

Case Number:	CM15-0160967		
Date Assigned:	09/24/2015	Date of Injury:	02/04/1994
Decision Date:	11/18/2015	UR Denial Date:	07/20/2015
Priority:	Standard	Application Received:	08/17/2015

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: 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 60 year old female injured worker suffered an industrial injury on 2-4-1994. The diagnoses included neck fusion, cervical radiculopathy, bilateral shoulder internal derangement, low back pain and radiculitis of lower extremities. On 4-3-2015, the treating provider reported the neck which had a fusion that had burning radicular neck pain that is constant, moderate and severe rated as 7 out of 10 with associated numbness and tingling in the upper extremities. The right shoulder had arthroscopy and had burning radiating pain going down the arms to the fingers with associated muscle spasms rated 7 out of 10 that is moderate to severe. The low back had radicular pain rated 7 out of 10 with associated numbness and tingling of the lower extremities. On exam the cervical spine, shoulders and lumbar spine had reduced range of motion. The Utilization Review on 7-20-2015 determined non-certification for Functional Capacity evaluation, Shockwave therapy for the cervical, lumbar spine and bilateral shoulders x 18, MRI of the cervical spine, MRI of the bilateral shoulders, EMG/NCV of the bilateral upper extremities, EMG/NCV of the bilateral lower extremities, Ketoprofen 20% cream 167gm, Synapryn 10mg/1ml oral suspension 500ml, Cyclobenzaprine 5% cream 110gm, Tabradol 1mg/ml oral suspension 250ml, Deprizine 15mg/ml oral suspension 250ml, Dicopanol 5mg/ml 150ml, Fanatrex 25mg/ml oral suspension 420ml, Urine drug screen and MRI of the lumbar spine.

IMR ISSUES, DECISIONS AND RATIONALES

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

Functional Capacity evaluation: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Fitness for Duty.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Fitness for Duty Chapter, Functional Capacity Evaluation and Other Medical Treatment Guidelines ACOEM, Chapter 7, p. 137-138.

Decision rationale: With regard to the request for a functional capacity evaluation, the CA MTUS does not specifically address functional capacity evaluations. Other well-established guidelines include ACOEM and ODG. ACOEM Chapter 7 Functional Capacity Evaluation states on pages 137-138: "The employer or claim administrator may request functional ability evaluations, also known as Functional Capacity Evaluations, to further assess current work capability. These assessments also may be ordered by the treating or evaluating physician, if the physician feels the information from such testing is crucial. Though Functional Capacity Evaluations (FCEs) are widely used and promoted, it is important for physicians and others to understand the limitations and pitfalls of these evaluations." The Official Disability Guidelines specify the following Guidelines for performing an FCE: If a worker is actively participating in determining the suitability of a particular job, the FCE is more likely to be successful. A FCE is not as effective when the referral is less collaborative and more directive. It is important to provide as much detail as possible about the potential job to the assessor. Job specific FCEs are more helpful than general assessments. The report should be accessible to all the return to work participants. Consider an FCE if: 1. Case management is hampered by complex issues such as: Prior unsuccessful RTW attempts. Conflicting medical reporting on precautions and/or fitness for modified job. Injuries that require detailed exploration of a worker's abilities. 2. Timing is appropriate: Close or at MMI/all key medical reports secured. Additional/secondary conditions clarified. Do not proceed with an FCE if the sole purpose is to determine a worker's effort or compliance. The worker has returned to work and an ergonomic assessment has not been arranged. (WSIB, 2003) It is important to note in this case that both the ACOEM and ODG are equivalent in the strength of evidence hierarchy as specify by statute. The ACOEM clearly has less stringent guidelines and allows for a functional capacity evaluation when a requesting provider feels that this testing is crucial despite the potential pitfalls of such an evaluation. In the case of this injured worker, there is documentation from another provider that the patient is not at maximal medical improvement and should have additional surgery. The note from date of service 4/28/15 indicates the patient is not at maximal medical improvement. The progress note associated with this request, which is dated 4/3/15, fails to describe any prior failed return to work attempts. Given this documentation, this request for FCE is not medically necessary.

Shockwave therapy for the cervical, lumbar spine and bilateral shoulders x 18: Upheld

Claims Administrator guideline: Decision based on MTUS Shoulder Complaints 2004.

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 Chapter, Shock wave therapy and Other Medical Treatment Guidelines Other Medical Treatment Guideline or Medical Evidence: Anthem Medical Policy # SURG.00045 Extracorporeal Shock Wave Therapy for Orthopedic Conditions.

Decision rationale: Regarding the request for ESWT for the lumbar spine, the California MTUS does not address the issue. The Official Disability Guidelines specifically do not recommend shockwave therapy for the lumbar spine as the available evidence does not support its effectiveness in treating low back pain. The direct excerpt from the Official Disability Guidelines (ODG) Low Back Chapter, Shock wave therapy is as follows: "Not recommended. The available evidence does not support the effectiveness of ultrasound or shock wave for treating LBP. In the absence of such evidence, the clinical use of these forms of treatment is not justified and should be discouraged. (Seco, 2011)" Given this direct non-recommendation by guidelines, the currently requested ESWT for lumbar spine is not medically necessary. Furthermore, although the ODG Neck and Upper Back Chapter does not address the issue of shockwave therapy for the cervical spine, the Anthem Blue Cross medical policy notes that ESWT for the treatment of musculoskeletal conditions is considered investigational and not medically necessary. In light of the above issues, the currently requested ESWT for lumbar and cervical spine is not medically necessary.

MRI of the cervical spine: Upheld

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

MAXIMUS guideline: Decision based on MTUS Neck and Upper Back Complaints 2004, Section(s): Special Studies. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Neck and Upper Back Chapter, MRI Topic.

Decision rationale: Regarding the request for cervical MRI, guidelines support the use of imaging for emergence of a red flag, physiologic evidence of tissue insult or neurologic deficit, failure to progress in a strengthening program intended to avoid surgery, and for clarification of the anatomy prior to an invasive procedure. Within the documentation available for review, there is no indication of any red flag diagnoses. The progress note from 4/3/15 indicates that the patient has 4/5 motor strength in the bilateral upper extremities with intact reflex testing. There is diminished light touch sensation found in many dermatomes. Furthermore, this is a chronic injury from 1994 and the results and timing of the last cervical MRI is not revealed. ODG recommend repeat studies only when a significant change in pathology is found. Given this, the requested cervical MRI is not medically necessary.

MRI of the bilateral shoulders: Upheld

Claims Administrator guideline: Decision based on MTUS Shoulder Complaints 2004.

MAXIMUS guideline: Decision based on MTUS Shoulder Complaints 2004, Section(s): Special Studies. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Shoulder Chapter, Magnetic resonance imaging (MRI).

Decision rationale: Regarding the request for repeat shoulder MRI, ACOEM Practice Guidelines do not have specific guidelines on when a repeat study is warranted. In general, lumbar MRI is recommended when there are unequivocal objective findings that identify specific nerve compromise on the neurologic examination in patients who do not respond to treatment and would consider surgery an option. The Official Disability Guidelines state that repeat MRIs should be reserved for cases in which a significant change in pathology has occurred. Within the documentation available for review, there is a lack of discussion of prior shoulder MRI or imaging studies. This likely has taken place given the chronicity of this injury. A review of the progress note since that time does not indicate any acute intervening injury or sudden change in pathology. Exam findings continue to demonstrate restricted ROM, but no sudden change in pathology. Given this, the current request is not medically necessary.

EMG/NCV of the bilateral upper extremities: Upheld

Claims Administrator guideline: Decision based on MTUS Forearm, Wrist, and Hand Complaints 2004.

MAXIMUS guideline: Decision based on MTUS Neck and Upper Back Complaints 2004, Section(s): Special Studies. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Neck Chapter, Electrodiagnostic Studies, Electromyography, Nerve Conduction Studies.

Decision rationale: Regarding the request for repeat EMG and nerve conduction study of the upper extremity, ACOEM Practice Guidelines state that the electromyography and nerve conduction study may help identify subtle focal neurologic dysfunction in patients with neck or arm symptoms, or both, lasting more than three or four weeks. Within the documentation available for review, the patient has had a prior EMG study done on 8/5/2010 according to a report from date of service 6/19/14. The progress note from 4/3/15 indicates that the patient has 4/5 motor strength in the bilateral upper extremities with intact reflex testing. There is diminished light touch sensation found in many dermatomes. It is unclear how the patient's symptoms have changed since the last exam to warrant to a repeat study at this time, and the requesting provider did not acknowledge or comment on the results of prior electrodiagnostic studies. As such, the current request is not medically necessary.

EMG/NCV of the bilateral lower extremities: Upheld

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

MAXIMUS guideline: Decision based on MTUS Low Back Complaints 2004, Section(s): Special Studies. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back Chapter, Nerve Conduction Studies, Electrodiagnostic Studies.

Decision rationale: With regard to EMG/NCS of the lower extremities to evaluate for lumbar radiculopathy, Section 9792.23.5 of the California Code of Regulations, Title 8, page 6 adopts ACOEM Practice Guidelines Chapter 12. ACOEM Chapter 12 on page 303 states: "Electromyography (EMG), including H-reflex tests, may be useful to identify subtle, focal neurologic dysfunction in patients with low back symptoms lasting more than three or four weeks." The update to ACOEM Chapter 12 Low Back Disorders on pages 60-61 further states: "The nerve conduction studies are usually normal in radiculopathy (except for motor nerve amplitude loss in muscles innervated by the involved nerve root in more severe radiculopathy and H-wave studies for unilateral S1 radiculopathy). Nerve conduction studies rule out other causes for lower limb symptoms (generalized peripheral neuropathy, peroneal compression neuropathy at the proximal fibular, etc.) that can mimic sciatica." Further guidelines can be found in the Official Disability Guidelines. The Official Disability Guidelines Low Back Chapter, states the following regarding electromyography: "Recommended as an option (needle, not surface). EMGs (electromyography) may be useful to obtain unequivocal evidence of radiculopathy, after 1-month conservative therapy, but EMGs are not necessary if radiculopathy is already clinically obvious. (Bigos. 1999) (Ortiz-Corredor. 2003) (Haig. 2005) EMGs may be required by the AMA Guides for an impairment rating of radiculopathy. (AMA 2001)" With regard to nerve conduction studies, the Official Disability Guidelines Low Back Chapter states: "Nerve conduction studies (NCS) section: 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)" However, it should be noted that this guideline has lower precedence than the ACOEM Practice Guidelines which are incorporated into the California Medical Treatment and Utilization Schedule, which do recommend NCS. Therefore, nerve conduction studies are recommended in evaluations for lumbar radiculopathy. Within the documentation available for review, there is a progress note dated 4/3/15 which documents 4/5 strength in the lower extremity, intact deep tendon reflexes, and sensory abnormalities in some distal lumbar dermatomes. However, it should be noted that this is a long-standing injury, and there is not specific commentary on any acute changes in pathology, or statements as to whether prior EMG/NCS has been previously carried out. Given that this injury has occurred many years ago, it is likely that prior electrodiagnostic studies have been carried out. The requesting provider in fact requests for a copy of prior records in the note from date of service 4/3/15. A review of prior studies should be carried out prior to ordering new studies. Given this, the current request is not medically necessary.

Ketoprofen 20% cream 167gm: 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 Chronic Pain Medical Treatment Guidelines on page 112 state the following: "Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. (Diaz, 2006) (Hindsen, 2006) Absorption of the drug depends on the base it is delivered in. (Gurol,

1996). Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. (Krummel 2000)" Within the submitted documentation, there is no explanation as to why the topical ketoprofen is prescribed despite MTUS recommendations against this formulation. It is not apparent if the worker has failed other forms of topical NSAIDs recommended by the CPMTG. Given this, this request is not medically necessary.

Synapryn 10mg/1ml oral suspension 500ml: 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): Glucosamine (and Chondroitin Sulfate), Opioids, criteria for use, Opioids, specific drug list.

Decision rationale: Regarding the request for Synapryn, the CA MTUS does not specifically mention this drug. It is noted that this is a compounded medication containing tramadol and glucosamine, which are both separately discussed in the CPMTG. With regard to opioids such as tramadol, California MTUS Chronic Pain Medical Treatment Guidelines state that, due to high abuse potential, close follow-up is recommended with documentation of analgesic effect, objective functional improvement, side effects, and discussion regarding any aberrant use. Guidelines go on to recommend discontinuing opioids if there is no documentation of improved function and pain. With regard to glucosamine, it is recommended as an option in patients with moderate arthritis pain, especially for knee osteoarthritis. Within the documentation available for review, there is no indication that the medication is improving the patient's pain (in terms of percent reduction in pain or reduced NRS), and no discussion regarding aberrant use. There is also no clear rationale for the use of this oral suspension compounded kit rather than the FDA-approved oral tablet forms (which is also the formulation recommended by the CA MTUS). In the absence of such documentation, the currently requested Synapryn is not medically necessary.

Cyclobenzaprine 5% cream 110gm: 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: This topical compound consists in part of topical cyclobenzaprine. Regarding the request for topical cyclobenzaprine, CA MTUS states that topical muscle relaxants are not recommended as there is no peer-reviewed literature to support the use of topical baclofen or any other muscle relaxant as a topical product. Furthermore, the same guidelines specify that if one component of a compounded medication is not recommended, then the entire formulation is not recommended. Given these guidelines, this request is not medically necessary.

Tabradol 1mg/ml oral suspension 250ml: 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): Muscle relaxants (for pain). Decision based on Non-MTUS Citation Medline, Tabradol, <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=5d19ef8b-eef3-4d52-95f5-929765ca6dc7>.

Decision rationale: Regarding the request for Tabradol, the CA MTUS does not address this specific drug/formulation. Tabradol contains cyclobenzaprine hydrochloride 1 mg/mL in oral suspension with MSM - compounding kit. Regarding cyclobenzaprine, Chronic Pain Medical Treatment Guidelines support the use of non-sedating muscle relaxants to be used with caution as a 2nd line option for the short-term treatment of acute exacerbations of pain. Guidelines go on to state that cyclobenzaprine specifically is recommended for a short course of therapy. Within the documentation available for review, there is no indication of a failed trial of oral generic cyclobenzaprine or documentation of why this oral suspension is medically necessary (i.e., in cases of dysphagia). Furthermore, the compounding MSM is not provided in either the CA MTUS, ODG, or ACOEM. Given this, the currently requested Tabradol is not medically necessary.

Deprizine 15mg/ml oral suspension 250ml: 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 based on Non-MTUS Citation <http://www.drugs.com/pro/deprizine.html>.

Decision rationale: Regarding the request for Deprizine, this medication is not specifically described in the CA MTUS or ACOEM. Deprizine contains active and inactive bulk materials to compound a ranitidine hydrochloride oral suspension. California MTUS states that H2 antagonists such as ranitidine are appropriate for the treatment of dyspepsia secondary to NSAID therapy or for patients at risk for gastrointestinal events with NSAID use. Within the documentation available for review, there is no indication that the patient has trialed a conventional H2 antagonist such as ranitidine or famotidine in pill form. The medical necessity of oral suspension form of ranitidine is not apparent from the submitted records. The worker also does not have clear documentation of complaints of dyspepsia secondary to NSAID use, a risk for gastrointestinal events with NSAID use, or another indication for this medication. In light of the above issues, the currently requested Deprizine is not medically necessary.

Dicopanorol 5mg/ml 150ml: 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, Insomnia treatment and Other Medical Treatment Guidelines Other: Drugs.com Listing of Dicopanol oral suspension, <http://www.drugs.com/pro/dicopanol.html>.

Decision rationale: Regarding the request for Dicopanol, California MTUS guidelines are silent regarding this medication. Dicopanol contains active and inactive bulk materials to compound a diphenhydramine hydrochloride oral suspension. There are also "proprietary ingredients" in Dicopanol, which have not been studied in peer-reviewed studies. ODG states sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine). Tolerance seems to develop within a few days. Next-day sedation has been noted as well as impaired psychomotor and cognitive function. They go on to state the failure of sleep disturbances to resolve in 7 to 10 days, may indicate a psychiatric or medical illness. Within the documentation available for review, there is no indication of why an oral suspension formulation is necessary, as opposed to a tablet form of this drug, which is available as a generic. It is not apparent in the records that the worker has failed a trial of generic diphenhydramine, which has more extensive safety studies. Furthermore, this oral suspension also has "proprietary" ingredients, which have not been subjected to peer reviewed research. Given this, the currently requested Dicopanol is not medically necessary.

Fanatrex 25mg/ml oral suspension 420ml: 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): Antiepilepsy drugs (AEDs). Decision based on Non-MTUS Citation Drugs.com Listing of Fanatrex, <http://www.drugs.com/pro/fanatrex.html>.

Decision rationale: Regarding the requested for Fanatrex, the CA MTUS does not specifically discuss this medication. Fanatrex contains active and inactive bulk materials to prepare 420 mL of a gabapentin oral suspension containing 25 mg/mL gabapentin. Per the MTUS, gabapentin is an anti-epileptic drug that is commonly used to treat neuropathic pain. The Chronic Pain Medical Treatment Guidelines state that antiepilepsy drugs are recommended for neuropathic pain. They go on to state that a good outcome is defined as 50% reduction in pain and a moderate response is defined as 30% reduction in pain. Guidelines go on to state that after initiation of treatment, there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. Within the documentation available for review, there is no discussion as to why an oral suspension as opposed to a tablet form that has been FDA approved for safety and efficacy, and is available in generic form. There is no extenuating circumstance such as dysphagia in this worker to suggest why this oral suspension is necessary. Given this, the currently requested Fanatrex is not medically necessary.

Urine drug screen: 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, dealing with misuse & addiction, Opioids, steps to avoid misuse/addiction, Drug testing. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain Chapter, Urine Drug Testing.

Decision rationale: Regarding the request for a urine toxicology test, CA MTUS Chronic Pain Medical Treatment Guidelines state the drug testing is recommended as an option in patients on controlled substances. Guidelines go on to recommend monitoring for the occurrence of any potentially aberrant (or non-adherent) drug related behaviors. ODG recommends urine drug testing on a yearly basis for low risk patients, 2-3 times a year for moderate risk patients, and possibly once per month for high risk patients. Risk stratification is an important component in assessing the necessity and frequency of urine drug testing. With the documentation available for review, there is documentation of prescription of controlled substances. The tramadol component of Synapryn is a controlled Schedule IV substance. It should be noted that this request is not recommended however. Furthermore, there is no notation of when the last previous urine toxicology testing was done. No risk factor assessment, such as the utilization of the Opioid Risk Tool or SOAPP is apparent in the records, which would dictate the schedule of random periodic drug testing. Given this, this request is not medically necessary.

MRI of the lumbar spine: Upheld

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

MAXIMUS guideline: Decision based on MTUS Low Back Complaints 2004, Section(s): Special Studies. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back Chapter, MRI Topic.

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. They are the test of choice for patients with previous back surgery. Typically, the indications for MRI require that x-rays of the lumbar spine be performed first and are non-diagnostic. Within the documentation available for review, a progress note dated 4/3/15 which documents 4/5 strength in the lower extremity, intact deep tendon reflexes, and sensory abnormalities in some distal lumbar dermatomes. However, it should be noted that this is a long standing injury, and there is not specific

commentary on any acute changes in pathology, or commentary as to how pathology has changed since the most recent imaging. The progress note from 6/19/14 indicates that the worker has had at least one prior lumbar MRI, and there is no mention as to whether the current examination can be explained by those findings. Given this, the currently requested lumbar MRI is not medically necessary.