) non-certified retrospective Celebrex 200mg #30 (09-23-2015), retrospective Aciphex 20mg #30 (09-23-2015), retrospective tramadol ER 150mg #30 (09-23-2015), Cymbalta 200mg #30 (09-23-2015), Norflex ER 100mg #60 (09-23-2015), Trazodone 50mg #60 (09-23-2015), and a MRI.

## IMR ISSUES, DECISIONS AND RATIONALES

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

### **Retrospective Celebrex 200mg, #30 (DOS: 8/26/15): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Anti-inflammatory medications.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Anti-inflammatory medications.

**Decision rationale:** The request is for the use of Celebrex. This medication is in the category of a COX-2 inhibitor anti-inflammatory medication. The MTUS guidelines state the following regarding its use: COX-2 inhibitors (e.g., Celebrex) may be considered if the patient has a risk of GI complications, but not for the majority of patients. Generic NSAIDs and COX-2 inhibitors have similar efficacy and risks when used for less than 3 months, but a 10-to-1 difference in cost. (Rate of overall GI bleeding is 3% with COX-2s versus 4.5% with ibuprofen.) In this case, celebrex is not indicated. This is secondary to inadequate documentation of significant gastrointestinal risk which would justify its use. Acetaminophen would be considered first-line treatment for chronic pain. In this case, the continued use of an NSAID is not medically necessary. This is secondary to inadequate documentation of functional improvement benefit seen. Also, the duration of use places the patient at risk for gastrointestinal and cardiovascular side-effects. In addition, it is known that use of NSAIDs delays the healing of soft tissue including ligaments, tendons, and cartilage.

### **Retrospective Ultracet 37.5mg, #60 (DOS: 8/26/15): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

**Decision rationale:** The request is for the use of a medication in the opioid class. The MTUS guidelines state that for ongoing treatment with a pharmaceutical in this class, certain requirements are necessary. This includes not only adequate pain control, but also functional improvement. Four domains have been proposed for management of patients on opioids. This includes pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug-related behaviors. As part of the pain treatment agreement, it is advised that "Refills are limited, and will only occur at appointments". In this case, there is inadequate documentation of persistent functional improvement seen. "Functional improvement" means either a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management visit and a reduction in the dependency on continued medical treatment. As such, the request is not medically necessary. All opioid medications should be titrated down slowly in order to prevent a significant withdrawal syndrome.

**Retrospective Flexeril, #60 (DOS: 8/26/15): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

**Decision rationale:** The request is for the use of a muscle relaxant to aid in pain relief. The MTUS guidelines state that the use of a medication in this class is indicated as a second-line option for short-term treatment of acute exacerbations of low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, which can increase mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain improvement. Efficacy appears to diminish over time, and prolonged use may lead to dependence. (Homik, 2004) In this case, the use of a muscle relaxant is not guideline-supported. This is secondary to poor effectiveness for chronic long-term use. As such, the request is not medically necessary.

**Retrospective Celebrex 200mg, #30 (DOS: 9/23/15): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Anti-inflammatory medications.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Anti-inflammatory medications.

**Decision rationale:** The request is for the use of Celebrex. This medication is in the category of a COX-2 inhibitor anti-inflammatory medication. The MTUS guidelines state the following regarding its use: COX-2 inhibitors (e.g., Celebrex) may be considered if the patient has a risk of GI complications, but not for the majority of patients. Generic NSAIDs and COX-2 inhibitors have similar efficacy and risks when used for less than 3 months, but a 10-to-1 difference in cost. (Rate of overall GI bleeding is 3% with COX-2s versus 4.5% with ibuprofen.) In this case, Celebrex is not indicated. This is secondary to inadequate documentation of significant gastrointestinal risk which would justify its use. Acetaminophen would be considered first-line treatment for chronic pain. In this case, the continued use of an NSAID is not medically necessary. This is secondary to inadequate documentation of functional improvement benefit seen. Also, the duration of use places the patient at risk for gastrointestinal and cardiovascular side-effects. In addition, it is known that use of NSAIDs delays the healing of soft tissue including ligaments, tendons, and cartilage.

**Retrospective AcipHex 20mg, #30 (DOS: 9/23/15): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** The request is for the use of a medication in the class of a proton pump inhibitor. It is indicated for patients with 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.

**Retrospective Tramadol ER 150mg, #30 (DOS: 9/23/15): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

**Decision rationale:** The request is for the use of a medication in the opioid class. The MTUS guidelines state that for ongoing treatment with a pharmaceutical in this class, certain requirements are necessary. This includes not only adequate pain control, but also functional improvement. Four domains have been proposed for management of patients on opioids. This includes pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug-related behaviors. As part of the pain treatment agreement, it is advised that "Refills are limited, and will only occur at appointments". In this case, there is inadequate documentation of persistent functional improvement seen. "Functional improvement" means either a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management visit and a reduction in the dependency on continued medical treatment. As such, the request is not medically necessary. All opioid medications should be titrated down slowly in order to prevent a significant withdrawal syndrome.

**Retrospective Cymbalta 200mg, #30 (DOS: 9/23/15): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): SNRIs (serotonin noradrenaline reuptake inhibitors).

**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)/Antidepressants for chronic pain.

**Decision rationale:** Medications in the class of antidepressants are recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. (Feuerstein, 1997) (Perrot, 2006) They are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Analgesia generally occurs within a few days to a week, whereas antidepressant effect usually takes longer to occur. (Saarto-Cochrane, 2005) Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality/duration, and psychological assessment. Side effects can include excessive sedation and should be assessed. It is recommended that these outcome measurements should be initiated at one week of

treatment with a recommended trial of at a minimum of 4 weeks. It has been suggested that if pain is in remission for 3-6 months, a gradual tapering of anti-depressants can be undertaken. In this case, the use of this medication is not medically necessary. This is secondary to the patient currently taking another antidepressant Effexor.

**Retrospective Norflex ER 100mg, #60 (DOS: 9/23/15): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

**Decision rationale:** The request is for the use of a muscle relaxant to aid in pain relief. The MTUS guidelines state that the use of a medication in this class is indicated as a second-line option for short-term treatment of acute exacerbations of low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, which can increase mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain improvement. Efficacy appears to diminish over time, and prolonged use may lead to dependence. (Homik, 2004) In this case, the use of a muscle relaxant is not guideline-supported. This is secondary to poor effectiveness for chronic long-term use. As such, the request is not medically necessary.

**Retrospective Trazodone 50mg, #60 (DOS: 9/23/15): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Tricyclics.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental illness & Stress/Trazodone (Desyrel).

**Decision rationale:** The request is for the use of the medication Trazodone. This is a medication in the category of a serotonin agonist and reuptake inhibitor and is used for depression. It also has anxiolytic and sedative hypnotic effects. The MTUS guidelines are silent regarding its use. The ODG guidelines state that this medication is indicated as an option for insomnia for patients with coexisting depression or anxiety. Its use as a first-line treatment for primary insomnia is not advised. Evidence for the off-label use of Trazodone for treatment of insomnia is poor. The current recommendation is to use a combined pharmacologic and psychological and behavior treatment when primary insomnia is diagnosed. In this case, there is inadequate documentation of a psychiatric evaluation revealing comorbid factors which would qualify the patient for use of Trazodone as a first-line agent. Also, the patient is already taking Effexor. As such, the request is not medically necessary.

**MRI: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Neck & Upper Back, Magnetic Resonance Imaging (MRI).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back - Lumbar & Thoracic (Acute & Chronic)/ MRIs (magnetic resonance imaging).

**Decision rationale:** The request is for an MRI of the lumbar spine. The ODG guidelines state the following regarding qualifying criteria: Indications for imaging - Magnetic resonance imaging: Thoracic spine trauma: with neurological deficit; Lumbar spine trauma: trauma, neurological deficit; Lumbar spine trauma: seat belt (chance) fracture (If focal, radicular findings or other neurologic deficit); Uncomplicated low back pain, suspicion of cancer, infection, other "red flags"; Uncomplicated low back pain, with radiculopathy, after at least 1 month conservative therapy, sooner if severe or progressive neurologic deficit; Uncomplicated low back pain, prior lumbar surgery; Uncomplicated low back pain, cauda equina syndrome; Myelopathy (neurological deficit related to the spinal cord), traumatic; Myelopathy, painful; Myelopathy, sudden onset; Myelopathy, stepwise progressive; Myelopathy, slowly progressive; Myelopathy, infectious disease patient; Myelopathy, oncology patient; Repeat MRI: When there is significant change in symptoms and/or findings suggestive of significant pathology (eg, tumor, infection, fracture, neurocompression, recurrent disc herniation). In this case, the patient would not qualify for an MRI based on the above set standards. This is secondary to a lack of a change in clinical status or described "red flags". There is a lack of documentation of progressive neurologic deficit. Pending further information revealing qualifying indications as listed above, the request is not medically necessary.