

<b>Case Number:</b>	CM13-0008594		
<b>Date Assigned:</b>	03/24/2014	<b>Date of Injury:</b>	07/15/2002
<b>Decision Date:</b>	06/11/2014	<b>UR Denial Date:</b>	07/12/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/08/2013

### 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 Pain 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 injured worker is a 34-year-old male with a date of injury of July 15, 2002. The injured worker carries diagnoses of cervical spine pain, cervical radiculopathy, cervical mild ligamentous injury, bilateral carpal tunnel syndrome, right ulnar neuropathy at the elbow s/p surgery, thoracic spine sprain, chronic low back pain, lumbar radiculopathy, and lumbar mild ligamentous injury. Treatments have included pain medications, cervical epidural steroid injections, occipital nerve blocks, wrist bracing for carpal tunnel syndrome, physical therapy, and a cubital tunnel surgery. A utilization review on date of service August 12, 2013 had noncertified the request for cyclobenzaprine, sumatriptan, ondansetron, omeprazole, the drugs pain relief ointment, Matrox patch, Norco, and levofloxacin. The request for Tramadol and Ketoprofen were recommended for modification.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**CYCLOBEZAPRINE HYDROCHLORIDE TABLETS 7.5MG, #120:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Muscle Relaxants Page(s): 64-65.

**Decision rationale:** The Chronic Pain Medical Treatment Guidelines on pages 64-65 states the following regarding Cyclobenzaprine: "Cyclobenzaprine (Flexeril®<sup>®</sup>, Amrix®<sup>®</sup>, Fexmid®<sup>®</sup>, generic available): Recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant with similar effects to tricyclic antidepressants (e.g. amitriptyline). Cyclobenzaprine is more effective than placebo in the management of back pain, although the effect is modest and comes at the price of adverse effects. It has a central mechanism of action, but it is not effective in treating spasticity from cerebral palsy or spinal cord disease. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement. The greatest effect appears to be in the first 4 days of treatment. (Browning, 2001) (Kinkade, 2007) (Toth, 2004) See Cyclobenzaprine. Cyclobenzaprine has been shown to produce a modest benefit in treatment of fibromyalgia. Cyclobenzaprine-treated patients with fibromyalgia were 3 times more likely to report overall improvement and to report moderate reductions in individual symptoms (particularly sleep). A meta-analysis concluded that the number needed to treat for patients with fibromyalgia was 4.8. (ICSI, 2007) (Tofferi, 2004)" Although this patient continues to have significant pain in the cervical and lumbar spine region, the California Medical Treatment and Utilization Schedule is clear in recommending only short-term use of cyclobenzaprine. The medical records indicate that cyclobenzaprine has been used since May 2012. The request is not medically necessary and appropriate.

**SUMATRIPTAN SUCCINATE TABLETS 25 MG, #18:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: McCracken G, Houston P, Lefebvre G, Society of Obstetricians and Gynecologists of Canada. Guideline for the management of postoperative nausea and vomiting. J. Obstet Gynecol Can 2008 Jul; 30(7):600-7. [75 references]

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

**Decision rationale:** The California Medical Treatment and Utilization Schedule does not specifically address Sumatriptan. Section 9792.21(c) of the California Medical Treatment Utilization Schedule states that: "Treatment shall not be denied on the sole basis that the condition or injury is not addressed by the MTUS. In this situation, the claims administrator shall authorize treatment if such treatment is in accordance with other scientifically and evidence-based, peer-reviewed, medical treatment guidelines that are nationally recognized by the medical community, in accordance with subdivisions (b) and (c) of section 9792.25, and pursuant to the Utilization Review Standards found in section 9792.6 through section 9792.10." Sumatriptan is an abortive medication that is indicated for migraine headaches. The patient in this case does not have a covered claim of migraine headaches as part of his original industrial injury. There is documentation that the neck pain results in cervicogenic headache. This is not an FDA approved usage of Triptan medication. Therefore, the request is not medically necessary and appropriate.

**ONDANSETRON ODT 8MG, #60:** 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.

**Decision rationale:** The California Medical Treatment and Utilization Schedule does not specifically address Zofran. Section 9792.21(c) of the California Medical Treatment Utilization Schedule states that: "Treatment shall not be denied on the sole basis that the condition or injury is not addressed by the MTUS. In this situation, the claims administrator shall authorize treatment if such treatment is in accordance with other scientifically and evidence-based, peer-reviewed, medical treatment guidelines that are nationally recognized by the medical community, in accordance with subdivisions (b) and (c) of section 9792.25, and pursuant to the Utilization Review Standards found in section 9792.6 through section 9792.10." Zofran is a rescue medication for the treatment of nausea and vomiting. In the case of this injured worker, there is documentation that the patient has complained of nausea associated with "his headaches and cervical spine pain." This was documented in a progress note on February 7th, 2013 and May 29th 2013. It was later recommended for continuation afterwards. However, there is no documentation of workup of this patient's nausea. Medical standard of care typically includes a workup for other causes of nausea rather than just treating the symptom. The request is not medically necessary and appropriate.

**MEDROX PAIN RELIEF OINTMENT 120GM, 2 PRESCRIPTIONS:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-113.

**Decision rationale:** Medrox is a compounded topical medication consisting of methyl salicylate, menthol, and capsaicin 0.0375%. The Chronic Pain Medical Treatment Guidelines on page 111 states "any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Thus, each active ingredient should be analyzed in making a determination of medical necessity. Given the guidelines, the capsaicin component of Medrox at a 0.0375% concentration is felt to be experimental and not indicated for this injured worker's diagnoses. Chronic Pain Medical Treatment Guidelines clearly state that there is no evidence to indicate that this increased dosage would provide any further efficacy. Therefore the request is not medically necessary and appropriate.

**MEDROX PATCH, #30:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111-113.

**Decision rationale:** Medrox is a compounded topical medication consisting of methyl salicylate, menthol, and capsaicin 0.0375%. The Chronic Pain Medical Treatment Guidelines on page 111 states "any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Thus, each active ingredient should be analyzed in making a determination of medical necessity. Given the guidelines, the capsaicin component of Medrox at a 0.0375% concentration is felt to be experimental and not indicated for this injured worker's diagnoses. Chronic Pain Medical Treatment Guidelines clearly state that there is no evidence to indicate that this increased dosage would provide any further efficacy. Therefore the request is not medically necessary and appropriate.

**TRAMADOL HYDROCHLORIDE ER 150MG, #90:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TRAMADOL Page(s): 94.

**Decision rationale:** The Chronic Pain Medical Treatment Guidelines on page 94 states the following regarding tramadol: "Tramadol is a synthetic opioid affecting the central nervous system. Tramadol is not classified as a controlled substance by the DEA. Side Effects: Dizziness, nausea, constipation, headache, somnolence, flushing, pruritus, vomiting, insomnia, dry mouth, and diarrhea. Tramadol may increase the risk of seizure especially in patients taking SSRIs, TCAs and other opioids. Do not prescribe to patients that at risk for suicide or addiction. Warning: Tramadol may produce life-threatening serotonin syndrome, in particular when used concomitantly with SSRIs, SNRIs, TCAs, and MAOIs, and triptans or other drugs that may impair serotonin metabolism. Analgesic dose: Tramadol is indicated for moderate to severe pain. The immediate release formulation is recommended at a dose of 50 to 100mg PO every 4 to 6 hours (not to exceed 400mg/day). This dose is recommended after titrating patients up from 100mg/day, with dosing being increased every 3 days as tolerated. For patients in need of immediate pain relief, which outweighs the risk of non-tolerability the initial starting dose, may be 50mg to 100mg every 4 to 6 hours (max 400mg/day). Ultram ER<sup>®</sup>: Patient currently not on immediate release tramadol should be started at a dose of 100mg once daily. The dose should be titrated upwards by 100mg increments if needed (Max dose 300mg/day). Patients currently on immediate release tramadol, calculate the 24-hour dose of IR and initiate a total daily dose of ER rounded to the next lowest 100mg increment (Max dose 300mg/day). (Product information, Ortho-McNeil 2003) (Lexi-Comp, 2008)" Since tramadol is an opioid, it is subject to the ongoing monitoring requirements as stated in the Chronic Pain Medical Treatment Guidelines. The patient is noted to have resumed regular duties in November 2013 according to a progress note on January 16, 2014. This was while continuing tramadol. In the submitted documentation, there are reports of urine drug testing performed on January 31, 2012, October 18, 2011, July 13, 2011. More recent urine drug testing is not available and screening information on opioid risk factors are also not available. The request is not medically necessary and appropriate.

**KETOPROFEN CAPSULES 75MG:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Non-Steroidal Anti-Inflammatory Drugs (NSAID)..

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 72.

**Decision rationale:** The Chronic Pain Medical Treatment Guidelines on page 72 state the following: "Ketoprofen 50, 75 mg, Ketoprofen ER 200 mg: Dosing: Osteoarthritis: Regular release capsule 50mg four times per day or 75mg three times per day (max 300mg/day). XR capsule 200mg once daily. Mild to moderate pain: Regular release capsule 50mg every 6 to 8 hours (Max 300mg/day)" However, standard of care in pain management generally recommend only one nonsteroidal anti-inflammatory drug at a time. This injured worker has been documented to be taking naproxen already. It is unclear as to why the additional Ketoprofen is medically necessary. The request is not medically necessary and appropriate.

**HYDROCODONE / ACETAMINOPHEN (NORCO) 10MG-325MG:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 76-80.

**Decision rationale:** The Chronic Pain Medical Treatment Guidelines on pages 76-80 state the following criteria for the ongoing use of opioids, including: "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 last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000)" Ongoing monitoring for opiates includes documentation of functional benefit, adverse side effects, analgesic efficacy, and monitoring for adverse side effects. Norco tablets were prescribed as early as January 31, 2012 for this patient. In the submitted documentation, there are reports of urine drug testing performed on January 31, 2012, October 18, 2011, July 13, 2011. More recent urine drug testing is not available and screening information on opioid risk factors are also not available. The request is not medically necessary and appropriate.

**LEVOFLOXACIN 750MG, #30: Overturned**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Bratzler DW, Dellinger EP, Olsen KM, Perl TM, Auwaerter PG, Bolon MK, Fish DN, Napolitano LM, Sawyer RG, Slain D, Steinberg JP, Weinstein RHEUMATOID ARTHRITIS (RA). Clinical Practice Guidelines for antimicrobial prophylaxis in surgery. Am J Health Syst Pharm. 2013. Feb 1; 70(3):195-283. [1075 references]

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

**Decision rationale:** Levofloxacin is not specifically addressed by the California Medical Treatment and Utilization Schedule. Section Â§9792.21(c) of the California Medical Treatment Utilization Schedule states that: "Treatment shall not be denied on the sole basis that the condition or injury is not addressed by the MTUS. In this situation, the claims administrator shall authorize treatment if such treatment is in accordance with other scientifically and evidence-based, peer-reviewed, medical treatment guidelines that are nationally recognized by the medical community, in accordance with subdivisions (b) and (c) of section 9792.25, and pursuant to the Utilization Review Standards found in section 9792.6 through section 9792.10." In the case of this injured worker, the recommendation for levofloxacin was requested in a progress note on date of service may 29 2013. This was a preoperative note for the patient's prior to cubital tunnel release on the right upper extremity. The levofloxacin was recommended for 7 days as a impairment prophylaxis for postoperative infection. Although not directly addressed by the California Medical Treatment and Utilization Schedule, this is considered standard of care following surgical procedures to decrease the risk of postoperative infection. The request is medically necessary and appropriate.