

<b>Case Number:</b>	CM14-0164525		
<b>Date Assigned:</b>	10/09/2014	<b>Date of Injury:</b>	07/01/2010
<b>Decision Date:</b>	12/24/2014	<b>UR Denial Date:</b>	09/08/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/06/2014

### 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 Family Medicine, and is licensed to practice in Ohio. 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 52 year old female with a date of injury of 7-1-2000. She presented for post-operative follow up on 8-25-2014 after evidently having a recent lumbar fusion at L4-L5. She described improved back pain at a level of 5/10 and worsening right shoulder pain at 8/10. The physical exam revealed a well healed lumbar incision with evidence of erythema at the wound edges. The lower extremity neurologic exam was normal. The right shoulder revealed tenderness of the anterior glenohumeral region and subacromial space with a positive Hawkin's and impingement signs. The diagnoses were shoulder joint derangement, cervicgia, lumbago, and S/P lumbar fusion. A cortisone injection was provided for the right shoulder that day.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Fenoprofen Calcium (Nalfon) 400mg #120:** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 66-67.

**Decision rationale:** NSAIDs like Fenoprofen are recommended for osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate

to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In this instance, Fenoprofen was previously denied because there were no objective signs of functional improvement. However, the guidelines do not specifically call for objective signs of functional improvement as a prerequisite for continuation. Merely, NSAIDs should be used at the lowest doses for the shortest amount of time possible. Consequently, Fenoprofen Calcium (Nalfon) 400mg #120 is medically necessary. The injured worker clearly has at least moderate pain with at least some element of osteoarthritis.

**Omeprazole 20mg #120: 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, and cardiovascular risk Page(s): 68-69.

**Decision rationale:** The referenced guidelines state that a proton pump inhibitor like omeprazole may be prescribed to lessen the chances for gastric ulceration for patients with any of the following risk factors: (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). In this instance, the injured worker is taking high dose Fenoprofen. Consequently, Omeprazole 20mg #120 is medically necessary.

**Ondansetron ODT 8mg #30: Overturned**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Treatment in Workers Compensation (TWC); Pain Procedure Summary.

**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), Anti-emetics

**Decision rationale:** Ondansetron 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 is not recommended for nausea and vomiting secondary to chronic opioid use. In this instance, the rationale for the use of Ondansetron was not provided and the progress notes did not indicate a gastrointestinal issue. Therefore, Ondansetron ODT 8mg #30 is not medically necessary.

**Cyclobenzaprine 7.5mg #120: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic), Muscle relaxants (for pain).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41-42. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic), Muscle relaxants (for pain)

**Decision rationale:** Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system (CNS) depressant that is marketed as Flexeril by [REDACTED]. Cyclobenzaprine (Flexeril) is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. Treatment should be brief. This medication is not recommended to be used for longer than 2-3 weeks. There is also a post-op use. The addition of Cyclobenzaprine to other agents is not recommended. In this instance, the quantity of cyclobenzaprine is sufficient to last for 40 days of continuous dosing. Hence, the intent of the prescription appears to be for chronic use. Consequently, Cyclobenzaprine 7.5mg #120 is not medically necessary.

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

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96.

**Decision rationale:** Those requiring chronic opioid treatment should have ongoing assessment for pain relief, functionality, medication side effects, and any aberrant drug taking behavior. The opioids may be continued if there is improvement in pain and functionality or if the injured worker has regained employment. These requirements may not apply as stringently, however, when the opioids are being used for acute pain. In this instance, the injured worker appears to be within 1-2 weeks of a lumbar fusion surgery. Given the acute nature of this pain, Tramadol ER 150mg #90 is medically necessary. It is noted that previous utilization reviews have not authorized the continuation of opioids like Tramadol ER but in this instance there appears to be an acute aspect to the pain picture.

**Levofloxacin 750mg #30:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Sanford Guide to Antimicrobial Therapy 2013, 43rd Edition Authors: Gilbert, David MD, Moellering, Jr, Robert MD, Eliopoulos, George MD, Chambers, Henry MD, Saag, Michael MD, pages 192-196, Official Disability Guidelines (ODG) Treatment in Workers Compensation (TWC); Infectious Diseases Procedure Summary.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Drugs. 1993; 45 Suppl 3:102-13. Fluoroquinolones and surgical prophylaxis.

**Decision rationale:** The objective of surgical prophylaxis is to prevent wound infections associated with surgery. The rates of wound infections vary according to the procedure: less than 3 infections per 100 for clean procedures; up to 4 per 100 for clean-contaminated procedures; and up to 9 per 100 for contaminated procedures. Surgical antimicrobial prophylaxis has been shown in many randomized clinical trials to reduce the incidence of postoperative wound infections. Such prophylaxis is actually recommended in many clean-contaminated and some clean procedures. Because of their antimicrobial, pharmacokinetic, and anti-adhesive properties, the fluoroquinolones have been recently proposed as prophylactic agents. Fluoroquinolones have proved to be useful in surgical prophylaxis and clinical trials have been performed in orthopedic, cardiovascular, biliary, colorectal and urological surgery. According to the surgical procedure, fluoroquinolones were compared either with the standard antimicrobial regimen or with placebo. Different regimens of fluoroquinolones were also compared. Generally, fluoroquinolones have been demonstrated to be as effective as the reference prophylactic agent. In transurethral surgery, fewer postoperative wound infections were reported in the treated group than in the placebo group. In most studies, single dose prophylaxis was as effective as a multiple dose regimen. It is important to note that strict methodology was limited to a few clinical trials. In most of the studies, patients were not randomized in a double-blind fashion and small patient numbers often prevented the formation of satisfactory conclusions. Further trials are needed to define the role of the fluoroquinolones in surgical prophylaxis. It will be important to evaluate not only the efficacy but also the cost-benefit of perioperative prophylaxis with the fluoroquinolones. Clinical trials are also required in other high risk clean procedures such as neurosurgery involving shunts and ocular surgery. However, the risks related to the extensive use of fluoroquinolones in surgical prophylaxis must be considered, including the development and dissemination of resistant pathogens and the occurrence of adverse effects. In the future, surgical prophylaxis with prosthetic devices coated with fluoroquinolones should be considered. In this instance, there was a request for 30 tablets/days of levofloxacin. The request for authorization from 9-2-2014 specifically states that the medication was to be taken once a day for 7 days to prevent infection after surgery. There is no clinical rationale provided to support the need for an additional 23 days of medication. Therefore, Levofloxacin 750mg #30 is not medically necessary.