

<b>Case Number:</b>	CM15-0123566		
<b>Date Assigned:</b>	07/08/2015	<b>Date of Injury:</b>	06/04/2012
<b>Decision Date:</b>	09/11/2015	<b>UR Denial Date:</b>	06/08/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/26/2015

### 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: New York

Certification(s)/Specialty: Anesthesiology

### 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 42 year old male, who sustained an industrial injury on 6/4/2012. The current diagnosis is lumbago. According to the progress report dated 5/12/2015, the injured worker complains of constant, sharp low back pain with radiation into the bilateral lower extremities. The pain is aggravated by bending, lifting, twisting, pushing, pulling, prolonged sitting/standing, and walking multiple blocks. The pain is unchanged, and rated 7/10 on a subjective pain scale. The physical examination of the lumbar spine reveals tenderness to palpation over the paravertebral muscles with spasm, restricted range of motion, and tingling/numbness in the lateral thigh, anterolateral and posterior leg as well as his foot, L5 and S1 dermatomal patterns. The current medications are Nabumetone, Omeprazole, Ondansetron, Cyclobenzaprine, Tramadol, Lunesta, Cymbalta, Tylenol # 4, Norco, and Methoderm gel. There is documentation of ongoing treatment with Ondansetron and Cyclobenzaprine since at least 1/13/2015. The records do not indicate when Tylenol # 4 was initiated. Treatment to date has included medication management, x-rays, physical therapy, home exercise program, MRI studies, electrodiagnostic testing, and pain injection. As of 9/16/2014, the injured worker was working full duty without limitations or restrictions. A request for Ondansetron, Cyclobenzaprine, and Tylenol # 4 has been submitted.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Ondansetron 8 mg Qty 30: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain (chronic) - Ondansetron (Zofran).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain Chapter - Ondansetron (Zofran).

**Decision rationale:** Ondansetron (Zofran) is used to prevent nausea and vomiting that may be caused by anesthesia/surgery, or chemotherapy or radiation therapy. It is also approved for use acutely with gastroenteritis. Ondansetron is not used and is ineffective for nausea associated with narcotic analgesics. In this case, the ODG does not support Ondansetron for nausea and vomiting secondary to chronic opioid use. Medical necessity of the requested medication has not been established. The requested medication is not medically necessary.

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

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 64-66.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 63-64.

**Decision rationale:** Per CA MTUS Chronic Pain Medical Treatment Guidelines, Cyclobenzaprine (Flexeril) is a skeletal muscle relaxant and a central nervous system (CNS) depressant. Guidelines recommend Cyclobenzaprine (Flexeril) be used as an option, using a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. Treatment should be brief. The addition of cyclobenzaprine to other agents is not recommended. In this case, the guidelines only recommend use of this medication for a short duration, and not longer than 2-3 weeks. There is documentation of ongoing treatment with Cyclobenzaprine since at least 1/13/2015, and continuation for any amount of time does not comply with the recommended guidelines. Therefore, based on CA MTUS guidelines and submitted medical records, the request for Cyclobenzaprine is not medically necessary.

**Acetaminophen/Codeine (Tylenol #4) 300/60 mg Qty 45: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for chronic pain Page(s): 80.

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

**Decision rationale:** According to the CA MTUS guidelines, Tylenol with Codeine is a short-acting opioid analgesic, and is in a class of drugs which has a primary indication to relieve symptoms related to pain. It is recommended as an option for mild to moderate pain. Codeine is a schedule C-II controlled substance, but codeine with acetaminophen is a C-III controlled substance. It is similar to morphine. 60 mg of codeine is similar in potency to 600 mg of acetaminophen. Tylenol #4 has twice as much codeine as Tylenol #3. The treatment of chronic pain with any opioid analgesic requires review and documentation of pain relief, functional status, appropriate medication use, and side effects. A pain assessment should include current pain, intensity of pain after taking the opiate, and the duration of pain relief. 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 non-adherent) 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. In this case, the submitted medical records failed to provide ongoing monitoring of the 4 A's, which include detailed pain levels (baseline, average, least, and worst). In addition, the records do not establish that drug screening has been performed or that issues of abuse, addiction, or poor pain control have been addressed. As noted in the references, opioids may be continued if there is documentation of an improvement in functioning and pain. Therefore, based on CA MTUS guidelines and submitted medical records, the request for Tylenol #4 is not medically necessary.