

<b>Case Number:</b>	CM14-0084941		
<b>Date Assigned:</b>	07/23/2014	<b>Date of Injury:</b>	05/31/2013
<b>Decision Date:</b>	09/16/2014	<b>UR Denial Date:</b>	05/27/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/06/2014

### 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, has a subspecialty in Pain Medicine 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 a 23 year-old female with a date of injury of 5/31/2013. The patient's industrially related diagnoses include left wrist sprain and strain, left wrist first compartment syndrome, and left wrist contusion. The disputed issues are extracorporeal shock-wave treatment, functional capacity evaluation, left wrist brace, interferential unit, hot-cold unit, Zantac 150mg, Gabapentin 10%/ Amitriptyline 10%/ Dextromethorphan 10%-240 gm, Flurbiprofen 20%/ Tramadol 20%-2140 gm and physical therapy evaluation and treatment for left wrist 2 x 6 (12). A utilization review determination on 5/29/2014 had noncertified these requests. The stated rationale for the denial of extracorporeal shock-wave treatment was that there is no indication of need for extracorporeal shockwave treatment to treat nonspecific wrist pain. The stated rationale for the denial of functional capacity evaluation is that there is little scientific evidence confirming that functional capacity evaluations predict an individual's actual capacity to perform in the work place. It is also stated that there is no job description. The request for a left wrist brace was non-certified because the patient has been given a brace in the past and it may not be appropriate to immobilize the wrist at this point a year after the injury. The interferential unit was non-certified because it is not recommended as an isolated intervention. The patient has not had a trial of any form of transcutaneous electrical stimulation. The rationale for the denial of the hot and cold unit is there is no indication of a need for a continuous flow cryotherapy unit. The first cream was non-certified because patient does not have the indicated diagnosis and the first cream has gabapentin which is not recommended. The cream containing Flurbiprofen and Tramadol was non-certified because the patient could be taking this orally with better analgesic effect. The stated rationale for the denial of Zantac is that there is no documentation of risk of IG events or GI actual events occurring in this patient. The request for physical therapy was non-certified because the patient has undergone significant therapy over the last year. This has not

changed the patient's condition. Therefore the patient should already be on a self-directed active exercise program as recommended by the guidelines.

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

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

**Extracorporeal shock-wave treatment:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 10 Elbow Disorders (Revised 2007) Page(s): 30.

**Decision rationale:** The ACOEM Practice Guidelines recommend against Shockwave Therapy for elbow epicondylitis in the most updated edition of these guidelines. The following excerpt and recommendation is found on page 30 of the update to ACOEM Chapter 10 (approved by ACOEM's Board of Directors on April 9, 2007): "Twelve articles were reviewed, 10 studies (82,83,84,85,86,87,88,89,90,91) and two meta-analyses.(62,92) Of the 10 studies, two were of high quality, five of intermediate quality and three of low quality. One of the high-quality studies 82 evaluated 60 subjects with symptoms for less than 1 year and more than 3 weeks, treating them with either active extracorporeal shockwave therapy (ESWT) with a simple stretching program (n = 31) or sham ESWT with a simple stretching program (n = 29). The authors concluded that "despite improvement in pain scores and pain-free maximum grip strength within groups, there does not appear to be a meaningful difference between treating lateral epicondylitis with extracorporeal shock wave therapy combined with forearm-stretching program and treating with forearm-stretching program alone, with respect to resolving pain within an 8-week period of commencing treatment." The second high-quality study evaluated 272 patients with at least 6 months of conservative treatment (135 received ESWT and 137 received placebo ESWT) and found that ESWT as "applied in the present study was ineffective in the treatment of lateral epicondylitis."<sup>85</sup> One of the meta-analyses reviewed two studies, concluding "no added benefit of ESWT over that of placebo in the treatment of LE [lateral epicondylitis]."<sup>62</sup> The other review analyzed nine studies (the studies reviewed above) and concluded that "when data were pooled, most benefits were not statistically significant. No difference for participants early or late in the course of condition."<sup>92</sup> Quality studies are available on extracorporeal shockwave therapy in acute, subacute, and chronic lateral epicondylalgia patients and benefits have not been shown. This option is moderately costly, has some short-term side effects, and is not invasive. Thus, there is a recommendation against using extracorporeal shockwave therapy [Evidence (A), Strongly Recommended Against]. "Since the guidelines are silent regarding this therapy for treating wrist pain, recommendation against using Extracorporeal Shock Wave Therapy (ESWT) to the elbow can be applied here. There is not enough evidence to support the use of ESWT in the treatment of non-specific wrist pain. There is reference in a procedure note dated 6/20/14 to an article that "Extracorporeal Shock Wave Therapy produces significant pain reduction in patients with Carpal Tunnel Syndrome. ESWT was found to be a safe and non-invasive therapeutic interventional option for decreasing pain in mild to moderately severe cases of CTS." This is the only reference cited supporting its use in the wrist but for the diagnosis of CTS only.

Until there is medical literature recommending ESWT for the use of the injured worker's diagnosis, it is not medically necessary.

**Functional capacity evaluation:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 125.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004) Chapter 7, page 138.

**Decision rationale:** The California MTUS does not specifically address functional capacity evaluations. Other well-established guidelines include ACOEM and Official Disability Guidelines. 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. There is little scientific evidence confirming that FCEs predict an individual's actual capacity to perform in the workplace; an FCE reflects what an individual can do on a single day, at a particular time, under controlled circumstances, that provide an indication of that individual's abilities. As with any behavior, an individual's performance on an FCE is probably influenced by multiple nonmedical factors other than physical impairments. For these reasons, it is problematic to rely solely upon the FCE results for determination of current work capability and restrictions. It is the employer's responsibility to identify and determine whether reasonable accommodations are possible to allow the examinee to perform the essential job activities. Furthermore, the Official Disability Guidelines discuss the complexities of FCE use and include suggested criteria to be met prior to an FCE. The following is an excerpt from the Official Disability Guidelines: Both job-specific and comprehensive FCEs can be valuable tools in clinical decision-making for the injured worker; however, FCE is an extremely complex and multifaceted process. Little is known about the reliability and validity of these tests and more research is needed. (Lechner, 2002) (Harten, 1998) (Malzahn, 1996) (Tramposh, 1992) (Isernhagen, 1999) (Wyman, 1999) Functional capacity evaluation (FCE), as an objective resource for disability managers, is an invaluable tool in the return to work process. (Lyth, 2001) There are controversial issues such as assessment of endurance and inconsistent or sub-maximum effort. (Schultz-Johnson, 2002) Little to moderate correlation was observed between the self-report and the Isernhagen Work Systems Functional Capacity Evaluation (FCE) measures. (Reneman, 2002) Inconsistencies in subjects' performance across sessions were the greatest source of FCE measurement variability. Overall, however, test-retest reliability was good and interrater reliability was excellent. (Gross, 2002) FCE subtests of lifting were related to RTW and RTW level for people with work-related chronic symptoms. Grip force was not related to RTW. (Matheson, 2002) Scientific evidence on validity and reliability is limited so far. An FCE is time-consuming and cannot be recommended as a routine evaluation. (Rivier, 2001). As referenced above, FCE cannot be recommended as a routine evaluation and there is no documentation of a specific job description that the injured worker is being evaluated for. Therefore the request for a functional capacity evaluation is not medically necessary.

**Left wrist brace:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 11 Forearm, Wrist, and Hand Complaints Page(s): 254, 264-265.

**Decision rationale:** As stated in the ACOEM Practice Guidelines in Chapter 11: Forearm, Wrist, and Hand Complaints, use of wrist splint for patient comfort and reduction in pain can be considered. However, when evaluated by an orthopedic specialist on 1/27/14, it was noted in the medical records that the injured worker received a wrist brace the following day after her work related injury. There is no documentation available regarding this wrist brace. Therefore it is not medically necessary for patient to have a second wrist brace.

**Interferential unit:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 118-119.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Interferential Stimulator Page(s): 118-120.

**Decision rationale:** The California MTUS specifies on page 118-120 of the Chronic Pain Medical Treatment Guidelines the following regarding Interferential Current Stimulation (ICS): Not recommended as an isolated intervention. There is no quality evidence of effectiveness except in conjunction with recommended treatments, including return to work, exercise and medications, and limited evidence of improvement on those recommended treatments alone. While not recommended as an isolated intervention, the following is the patient selection criteria if Interferential stimulation is to be used anyway: Possibly appropriate for the following conditions if it is documented and proven to be effective as directed or applied by the physician or a provider licensed to provide physical medicine: - Pain is ineffectively controlled due to diminished effectiveness of medications; or - Pain is ineffectively controlled with medications due to side effects; or - History of substance abuse; or - Significant pain from postoperative conditions limits the ability to perform exercise programs/physical therapy treatment; or - Unresponsive to conservative measures (e.g., repositioning, heat/ice, etc.). The injured worker does not meet the criteria for use of an interferential unit as there is no documentation stating that she has returned to work and is continuing self-directed exercise program at home after finishing her physical therapy. A progress note on 1/27/14 stated that the injured worker did not benefit from physical therapy. Due to lack of documentation supporting that the injured worker meets the above criteria stated in the guidelines, an interferential stimulator unit is not medically necessary.

**Hot-cold unit:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines-Wrist and Hand/Cold packs.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 11 Forearm, Wrist, and Hand Complaints Page(s): 265-271.

**Decision rationale:** A hot-cold unit is an automatic hot cold therapy system that delivers instant heat through wraps that go around the user's feet or hands to help with circulation and to reduce pain. In ACOEM Guidelines, Chapter 11, Table 11-7 Summary of Recommendations for Evaluating and Managing Forearm, Wrist, and Hand Complaints recommends at-home applications of heat or cold packs under physical methods. Furthermore it states patients' at-home applications of heat or cold packs may be used before or after exercises and are as effective as those performed by a therapist. The injured worker is not expected to benefit from the hot-cold unit as compared to the recommended standard heat therapy and cold packs at home. Therefore this request is not medically necessary.

**Gabapentin 10%/ Amitriptyline 10%/ Dextromethorphan 10%-240 gm:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** The California MTUS Chronic Pain Medical Treatment Guidelines, on pages 111-113, specify the following regarding topical Analgesics recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. Gabapentin: Not recommended. There is no peer-reviewed literature to support use. Since Gabapentin is one of the ingredients in this compounded formulation, this prescription is not recommended. Therefore it is not medically necessary.

**Flurbiprofen 20%/ Tramadol 20%-2140 gm:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** The California MTUS Chronic Pain Medical Treatment Guidelines, on pages 111-113, specify the following regarding topical Analgesics: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The California Medical Treatment and Utilization Schedule do not have provisions for topical Tramadol. There is an absence of peer review controlled studies on topical Tramadol and it is not recommended. Therefore, this compounded formulation containing this product is not medically necessary.

**Zantac 150 mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Section 9792.21(c). Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Physician Desk Reference.

**Decision rationale:** Since there are no guidelines available regarding Zantac which is a H2 blocker in the Official Disability Guidelines, ACOEM, or MTUS, then the MTUS Section 9792.21(c) of the California Medical Treatment Utilization Schedule states that: Treatment shall not be denied on the sole basis that the condition or injury is not addressed by the MTUS. In this situation, the claims administrator shall authorize treatment if such treatment is in accordance with other scientifically and evidence-based, peer-reviewed, medical treatment guidelines that are nationally recognized by the medical community, in accordance with subdivisions (b) and (c) of section 9792.25, and pursuant to the Utilization Review Standards found in section 9792.6 through section 9792.10. According to the PDR, Zantac is indicated for the short-term treatment of GERD, gastric and duodenal ulcers, erosive esophagitis, hypersecretory conditions, H. pylori infection, and dyspepsia. The injured worker does not have any documented GI or cardiovascular risk factors or GI side effects from her current oral NSAID therapy. Nor does she have any of the diagnoses stated in the PDR. Therefore, Zantac is not medically necessary.

**Physical therapy evaluation and treatment for left wrist 2 x 6 (12):** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 99.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Physical Medicine Page(s): 98-99.

**Decision rationale:** By statute, the independent medical review process prioritizes the guidelines offered in the California Medical Treatment Utilization Schedule as a first priority, followed then by other national guidelines. In the case of this injured worker, the duration of physical therapy for this worker's diagnosis is not adequately addressed by the California MTUS Chronic Pain Medical Treatment Guidelines and therefore additional guidelines are utilized. With regard to the wrist, Section 9792.23.4 Forearm, Wrist, and Hand Complaints of the California Code of Regulations, Title 8, page 5 states the following: The Administrative Director adopts and incorporates by reference the Forearm, Wrist, and Hand Complaints Chapter (ACOEM Practice Guidelines, 2nd Edition (2004), Chapter 11) into the MTUS from the ACOEM Practice Guidelines. ACOEM Chapter 11 recommends in Table 11-4 on page 264 for initial and follow-up visits for education, counseling, and evaluating home exercise. The specific number of sessions is not directly addressed, and therefore Official Disability Guidelines are cited. Official Disability Guidelines specify the following regarding physical therapy of the forearm, wrist, and hand: Sprains and strains of wrist and hand (ICD9 842): 9 visits over 8 weeks. The injured worker was noted to have completed 12 sessions of physical therapy without benefit on a progress noted dated 1/27/14. There is no documentation of any change in injured worker's condition. At this point, the patient should be on a self-directed active exercise program at home. Therefore, the additional 12 sessions of physical therapy is not medically necessary.