

<b>Case Number:</b>	CM15-0015158		
<b>Date Assigned:</b>	03/17/2015	<b>Date of Injury:</b>	05/31/2005
<b>Decision Date:</b>	04/16/2015	<b>UR Denial Date:</b>	01/02/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/27/2015

### 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: Pennsylvania

Certification(s)/Specialty: Internal 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 53 year old female, who sustained an industrial injury on 5/31/2005, with injuries to neck, left shoulder, low back, both hands, both elbows, left ankle, and left hip. Diagnoses include chronic pain syndrome, discogenic cervical and lumbar spine condition, cervical disc bulge with protrusion and facet inflammation, headaches, right shoulder impingement syndrome and partial rotator cuff tear, bilateral carpal tunnel syndrome status-post decompression, and ankle sprain. Additional past medical history includes hypertension and diabetes. Treatments/evaluation to date have included consultations, with diagnostic laboratory and imaging studies, physical therapy, injection therapy, carpal tunnel surgery, and medications. The latest physician progress notes, dated 11/21/2014, document the injured worker had severe pain along the neck and shoulders, pain across the low back that shoots into the lower extremities, with numbness and tingling; has difficulty with fine motor skills; and is awaiting authorization for left shoulder surgery. Examination showed tenderness of the cervical paraspinal muscles, trapezius and shoulder girdle, and tenderness across lumbar paraspinal muscles with pain with facet loading. The treatment plan included recommendations for continuation of medications, a low-back brace, elbow brace, cervical traction with cervical pillow and air bladder, and a psychiatric evaluation due to anxiety and depression related to chronic pain. It was noted that protonix was for upset stomach and Effexor was for depression. A spine consultation for neck and low back pain was requested. The Utilization Review determination states that the specific physician requested for the spine consultation was a spine surgeon. It was noted that this injured worker is currently not working and has not worked since 2007. On 1/2/15, Utilization

Review (UR) non-certified requests for 1 hinged elbow brace, 1 consultation for the lumbar spine, 60 flexeril 7.5 mg, 60 nalfon 400 mg, 30 tramadol ER 150 mg, 60 protonix 20 mg, lidopro lotion 4 oz, 20 terocin patches. UR modified a request for 60 effexor 75 mg to 40 effexor 75 mg. UR cited the MTUS, ACOEM, and ODG guidelines.

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

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

#### **1 Hinged Elbow Brace: Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 10 Elbow Disorders (Revised 2007) Page(s): 26. Decision based on Non-MTUS Citation Official Disability Guidelines, Elbow (Acute & Chronic).

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 10 Elbow Disorders (Revised 2007) Page(s): 26. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) elbow chapter: splinting.

**Decision rationale:** The documentation notes that the injured worker sustained injuries to both elbows, but there is no other discussion of pathology related to the elbow. No elbow examination was documented. There were no diagnoses noted related to the elbow. The request for a hinged elbow brace did not specify which elbow was to have the brace applied. The ACOEM elbow chapter discusses use of braces for epicondylalgia, noting that while there is insufficient evidence to support their use, they are recommended as they are not invasive, have few side effects, and are low cost. The ODG notes that a splint is recommended for cubital tunnel syndrome. However, there was no documentation of a diagnosis of epicondylalgia or cubital tunnel syndrome for this injured worker. Due to lack of sufficient documentation of elbow disorder and specific indication for an elbow brace, the request for 1 hinged elbow brace is not medically necessary.

#### **1 Consultation For The Lumbar Spine: Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 305.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 305-307.

**Decision rationale:** The treating physician indicated a request for a consultation with a specific physician who was noted to be a spine surgeon. The documentation from the physician states that the injured worker has a discogenic lumbar condition with MRI showing progression of disease. The date and specific results of this MRI were not submitted. Physical examination showed tenderness across the lumbar paraspinal muscles, pain along facets and pain with facet loading. No other physical examination findings pertinent to the lumbar spine were noted, and no radicular findings were described. The ACOEM states that referral for surgical consultation is indicated for patients who have severe and disabling lower leg symptoms in a distribution

consistent with abnormalities on imaging studies (radiculopathy), preferably with accompanying objective signs of neural compromise, activity limitations due to radiating leg pain for more than one month or extreme progression of lower leg symptoms, clear clinical, imaging, and electrophysiologic evidence of a lesion that has been shown to benefit in both the short and long term from surgical repair, and failure of conservative treatment to resolve disabling radicular symptoms. In this case there were no symptoms, physical examination findings, imaging studies, or electrodiagnostics consistent with radiculopathy. The physician documented that the injured worker had low back pain shooting into the lower extremities associated with numbness and tingling. No decrease in strength, sensation, or reflexes on examination were documented. There are insufficient clinical findings of radiculopathy, such as dermatomal sensory loss or motor deficits correlating with a specific lesion identified by objective testing. Due to lack of specific indication, the request for consultation for the lumbar spine is not medically necessary.

**60 Flexeril 7.5mg:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines cyclobenzaprine p. 41-42 muscle relaxants p. 63-66 Page(s): 41-42, 63-66.

**Decision rationale:** The MTUS for chronic pain does not recommend muscle relaxants for chronic pain. Non-sedating muscle relaxants are an option for short-term exacerbations of chronic low back pain. The muscle relaxant prescribed in this case is sedating. The injured worker has chronic pain with no evidence of prescribing for flare-ups. The quantity prescribed implies long-term use, not for a short period of use for acute pain. Per the MTUS chronic pain medical treatment guidelines, cyclobenzaprine (Flexeril, fexmid) is a skeletal muscle relaxant and a central nervous system depressant. It is recommended as an option for a short course of therapy, with greatest effect in the first four days of treatment. Guidelines state that treatment should be brief. The addition of cyclobenzaprine to other agents is not recommended. Limited, mixed evidence does not allow for a recommendation for chronic use. Due to quantity prescribed inconsistent with the guideline recommendation for short-term use, and prescription of flexeril in combination with other agents, which is not in accordance with the guidelines, the request for flexeril is not medically necessary.

**60 Nalfon 400mg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Nalfon (Fenoprofen), NSAIDs (non-steroidal anti-inflammatory drugs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines medication therapy p. 60 NSAIDs p. 67-73 Page(s): 60, 67-73, Postsurgical Treatment Guidelines.

**Decision rationale:** Per the MTUS, nonsteroidal anti-inflammatory drugs (NSAIDs) are recommended as a second line treatment after acetaminophen for treatment of acute

exacerbations of chronic back pain. The MTUS does not specifically reference the use of NSAIDs for long term treatment of chronic pain in other specific body parts. NSAIDs are noted to have adverse effects including gastrointestinal side effects and increased cardiovascular risk; besides these well-documented side effects of NSAIDs, NSAIDs have been shown to possibly delay and hamper healing in all the soft tissues including muscles, ligaments, tendons, and cartilage. NSAIDs can increase blood pressure and may cause fluid retention, edema, and congestive heart failure; all NSAIDs are relatively contraindicated in patients with renal insufficiency, congestive heart failure, or volume excess. They are recommended at the lowest dose for the shortest possible period in patients with moderate to severe pain. The MTUS does not recommend chronic NSAIDs for low back pain, NSAIDs should be used for the short term only. Systemic toxicity is possible with NSAIDs. The FDA and MTUS recommend monitoring of blood tests and blood pressure. This injured worker has additional diagnoses of hypertension and diabetes, which increase the risk of adverse effect on the kidneys. There was no documentation of current laboratory tests to document lack of baseline renal insufficiency. Blood pressure at the November 2014 visit was elevated at 151/90. Page 60 of the MTUS, cited above, recommends that medications be trialed one at a time. In this case, medications were prescribed together, making the determination of results, side effects, and benefits very difficult to determine. Due to potential for toxicity, and quantity prescribed not consistent with the guideline for short-term use only, the request for nalfon is not medically necessary.

### **30 Tramadol ER 160mg: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines medications for chronic pain p. 60 opioids p. 74-96 Page(s): p. 60, 74-96.

**Decision rationale:** Tramadol is a centrally acting synthetic opioid analgesic which is not recommended as a first line oral analgesic. Multiple side effects have been reported including increased risk of seizure especially in patients taking selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants (TCAs) and other opioids. It may also produce life-threatening serotonin syndrome. There is no evidence that the treating physician is prescribing opioids according to the MTUS, which recommends prescribing according to function, with specific functional goals, return to work, random drug testing, and opioid contract. The injured worker has not worked since 2007, and no functional goals were discussed including return to work. There was no discussion of an opioid contract. The injured worker was noted to have chronic back pain. Per the MTUS, opioids are minimally indicated, if at all, for chronic non-specific pain, osteoarthritis, "mechanical and compressive etiologies," and chronic back pain. The injured worker has also been prescribed effexor, which increases the risk of serotonin syndrome and seizures in combination with tramadol. Only one progress note was submitted, and this note was unclear as to whether the request for tramadol was a new prescription or continuation of prior therapy. Page 60 of the MTUS, cited above, recommends that medications be trialed one at a time. In this case, medications were given as a group, making the determination of results, side effects, and benefits very difficult to determine. Due to lack of prescribing in accordance with the MTUS and the potential for toxicity, the request for tramadol is not medically necessary.

## **60 Protonix 20mg: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI Symptoms & Cardiovascular Risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risk Page(s): p. 68-69.

**Decision rationale:** The injured worker has been prescribed nalfon, a NSAID, and protonix, a PPI. Per the MTUS, co-therapy with a non-steroidal anti-inflammatory medication (NSAID) and a proton pump inhibitor (PPI) is not indicated in patients other than those at intermediate or high risk for gastrointestinal events (including age > 65 years, history of peptic ulcer, gastrointestinal (GI) bleeding or perforation, concurrent use of aspirin, corticosteroids and/or an anticoagulant, or high dose/multiple NSAIDS such as NSAID plus low dose aspirin). Long term proton pump inhibitor (PPI) use (> 1 year) has been shown to increase the risk of hip fracture. None of the risk factors noted above were documented for this injured worker. No signs or symptoms of GI disease were discussed, and no examination of the abdomen was documented. The associated NSAID has been determined to be not medically necessary. Due to lack of indication, the request for protonix is not medically necessary.

## **1 prescription of Lidopro Lotion 4oz: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Capsaicin, Lidocaine, Salicylate.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics p. 111-113 salicylate topicals p. 104 Page(s): p. 111-113, 104. Decision based on Non-MTUS Citation Uptodate: camphor and menthol: drug information. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

**Decision rationale:** Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. Lidopro contains lidocaine, capsaicin, menthol, and methyl salicylate. LidoPro duplicates some of the ingredients in Terocin, another prescribed medication, which is redundant and possibly toxic. Lidocaine is only FDA approved for treating post-herpetic neuralgia, and the dermal patch form (Lidoderm) is the only form indicated for neuropathic pain. No other commercially approved topical formulations of lidocaine (whether creams, lotions, or gels) are indicated for neuropathic pain. Non-dermal patch forms are generally indicated as local anesthetics or anti-pruritics. Capsaicin has some indications, in the standard formulations readily available without custom compounding. The MTUS also states that capsaicin is only recommended when other treatments have failed. The treating physician did not discuss the failure of other, adequate trials of conventional treatments. It may be used for treatment of osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in high doses. The MTUS is silent with regards to menthol. It may be used for

relief of dry, itchy skin. This agent carries warnings that it may cause serious burns. Topical salicylates are recommended for use for chronic pain and have been found to be significantly better than placebo in chronic pain. The directions for use and site of application were not specified by the prescribing physician. Multiple ingredients in this compounded product are not recommended; therefore, the compounded product is not recommended. The documentation submitted did not indicate that the injured worker had failed a trial of oral antidepressant or antiepileptic medication. Another topical product with some of the same ingredients has also been prescribed. As such, the request for lidopro lotion is not medically necessary.

## **20 Terocin Patches: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): p. 111-113. Decision based on Non-MTUS Citation Uptodate: camphor and menthol: drug information. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

**Decision rationale:** Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The documentation submitted did not indicate that the injured worker had failed a trial of oral antidepressant or antiepileptic medication. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. Terocin patches contain lidocaine and menthol. These ingredients are also contained in Lidopro lotion, which has also been prescribed, which is duplicative and potentially toxic. Lidocaine is only FDA approved for treating post-herpetic neuralgia, and the Lidoderm patch is the only form indicated for neuropathic pain. There was no documentation that this injured worker had postherpetic neuralgia. The MTUS is silent with regards to menthol. It may be used for relief of dry, itchy skin. This agent carries warnings that it may cause serious burns. The directions and site of use for Terocin patches were not specified. Due to lack of indication, lack of documentation of failure of antidepressant or antiepileptic medication, and lack of recommendation of the agents in this patch, the request for Terocin patches is not medically necessary.

## **60 Effexor 75mg: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Effexor (Venlafaxine).

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 15 Stress Related Conditions Page(s): 401-402, Chronic Pain Treatment Guidelines antidepressants p. 14-16, SNRIs p. 105 Page(s): 14-16, 105. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) mental illness and stress chapter: antidepressants for treatment of major depressive disorder.

**Decision rationale:** Venlafaxine (Effexor) is a selective serotonin and norepinephrine reuptake inhibitor (SNRI) which is FDA approved for treatment of depression and anxiety. It is recommended off-label for treatment of neuropathic pain, diabetic neuropathy, fibromyalgia, and headaches. The MTUS states that it is recommended as an option in first-line treatment of neuropathic pain. Dosage adjustments may be necessary in patients with hepatic and renal impairment. The MTUS states that antidepressants are recommended as a first line option for neuropathic pain and as a possibility for non-neuropathic pain. Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment. The ACOEM notes that brief courses of antidepressants may be helpful to alleviate symptoms of depression, but that given the complexity of available agents, referral for medication evaluation is advised. The ODG states that antidepressants offer significant benefit in the treatment of the severest depressive symptoms, but may have little or no therapeutic benefit over and above placebo in patients with mild to moderate depression. The documentation notes that effexor has been prescribed for depression, however depression was not among the list of diagnoses for this injured worker. There was no other documentation related to depression, including pertinent psychiatric signs and symptoms, mental status examination, or discussion of severity. The injured worker has also been prescribed tramadol, which may increase the risk of serotonin syndrome and seizures in combination with effexor. No documentation of renal or hepatic function was submitted. Due to lack of adequate psychiatric evaluation and potential for toxicity, the request for effexor is not medically necessary.