

<b>Case Number:</b>	CM15-0141862		
<b>Date Assigned:</b>	08/05/2015	<b>Date of Injury:</b>	01/16/2012
<b>Decision Date:</b>	09/15/2015	<b>UR Denial Date:</b>	06/29/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/21/2015

### 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: New York

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 65-year-old male who sustained an industrial injury on 01-16-2012 resulting in injury to multiple body parts. Treatment provided to date has included: psychological evaluation and therapy; medications; and conservative therapies and care. Diagnostic testing was not available for review or mentioned in progress notes. There were no noted comorbidities or other dates of injury noted. On 05-19-2015, physician progress report noted complaints of ongoing chronic low back pain. No pain rating was mentioned; however, it was noted that the injured worker was seen 2 months prior and was there for medication refills as he has difficulties with activities of daily living without medications. Current medications include Norco, Alprazolam, Ambien, Tizanidine, tramadol, and Colace. The physical exam revealed no acute distress, good mood and affect, mild antalgic gait, mild pain and some weakness with heel and toe walk maneuver, midline tenderness, spasm and tightness in the paralumbar musculature, reduced range of motion (ROM) in the lumbar spine, bilateral leg raises to 60° with lumbar pain with end range, and reduced strength in the lower extremities. The provider noted diagnoses of L3-4 and L4-5 discopathy with intermittent radiculopathy, and four-level cervical degenerative discopathy with mild canal narrowing. Other progress reports and exams noted additional findings and diagnoses of anxiety and depression. Plan of care includes refills for hydrocodone (Norco), tramadol, Tizanidine, Ambien, Alprazolam, and Colace; acupuncture, and follow-up in 2 months. The injured worker's work status remained permanent and stationary. The request for authorization and IMR (independent medical review) includes: 8 sessions of acupuncture for the lumbar spine, Norco 10-325mg #45, Alprazolam 1mg #60, Ambien 10mg #30, Tizanidine 4mg #60, tramadol 50mg #90, and a topical analgesic cream consisting of: 20% Flurbiprofen, 10% Baclofen, 2% dexamethasone, 2% menthol, 2% camphor and 0.037% capsaicin.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Acupuncture 2 x 4 lumbar spine:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Acupuncture Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back - Lumbar & Thoracic (Acute & Chronic), Acupuncture.

**Decision rationale:** This prescription for acupuncture is evaluated in light of the MTUS recommendations for acupuncture. The MTUS recommends an initial trial of 3-6 visits of acupuncture. Per the MTUS, "acupuncture is used as an option when pain medication is reduced or not tolerated, it may be used as an adjunct to physical rehabilitation and/or surgical intervention to hasten functional recovery." Medical necessity for any further acupuncture is considered in light of "functional improvement". The ODG states that acupuncture is recommended as an option for chronic low back pain using a short course of treatment in conjunction with other interventions. The ODG also goes on to say that "Evidence for the benefit of acupuncture is conflicting, with higher-quality trials showing no benefit". The ODG recommends that an initial trial of 3-4 visits over 2 weeks be initiated, and if evidence of objective functional improvement is noted, then a total of up to 8-12 sessions over 4-6 weeks may be appropriate. (Note: "The evidence is inconclusive for repeating this procedure beyond an initial short course of therapy.") There was no discussion by the treating physician regarding a decrease or intolerance to pain medications. Also 08 visits of acupuncture exceed the MTUS recommendation. Given the MTUS recommendations for use of acupuncture, the prescription for 08 visits is not medically necessary.

**Norco 10/325mg #45:** 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 rationale:** Hydrocodone/ Acetaminophen (Norco) is an opioid drug that is used to treat moderate to moderately severe pain. The MTUS discourages long term usage unless there is evidence of "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 MTUS also recommends the discontinuation of opioids when there is no overall improvement in function, unless there are extenuating circumstances. Weaning should occur under direct ongoing medical supervision as a slow taper except for the below mentioned possible indications for immediate discontinuation. Upon review of the submitted documentation, it is clear that the injured worker has been prescribed Norco for several months. However, the progress reports demonstrate that the treating physician did not

document: 1) the least reported pain over the period since last assessment; 2) intensity of pain after taking the opioid; 3) how long it takes for pain relief; 4) how long pain relief lasts; 5) improvement in pain; or 6) improvement in function. Additionally, there is not documented evidence of monitoring for misuse or side effects. As such, hydrocodone/acetaminophen (Norco) 10-325mg #45 is not medically necessary.

**Alprazolam 1mg #60: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (chronic) chapter; Alprazolam (Xanax) and Benzodiazepines.

**Decision rationale:** Alprazolam (Xanax) is a short-acting benzodiazepine drug having anxiolytic, sedative, and hypnotic properties. The medication is used in conjunction with antidepressants for the treatment of depression with anxiety, and panic attacks. The MTUS is silent in regards to the recommendations for Xanax; therefore, other guidelines were used in the review of this medication. Per ODG Guidelines, Xanax (Alprazolam) is not recommended for long-term use, and is a short-acting drug of the benzodiazepine class used to treat moderate to severe anxiety disorders, panic attacks, and as an adjunctive treatment for anxiety associated with major depression. Benzodiazepines are not recommended for long-term use for the treatment of chronic pain because long-term efficacy is unproven and there is a risk of dependency. Most guidelines limit use to four weeks as long-term use can result in increased anxiety. Additionally, there is potential for increased adverse outcomes with concurrent prescribing of medications with sedative properties; as a result, simultaneous prescribing of opioids, tramadol, benzodiazepines and other sedating medications is not recommended. In this case, the injured worker has been prescribed Alprazolam for several months without improvement in function or return to work. Additionally, the injured worker is currently being prescribed multiple medications with sedating factors such as opioids, tramadol, and muscle relaxants. Furthermore, long-term use of this medication is discouraged and can increase anxiety symptoms. Therefore, the request for Alprazolam 1mg #60 is not medically necessary.

**Ambien 10mg #30: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Treatment Index, 11th Edition (web), 2013, Pain Chapter: Zolpidem (Ambien).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness & Stress, Insomnia.

**Decision rationale:** The MTUS (Medical Treatment Utilization Schedule) is silent in regards to the use of Ambien (zolpidem); therefore, alternative guidelines were consulted in the review and decision of this medication. The ODG states: "Recommend that treatment be based on the etiology, with the medications recommended below. Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness." The ODG

recommends Ambien, a short-acting non-benzodiazepine hypnotic, for the short-term (7-10 days) treatment of insomnia. This medication is not recommended for long-term use as it can be habit-forming, and may impair function and memory more than opioid pain relievers. "There is also concern that it may increase pain and depression over the long-term." In this case, there is no ongoing complaints of insomnia. Additionally, the injured worker has been prescribed this medication for several months, and this medication is not recommended for long-term use (longer than 7-10 days). As such, the request for Ambien 10mg #30 is not medically necessary.

**Tizanidine 4mg #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tizanidine (Zanaflex), Antispasticity/Antispasmodic Drugs.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 63-66.

**Decision rationale:** Tizanidine (Zanaflex) is a centrally acting alpha 2-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. Side effects include somnolence, dizziness, dry mouth, hypotension, weakness, and hepatotoxicity (for which LFTs (liver function testing) should be monitored baseline, 1, 3, and 6 months). It may also be recommended as a first line option to treat myofascial pain. The MTUS recommends non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP (low back pain) as they can reduce pain from muscle tension and possibly increase mobility. However, in most cases involving LBP, they provide no more benefit beyond NSAIDs in pain and overall improvement. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. In this case, the injured worker has been prescribed this medication for at least 5-6 months; however, there has been no documented measurable objective functional improvement, and there was no LFT submitted or discussed in the available medical records. As such, the requested Tizanidine 4mg #60 is not medically necessary.

**Tramadol 50mg #90: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol (Ultram) Page(s): 93 and 94.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96.

**Decision rationale:** Ultram (tramadol) is an opioid medication used to treat moderate to severe pain. MTUS discourages long term usage unless there is evidence of 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, return to work, or improved quality of life. Opioids are to be weaned and discontinued if there is no overall improvement in function, unless there are extenuating circumstances. After reviewing the clinical documentation submitted for review, it is found that the treating physician does not document: 1) the least reported pain over the period since last assessment; 2) intensity of pain after taking the opioid; 3) how long it takes for pain relief; 4) how long pain relief lasts; 5) improvement in pain; or 6) improvement in

function. These are necessary to meet MTUS guidelines. Additionally, the progress reports show that the injured worker has been prescribed this medication for several months with increased pain levels since the initiation of the tramadol. As such, the request for tramadol 50mg #90 is not medically necessary.

**Flurbiprofen 20%, Baclofen 10%, Dexamethasone 2%, Menthol 2%, Camphor 2%, Capsaicin 0.037% 180gm:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, NSAIDS Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Capsaicin (topical) Page(s): 111-113, 28-29. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter; Flurbiprofen (Ansaid).

**Decision rationale:** According to the MTUS guidelines: "Topical Analgesic are recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. 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." Flurbiprofen is classified as a NSAID. NSAIDs, in the topical form, are not recommended for neuropathic pain as there is no evidence to support use. The ODG also states: Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor); however, there is little to no research to support the use of many these agents. Custom compounding and dispensing of combinations of medicines that have never been studied is not recommended, as there is no evidence to support their use and there is potential for harm. At this time, the only available FDA-approved topical NSAID is diclofenac. The MTUS goes on to specify that Baclofen is "not" recommended, as there is no peer-reviewed literature to support its use. Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. Formulations: Capsaicin is generally available as a 0.025% formulation (as a treatment for osteoarthritis) and a 0.075% formulation (primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain). There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. In regards to the topical analgesic cream (consisting of: 20% Flurbiprofen, 10% Baclofen, 2% dexamethasone, 2% menthol, 2% camphor and 0.037% capsaicin), Flurbiprofen is not FDA approved for topical application; Baclofen is specifically not recommended by the MTUS; and capsaicin is not recommended in formulations greater than 0.025%. As such, the requested topical analgesic cream consisting of: 20% Flurbiprofen, 10% Baclofen, 2% dexamethasone, 2% menthol, 2% camphor and 0.037% capsaicin is not medically necessary.