

Case Number:	CM15-0119511		
Date Assigned:	07/06/2015	Date of Injury:	03/25/2007
Decision Date:	12/10/2015	UR Denial Date:	05/27/2015
Priority:	Standard	Application Received:	06/22/2015

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 injured worker is a 53 year old male who sustained an industrial injury on March 23, 2007. He has reported injury to the neck, bilateral shoulders, bilateral wrists, and mid back pain and has been diagnosed with cervicalgia, radiculopathy, cervical region, bilateral shoulder sprain strain, median nerve release, pain in wrist, bilateral, and thoracic spine sprain strain. Treatment has included medications, acupuncture, and surgery. There was tenderness to Palpation of the cervical spine, bilateral shoulders, and bilateral wrist. The treatment request included medication, physical therapy, chiropractic, acupuncture, EMG, NCV, and shockwave therapy.

IMR ISSUES, DECISIONS AND RATIONALES

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

Synapryn 10mg/ml 500ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Glucosamine (and Chondroitin Sulfate), Opioids, criteria for use.

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). There is a statement that patients with chronic pain conditions generally respond better to oral suspension than swallowing pills without any evidence or studies to support that claim. Given this, the currently requested Synapryn is not medically necessary.

Tabradol 1mg/ml 250ml: Upheld

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

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 nonsedating 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 (ie, in cases of dysphagia). There is a statement that patients with chronic pain conditions generally respond better to oral suspension than swallowing pills without any evidence or studies to support that claim. 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 250ml: Upheld

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

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. There is a statement that patients with chronic pain conditions generally respond better to oral suspension than swallowing pills without any evidence or studies to support that claim. 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.

Dicopanol 5mg/1ml 150ml: Upheld

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

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.

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. This drug is typically utilized for insomnia management. 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 420ml: Upheld

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

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 compelling rationale 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 a statement that patients with chronic pain conditions generally respond better to oral suspension than swallowing pills without any evidence or studies to support that claim. 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.

Physical therapy x18 for the bilateral shoulders, wrists, thoracic spine: 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): Physical Medicine.

Decision rationale: In the case of this injured worker, the submitted documentation failed to indicate functional improvement from previous physical therapy. This functional improvement can include a reduction in work restrictions or other clinically significant improved function in activities of daily living. According to the Chronic Pain Medical Treatment Guidelines, continuation of physical therapy is contingent on demonstration of functional improvement from previous physical therapy. There is no comprehensive summary of how many sessions have been attended in total over the course of this injury, and what functional benefit the worker gained from PT. Therefore additional physical therapy is not medically necessary.

Chiropractic therapy x 18 for the bilateral shoulders, wrists, thoracic spine: 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): Manual therapy & manipulation.

Decision rationale: Regarding the request for chiropractic care, the Chronic Pain Medical Treatment Guidelines state on pages 58-60 the following regarding manual therapy & manipulation: "Recommended for chronic pain if caused by musculoskeletal conditions. Manual Therapy is widely used in the treatment of musculoskeletal pain. The intended goal or effect of Manual Medicine is the achievement of positive symptomatic or objective measurable gains in functional improvement that facilitate progression in the patient's therapeutic exercise program and return to productive activities. Manipulation is manual therapy that moves a joint beyond the physiologic range-of-motion but not beyond the anatomic range-of-motion. Low back: Recommended as an option. Therapeutic care. Trial of 6 visits over 2 weeks, with evidence of objective functional improvement, total of up to 18 visits over 6-8 weeks. Elective/maintenance care. Not medically necessary. Recurrences/flare-ups. Need to re-evaluate treatment success, if RTW achieved then 1-2 visits every 4-6 months. Ankle & Foot: Not recommended. Carpal tunnel syndrome: Not recommended. Forearm, Wrist, & Hand: Not recommended. Knee: Not recommended. Treatment Parameters from state guidelines A.) Time to produce effect: 4 to 6 treatments B.) Frequency: 1 to 2 times per week the first 2 weeks, as indicated by the severity of the condition. Treatment may continue at 1 treatment per week for the next 6 weeks. C.) Maximum duration: 8 weeks. At week 8, patients should be reevaluated. Care beyond 8 weeks may be indicated for certain chronic pain patients in whom manipulation is helpful in improving function, decreasing pain and improving quality of life. In these cases, treatment may be continued at 1 treatment every other week until the patient has reached plateau and maintenance treatments have been determined." In the case of this injured worker, there is no comprehensive summary of chiropractic to date or functional benefit from prior chiropractic treatment. Upon review of the records, it is not apparent how many prior sessions of chiropractic have been performed to date. Although the patient routinely follows a licensed chiropractor, the notes do not document chiropractic manipulation. Without this information, further visits cannot be recommended. If this is an initial request, then it exceeds guideline recommendations which specify for an initial trial of up to 6 visits. Given these factors, this request is not medically necessary.

Acupuncture x 18 for bilateral shoulders, wrists, thoracic spine: 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 additional 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 acupuncture 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. Within the documentation available for review, there is documentation of prior acupuncture as documented in a progress noted by a licensed acupuncture and chiropractor on 4/7/15. There is documentation of acupuncture have "helped his pain" in the past. However, the functional outcome of this prior treatment is not available in the submitted records. Given this, the currently requested acupuncture is not medically necessary.

EMG/NCV of bilateral upper extremities: Upheld

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

MAXIMUS guideline: Decision based on MTUS Forearm, Wrist, and Hand Complaints 2004, Section(s): Diagnostic Criteria. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Carpal Tunnel Syndrome Chapter, Electrodiagnostic Studies.

Decision rationale: Regarding the request for repeat EMG and NCS of the upper extremities, ACOEM Chapter 11 states: "Appropriate electrodiagnostic studies (EDS) may help differentiate between CTS and other conditions, such as cervical radiculopathy. These may include nerve conduction studies (NCS), or in more difficult cases, electromyography (EMG) may be helpful. NCS and EMG may confirm the diagnosis of CTS but may be normal in early or mild cases of CTS. If the EDS are negative, tests may be repeated later in the course of treatment if symptoms persist." Therefore, repeat studies are indicated when initial studies do not demonstrate nerve abnormalities yet symptoms persists, or possibly if there is a significant change in symptoms. Within the documentation available for review, there is documentation of at least 2 prior electrodiagnostic studies. It is noted that the worker underwent left carpal tunnel release in 2007. Then the patient had an EMG/NCS on 9/24/2013 followed by right carpal tunnel release on 12/4/2013. Then the patient had another repeat EMG/NCS in 2014 according to a progress note dated 4/7/15. The original electrodiagnostic reports were not noted in the submitted records. It is unclear at this juncture what were the results of the latest electrodiagnostic study. Given this lack of information, the request for another repeat study is not medically necessary.

Shockwave therapy x 18 to bilateral wrists: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Policy of a National Insurer: Anthem Medical Policy # SURG.00045 Extracorporeal Shock Wave Therapy for Orthopedic Conditions.

Decision rationale: Regarding the request for ECSWT (Extracorporeal shock wave therapy) for the wrist, neither the California MTUS, ACOEM, nor ODG directly address this therapy for this

body region. Instead the policy by a national insurance carrier is cited. [REDACTED] notes that ESWT for the treatment of musculoskeletal conditions is considered investigational and not medically necessary. In light of this, the currently requested ECSWT (Extracorporeal shock wave therapy) for the wrist is not medically necessary.

Terocin patch: 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: 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 recommended.