

<b>Case Number:</b>	CM15-0109029		
<b>Date Assigned:</b>	06/15/2015	<b>Date of Injury:</b>	03/15/2004
<b>Decision Date:</b>	09/23/2015	<b>UR Denial Date:</b>	05/06/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/05/2015

### 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 56 year old female, who sustained an industrial injury on 3/15/2004. The mechanism of injury is unknown. The injured worker was diagnosed as having cervical anterior cervical discectomy and fusion, lumbar arthrodesis, scoliosis, cervical spinal stenosis, post laminectomy syndrome, cervical and lumbar disc degeneration and cervical degenerative disc disease. Lumbar x rays showed posterior intact fusion and multilevel degenerative disc disease with mild osteoarthritis. Treatment to date has included injections, home exercise program, therapy and medication management. In a progress note dated 4/28/2015 the injured worker complains of neck, back and right shoulder pain with an average pain rating of 6/10. Physical examination showed a tender sacroiliac joint and painful cervical range of motion. The treating physician is requesting Cymbalta 60 mg delayed release #60 with 1 refill, Cyclobenzaprine 10 mg #90 with 1 refill, Reglan 10 mg #90 with 1 refill, Ibuprofen 800 mg #90, Pentazocine/Acetaminophen 25/650 mg #120, Dexilant 60 mg delayed release #60 with one refill, Amrix 30 mg extended release #30 with 1 refill, Talwin 50 mg/0.5 mg #120 and Talwin 50 mg/0.5 mg #120-do not fill until 5/27/2015.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Cyclobenzaprine 10mg #90 with 1 refill:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): (s) 63 of 127.

**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) Due to inadequate qualifying evidence for use of a muscle relaxant, the request is not medically necessary. All muscle relaxant medications should be titrated down slowly to prevent an acute withdrawal syndrome.

**Reglan 10mg #90 with 1 refill:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Physicians' Desk Reference 67th Edition.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Antiemetics (for opioid nausea).

**Decision rationale:** The request is for the use of reglan. There is a medication usually used for nausea in certain circumstances. The MTUS guidelines are silent regarding this issue but the ODG state the following regarding antiemetics in patients taking opioids: Not recommended for nausea and vomiting secondary to chronic opioid use recommended for acute use as noted below per FDA-approved indications. Nausea and vomiting is common with use of opioids. These side effects tend to diminish over days to weeks of continued exposure. Studies of opioid adverse effects including nausea and vomiting are limited to short-term duration (less than four weeks) and have limited application to long-term use. If nausea and vomiting remains prolonged, other etiologies of these symptoms should be evaluated for. The differential diagnosis includes gastroparesis (primarily due to diabetes). Current research for treatment of nausea and vomiting as related to opioid use primarily addresses the use of antiemetics in patients with cancer pain or those utilizing opioids for acute/postoperative therapy. Recommendations based on these studies cannot be extrapolated to chronic non-malignant pain patients. There is no high-quality literature to support any one treatment for opioid-induced nausea in chronic non-malignant pain patients. (Moore 2005) Promethazine (Phenergan): This drug is a phenothiazine. It is recommended as a sedative and antiemetic in pre-operative and post-operative situations. Multiple central nervous system effects are noted with use including somnolence, confusion and sedation. Tardive dyskinesia is also associated with use. This is characterized by involuntary movements of the tongue, mouth, jaw, and/or face. Choreoathetoid movements of the extremities can also occur. Development appears to be associated with prolonged treatment and in some cases can be

irreversible. Anticholinergic effects can occur (dry mouth, dry eyes, urinary retention and ileus). In this case, as indicated above, the patient does not qualify for the use of this medication. It is not indicated for use in patients who develop nausea or vomiting secondary to chronic opioid use. As such, the request is not medically necessary.

**Ibuprofen 800mg #90: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): (s) 67-68 of 127.

**Decision rationale:** The request is for the use of NSAIDS to aid in pain relief. NSAIDS are usually used to aid in pain and inflammation reduction. The MTUS guidelines states that for osteoarthritis NSAIS are 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, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDS appear to be superior to acetaminophen especially for patients with moderate to severe pain. There is no evidence to support one drug in this class over another based on efficacy. In particular, there appears to be no difference between NSAIDS and COX-2 NSAIDS in terms of pain relief. The main concern of selection is based on adverse effects, with COX-2 NSAIDS having fewer GI side effects at the risk of increased cardiovascular side effects. The FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDS and is a class effect (with naproxen being the safest drug). There is no evidence of long-term effectiveness for pain and function. (Chen, 2008) (Laine, 2008) For back pain, NSAIDS are recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDS are more effective than acetaminophen for acute LBP. (Van Tulder, 2006) (Hancock, 2007) For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDS vs. placebo. In patients with axial low back pain this same review found that NSAIDS were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. (Roelofs-Cochrane, 2008) The addition of NSAIDS or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician. (Hancock, 2007) In this case, there is inadequate documentation of functional improvement to justify continued use, as the guidelines recommend the lowest dose for the shortest period of time. The significant side effect profile of medications in this class put the patient at risk when used chronically. As such, the request is not medically necessary.

**Pentazocine/Acetaminophen 25/650mg #120: Upheld**

**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 Index, 20Th Edition (web), 2015, Pain Chapter, Pentazocine.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pentazocine (Talwin/Talwin NX).

**Decision rationale:** Not recommended for the treatment of chronic pain. There is no evidence that supports the addition of pentazocine (Talwin) to decrease side effects from opioids, and see Opioids, Mixed agonists-antagonists, where it says that mixed agonists-antagonists, including butorphanol (Stadol), dezocine (Dalgan), nalbuphine (Nubain) and pentazocine (Talwin), have limited use among chronic pain patients because of their ceiling effect for analgesia that results in the analgesic effect not increasing with dose escalation. In this case, as stated above, this medication is not indicated. This is secondary to poor scientific evidence regarding its efficacy for chronic pain. As such, the request is not medically necessary.

**Talwin 50mg/0.5mg #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Mixed agonist-antagonists.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pentazocine (Talwin/Talwin NX).

**Decision rationale:** Not recommended for the treatment of chronic pain. There is no evidence that supports the addition of pentazocine (Talwin) to decrease side effects from opioids, and see Opioids, Mixed agonists-antagonists, where it says that mixed agonists-antagonists, including butorphanol (Stadol), dezocine (Dalgan), nalbuphine (Nubain) and pentazocine (Talwin), have limited use among chronic pain patients because of their ceiling effect for analgesia that results in the analgesic effect not increasing with dose escalation. In this case, as stated above, this medication is not indicated. This is secondary to poor scientific evidence regarding its efficacy for chronic pain. As such, the request is not medically necessary.

**Talwin 50mg/0.5mg (do not fill until 5/27/15) #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Mixed agonist-antagonists.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pentazocine (Talwin/Talwin NX).

**Decision rationale:** Not recommended for the treatment of chronic pain. There is no evidence that supports the addition of pentazocine (Talwin) to decrease side effects from opioids, and see Opioids, Mixed agonists-antagonists, where it says that mixed agonists-antagonists, including butorphanol (Stadol), dezocine (Dalgan), nalbuphine (Nubain) and pentazocine (Talwin), have limited use among chronic pain patients because of their ceiling effect for analgesia that results in the analgesic effect not increasing with dose escalation. In this case, as stated above, this

medication is not indicated. This is secondary to poor scientific evidence regarding its efficacy for chronic pain. As such, the request is not medically necessary.

**Dexilant 60mg Delayed Release #60 with 1 refill:** 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 Page(s): 68 of 127.

**Decision rationale:** The request is for the use of a medication in the class of a proton pump inhibitor. This is usually given as an acid reducing medication for patients with esophageal reflux, gastritis, or 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.

**Amrix 30mg Extended Release #30 with 1 refill:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): (s) 63 of 127.

**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) Due to inadequate qualifying evidence for use of a muscle relaxant, the request is not medically necessary. All muscle relaxant medications should be titrated down slowly to prevent an acute withdrawal syndrome.