

<b>Case Number:</b>	CM14-0120116		
<b>Date Assigned:</b>	08/11/2014	<b>Date of Injury:</b>	11/15/2012
<b>Decision Date:</b>	09/30/2014	<b>UR Denial Date:</b>	07/03/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/30/2014

### 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. The expert reviewer is Board Certified in Physical Medicine and Rehabilitation and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### 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 an 80-year-old female who reported injury on 11/15/2012 while working as a hairstylist at [REDACTED]; slipped and fell, landing on the ground and injuring her left arm and shoulder. The injured worker had diagnoses of cervicgia, cervical spine radiculopathy, cervical disc displacement, left shoulder pain, left shoulder AC arthrosis, left shoulder tendonitis, shoulder internal derangement, left wrist tenosynovitis, left wrist ganglion cyst, thoracic spine pain, intervertebral disc displacement of the thoracic region, Schmorl's nodes of the thoracic region, lumbosacral pain, lumbar spine radiculopathy, and intervertebral disc displacement of the lumbar region. The past medical treatment for the injured worker consisted of acupuncture, shockwave therapy, the use of a TENS unit, physical therapy, and medication therapy. Medications include Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, Capsaicin, Flurbiprofen, Tramadol, Menthol, and Cyclobenzaprine. The injured worker underwent an MRI of the thoracic spine on 07/08/2014 which revealed no fracture. The vertebral body heights and marrow signal appeared unremarkable. The alignment of the thoracic vertebra appeared to be within normal limits. An MRI of the left wrist was obtained on 11/26/2013 which revealed that alignment of the wrist joint was normal. Tiny bone cysts were seen in the triquetrum. The rest of the carpal bones appeared unremarkable. There was minimal fluid seen in the pisiform. A urinalysis that was collected on 06/02/2014 revealed that the injured worker was in compliance with her medications. On 07/25/2014, the injured worker complained of neck, left shoulder, left wrist, upper mid back, low back pain. Physical examination of the neck revealed muscle spasm, greater on the left side which the injured worker rated at a 7/10. Range of motion revealed a flexion of 25 degrees, extension of 30 degrees, left rotation of 45 degrees, right rotation of 55 degrees, left lateral flexion of 40 degrees, and right lateral flexion of 40 degrees. There was tenderness at the sub occipital region, as well as over the trapezius and scalene muscles.

Examination of the left shoulder revealed that the injured worker had muscle spasms which the injured worker rated at a 7/10 on a pain scale. The exam revealed tenderness to palpation at the deltoid pectoral groove and over the insertion site of the supraspinatus muscle. Range of motion revealed a flexion of 150 degrees, extension 40 degrees, abduction 150 degrees, adduction 40 degrees, external rotation 45 degrees, and internal rotation 60 degrees. Examination of the left wrist revealed that the injured worker had mild to moderate pain which she rated at a 7/10. There was tenderness to palpation noted over the carpal bones. Range of motion revealed a flexion of 35 degrees, extension 35 degrees, radial deviation 10 degrees, and ulnar deviation of 15 degrees. Sensation to pinprick and light touch was diminished over C5, C6, C7, C8, and T1 dermatomes in the bilateral upper extremities. Motor strength was decreased secondary to pain in the bilateral upper extremities. Deep tendon reflexes were 2+ and symmetrical in the bilateral upper extremities. Examination of the thoracic spine revealed that the injured worker had moderate to severe pain that she rated at 7/10. There was tenderness to palpation noted over the bilateral thoracic paraspinals and over the spinous process at T1-12 levels. Range of motion revealed a flexion of 40 degrees, extension 20 degrees, left rotation 60 degrees, and right rotation 60 degrees. The treatment plan is for the injured worker to undergo an NCV/EMG of the cervical spine, and continue with the use of medications. The rationale behind the request is the provider feels that he needs to continue to address the symptoms that the injured worker has at the moment. The Request for Authorization form was not submitted for review.

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

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

**Synapryn 10mg/1ml Oral Suspension 100 ML:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids (Tramadol) Page(s): 78,93-94.

**Decision rationale:** The request for Synapryn 10mg/1ml Oral Suspension 100 ML is not medically necessary. The California Medical Treatment Utilization Schedule (MTUS) Guidelines state that central analgesic drugs such as Synapryn (Tramadol) are reported to be effective in managing neuropathic pain and it is not recommended as a first line oral analgesic. The California MTUS Guidelines recommend there should be documentation of the 4 A's for ongoing monitoring, including analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors. MTUS Guidelines also state there should be a current pain assessment that should include: current pain, the least reported pain over the period since last assessment, average pain, and intensity of pain after taking the opioid, how long it takes for pain relief, and how long pain relief lasts. There should also be the use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control. As per the guidelines, recommendations state that Synapryn (Tramadol) is not recommended as a first line oral analgesic. The submitted report lacked any information suggesting that the injured worker had any neuropathic pain. The report also lacked any evidence of the effectiveness of the medication. There were no notes suggesting what pain levels were before, during, and after the

medication. There was also no documentation of the 4 A's, to include analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behavior. There was a drug screen submitted on 06/02/2014 showing that the injured worker was in compliance with the MTUS. However, the efficacy of the medication was not submitted in the report. Additionally, the submitted lacked any indication as to why the injured worker would not benefit from the use of oral medications. Furthermore, the request submitted did not include a frequency or duration. Given that the documentation submitted for review lacked evidence, the request for Synapryn 10mg/1ml Oral Suspension 100 ML is not medically necessary.

**Tabradol 1mg/ml Oral Suspension 250 ML: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Cyclobenzaprine (Tabradol) Page(s): 63-64.

**Decision rationale:** The request for Tabradol 1mg/ml Oral Suspension 250 ML is not medically necessary. The California Medical Treatment Utilization Schedule (MTUS) Guidelines recommend non-sedating muscle relaxants with caution as a second line option for short term treatment of acute exacerbations in patients with chronic low back pain. Efficacy appears to diminish over time and prolonged use of some medications in this class may lead to dependence. The MTUS Guidelines also state that, despite their popularity, skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. Limited, mixed evidence on Cyclobenzaprine (Tabradol) does not allow for a recommendation for chronic use. This medication is not recommended to be used for longer than 2 to 3 weeks. The request submitted did not specify the frequency or duration of the medication. There was also no quantified information regarding pain relief. The efficacy of the medication was not submitted for review. There was no documentation as to whether the above medication helped with the injured worker's functional deficits. The submitted report also noted that the injured worker had been on Tabradol since at least 03/05/2013, exceeding the recommended 2 to 3 weeks. There was also no assessment regarding current pain on VAS which would include average pain, intensity of pain, or longevity of pain. In addition, there was no mention of a lack of side effects. Furthermore, the submitted lacked any indication as to why the injured worker would not benefit from the use of oral medications. Given the above, the request for ongoing use of Tabradol is not supported by the California MTUS guideline recommendations. As such, the request is not medically necessary.

**Deprizine 15mg/ml Oral Suspension 250 ML: 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 Other Medical Treatment Guideline or Medical Evidence:Drugs.com, Deprizine (ranitidine hydrochloride).

**Decision rationale:** The request for Deprizine 15mg/ml Oral Suspension 250 ML is not medically necessary. The MTUS/ACOEM and ODG do not address this medication. As such, Drugs.com was used as reference. According to Drugs.com, Deprizine is a histamine 2 blocker. It is used in the treatment of GERD and other conditions in which acid backs up from the stomach into the esophagus. Using Deprizine may increase your risk of developing pneumonia. Symptoms of pneumonia include chest pain, fever, feeling short of breath, and coughing up green or yellow mucus. The submitted report did not indicate that the injured worker had any complaints of dyspepsia with the use of medication, cardiovascular disease or significant risk factors for gastrointestinal events. The submitted report also lacked any evidence as to how long the injured worker was using any type of NSAID medication. The efficacy of the medication was also not submitted for review. Furthermore, the submitted lacked any indication as to why the injured worker would not benefit from the use of oral medications. In the absence of this documentation, the request is not supported by the evidence based guidelines. Additionally, the request as submitted did not include a frequency or duration. As such, the request for Deprizine 15mg/ml Oral Suspension 250 ML is not medically necessary.

#### **Dicopanol 5mg/ml Oral Suspension 150 ML: 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) Antihistamines, Mental Illness and Stress, Insomnia (Dicopanol).

**Decision rationale:** The request for Dicopanol 5mg/ml Oral Suspension 150 ML is not medically necessary. The Official Disability Guidelines state that sedating antihistamines have been suggested for sleep aids, tolerance seems to develop within a few days and next day sedation has been noted, as well as impaired psychomotor and cognitive function. Sedating antihistamines have been shown to build tolerance against the sedation effectiveness very quickly. The Official Disability Guidelines further state compound medication should include at least one drug substance (or active ingredient) that is the sole active ingredient in any FDA approved prescription drug, not included LTC drugs. The guidelines note compounded medications should include only bulk ingredients that are components of FDA approved drugs that have been made in a FDA registered facility and have an NDC code and should not include any drug that was withdrawn or removed for the market from the safety reasons and is not a copy of a commercially available FDA approved drug product. The guidelines also note that medications should include only drug substances that have been reported as safe and effective for the prescribed indication by the FDA approval process and/or by adequate medical and scientific evidence in medical literature. The provider's rationale for the use of the medication is unclear. It was unclear as to why the injured worker would require compounded oral suppression medications as opposed to non-compounded traditional oral medications. Furthermore, the request as submitted did not indicate a frequency or duration of the medication. As such, the request for Dicopanol 5mg/ml Oral Suspension 150 ML is not medically necessary.

## **Fanatrex 25mg/ml Oral Suspension 420 ML: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs) Page(s): 16-22.

**Decision rationale:** The request for Fanatrex 25mg/ml Oral Suspension 420 ML is not medically necessary. The California MTUS Guidelines state gabapentin has been shown to be effective for diabetic painful neuropathy and postherpetic neuralgia and has been considered a first line treatment for neuropathic pain. 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 continuous use of AEDs depends on improved outcomes versus tolerability of adverse effects. The injured worker has been prescribed Fanatrex since at least 03/05/2013. The efficacy of the medication was not documented. The provider's rationale was not provided. The medical documents did not indicate that the injured worker had significant difficulties taking traditional tablet medications which would indicate the injured worker's need for oral suspension medications. The provider's request did not indicate a frequency or duration of the medication. As such, the request for Fanatrex 25mg/ml Oral Suspension 420 ML is not medically necessary.

## **1 Periodic UA Toxicological Evaluation: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Urine Drug Testin.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Urine Drug Test Page(s): 43.

**Decision rationale:** The request for 1 Periodic UA Toxicological Evaluation is not medically necessary. The California MTUS Guidelines recommend a urine drug test as an option to assess for the use or the presence of illegal drugs. It may also be used in conjunction with a therapeutic trial of opioids, for ongoing management, and as a screening for a risk for misuse and addiction. The documentation did not indicate that the injured worker displayed any aberrant behaviors, drug seeking behavior, or that the injured worker was suspected of illegal drug use. It was documented in the submitted report that the injured worker underwent a UA on 06/02/2014 revealing that the injured worker was in compliance with the MTUS guidelines. The frequency of a urine drug screen can be determined based upon the risk factors. Based on the current available information submitted for review, the medical necessity for an additional drug screen has not been established. As such, the request for 1 Periodic UA Toxicological Evaluation is not medically necessary.

## **Terocin patches: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Medications.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidocaine (Terocin) Page(s): 112.

**Decision rationale:** The request for Terocin patches is not medically necessary. The California MTUS states that Lidocaine is a transdermal application that is recommended for neuropathic pain and recommended for localized peripheral pain after there has been evidence of a trial of first line therapy, such as tricyclic or SNRI antidepressants, or an AED, such as Gabapentin or Lyrica. No other commercially approved topical formulation of Lidocaine (whether creams, lotions, or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and antipruritic. In 02/2007, the FDA notified consumers and health care professionals of the potential hazards of the use of topical Lidocaine. Those at particular risk were individuals that applied large amounts of this substance over large areas, left the products on for long periods of time, or used the agent with occlusive dressings. Only FDA-approved products are currently recommended. The guidelines state that Lidocaine is recommended for localized peripheral pain; however, there was no documentation submitted in the report that the injured worker had such pain. The submitted report also lacked any indication as to what the injured worker's pain levels were before, during, and after the application of the Terocin patch. Furthermore, there was no evidence submitted in the report showing that the injured worker had trialed and failed any first line therapy. The efficacy of the medication was not provided to support the continuation and the request as submitted did not include a frequency or duration of the medication. As such, the request for Terocin patches is not medically necessary.

**MRI Thoracic Spine:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 177-178.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 303-305.

**Decision rationale:** The request for MRI Thoracic Spine is not medically necessary. ACOEM Guidelines indicate there is to be unequivocal objective findings that identify specific nerve compromise on the neurological exam. Sufficient evidence to warrant imaging in patients who do not respond to treatment and who would consider surgery an option. When the neurologic examination is less clear; however, further physiological evidence of nerve dysfunction should be obtained before ordering an imaging study. The submitted report indicated that the injured worker had an MRI of the thoracic spine on 07/08/2014. Results revealed no fracture. The vertebral body heights and marrow signal appeared unremarkable. The alignment of the thoracic vertebra appeared to be within normal limits. There were no destructive bone lesions identified. Guidelines stipulate that there is to be an MRI if there has been unequivocal objective findings that identify specific nerve compromise. There was no evidence of any substantial changes to the injured worker's thoracic spine to warrant an additional MRI. Furthermore, the request

lacked a specific level of the thoracic spine to be MRI'd. As such, the request for MRI Thoracic Spine is not medically necessary.

**MRI Left Wrist:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 11 Forearm, Wrist, and Hand Complaints Page(s): 98.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 11 Forearm, Wrist, and Hand Complaints Page(s): 268-269.

**Decision rationale:** The request for MRI Left Wrist is not medically necessary. ACOEM Guidelines indicate there is to be unequivocal objective findings that identify specific nerve compromise on the neurological exam. Sufficient evidence to warrant imaging in patients who do not respond to treatment and who would consider surgery an option. When the neurologic examination is less clear; however, further physiological evidence of nerve dysfunction should be obtained before ordering an imaging study. The submitted reports indicated that the injured worker underwent an MRI of the left wrist on 11/26/2013 that revealed alignment of the wrist joint was normal. A tiny bone cyst was seen on the triquetrum. The rest of the carpal bones appeared unremarkable. There was minimal fluid seen in the pisiform. Guidelines stipulate that there is to be an MRI if there has been unequivocal objective findings that identify specific nerve compromise. There was no evidence of any substantial changes to the injured worker's left wrist. The report also lacked any concrete evidence as to why an additional MRI was warranted. Given the above, the injured worker is not within the MTUS guidelines. As such, the request for MRI Left Wrist is not medically necessary.

**Shockwave Therapy Unknown Frequency and Duration:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints Page(s): 203.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints Page(s): 201-205.

**Decision rationale:** The request for Shockwave Therapy Unknown Frequency and Duration is not medically necessary. The ACOEM notes some medium quality evidence supports manual physical therapy, ultrasound, and high energy extracorporeal shockwave therapy for calcifying tendonitis of the shoulder. Initial use of less invasive techniques provides an opportunity for the clinician to monitor progress before referral to a specialist. There was a lack of information in physical exam and a lack of documentation of other treatments the injured worker underwent previously, and the measurement of progress with the prior treatments. The documentation provided was unclear as to how shockwave therapy would provide the injured worker with functional improvements. Furthermore, the request as submitted lacked a frequency and duration. As such, the request for Shockwave Therapy Unknown Frequency and Duration is not medically necessary.

## **1 LINT: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Localized High-Intensity Neurostimulation (LINT) see Hyperstimulation Analgesia.

**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, Localized High Intensity (LINT).

**Decision rationale:** The request for 1 LINT is not medically necessary. The Official Disability Guidelines do not recommend LINT examination until there are higher quality studies. Initial results are promising, but only from 2 low quality studies sponsored by the manufacturer. Localized manual high intensity neurostimulation devices are applied to small surface area to stimulate peripheral nerve endings that cause the release of endogenous endorphins. This procedure, usually described as hyper stimulation analgesia, has been investigated in several controlled studies; however, such treatments are time consuming and cumbersome and require previous knowledge of the localization of peripheral nerve endings responsible for low back pain or manual impedance mapping of the back. As the guidelines do not recommend hyper stimulation analgesia, the LINT exam and treatment would not be indicated. As such, the request for 1 LINT is not medically necessary.