

<b>Case Number:</b>	CM14-0165578		
<b>Date Assigned:</b>	10/10/2014	<b>Date of Injury:</b>	02/07/2001
<b>Decision Date:</b>	11/12/2014	<b>UR Denial Date:</b>	09/25/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/08/2014

### 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 Occupational Medicine, has a subspecialty in Preventive Medicine and is licensed to practice in Iowa. 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:

This patient is a 58 year old employee with date of injury of 2/7/2001. Medical records indicate the patient is undergoing treatment for lumbar disc displacement; lumbar radiculopathy, post laminectomy syndrome of the lumbar region; low back pain; sacroilitis and insomnia. He is s/p placement of spinal cord stimulator (with subsequent removal). He is s/p abdominal surgery (10/2009). Subjective complaints include low back pain described as sharp, stabbing, burning, constant and radiating. The pain radiates to the bilateral lower extremities. Numbness, weakness and paresthesia are noted. He has had ice, heat and NSAIDS without improvement. He says his low back pain is becoming worse and makes it difficult to do activities of daily living. With medication, his pain level is a 9/10. Objective findings on exam include no foot drop, an unstable gait and he walks on his heels with difficulty due to pain. He has paralumbar spasm and severe tenderness in the right buttock where the battery sits. Atrophy is present in the quadriceps. Lateral bending to the right is 0-10 degrees, to the left 20-30 with pain. Extension is 0-10 degrees. Right and left resisted rotation (ROM) is diminished. Straight leg raise is positive at 40 degrees on the left. ROM of the spine is limited due to pain. Lower extremity deep tendon reflexes are absent at the knees. Sensation to light touch is decreased on the left in the lateral thigh. Motor strength of the lower extremities measures 5/5 bilaterally. Treatment has consisted of PT. The patient has had ice and NSAIDS with no relief. Medications include: Restoril, Anaprox, Tizanidine tablet, Norco, Prilosec delayed release, Lidoderm film 5% (topical) and Opana ER. He had an LESI on 11/2013 with 50% relief. He had a caudal steroid epidural injection on 5/3/2013. The utilization review determination was rendered on 9/25/2014 recommending non-certification of Opana ER 10mg 1 tab by mouth twice a day #60; Restoril 30mg #30 1 cap once a day at bedtime no refills; Anaprox 550mg #60 1 tab twice a day no refills; Tizanidine 4mg tablet #60 every 12 hours; Norco tablet 325mg -7.5mg #60 1 tab every 12

hours; Prilosec delayed release capsule 20mg #30 1 cap once a day and Lidoderm film 5% #60 patch twice day.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Opana ER 10mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioid use for chronic pain.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Low Back - Lumbar & Thoracic (Acute & Chronic), Opioids, Opana

**Decision rationale:** ODG states concerning Opana" Not recommended. See Opioids for general guidelines, as well as specific Oxymorphone (Opana) listing for more information and references. Due to issues of abuse and Black Box FDA warnings, Oxymorphone is recommended as second line therapy for long acting opioids. Oxymorphone products do not appear to have any clear benefit over other agents and have disadvantages related to dose timing (taking the IR formulation with food can lead to overdose), and potential for serious adverse events (when the ER formulation is combined with alcohol use a potentially fatal overdose may result). (Opana FDA labeling)". ODG does not recommend the use of opioids for low back pain "except for short use for severe cases, not to exceed 2 weeks." The patient has exceeded the 2 week recommended treatment length for opioid usage. MTUS does not discourage use of opioids past 2 weeks, but does state that "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." While the treating physician does document a pain contract and urine drug screening, the patient continues to have 9/10 intermittent pain that shoots down the lower extremities. In addition, the treating physician does not fully document the least reported pain over the period since last assessment, intensity of pain after taking opioid, pain relief, trials and failures of first line treatment, or an increased level of function, or improved quality of life. The patient is also taking Norco. As such the request for Opana ER #60 is not medically necessary.

**Restoril 30mg #30 no refills:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Anxiety medications in chronic pain and Benzodiazepines

**Decision rationale:** MTUS states that benzodiazepine (i.e. Restoril) is "Not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks." ODG states "Benzodiazepines are not recommended as first-line medications by ODG. Criteria for use if provider & payor agree to prescribe anyway: 1) Indications for use should be provided at the time of initial prescription. 2) Authorization after a one-month period should include the specific necessity for ongoing use as well as documentation of efficacy." The medical record does not provide any extenuating circumstances to recommend exceeding the guideline recommendations. Additionally, no documentation as to if a trial of antidepressants was initiated and the outcome of this trial. As such, the request Restoril 30mg #30 no refills is not medically necessary.

**Anaprox 550mg #60 no refills:** 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 NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-73. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic), Naproxen, NSAIDs (non-steroidal anti-inflammatory drugs)

**Decision rationale:** MTUS specifies four recommendations regarding NSAID use:1) Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain.2) Back Pain - Acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute LBP.3) Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics.4) Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in with neuropathic pain. The medical documents do not indicate that the patient is being treated for osteoarthritis. Additionally, the treating physician does not document failure of primary (Tylenol) treatment and there is no documentation of functional improvement while taking Anaprox. Progress notes do not indicate how long the patient has been on naproxen, but the MTUS guidelines recommend against long-term use. The patient continues to have 9/10 intermittent pain that shoots down the lower extremities, but as

MTUS outlines, the evidence for NSAID use in neuropathic pain is inconsistent. As such, the request for Anaprox 550mg #60 no refills is not medically necessary.

**Tizanidine 4mg tablet #60: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants, Zanaflex Page(s): 63-67.

**Decision rationale:** Tizanidine (Zanaflex) is a muscle relaxant. MTUS states concerning muscle relaxants "Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used with caution in patients driving motor vehicles or operating heavy machinery. Drugs with the most limited published evidence in terms of clinical effectiveness include chlorzoxazone, Methocarbamol, Dantrolene and Baclofen. According to a recent review in American Family Physician, skeletal muscle relaxants are the most widely prescribed drug class for musculoskeletal conditions (18.5% of prescriptions), and the most commonly prescribed antispasmodic agents are Carisoprodol, Cyclobenzaprine, Metaxalone, and Methocarbamol, but despite their popularity, skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. (See2, 2008)." MTUS states, "Tizanidine (Zanaflex, generic available) is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. Eight studies have demonstrated efficacy for low back pain. One study (conducted only in females) demonstrated a significant decrease in pain associated with chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain. May also provide benefit as an adjunct treatment for fibromyalgia.." The medical documents indicate that patient is far in excess of the initial treatment window and period and ODG recommends short term use of muscle relaxants. In addition, it is not clear that the patient is getting relief from Tizanidine, as the patient continues to have pain with radiculopathy and muscle spasms. As such, the request for Tizanidine 4mg tablet #60 is not medically necessary.

**Norco tablet 325mg -7.5mg #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioid use for chronic pain.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG),

Neck and Upper Back (Acute and Chronic), Low Back - Lumbar & Thoracic (Acute & Chronic), Pain, Opioids

**Decision rationale:** ODG does not recommend the use of opioids for neck and low back pain "except for short use for severe cases, not to exceed 2 weeks." The patient has exceeded the 2 week recommended treatment length for opioid usage. MTUS does not discourage use of opioids past 2 weeks, but does state that "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." While the treating physician does document a pain contract and urine drug screening, the patient continues to have 9/10 intermittent pain that shoots down the lower extremities. In addition, the treating physician does not fully document the least reported pain over the period since last assessment, intensity of pain after taking opioid, pain relief, trials and failures of first line treatment, or an increased level of function, or improved quality of life. The patient is also taking Opana ER. As such the request for Norco tablet 325mg -7.5mg #60 is not medically necessary.

**Prilosec delayed release capsule 20mg #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic), NSAIDs, GI symptoms & cardiovascular risk

**Decision rationale:** MTUS states "Determine if the patient is at risk for gastrointestinal events: (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)." And "Patients at intermediate risk for gastrointestinal events and no cardiovascular disease:(1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44)." The medical documents provided do not establish the patient has having documented GI bleeding, perforation, peptic ulcer, high dose NSAID, or other GI risk factors as outlined in MTUS. As such, the request for Prilosec delayed release capsule 20mg #30 1 cap once a day is not medically necessary.

**Lidoderm film 5% #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound creams

**Decision rationale:** MTUS and ODG recommends usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." ODG also states that topical lidocaine is appropriate in usage as patch under certain criteria, but that "no other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain." MTUS states regarding lidocaine, "Neuropathic pain Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica)." MTUS indicates lidocaine "Non-neuropathic pain: Not recommended." While the treating physician does document neuropathic pain, the medical records do not indicate failure of first-line therapy for neuropathic pain and functional improvement while utilizing the Lidoderm patch. ODG states regarding lidocaine topical patch, "This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia". Medical documents do not document the patient as having post-herpetic neuralgia. As such, the request for Lidoderm film 5% #60 is not medically necessary.