

<b>Case Number:</b>	CM15-0193218		
<b>Date Assigned:</b>	10/07/2015	<b>Date of Injury:</b>	07/11/2014
<b>Decision Date:</b>	12/11/2015	<b>UR Denial Date:</b>	09/11/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/01/2015

### 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 57-year-old female, with a reported date of injury of 07-11-2014. The diagnoses include lumbar spine sprain and strain with bilateral extremity radiculitis, cervical spine sprain and strain, bilateral shoulder sprain and strain, bilateral elbow lateral epicondylitis, and bilateral wrist tendinosis with probable carpal tunnel syndrome. Treatments and evaluation to date have included a home exercise program, Tylenol #3 (since at least 02-2015), Anaprox, and Voltaren (since at least 02-2015). The diagnostic studies to date have included an MRI of the lumbar spine on 02-18-2015 which showed grade 1 anterolisthesis of L5 on S1, facet arthropathy of the lower lumbar spine, and broad midline disc protrusion at L4-5 and a moderate degree of central canal stenosis at this level; an MRI of the right shoulder on 08-12-2015 which showed mild osteoarthritic changes of the acromioclavicular joint, lateral downsloping acromion, tendinosis and peritendinitis of the supraspinatus tendon with no rotator cuff tear, tenosynovitis of the long head of the biceps tendon, and mild osteoarthritic changes of the glenohumeral joint. The progress report dated 08-07-2015 indicates that the injured worker had low back pain and discomfort with bilateral numbness and tingling in the lower extremities, right greater than left; and difficulty walking and prolonged standing and sitting due to low back pain and radiation of symptoms down the legs. The injured worker also complained of right shoulder pain, with numbness and tingling to the hands. The injured worker was not working. The objective findings include tenderness to palpation of the lumbar spine, a slow gait, tenderness to palpation of the bilateral subacromial and acromioclavicular, positive bilateral Faber, positive bilateral Kemp, positive straight leg raise, positive bilateral impingement, decreased range of motion of

the bilateral shoulders, and decreased sensation at the right L4-S1. The pain rating was not included in the medical report. The injured worker's work status was noted as temporarily totally disabled for 4-6 weeks. The progress report dated 06-23-2015 indicates that the injured worker rated her pain 3 out of 10 with medications and 6 out of 10 without medications. The duration of pain relief was noted as 6 hours. It was noted that the injured worker had an improvement in function and activity of daily living with use of medications. The request for authorization was dated 08-07-2015. The treating physician requested Tylenol #3 (with codeine) #120, Voltaren XR 100mg #60, NCV (nerve conduction velocity) of the right lower extremity, NCV of the left lower extremity, and a random urine drug screen (quantitative). On 09-11-2015, Utilization Review (UR) non-certified the request for Tylenol #3 (with codeine) #120, Voltaren XR 100mg #60, NCV (nerve conduction velocity) of the right lower extremity, NCV of the left lower extremity, and a random urine drug screen (quantitative).

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

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

#### **Tylenol No 3 #120: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Neck and Upper Back Complaints 2004.

**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.

#### **Voltaren XR 100 mg #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs).

**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, postmarketing 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 nonpharmacological 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.

**EMG/NCV of right lower extremities:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Low Back Complaints 2004. 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) Lumbar & Thoracic (Acute & Chronic)/Nerve conduction studies (NCS).

**Decision rationale:** The request is for nerve conduction studies. The ODG state the following regarding this study: Not recommended. There is minimal justification for performing nerve conduction studies when a patient is presumed to have symptoms on the basis of radiculopathy. (Utah, 2006) This systematic review and meta-analysis demonstrate that neurological testing procedures have limited overall diagnostic accuracy in detecting disc herniation with suspected radiculopathy. (Al Nezari, 2013) In the management of spine trauma with radicular symptoms, EMG/nerve conduction studies (NCS) often have low combined sensitivity and specificity in confirming root injury, and there is limited evidence to support the use of often uncomfortable and costly EMG/NCS. (Charles, 2013) See also the Carpal Tunnel Syndrome Chapter for more details on NCS. Studies have not shown portable nerve conduction devices to be effective. EMGs (electromyography) are recommended as an option (needle, not surface) to obtain unequivocal evidence of radiculopathy, after 1-month conservative therapy, but EMG's are not necessary if radiculopathy is already clinically obvious. In this case, the patient does not meet criteria for the study requested. This is secondary to radiculopathy already diagnosed in the records. Pending receipt of information further clarifying how this would change the management rendered, the study is not medically necessary.

**EMG/NCV of left lower extremities:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Low Back Complaints 2004. 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) Lumbar & Thoracic (Acute & Chronic)/Nerve conduction studies (NCS).

**Decision rationale:** The request is for nerve conduction studies. The ODG state the following regarding this study: Not recommended. There is minimal justification for performing nerve conduction studies when a patient is presumed to have symptoms on the basis of radiculopathy. (Utah, 2006) This systematic review and meta-analysis demonstrate that neurological testing procedures have limited overall diagnostic accuracy in detecting disc herniation with suspected radiculopathy. (Al Nezari, 2013) In the management of spine trauma with radicular symptoms, EMG/nerve conduction studies (NCS) often have low combined sensitivity and specificity in confirming root injury, and there is limited evidence to support the use of often uncomfortable and costly EMG/NCS. (Charles, 2013) See also the Carpal Tunnel Syndrome Chapter for more details on NCS. Studies have not shown portable nerve conduction devices to be effective. EMGs (electromyography) are recommended as an option (needle, not surface) to obtain unequivocal evidence of radiculopathy, after 1-month conservative therapy, but EMG's are not necessary if radiculopathy is already clinically obvious. In this case, the patient does not meet criteria for the study requested. This is secondary to radiculopathy already diagnosed in the records. Pending receipt of information further clarifying how this would change the management rendered, the study is not medically necessary.

**Retro random urine drug screen (quantitative): 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. 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, the request is not medically necessary.