

<b>Case Number:</b>	CM14-0050204		
<b>Date Assigned:</b>	07/07/2014	<b>Date of Injury:</b>	09/09/2008
<b>Decision Date:</b>	08/26/2014	<b>UR Denial Date:</b>	04/11/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/17/2014

### 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 California. 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 9/9/2008. Medical records indicate the patient is undergoing treatment for lumbar disc disease with radiculopathy. Subjective complaints include lumbar spine pain, 6-7/10 on average; pain is 8-9/10 during cold and rainy weather; as well as standing, sitting and walking greater than 2 blocks. She reports numbness across the sacrum, into the right buttocks and mid thighs to the knees and right foot. Objective findings include no obvious deformities or palpable tenderness in lumbar spine. Lumbar range of motion was at 90 degrees flexion; 15 degrees extension and lateral bending bilaterally; mild tenderness over sacrum more right than left; straight leg test raise was negative; no strength decrease and a slight decrease in sensation in lower extremity. Deep tendon reflexes were symmetrical. Patient could walk with a strong, steady gait without limping or guarding to lower extremities. Treatment has consisted of Omeprazole, Tylenol and Ibuprofen. She uses heat and ice as needed. She was taking Norco, Soma and Vicodin. She uses marijuana, smokes one joint a day and has a current card. The utilization review determination was rendered on 4/10/2014 recommending non-certification of Prescription of Tramcap C; for Prescription of Ibuprofen 600mg, #90; Prescription of Omeprazole 20mg, #60 and Prescription of Baclofen 10mg, #60.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Prescription of Tramcap C: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Compounded.

**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 (Chronic), Topical Analgesics.

**Decision rationale:** Tramcap C is a compound analgesic that contains Capsaicin and Tramadol. The Chronic Pain Medical Treatment Guidelines on Topical Analgesics indicates that topical medications are largely experimental in use with few randomized controlled trials to determine efficacy or safety. These are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. It is also noted this particular formulation contains agents that are not recommended for topical use under guidelines, specifically Tramadol. The guidelines also indicate that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. There is no evidence for efficacy and safety of topical Tramadol. As such, the request for prescription of Tramcap C is not medically necessary.

**Prescription of Ibuprofen 600mg, #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 Meloxicam, NSAIDs Page(s): 67-72.

**Decision rationale:** MTUS recommends the use of NSAIDs for the acute exacerbation of back pain at the lowest effective dose for the shortest amount of time due to the increased cardiovascular risk, renal, hepatic and GI side effects associated with long term use. MTUS states Ibuprofen (Motrin, Advila [otc], generic available): 300, 400, 600, 800 mg. Dosing: Osteoarthritis and off-label for ankylosing spondylitis: 1200 mg to 3200 mg daily. Individual patients may show no better response to 3200 mg as 2400 mg, and sufficient clinical improvement should be observed to offset potential risk of treatment with the increased dose. Higher doses are generally recommended for rheumatoid arthritis: 400-800 mg PO 3-4 times a day, use the lowest effective dose. Higher doses are usually necessary for osteoarthritis. Doses should not exceed 3200 mg/day. Mild pain to moderate pain: 400 mg PO every 4-6 hours as needed. Doses greater than 400 mg have not provided greater relief of pain. The patient reported on going GI symptoms with concurrent use of Omeprazole while taking Ibuprofen. The treating physician did not document a decrease in pain or functional improvement from the use of Ibuprofen. As such the request for Ibuprofen 600mg, #90 is not medically necessary.

**Prescription of Omeprazole 20mg, #60: 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). While the treating physician does document dyspepsia, the treating physician did not document GI bleeding/perforation/peptic ulcer or other GI risk factors as outlined in MTUS to meet the above guidelines. As such, the request for Omeprazole 20mg #60 is not medically necessary.

**Prescription of Baclofen 10mg, #60: Upheld**

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

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

**Decision rationale:** Baclofen 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. (Chou, 2007) (Mens, 2005) (Van Tulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) 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 Baclofen (Lioresal, generic available): The mechanism of action is blockade of the pre- and post-synaptic GABAB receptors. It is recommended orally for the treatment of spasticity and muscle spasm related to multiple sclerosis and spinal cord injuries. Baclofen has been noted to have benefits for treating lancinating, paroxysmal neuropathic pain (trigeminal neuralgia, non-FDA approved). (ICSI, 2007). The treating physician has not provided documentation of muscle spasms related to multiple sclerosis or spinal cord injuries. Additionally, the treating physician has not provided documentation of trials and failures of first line therapies. As such the request for Baclofen 10mg, #60 is not medically necessary.