

<b>Case Number:</b>	CM15-0170783		
<b>Date Assigned:</b>	09/17/2015	<b>Date of Injury:</b>	06/03/2000
<b>Decision Date:</b>	11/06/2015	<b>UR Denial Date:</b>	08/08/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/31/2015

### 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: California

Certification(s)/Specialty: Emergency 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(n) 62 year old female, who sustained an industrial injury on 6-3-00. The injured worker was diagnosed as having lumbar disc displacement without myelopathy and lumbago. Treatment to date has included thoracic and lumbar x-rays (results not provided). As of the PR2 dated 7-8-15, the injured worker reports pain in her thoraco-lumbar spine, cervical spine and bilateral wrists. She rates her pain 9 out of 10. Objective findings include progressive pain and stiffness while walking to the lumbar spine. The treating physician requested physical therapy x 12 for the lumbar and cervical spine, an IF unit x 60 day rental, an IF unit for indefinite use, a urine drug screen, Norco 10-325mg #50, Orphenadrine-Caffeine 60-10mg #60, Gabapentin-Pyridoxine 250-10mg #60, Flurbiprofen- Cyclo-Menthol 20%, 10%, 4% cream, Keratek gel 4oz bottle, Mometasone-Doxepin 0.15%, 5% 60gm and Omeprazole-Flurbiprofen 10-100mg #60. On 7-24-15 the treating physician requested a Utilization Review for physical therapy x 12 for the lumbar and cervical spine, an IF unit x 60 day rental, an IF unit for indefinite use, a urine drug screen, Norco 10-325mg #50, Orphenadrine-Caffeine 60-10mg #60, Gabapentin-Pyridoxine 250-10mg #60, Flurbiprofen- Cyclo-Menthol 20%, 10%, 4% cream, Keratek gel 4oz bottle, Mometasone-Doxepin 0.15%, 5% 60gm and Omeprazole-Flurbiprofen 10-100mg #60. The Utilization Review dated 8-8-15, non-certified the request for physical therapy x 12 for the lumbar and cervical spine, an IF unit x 60 day rental, an IF unit for indefinite use, a urine drug screen, Norco 10-325mg #50, Orphenadrine-Caffeine 60-10mg #60, Gabapentin-Pyridoxine 250-10mg #60, Flurbiprofen- Cyclo-Menthol 20%, 10%, 4% cream,

Keratek gel 4oz bottle, Mometasone-Doxepin 0.15%, 5% 60gm and Omeprazole-Flurbiprofen 10-100mg #60.

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

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

**Physical therapy x 12 for the lumbar and cervical spine:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Low Back Complaints 2004.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Manual therapy & manipulation.

**Decision rationale:** The request is for physical therapy to aid in pain relief. The MTUS guidelines states that manipulation is recommended for chronic pain if caused by musculoskeletal conditions. Manual Therapy is widely used in the treatment of musculoskeletal pain. The intended goal or effect of Manual Medicine is the achievement of positive symptomatic or objective measurable gains in functional improvement that facilitate progression in the patient's therapeutic exercise program and return to productive activities. Manipulation is manual therapy that moves a joint beyond the physiologic range-of-motion but not beyond the anatomic range-of-motion. It is indicated for low back pain but not ankle and foot conditions, carpal tunnel syndrome, forearm/wrist/hand pain, or knee pain. The use of active treatment modalities instead of passive treatments is associated with substantially better clinical outcomes. (Fritz, 2007) Active treatments also allow for fading of treatment frequency along with active self-directed home PT, so that less visits would be required in uncomplicated cases. The guidelines state the following: Low back: Recommended as an option. Therapeutic care "Trial of 6 visits over weeks, with evidence of objective functional improvement, total of up to 18 visits over 6-8 weeks. Elective/maintenance care" Not medically necessary. Recurrences/flare-ups "Need to reevaluate treatment success, if RTW achieved then 1-2 visits every 4-6 months." Ankle & Foot: Not recommended. Carpal tunnel syndrome: Not recommended. Forearm, Wrist, & Hand: Not recommended. Knee: Not recommended. In this case, the patient would benefit most from at home active therapy. There is inadequate documentation of functional improvement seen with previous therapy. As such, the request is not medically necessary.

**Interferential unit x 60 day rental:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Interferential current therapy (IFC).

**Decision rationale:** The request is for the use of Interferential current therapy (IFC). The MTUS guidelines are silent regarding this issue. The ODG guidelines state the following: Under study for osteoarthritis and recovery post knee surgery. Not recommended for chronic

pain or low back problems. After knee surgery, home interferential current therapy (IFC) may help reduce pain, pain medication taken, and swelling while increasing range of motion, resulting in quicker return to activities of daily living and athletic activities. (Jarit, 2003) See also the Pain Chapter. A recent industry-sponsored study concluded that interferential current therapy plus patterned muscle stimulation (using the RS-4i Stimulator) has the potential to be a more effective treatment modality than conventional low-current TENS for osteoarthritis of the knee. (Burch, 2008) In this case the patient does not qualify for the use of this product as it is under study for the recovery post knee surgery. It is not advised for chronic pain otherwise. As such, the request is not medically necessary.

**Interferential unit indefinite use:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Interferential current therapy (IFC).

**Decision rationale:** The request is for the use of Interferential current therapy (IFC). The MTUS guidelines are silent regarding this issue. The ODG guidelines state the following: Under study for osteoarthritis and recovery post knee surgery. Not recommended for chronic pain or low back problems. After knee surgery, home interferential current therapy (IFC) may help reduce pain, pain medication taken, and swelling while increasing range of motion, resulting in quicker return to activities of daily living and athletic activities. (Jarit, 2003) See also the Pain Chapter. A recent industry-sponsored study concluded that interferential current therapy plus patterned muscle stimulation (using the RS-4i Stimulator) has the potential to be a more effective treatment modality than conventional low-current TENS for osteoarthritis of the knee. (Burch, 2008) In this case, the patient does not qualify for the use of this product as it is under study for the recovery post knee surgery. It is not advised for chronic pain otherwise. As such, the request is not medically necessary.

**Urine drug screen:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**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)/Urine drug testing (UDT).

**Decision rationale:** The request is for a urine drug screen. The ODG states the following regarding this topic: Recommended as a tool to monitor compliance with prescribed substances, identify use of undisclosed substances, and uncover diversion of prescribed substances. The test should be used in conjunction with other clinical information when decisions are to be made to continue, adjust or discontinue treatment. This information includes clinical observation, results

of addiction screening, pill counts, and prescription drug monitoring reports. The prescribing clinician should also pay close attention to information provided by family members, other providers and pharmacy personnel. The frequency of urine drug testing may be dictated by state and local laws. Indications for UDT: At the onset of treatment: (1) UDT is recommended at the onset of treatment of a new patient who is already receiving a controlled substance or when chronic opioid management is considered. Urine drug testing is not generally recommended in acute treatment settings (i.e. when opioids are required for nociceptive pain). (2) In cases in which the patient asks for a specific drug. This is particularly the case if this drug has high abuse potential, the patient refuses other drug treatment and/or changes in scheduled drugs, or refuses generic drug substitution. (3) If the patient has a positive or at risk addiction screen on evaluation. This may also include evidence of a history of comorbid psychiatric disorder such as depression, anxiety, bipolar disorder, and/or personality disorder. See Opioids, screening tests for risk of addiction & misuse. (4) If aberrant behavior or misuse is suspected and/or detected. See Opioids, indicators for addiction & misuse. Ongoing monitoring: (1) If a patient has evidence of a high risk of addiction (including evidence of a comorbid psychiatric disorder (such as depression, anxiety, attention-deficit disorder, obsessive-compulsive disorder, bipolar disorder, and/or schizophrenia), has a history of aberrant behavior, personal or family history of substance dependence (addiction), or a personal history of sexual or physical trauma, ongoing urine drug testing is indicated as an adjunct to monitoring along with clinical exams and pill counts. See Opioids, tools for risk stratification & monitoring. (2) If dose increases are not decreasing pain and increasing function, consideration of UDT should be made to aid in evaluating medication compliance and adherence. In this case, a urine drug screen is not supported by the guidelines. This is secondary to inadequate documentation of risk level commensurate to the frequency of evaluation requested. As such, it is not medically necessary.

**Norco 10/325mg #50:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

**Decision rationale:** The request is for the use of a medication in the opioid class. The MTUS guidelines state that for ongoing treatment with a pharmaceutical in this class, certain requirements are necessary. This includes not only adequate pain control, but also functional improvement. Four domains have been proposed for management of patients on opioids. This includes pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug-related behaviors. In this case, there is inadequate documentation of persistent functional improvement which should eventually lead to medication discontinuation. As such, the request is not medically necessary. All opioid medications should be titrated down slowly in order to prevent a significant withdrawal syndrome.

**Orphenadrine/Caffeine 60/10mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

**Decision rationale:** The request is for the use of a muscle relaxant to aid in pain relief. The MTUS guidelines state that the use of a medication in this class is indicated as a second-line option for short-term treatment of acute exacerbations of low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, which can increase mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain improvement. Efficacy appears to diminish over time, and prolonged use may lead to dependence. (Homik, 2004) Due to inadequate qualifying evidence and prolonged duration of use, the request is not medically necessary.

**Gabapentin/Pyridoxine 250/10mg #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antiepilepsy drugs (AEDs).

**Decision rationale:** The request is for the use of a medication in the category of an anti-epileptic drug (AED). These medications are recommended for certain types of neuropathic pain. Most of the randomized clinical control trials involved include post-herpetic neuralgia and painful polyneuropathy such as in diabetes. There are few trials which have studied central pain or radiculopathy. The MTUS guidelines state that a good response to treatment is 50% reduction in pain. At least a 30% reduction in pain is required for ongoing use, and if this is not seen, this should trigger a change in therapy. There also should be documentation of functional improvement and side effects incurred with use. Disease states which prompt use of these medications include post-herpetic neuralgia, spinal cord injury, chronic regional pain syndrome, lumbar spinal stenosis, post-operative pain, and central pain. There is inadequate evidence to support use in non-specific axial low back pain or myofascial pain. In this case, there is lack of documentation of evidence of neuropathic pain or adequate pain reduction for continued use. The records also do not reveal functional improvement or screening measures as required. As such, the request is not medically necessary.

**Flurbiprofen/ Cyclo/ Menthol 20%, 10%, 4% cream: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** The request is for the use of a compounded medication for topical use to aid in pain relief. These products contain multiple ingredients which each have specific properties and mechanisms of action. The MTUS guidelines state the following: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In this case, the compounded topical treatment contains an NSAID. Qualifying factors for this product is indicated by the following per the guidelines: The efficacy in clinical trials for this treatment modality 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. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. FDA-approved agents: Voltaren Gel 1% (diclofenac): 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. In this case, as stated above, the patient would not qualify for the use of a topical NSAID. This is based on the diagnosis and treatment duration. As such, the request is not medically necessary.

**Keratek gel 4oz bottle:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS General Approaches 2004, Section(s): Initial Approaches to Treatment, and Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** The request is for the topical use of menthol. The MTUS and ACOEM as well as ODG do not comment specifically regarding this topic. The ACOEM guidelines do generally state that the use of topical therapy for pain control does not have good evidence regarding efficacy. In this case, the use of topical menthol would not be supported. This is secondary to poor scientific evidence for the patient's condition. As such, the request is not certified. The request is for the use of a compounded medication for topical use to aid in pain relief. These products contain multiple ingredients which each have specific properties and mechanisms of action. The MTUS guidelines state the following: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In this case, the compounded topical treatment contains an NSAID. Qualifying factors for this product is indicated by the following per the guidelines: The efficacy in clinical trials for this treatment modality 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. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. Indications: Osteoarthritis and tendinitis, in particular, that of the

knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. FDA-approved agents: Voltaren Gel 1% (diclofenac): 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. In this case, as stated above, the patient would not qualify for the use of a topical NSAID. This is based on the diagnosis and treatment duration. As such, the request is not medically necessary.

**Mometasone/Doxepin 0.15%, 5% 60gm: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**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)/topical analgesics.

**Decision rationale:** The request is for the use of a compounded topical medication to aid in pain relief. The official disability guidelines state the following regarding this topic: "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. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) 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," agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor)." As stated above, the use of any topical compounded medication with an antidepressant included is not evidence based. As such, it cannot be medically necessary.

**Omeprazole/Flurbiprofen 10/100mg #60: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** The request is for the use of a medication in the class of a proton pump inhibitor. It is indicated for patients with peptic ulcer disease. It can also be used as a preventative measure in patients taking non-steroidal anti-inflammatories for chronic pain. Unfortunately, they do have certain side effects including gastrointestinal disease. The MTUS guidelines states that patients who are classified as intermediate or high risk, should be treated prophylactically. Criteria for risk are as follows: "(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." Due to the fact the patient does not meet to above stated criteria, the request for use is not medically necessary.