

<b>Case Number:</b>	CM14-0046602		
<b>Date Assigned:</b>	09/10/2014	<b>Date of Injury:</b>	01/02/2006
<b>Decision Date:</b>	10/06/2014	<b>UR Denial Date:</b>	04/01/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/14/2014

### 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 Preventative Medicine, has a subspecialty in Occupational 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 55 year old employee with date of injury of 1/2/2006. Medical records indicate the patient is undergoing treatment for cervical radiculopathy; lumbosacral radiculopathy; shoulder tendinitis/bursitis; wrist tendinitis/bursitis and knee sprain/strain. He is s/p lumbar arthrodesis at the L5-S1 level on 12/3/2013 with pain. Subjective complaints include hand, shoulder and cervical pain. He has problems bending, stooping, squatting and prolonged standing and walking. He has difficulty bathing, dressing and undressing. Objective findings include spasm, tenderness and guarding in the paravertebral musculature of the lumbar spine with a decreased range of motion (ROM). He has decreased sensation over L5 dermatomes bilaterally with pain. He ambulates with an antalgic gait and a cane. He has weakness with toe and heel walking bilaterally. Treatment has consisted of trigger point injections, PT, Ambien, Gabapentin, Norco and Paxil. The utilization review determination was rendered on 4/1/2014 recommending non-certification of 1 Prescription of Norflex (Orphenadrine) 100 Mg #100; 1 Prescription of Prilosec 20mg #90; 1 Prescription of Norco 10/325mg #30; 1 Prescription of Flector 1.3 patch and Voltaren gel 1%.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**1 Prescription of Norflex (Orphenadrine) 100 Mg #100: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain) Page(s): 63-65.

**Decision rationale:** Norflex is classified as a muscle relaxant. MTUS states, "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." Additionally, MTUS states "Orphenadrine (Norflex, Banflex, Antiflex, Mio-Rela, Orphenate generic available): This drug is similar to diphenhydramine, but has greater anticholinergic effects. The mode of action is not clearly understood. Effects are thought to be secondary to analgesic and anticholinergic properties. This drug was approved by the FDA in 1959. Side Effects: Anticholinergic effects (drowsiness, urinary retention, dry mouth). Side effects may limit use in the elderly. This medication has been reported in case studies to be abused for euphoria and to have mood elevating effects. (Shariatmadari, 1975) Dosing: 100 mg twice a day; combination products are given three to four times a day. (See, 2008)." MTUS guidelines recommend against the long term use of muscle relaxants. The treating physician has not provided documentation of acute muscle spasms, documentation of functional improvement while on Norflex, and the treating physician has not provided documentation of trials and failures of first line therapies. As such the request for 1 Prescription of Norflex (Orphenadrine) 100 Mg #100 is not medically necessary.

**1 Prescription of Prilosec 20mg #90: Upheld**

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

**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 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 or other GI risk factors as outlined in MTUS. Additionally, there is no evidence provided to indicate the patient suffers from dyspepsia because

of the present medication regimen. As such, the request for 1 Prescription of Prilosec 20mg #90 is not medically necessary.

### **1 Prescription of Norco 10/325mg #30: Upheld**

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

**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) Official Disability Guidelines (ODG) Neck and Upper Back (Acute and Chronic), Low Back - Lumbar & Thoracic (Acute & Chronic), Opioids, Pain

**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." 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, increased level of function, or improved quality of life. In addition, the utilization reviewer recommended weaning and modified the request. As such, the question for Norco 325/10mg # 30 is not medically necessary.

### **1 Prescription of Flector 1.3 patch: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation (ODG) Official Disability Guidelines Chronic Pain Topical NSAIDs

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Flector patch (diclofenac epolamine)

**Decision rationale:** MTUS is silent concerning Flector patch (diclofenac epolamine). ODG states, "Not recommended as a first-line treatment. See the Diclofenac listing, where topical diclofenac is recommended for osteoarthritis after failure of an oral NSAID or contraindications to oral NSAIDs, after considering the increased risk profile with diclofenac, including topical formulations. Flector patch is FDA indicated for acute strains, sprains, and contusions. (FDA, 2007) On 12/07/09 the FDA issued warnings about the potential for elevation in liver function tests during treatment with all products containing diclofenac. Postmarketing surveillance has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure. Physicians should measure transaminases

periodically in patients receiving long-term therapy with diclofenac. (FDA, 2009) The efficacy in clinical trials for topical NSAIDs has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. In addition, there is no data that substantiate Flector efficacy beyond two weeks. See also Topical analgesics, Non-steroidal antiinflammatory agents (NSAIDs), and the diclofenac topical listing. [Flector ranked #17 in amount billed for WC in 2011. (Coventry, 2012)]. The treating physician did not detail a trial and failure of oral NSAIDs or evidence of NSAID induced dyspepsia. In addition, the treating physician did not document functional improvement from Flector patches. As such, the request for 1 Prescription of Flector 1.3 patch is not medically necessary.

**Voltaren gel 1%:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation (ODG) Official Disability Guidelines Chronic Pain Topical NSAIDs

**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 recommend usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. 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. MTUS specifically states for Voltaren Gel 1% (diclofenac) that it is, "Indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder." Medical records do not indicate that the patient is being treated for osteoarthritis pain in the joints. In addition, the treating physician did not document failure of oral NSAID medication and gastrointestinal intolerance. As such, the request for Voltaren gel 1% is not medically necessary.