

<b>Case Number:</b>	CM14-0051857		
<b>Date Assigned:</b>	07/07/2014	<b>Date of Injury:</b>	03/23/2011
<b>Decision Date:</b>	09/05/2014	<b>UR Denial Date:</b>	04/01/2014
<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 Internal Medicine, has a subspecialty in Emergency Medicine and is licensed to practice in Florida. 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 59 year-old with a date of injury of 03/23/11. A progress report associated with the request for services, dated 03/06/14, identified subjective complaints of neck, mid, and low back pain into the right leg. Objective findings included tenderness to palpation of the cervical, thoracic, and lumbar spines. Motor and sensory function was normal with the exception of the left deltoid. Diagnoses included cervical, mid-back, and low back myofascial pain; cervical spondylosis; and possible lumbar spondylosis. Treatment had included oral analgesics and muscle relaxants. A Utilization Review determination was rendered on 04/01/14 recommending non-certification of "Norco 10/325mg #60; Cyclobenzaprine 5mg #60; and Compound analgesic cream-Tramadol / Capsaicin / Gabapentin / Camphor / Menthol #1".

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Norco 10/325mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for use of Opioids.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 308, Chronic Pain Treatment Guidelines Opioids Page(s): 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Opioids for Chronic Pain.

**Decision rationale:** Norco 10/325 is a combination drug containing acetaminophen and the opioid hydrocodone. The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Guidelines related to on-going treatment of opioids state that there should be documentation and ongoing review of pain relief, functional status, appropriate 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 state that there should be documentation and ongoing review of pain relief, functional status, appropriate use, and side effects. The guidelines note that a recent epidemiologic study found that opioid treatment for chronic non-malignant pain did not seem to fulfill any of the key outcome goals including pain relief, improved quality of life, and/or improved functional capacity (Eriksen 2006). The Chronic Pain Guidelines also state that with chronic low back pain, opioid therapy "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (> 16 weeks), but also appears limited." Additionally, "There is also no evidence that opioids showed long-term benefit or improvement in function when used as treatment for chronic back pain (Martell - Annals, 2007)." The MTUS Guidelines further state that opioid therapy is not recommended for the low back beyond 2 weeks. The patient has been on Norco in excess of 16 weeks. The Official Disability Guidelines (ODG) state: "While long-term opioid therapy may benefit some patients with severe suffering that has been refractory to other medical and psychological treatments, it is not generally effective achieving the original goals of complete pain relief and functional restoration." Therapy with Norco appears to be ongoing. The documentation submitted lacked a number of the elements listed above, including the level of functional improvement afforded by the chronic opioid therapy. Therefore, the record does not demonstrate medical necessity for Norco.

**Cyclobenzaprine 5mg #60:** 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 Cyclobenzaprine; Muscle Relaxants Page(s): 41-42; 63-66.

**Decision rationale:** Flexeril (cyclobenzaprine) is an antispasmodic muscle relaxant. The Medical Treatment Utilization Schedule (MTUS) states that muscle relaxants are recommended with caution as a second-line option for short-term treatment of acute exacerbations of low back pain. They note that in most low-back pain cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also, there is no additional benefit shown in combination of NSAIDs. Likewise, the efficacy diminishes over time. The MTUS states that cyclobenzaprine (Flexeril) is indicated as a short course of therapy. Limited, mixed evidence does not allow a recommendation for cyclobenzaprine for chronic use. Though it is noted that cyclobenzaprine is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. They further state that treatment should be brief and that addition of cyclobenzaprine to other agents is not recommended. The Guidelines do note that cyclobenzaprine has been shown to produce a moderate benefit in the treatment of fibromyalgia. The record does not show any evidence of fibromyalgia, and other indications for Flexeril beyond a short course are not well supported. The patient has been on Flexeril for a

prolonged period. Likewise, it has not been prescribed in the setting of an acute exacerbation of symptoms. Therefore, based upon the Guidelines, the record does not document the further medical necessity for Flexeril (cyclobenzaprine).

**Compound analgesic cream-Tramadol/Capsaicin/Gabapentin/Camphor/Menthol #1:**  
Upheld

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

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 308, Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Topical Analgesics Other Medical Treatment Guideline or Medical Evidence: [www.updates.pain-topics.org](http://www.updates.pain-topics.org); J Anesth. 2010 Oct; 24(5):705-8.

**Decision rationale:** The Medical Treatment Utilization Schedule (MTUS) Chronic Pain Guidelines state that topical analgesics are recommended as an option in specific circumstances. However, they do state that they are "Largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." Menthol is a topical form of cryotherapy. The Medical Treatment Utilization Schedule (MTUS) does not specifically address menthol as a topical analgesic. However, at-home applications of local heat or cold to the low back are considered optional. The Official Disability Guidelines (ODG) state that Biofreeze (menthol) is recommended as an optional form of cryotherapy for acute pain. Studies on acute low back pain showed significant pain reduction after each week of treatment. There is no recommendation related to the use of menthol for chronic pain. Capsaicin is an active component of chili peppers and acts as an irritant. The Guidelines for Chronic Pain state that capsaicin topical is "Recommended only as an option in patients who have not responded or are intolerant to other treatments." It is noted that there are positive randomized trials with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific low back pain, but it should be considered experimental at very high doses. The Guidelines further note that although capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in combination with other modalities) in patients whose pain has not been controlled successfully with conventional therapy. The Official Disability Guidelines (ODG) state that neither salicylates nor capsaicin has shown efficacy in the treatment of osteoarthritis. Tramadol 20% is an opioid analgesic being used as a topical agent. The efficacy of topical tramadol is not specifically addressed in the MTUS or the Official Disability Guidelines (ODG). There is some data that topical tramadol has efficacy directly at an acute postsurgical site. However, there is insufficient data to assure that significant systemic absorption does not occur. Gabapentin is an anti-epilepsy drug. The MTUS Guidelines state that gabapentin is: "Not recommended. There is no peer-reviewed literature to support use." In this case, considering its moderate to poor efficacy, there is no documentation of the failure of conventional therapy for the medical necessity of capsaicin topical or the 0.375% formulation. Also, lacking definitive data on the efficacy of topical tramadol, the medical record does not document neuropathic pain that has failed antidepressant or anticonvulsant therapy or other compelling reason for its use. The Guidelines further state:

"Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore, in this case, there is no documentation of the failure of conventional therapy, documented functional improvement, or recommendation for all the ingredients of the compound and therefore the medical necessity of the compounded formulation.