

<b>Case Number:</b>	CM15-0204068		
<b>Date Assigned:</b>	10/21/2015	<b>Date of Injury:</b>	03/05/2006
<b>Decision Date:</b>	12/23/2015	<b>UR Denial Date:</b>	10/06/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/16/2015

### 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 65 year old female, who sustained an industrial injury on 3-5-06. The injured worker was being treated for failed back syndrome and lumbar radiculopathy. On 9-14-15, the injured worker complains of low back pain. She notes she received substantial help with the use of medical marijuana. She rated the pain 8-9 out of 10. She is currently not working. Physical exam performed on 5-4-15 revealed tenderness upon palpation, increased range of motion and increased strength with acupuncture. Treatment to date has included chiropractic care, lumbar epidural injections (failed to resolve symptoms), oral medications including Vicodin, Soma, Prilosec, Valium, Celexa and topical Flector patches and Lidoderm patches (it is noted all pain medications were inadequate), chiropractic care (was somewhat helpful), laminectomy and activity modifications. MRI previously performed revealed L3-5, L4-5 and L5-S1 degenerative disc disease. The treatment plan included request for Vicodin 5-325mg (since at least 1-16-12), Soma (since at least 1-16-12), Lidoderm patches (since at least 1-16-12), Flector patches (since at least 1-16-12), physical therapy, acupuncture and urine drug testing. On 6-24-15 it is noted the injured worker should not undergo additional chiropractic and physical therapy and or acupuncture as these therapies seem to have aggravated her condition. On 10-6-15 request for Norco 5-325mg #60 was non-certified by utilization review, Soma 350mg #60, Vicodin 5-325mg was non-certified, ortho referral was non-certified by utilization review, L5-S1 T.F.L.E. was non-certified by utilization review, physical therapy was non-certified by utilization review, acupuncture was non-certified by utilization review, urine drug testing once every 6 months was modified to once, Vicodin 5-325mg, Lidoderm patches was non-certified by utilization review and Flector patches was non-certified by utilization review.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Norco 5/325mg Qty: 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): 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. As part of the pain treatment agreement, it is advised that "Refills are limited, and will only occur at appointments". In this case, there is inadequate documentation of persistent functional improvement seen. "Functional improvement" means either a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management visit and a reduction in the dependency on continued medical treatment. As such, the request is not medically necessary or indicated. All opioid medications should be titrated down slowly in order to prevent a significant withdrawal syndrome.

**Soma 350mg Qty: 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) In this case, the use of a muscle relaxant is not guideline-supported. This is secondary to poor effectiveness for chronic long-term use. As such, the request is not medically necessary or indicated.

**Ortho referral:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ACOEM Practice Guidelines page 127; Official Disability Guidelines (ODG) Low Back Chapter.

**MAXIMUS guideline:** Decision based on MTUS General Approaches 2004, Section(s): General Approach to Initial Assessment and Documentation.

**Decision rationale:** The request is for orthopedic surgery consultation. The ACOEM guidelines state the following regarding this topic: In assessing acute or subacute complaints, the occupational health practitioner should first exclude conditions that could threaten life or limb if not diagnosed and treated emergently or urgently. The recommended process is therefore to: Seek red flags for potentially dangerous underlying conditions; In the absence of red flags, work-related complaints can be handled safely and effectively by occupational and primary care providers. The focus is on monitoring for complications, facilitating the healing process, and facilitating return to work in a modified or full-duty capacity. Evaluation and treatment generally can proceed in the acute phase without special studies because the findings from such studies seldom alter treatment. Yet, in some body systems (e.g., eye, bone, and head injuries), special studies may be mandatory. The term red flag, as generally used by payors, is not applicable to this discussion. Payors generally use red flags to earmark a case that may become problematic from a claims management perspective. In these guidelines, red flag is a non-pejorative term that refers only to serious medical conditions. They are defined as a sign or symptom of a potentially serious condition indicating that further consultation, support, or specialized treatment may be necessary. The term yellow flag is used to indicate psychosocial or other barriers to recovery. In this case, there is inadequate submitted documentation to support an orthopedic surgery consultation. There are no notes indicating why such a referral is needed or what specific issue necessitates further specialty evaluation. Pending receipt of this information, the request is not medically necessary or indicated.

**L5-S1 T.F.L.E:** 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): Epidural steroid injections (ESIs).

**Decision rationale:** The request is for an epidural steroid injection to aid in pain relief. There are certain qualifying criteria regarding the use of this treatment modality. The MTUS guidelines state the following on this topic: Criteria for the use of Epidural steroid injections: Note: The purpose of ESI is to reduce pain and inflammation, restoring range of motion and thereby facilitating progress in more active treatment programs, and avoiding surgery, but this treatment alone offers no significant long-term functional benefit. 1) Radiculopathy must be documented by physical examination and corroborated by imaging studies and/or electrodiagnostic testing. 2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants). 3) Injections should be performed using fluoroscopy (live x-ray) for guidance. 4) If used for diagnostic purposes, a maximum of two injections should be performed. A second block is not recommended if there is inadequate response to the first block. Diagnostic blocks should be at an interval of at least one to two weeks between injections. 5) No more than two nerve root levels should be injected using transforaminal blocks. 6) No more than one interlaminar level should be injected at one session. 7) In the therapeutic phase, repeat blocks should be based on continued objective documented pain and functional improvement, including at least 50% pain relief with associated reduction of medication use for six to eight weeks, with a general recommendation of no more than 4 blocks per region per year. (Manchikanti, 2003) (CMS, 2004) (Boswell, 2007) 8) Current research does not support a "series-of-three" injections in either the diagnostic or therapeutic

phase. We recommend no more than 2 ESI injections. In this case, the patient does not meet the criteria set above. This is secondary to inadequate documentation of at least 50% pain relief with associated reduction of medication use for six to eight weeks. As such, the request is not medically necessary or indicated.

**Physical therapy (unspecified quantity): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) <http://www.odgtwc.com/preface.htm#Physicaltherapyguidelines>.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Lumbar & Thoracic (acute & chronic)/Physical therapy.

**Decision rationale:** The request is for physical therapy. The ODG state the following regarding this topic: ODG Physical Therapy Guidelines: Allow for fading of treatment frequency (from up to 3 or more visits per week to 1 or less), plus active self-directed home PT. Also see other general guidelines that apply to all conditions under Physical Therapy in the ODG Preface, including assessment after a "six-visit clinical trial". Lumbar sprains and strains: 10 visits over 8 weeks. Sprains and strains of unspecified parts of back: 10 visits over 5 weeks. Sprains and strains of sacroiliac region: Medical treatment: 10 visits over 8 weeks. Lumbago; Backache, unspecified: 9 visits over 8 weeks. Intervertebral disc disorders without myelopathy: Medical treatment: 10 visits over 8 weeks. Post-injection treatment: 1-2 visits over 1 week. Post-surgical treatment (discectomy/laminectomy): 16 visits over 8 weeks. Post-surgical treatment (arthroplasty): 26 visits over 16 weeks. Post-surgical treatment (fusion, after graft maturity): 34 visits over 16 weeks. Intervertebral disc disorder with myelopathy Medical treatment: 10 visits over 8 weeks. Post-surgical treatment: 48 visits over 18 weeks. Spinal stenosis: 10 visits over 8 weeks. Sciatica; Thoracic/lumbosacral neuritis/radiculitis, unspecified: 10-12 visits over 8 weeks. Curvature of spine: 12 visits over 10 weeks. Fracture of vertebral column without spinal cord injury: Medical treatment: 8 visits over 10 weeks. Post-surgical treatment: 34 visits over 16 weeks. Fracture of vertebral column with spinal cord injury: Medical treatment: 8 visits over 10 weeks. Post-surgical treatment: 48 visits over 18 weeks Torticollis: 12 visits over 10 weeks. Other unspecified back disorders: 12 visits over 10 weeks. Work conditioning (See also Procedure Summary entry): 10 visits over 8 weeks. In this case, the request is not supported. An initial "six-visit clinical trial" is required and with functional improvement seen, further therapy is allowed. The number of treatments requested or functional improvement seen with previous therapy is not documented. As such, the request is not medically necessary or indicated.

**Acupuncture (unspecified quantity): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Acupuncture Treatment 2007.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back - Lumbar & Thoracic (Acute & Chronic)/Acupuncture.

**Decision rationale:** The request is for the use of acupuncture. The official disability guidelines state the following regarding this topic: Not recommended for acute low back pain. (Tulder-Cochrane, 2000) (Furlan-Cochrane, 2005) Recommended as an option for chronic low back pain using a short course of treatment in conjunction with other interventions. (See the Pain

Chapter.) Acupuncture has been found to be more effective than no treatment for short-term pain relief in chronic low back pain, but the evidence for acute back pain does not support its use. (Furlan- Cochrane, 2005) (Manheimer, 2005) (Van Tulder, 2005) (Thomas, 2005) (Ratcliffe, 2006) (Thomas, 2006) (Haake, 2007) (Santaguida, 2009) These authors have reported that acupuncture provides a greater effect than sham treatment, while others have reported non-significant differences between the two modalities. (Brinkhaus, 2006)ODG Acupuncture Guidelines: Initial trial of 3-4 visits over 2 weeks. With evidence of objective functional improvement, total of up to 8-12 visits over 4-6 weeks (Note: The evidence is inconclusive for repeating this procedure beyond an initial short course of therapy.) In this case, the request is not medically necessary or indicated. This is secondary to an unspecified quantity requested.

**Urine drug testing once every 6 months:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**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. The frequency of drug testing is indicated below: Patients at "low risk" of addiction/aberrant behavior should be tested within six months of initiation of therapy and on a yearly basis thereafter. There is no reason to perform confirmatory testing unless the

test is inappropriate or there are unexpected results. If required, confirmatory testing should be for the questioned drugs only. Patients at "moderate risk" for addiction/aberrant behavior are recommended for point-of-contact screening 2 to 3 times a year with confirmatory testing for inappropriate or unexplained results. This includes patients undergoing prescribed opioid changes without success, patients with a stable addiction disorder, those patients in unstable and/or dysfunction social situations, and for those patients with comorbid psychiatric pathology. Patients at "high risk" of adverse outcomes may require testing as often as once per month. This category generally includes individuals with active substance abuse disorders. 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 or indicated.

**Vicodin 5/325mg (unspecified quantity): 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. As part of the pain treatment agreement, it is advised that "Refills are limited, and will only occur at appointments". In this case, there is inadequate documentation of persistent functional improvement seen. "Functional improvement" means either a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management visit and a reduction in the dependency on continued medical treatment. As such, the request is not medically necessary or indicated. All opioid medications should be titrated down slowly in order to prevent a significant withdrawal syndrome.

**Lidoderm patches (unspecified quantity): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG).

**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 Lidoderm patch to aid in pain relief. The MTUS guidelines state that its use is indicated for post herpetic neuralgia after an initial trial of an anti-epileptic medication. Further research is needed to recommend use for chronic neuropathic disorders besides post-herpetic neuralgia. In this case, the patient does not have a diagnosis documented which would justify the use of Lidoderm patches. As such, the request is not medically necessary or indicated.

**Flector patches (unspecified quantity):** 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), Pain Chapter.

**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)/Diclofenac.

**Decision rationale:** The request is for the use of the medication Diclofenac. The official disability guidelines state the following regarding this topic: Not recommended as first line due to increased risk profile. A large systematic review of available evidence on NSAIDs confirms that diclofenac, a widely used NSAID, poses an equivalent risk of cardiovascular events to patients as did rofecoxib (Vioxx), which was taken off the market. According to the authors, this is a significant issue and doctors should avoid diclofenac because it increases the risk by about 40%. For a patient who has a 5% to 10% risk of having a heart attack that is a significant increase in absolute risk, particularly if there are other drugs that don't seem to have that risk. For people at very low risk, it may be an option. (McGettigan, 2011) Another meta-analysis supported the substantially increased risk of stroke with diclofenac, further suggesting it not be a first-line NSAID. (Varas-Lorenzo, 2011) In this nationwide cohort study the traditional NSAID diclofenac was associated with the highest increased risk of death or recurrent myocardial infarction (hazard ratio, 3.26; 95% confidence interval, 2.57 to 3.86 for death/MI at day 1 to 7 of treatment) in patients with prior MI, an even higher cardiovascular risk than the selective COX-2 inhibitor rofecoxib, which was withdrawn from the market due to its unfavorable cardiovascular risk profile. (Schjerning, 2011) According to FDA MedWatch, post-marketing surveillance of topical diclofenac has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure. Some of these reported cases resulted in fatalities or liver transplantation. If using diclofenac then consider discontinuing as it should only be used for the shortest duration possible in the lowest effective dose due to reported serious adverse events. Post marketing surveillance has revealed that treatment with all oral and topical diclofenac products may increase liver dysfunction, and use has resulted in liver failure and death. Physicians should measure transaminases periodically in patients receiving long-term therapy with diclofenac. (FDA, 2011) In 2009 the FDA issued warnings about the potential for elevation in liver function tests during treatment with all products containing diclofenac sodium. (FDA, 2009) With the lack of data to support superiority of diclofenac over other NSAIDs and the possible increased hepatic and cardiovascular risk associated with its use, alternative analgesics and/or non-pharmacological therapy should be considered. The AGS updated Beers criteria for inappropriate medication use includes diclofenac. (AGS, 2012) Diclofenac is associated with a significantly increased risk of cardiovascular complications and should be removed from essential-medicines lists, according to a new review. The increased risk with diclofenac was similar to Vioxx, a drug withdrawn from worldwide markets because of cardiovascular toxicity. Rofecoxib, etoricoxib, and diclofenac were the three agents that were consistently associated with a significantly increased risk when compared with nonuse. With diclofenac even in small doses it increases the risk of cardiovascular events. They recommended naproxen as the NSAID of choice. (McGettigan, 2013) See also NSAIDs (non-steroidal anti-inflammatory drugs); NSAIDs, GI symptoms & cardiovascular risk; NSAIDs, hypertension and renal function; & NSAIDs, specific drug list & adverse effects for general guidelines. See also Arthrotec (diclofenac/ misoprostol); Dyloject (diclofenac sodium injection); Flector patch (diclofenac epolamine); Pennsaid (diclofenac sodium topical solution); Zipsor (diclofenac potassium liquid-filled capsules); Zorvolex (diclofenac). In this case, the use of this medication is not guideline-supported. This is secondary to an increased cardiovascular risk seen. There is inadequate documentation of failed first-line therapy attempted. As such, the request is not medically necessary or indicated.