

Case Number:	CM14-0135710		
Date Assigned:	10/14/2014	Date of Injury:	04/22/2014
Decision Date:	10/19/2015	UR Denial Date:	07/16/2014
Priority:	Standard	Application Received:	08/21/2014

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: Physical Medicine & Rehabilitation, Pain Management

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 (IW) is a 52 year old female who sustained an industrial injury on 04/22/2014. She reported lifting a heavy box to place it on a cart and experiencing intense dull pain through the right elbow, back and hip. The injured worker was diagnosed as having Lumbar sprain/strain; right elbow lateral epicondylitis; insomnia; adjustment disorder; and rule out cardiac and respiratory autonomic nervous system dysfunction, idiopathic peripheral autonomic neuropathy, and diabetic neuropathy. Treatment to date has included ice, rest, x-rays, and medication. An X-ray of the right elbow (04/25/2014) was normal and showed no fracture, dislocation or arthritic changes. An x-ray of the thoracolumbar spine was also normal, as was an x-ray of the lumbosacral spine. In the visit of 06/12/2014, the injured worker complains of frequent low back pain located on the right, left and center of the back. She indicates the pain is sharp and stabbing tightness. Her pain is rated at best 0/10 and at worst 10/10. The back pain is aggravated by exercise, standing or walking greater than 40 minutes, lifting or carrying, pushing/pulling or sitting greater than 40 minutes. She complains of frequent generalized right elbow pain which is dull in character and does not radiate. Her current pain level was 0/10. At its best the pain is 0/10 and worse is 10/10. The pain is aggravated by exercise, fine finger manipulation, keyboarding, lifting or carrying 5 lbs., pushing/pulling 5 lbs., twisting/torqueing, or simple gripping or forceful gripping. On exam, elbow supination and pronation are each 10 degrees less than normal. Thoracic spine range of motion is decreased in all planes, and palpation of the lumbar spine reveals tenderness and spasm of the lumbar paravertebral muscles. Flexion of the lumbar spine in 30 degrees, extension is 10 degrees, and right/left lateral bending

is 15 degrees. Motor strength of the hips and lower extremities is normal, and reflexes are normal. The treatment plan is for acupuncture, chiropractic manipulation, physical therapy, lumbar spine transcutaneous electrical nerve stimulation (TENS) unit trial, psychological evaluation, cardio-respiratory testing, and medications. A request for authorization is made for the following: 1. Xolido Topical Cream 118 ml; 2. Cardio-vagal innervation and heart rate variability testing; 3. Vitamin B12 injection; 4. Somnicin #30 capsules (Melatonin 2mg, 5HTP 50mg, L-tryptophan 100mg, Pyridoxine 10 mg, Magnesium 50mg); 5. Adrenergic blood pressure testing; 6. Laxacin (Ducusate Sodium & Sessosidoes 8.6mg) #100 7. MRI of lumbar spine without contrast; 8. Terocin topical cream 120ml (Capsaicin 0.025%, Methyl Salicylate 25%, Menthol 10%, Lidocaine 2.5%); and 9. Acupuncture to lumbar spine, 2x4 weeks.

IMR ISSUES, DECISIONS AND RATIONALES

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

Xolido Topical Cream 118 ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain Chapter, Topical Analgesics.

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

Decision rationale: This topical formulation contains lidocaine as one of its components. Regarding request for topical lidocaine, Chronic Pain Medical Treatment Guidelines recommend the use of topical lidocaine for localized peripheral pain after there has been evidence of a trial of the first line therapy such as tricyclic antidepressants, SNRIs, or antiepileptic drugs. Guidelines further stipulate that no commercially approved topical formulations of lidocaine cream, lotion, or gel are indicated for neuropathic pain. The CPMTG states that if one drug or drug class of compounded formulation is not recommended, then the entire formulation is not recommended. Given this guideline recommendation, the currently requested topical formulation which contains lidocaine is not medically necessary.

Cardio-vagal innervation and heart rate variability testing: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Heart rate variability with deep breathing as a clinical test of cardiovagal function Author: Robert W. Shields, Jr, MD.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <https://www.aan.com/>, Autonomic Testing Policy by the American Academy of Neurology.

Decision rationale: The American Academy of Neurology has a policy statement on autonomic testing. With regard to cardiovagal innervation testing, this can be defined as "the para-sympathetic response measured via cardiac function, which is under control of the vagus

nerve, which influences heart rate variability." Furthermore, the American Diabetes Association (ADA) recommends that autonomic testing (including cardiovagal testing) be performed for all patients with type 2 diabetes mellitus at the time of diagnosis and five years after diagnosis in individuals with type 1 diabetes. Those recommendations are based on evidence showing that individuals with diabetes that have evidence of cardiac autonomic neuropathy have significantly higher rates of mortality and silent myocardial ischemia. The AAN also mentions additional indications: "Guidelines for anesthesia, surgery and medical therapies to affect outcomes have been established for diabetic patients based on autonomic test findings. Cardiovagal testing has been demonstrated in a number of disease states to be an early marker of autonomic parasympathetic dysfunction. 12-15 Some disorders, such as amyloidosis and autoimmune autonomic ganglionopathy, preferentially affect autonomic nerve fibers and may not exhibit abnormalities of somatic nerve fiber tests (the latter detectable by nerve conduction tests and electromyography). 1 Heart rate variability is a simple and reliable test of cardiovagal function. It has a sensitivity of 97.5 percent for detection of parasympathetic dysfunction in diabetes when age-adjusted normative values are used. 10, 18 The heart rate response to deep breathing, tilt table test, and the Valsalva maneuver are considered standard clinical tests of autonomic function and are sensitive, specific, and reproducible methods for grading the degree of autonomic dysfunction. 5 Evaluation of parasympathetic function through cardiovagal testing has been firmly established for clinical use for decades." In the case of this injured worker, the specific rationale for autonomic testing is not apparent. There is a generic letter of medical necessity regarding the benefits of autonomic and cardiac testing, but there should be a specific indication identified for this. In fact, the AAN states "A number of automated testing devices have been developed over the past several years and advertised directly to non-neurologists and general practitioners who do not have training or expertise in the autonomic nervous system. Some of these automated devices may also generate patient-specific recommendations for treatment. As a result, physicians who do perform full autonomic testing have seen a large increase in the number of patients erroneously diagnosed with an autonomic disorder (unpublished data from the authors' practices). Prescribing unnecessary medications on the basis of an incorrect autonomic diagnosis could potentially harm patients because of the potential for serious adverse reactions." Given the lack of rationale documented, this request is not medically necessary.

Vitamin B12 injection: 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 Chapter, Vitamin B.

Decision rationale: Regarding the request for Vitamin B12 injection, California MTUS guidelines do not contain criteria for the use of B12. ODG states that vitamin B is not recommended. They go on to state that when comparing vitamin B with placebo, there is no significant short-term benefit in pain intensity. The medical indication for this injection is when there is documentation of B12 deficiency on laboratory results, and there are symptoms of this

present. There were not low B12 serum levels noted in the submitted records. As such, the current request is not medically necessary.

Somnicin #30 capsules (Melatonin 2mg, 5HTP 50mg, L-tryptophan 100mg, Pyridoxine 10 mg, Magnesium 50mg): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://sales.advancedrxmgt.com/sales-content/uploads/2012/04/Somnicin-patient-info-sheet.pdf>.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain Chapter, Medical Food.

Decision rationale: Regarding the request for Somnicin, the California MTUS and ACOEM guidelines do not contain criteria for the use of medical foods. This is a medical food which contains L-tryptophan, pyridoxine, magnesium, and melatonin. ODG states that medical foods are recommended for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements. Within the documentation available for review, the requesting physician has not indicated that this patient has any specific nutritional deficits. Although the melatonin component can aid with insomnia complaints, the other ingredients of this medical food are not demonstrated to be medically necessary by serum testing. Additionally, there are no diagnoses, conditions, or medical disorders for which distinctive nutritional requirements are present. In the absence of such documentation, the current request is not medically necessary.

Adrenergic blood pressure testing: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Clinical Investigation and Reports: Abnormal Norepinephrine Clearance and Adrenergic Sensitivity in Idiopathic Orthostatic Intolerance, Vanderbilt University, Nashville, TN.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation BCBS Policy Statement on Autonomic Testing, <http://www.bcbsms.com/com/bcbsms/apps/PolicySearch/views/ViewPolicy.php?noprint=yes&path=/policy/emed/Autonomic+Nervous+System+Testing.html>.

Decision rationale: Regarding the request for adrenergic blood pressure testing, the CA MTUS, ODG, and ACOEM do not comment upon this. Instead, guidelines from a national health insurance carrier are cited. Vasomotor adrenergic innervation testing evaluates response of beat-to-beat blood pressure to the head-up tilt and Valsalva maneuver. The head-up tilt shifts blood to dependent parts, causing reflex responses. The Valsalva maneuver increases intrathoracic pressure and reduces venous return, causing blood pressure changes and reflex vasoconstriction. In both tests, the pattern of responses is an index of adrenergic function. BCBS Policy further lists the following indications for autonomic testing: 1. Diagnose the presence of autonomic

neuropathy in a patient with signs or symptoms suggesting a progressive autonomic neuropathy, including:-Diabetic neuropathy-Amyloid neuropathy-Sjogren's syndrome-Idiopathic neuropathy-Pure autonomic failure-Multiple system dystrophy. 2. Evaluate the severity and distribution of a diagnosed progressive autonomic neuropathy; 3. Differentiate the diagnosis between certain complicated variants of syncope from other causes of loss of consciousness; 4. Evaluate inadequate response to beta blockade in vasodepressor syncope; 5. Evaluate distressing symptoms in the patient with a clinical picture suspicious for distal small fiber neuropathy in order to diagnose the condition; 6. Differentiate the cause of postural tachycardia syndrome; 7. Evaluate change in type, distribution or severity of autonomic deficits in patients with autonomic failure; 8. Evaluate the response to treatment in patients with autonomic failure who demonstrate a change in clinical exam; 9. Diagnose axonal neuropathy or suspected autonomic neuropathy in the symptomatic patient; 10. Evaluate and diagnose sympathetically maintained pain, as in reflex sympathetic dystrophy or causalgia; or 11. Evaluate and treat patients with recurrent unexplained syncope to demonstrate autonomic failure. In the case of this injured worker, no autonomic disorders, cardiac disorders, or syncopal disorders have been identified. The baseline use of this type of testing for pain is not indicated. This request is not medically necessary.

Laxacin (Ducusate Sodium & Sessosidoes 8.6mg) #100: 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 in Workers' Compensation 2014, Pain Chapter.

MAXIMUS 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) Pain Chapter, Opioid Induced Constipation Treatment.

Decision rationale: The CPMTG on pages 77-78 recommend prophylactic treatment of opioid related constipation. Specifically, the following is state with regard to Initiating Opioid Therapy: "(d) Prophylactic treatment of constipation should be initiated." However, in this injured worker, there does not appear to be any opioids taking currently. There is no mention of constipation symptoms, and therefore routine prophylaxis without narcotics is not indicated. This request is not medically necessary.

MRI of lumbar spine without contrast: Upheld

Claims Administrator guideline: Decision based on MTUS Low Back Complaints 2004. Decision based on Non-MTUS Citation Official Disability Guidelines, Low back-Lumbar and Thoracic, MRIs (magnetic resonance imaging).

MAXIMUS guideline: Decision based on MTUS Low Back Complaints 2004, Section(s): Special Studies.

Decision rationale: Regarding the request for lumbar MRI, ACOEM Practice Guidelines state that unequivocal objective findings that identify specific nerve compromise on the neurologic examination are sufficient evidence to warrant imaging in patients who do not respond to

treatment and would consider surgery an option. When the neurologic examination is less clear, however, further physiologic evidence of nerve dysfunction should be obtained before ordering an imaging study. ODG states that MRIs are recommended for uncomplicated low back pain with radiculopathy after at least one month of conservative therapy. Within the documentation available for review, there is no identification of any objective findings that identify specific nerve compromise on the neurologic exam. In fact, the neurologic exam of motor and sensory components was within normal limits in a progress note associated with this request on 6/12/14. Additionally, there is no statement indicating what medical decision-making will be based upon the outcome of the currently requested MRI. Given this, the currently requested lumbar MRI is not medically necessary.

Terocin topical cream 120ml (Capsaicin 0.025%, Methyl Salicylate 25%, Menthol 10%, Lidocaine 2.5%): Upheld

Claims Administrator guideline: Decision based on MTUS General Approaches 2004, Section(s): Initial Approaches to Treatment. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter, Topical Analgesics.

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

Decision rationale: Terocin Patch is a topical formulation consisting of Methyl Salicylate 25%, Capsaicin 0.025%, Menthol 10%, and Lidocaine 2.50%. The Chronic Pain Medical Treatment Guidelines, on pages 111-113, specify that, "any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Regarding the use of topical nonsteroidal anti-inflammatory, guidelines state that 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 1st 2 weeks of treatment osteoarthritis, but either not afterwards, or with the diminishing effect over another two-week period. Regarding use of capsaicin, guidelines state that it is recommended only as an option for patients who did not respond to or are intolerant to other treatments. Regarding the use of topical lidocaine, guidelines the state that it is recommended for localized peripheral pain after there is evidence of a trial of first-line therapy. Guidelines further stipulate that no preparation of topical lidocaine except as Lidoderm patch is approved. Therefore, since this component is not recommended, the entire Terocin formulation is not medically necessary.

acupuncture to lumbar spine, 2x4 weeks: Upheld

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

MAXIMUS guideline: Decision based on MTUS Acupuncture Treatment 2007.

Decision rationale: Regarding the request for acupuncture, California MTUS does support the use of acupuncture for chronic pain. Acupuncture is recommended to be used as an adjunct to physical rehabilitation and/or surgical intervention to hasten functional recovery. Additional use is supported when there is functional improvement documented, which is defined as either a

clinically significant improvement in activities of daily living or a reduction in work restrictions and a reduction in the dependency on continued medical treatment. A trial of up to 6 sessions is recommended, with up to 24 total sessions supported when there is ongoing evidence of functional improvement. In the case of this particular request (for 8 sessions), the number of requested sessions of acupuncture is in excess of that recommended by guidelines cited above. This appears to be an initial request as prior acupuncture was not documented. The guidelines specifically state that the time to produce functional improvement is within six treatments. The independent medical review process cannot modify requests. Therefore, this request is not medically necessary.