

<b>Case Number:</b>	CM14-0161118		
<b>Date Assigned:</b>	10/24/2014	<b>Date of Injury:</b>	04/23/2013
<b>Decision Date:</b>	12/04/2014	<b>UR Denial Date:</b>	09/05/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/01/2014

### 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 General Preventive Medicine and is licensed to practice in Indiana. 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:

This employee is a 49 year old female with date of injury of 4/23/2012. A review of the medical records indicate that the patient is undergoing treatment for cervicalgia, lumbago, intervertebral disc disease of the cervical and lumbar spine, and left shoulder strain/sprain. Subjective complaints include 9/10 pain in her neck with some radiation down her left arm to her hand with feelings of tingling and numbness; low back pain with some radiation down right lower extremity. Objective findings include limited range of motion of the cervical and lumbar spine with tenderness to palpation of the paravertebrals; positive straight leg raise on right; motor strength is 5/5 in the upper and lower extremities. Treatment has included physical therapy and acupuncture. The utilization review dated 9/5/2014 partially-certified Ketoprofen cream, Cyclobenzaprine cream, Synapryn, Tabradol, Deprizine, Dicopanol, Fanatrex, Platelet-Rich Plasma treatment of shoulders, urinalysis, physical therapy, Terocin patches, and shockwave therapy of both shoulders.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Ketoprofen 20% Cream 165 grams:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound creams

**Decision rationale:** MTUS and Official Disability Guidelines recommend usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "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." Per Official Disability Guidelines and MTUS, Ketoprofen is "not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis and photosensitization reactions." Therefore, the request for Ketoprofen 20% Cream is not medically necessary.

**Cyclobenzaprine 5% Cream, 100gm:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound creams

**Decision rationale:** MTUS and Official Disability Guidelines recommend usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "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." MTUS states regarding topical muscle relaxants, "Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Topical Cyclobenzaprine is not indicated for this usage, per MTUS. Therefore, the request for Cyclobenzaprine 5% Cream is not medically necessary.

**Synapryn 10mg/1ml oral suspension 500ml:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 76.

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

**Decision rationale:** Synapryn is the liquid version of Tramadol that also contains Glucosamine and Tramadol. MTUS states regarding Tramadol that "A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals." The treating physician did not provide sufficient documentation that the patient has

failed her trial of non-opioid analgesics at the time of prescription or in subsequent medical notes. Additionally, no documentation was provided which discussed the setting of goals for the use of Synapryn prior to the initiation of this medication. While the MTUS states that Synapryn (Tramadol) may be used for neuropathic pain it is "not recommended as a first-line therapy". The treating physician has not provided documentation of a trial and failure of first line therapy. As such, the request for Synapryn (Tramadol Glucosamine suspension) 10MG/1 ML is not medically necessary.

**Tabradol 1mg/ml oral suspension 250ml: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63-64.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Medications for chronic pain, Antispasmodics Page(s): 41-42, 60-61, 64-66. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Cyclobenzaprine (Flexeril); Other Medical Treatment Guideline or Medical Evidence: UpToDate, Flexeril

**Decision rationale:** MTUS Chronic Pain Medical Treatment states for Tabradol (Cyclobenzaprine), "Recommended as an option, using a short course of therapy. . . The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. (Browning, 2001) Treatment should be brief." The medical documents indicate that patient is far in excess of the initial treatment window and period. Additionally, MTUS outlines that "Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity. Before prescribing any medication for pain the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005)" UpToDate "Flexeril" also recommends "Do not use longer than 2-3 weeks". Medical documents do not fully detail the components outlined in the guidelines above and do not establish the need for long term/chronic usage of Cyclobenzaprine. Official Disability Guidelines states regarding Cyclobenzaprine, "Recommended as an option, using a short course of therapy . . . The addition of Cyclobenzaprine to other agents is not recommended." Several other pain medications are being requested, along with Cyclobenzaprine, which Official Disability Guidelines recommends against. As such, the request for Tabradol is not medically necessary.

**Deprizine 15mg/ml oral suspension 250ml: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69.

**Decision rationale:** Deprizine contains Ranitidine and other proprietary ingredients. Ranitidine is an H2 blocker and like a PPI can be utilized to treat dyspepsia secondary to NSAID therapy. MTUS states "Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA)." MTUS also states that, "Patients at intermediate risk for gastrointestinal events and no cardiovascular disease:(1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or Misoprostol or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44)." The medical documents provided do not establish the patient has having documented GI bleeding, perforation, peptic ulcer, high dose NSAID, treatment of dyspepsia secondary to NSAID therapy or other GI risk factors as outlined in MTUS. As such, the request for Deprizine 15mg/ MI Oral Suspension 250 MI is not medically necessary.

**Dicopanol 5mg/ml oral suspension 150ml:** Upheld

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

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

**Decision rationale:** MTUS is silent on the use of Diphenhydramine. Official Disability Guidelines discusses the use of Diphenhydramine as an over the counter sleep aid in the chronic pain segment. For insomnia Official Disability Guidelines recommends that "Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness. (Lexi-Comp, 2008) Primary insomnia is generally addressed pharmacologically. Secondary insomnia may be treated with pharmacological and/or psychological measures. The specific component of insomnia should be addressed: (a) Sleep onset; (b) Sleep maintenance; (c) Sleep quality; & (d) Next-day functioning. Official Disability Guidelines recommends that, "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. Side effects include urinary retention, blurred vision, orthostatic hypotension, dizziness, palpitations, increased liver enzymes, drowsiness, dizziness, grogginess and tiredness." There is very little documentation in the medical records regarding the employee's sleeping problems. There is no discussion of specific components of insomnia such as sleep onset, sleep maintenance, or sleep quality. Furthermore, Official Disability Guidelines only recommends a 7 to 10 day trial of this medication before a potential psychiatric evaluation for other organic causes, and the request medication is for longer than that. Therefore, the request for Dicopanol 5mg/ml oral suspension 150ml is not medically necessary.

**Fanatrex 25mg/ml oral suspension 420ml: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 18.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-Epilepsy Drugs Page(s): 16-22. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, Anti-epilepsy drugs (AEDs) for pain, Gabapentin (Neurontin)

**Decision rationale:** The MTUS considers Gabapentin as a first-line treatment for neuropathic pain and effective for the treatment of spinal cord injury, lumbar spinal stenosis, and post operative pain. MTUS also recommends a trial of Gabapentin for complex regional pain syndrome. Official Disability Guidelines states "Recommended Trial Period: One recommendation for an adequate trial with Gabapentin is three to eight weeks for titration, then one to two weeks at maximum tolerated dosage. (Dworkin, 2003) The patient should be asked at each visit as to whether there has been a change in pain or function. Current consensus based treatment algorithms for diabetic neuropathy suggests that if inadequate control of pain is found, a switch to another first-line drug is recommended." Additionally, Official Disability Guidelines states that Gabapentin "has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain". The treating physician does document neuropathic pain along the median and ulnar nerve distribution of the right upper extremity but the treating physician did not document improved functionality and decreased pain after starting Gabapentin. Based on the clinical documentation provided, there is no evidence that after starting a trial of Gabapentin that the patient was asked at each subsequent visit if the patient had decreased pain and improved functionality. As such, without any evidence of neuropathic type pain, the medication is not medically necessary.

**Physical Therapy three times per week for six weeks (no body part specified) QTY: 18: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 98-99.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Physical Therapy, Physical Medicine Page(s): 98-99. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Shoulder (Acute & Chronic), Physical Therapy, ODG Preface - Physical Therapy

**Decision rationale:** California MTUS guidelines refer to physical medicine guidelines for physical therapy. "Allow for fading of treatment frequency (from up to 3 visits per week to 1 or less), plus active self-directed home Physical Medicine." Regarding physical therapy, Official Disability Guidelines states "Patients should be formally assessed after a "six-visit clinical trial" to see if the patient is moving in a positive direction, no direction, or a negative direction (prior to continuing with the physical therapy); & (6) When treatment duration and/or number of visits

exceeds the guideline, exceptional factors should be noted." At the conclusion of this trial, additional treatment would be assessed based upon documented objective, functional improvement, and appropriate goals for the additional treatment. The request for 18 sessions is far in excess of the initial trials per MTUS and Official Disability Guidelines. Additionally, there is not specificity regarding which injury the physical therapy is for. As such, the request for 18 sessions of Physical Therapy 18 is not medically necessary.

### **PRP Injection Right Shoulder, QTY: 3: Upheld**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Elbow, Platelet-rich plasma (PRP)

**Decision rationale:** The MTUS is silent on Platelet Rich Plasma (PRP) injections, but according to the Official Disability Guidelines, "Recommend single injection as a second-line therapy for chronic lateral epicondylitis after first-line physical therapy such as eccentric loading, stretching and strengthening exercises, based on recent research below." The medical documentation does not show that any form of first-line therapy have been tried and failed. Official Disability Guidelines additionally writes, "This small pilot study found that 15 patients with chronic elbow tendinosis treated with buffered platelet-rich plasma (PRP) showed an 81% improvement in their visual analog pain scores after six months, and concluded that PRP should be considered before surgical intervention. Further evaluation of this novel treatment is warranted." Therefore, PRP injection of the right shoulder is not medically necessary.

### **PRP Injection Left Shoulder QTY: 3: Upheld**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Elbow, Platelet-rich plasma (PRP)

**Decision rationale:** The MTUS is silent on Platelet Rich Plasma (PRP) injections, but according to the Official Disability Guidelines, "Recommend single injection as a second-line therapy for chronic lateral epicondylitis after first-line physical therapy such as eccentric loading, stretching and strengthening exercises, based on recent research below." The medical documentation does not show that any form of first-line therapy have been tried and failed. Official Disability Guidelines additionally writes, "This small pilot study found that 15 patients with chronic elbow tendinosis treated with buffered platelet-rich plasma (PRP) showed an 81% improvement in their visual analog pain scores after six months, and concluded that PRP should be considered before surgical intervention. Further evaluation of this novel treatment is warranted." Therefore, PRP injection of the left shoulder is not medically necessary.

**Urinalysis:** 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 and Substance abuse Page(s): 74-96; 108-109. Decision based on Non-MTUS Citation University of Michigan Health System Guidelines for Clinical Care: Managing Chronic Non-terminal Pain, Including Prescribing Controlled Substances (May 2009), page 32 Established Patients Using a Controlled Substance

**Decision rationale:** MTUS states that use of urine drug screening for illegal drugs should be considered before therapeutic trial of opioids are initiated. Additionally, "Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control. Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion) would indicate need for urine drug screening." There is insufficient documentation provided to suggest issues of abuse, addiction, or poor pain control by the treating physician. University of Michigan Health System Guidelines for Clinical Care: Managing Chronic Non-terminal Pain, Including Prescribing Controlled Substances (May 2009) recommends for stable patients without red flags "twice yearly urine drug screening for all chronic non-malignant pain patients receiving opioids - once during January-June and another July-December." The patient has been on chronic opioid therapy. The treating physician has not indicated why a urine drug screen is necessary at this time and has provided no evidence of red flags. As such, the request for a urinalysis is not medically necessary.

**Terocin Patches (quantity not provided):** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound creams

**Decision rationale:** MTUS and Official Disability Guidelines recommend usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "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." Terocin lotion is topical pain lotion that contains Lidocaine and menthol. Official Disability Guidelines states regarding Lidocaine topical patch, "This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia". Medical documents do not document the patient as having post-herpetic neuralgia. Additionally, Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The treating physician did not

document a trial of first line agents and the objective outcomes of these treatments. MTUS states regarding topical analgesic creams, "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." In this case, topical Lidocaine is not indicated. As such Terocin patches are not medically necessary.

### **Shockwave Therapy Right Shoulder, QTY: 3: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Shoulder-ESWT

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 122. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Shoulder and Knee, ESWT; Other Medical Treatment Guideline or Medical Evidence: pub med search ESWT and wrist

**Decision rationale:** MTUS does not specifically refer to Electric Shockwave therapy. The Official Disability Guidelines were consulted for ESWT treatment of the shoulder and only recommended Shoulder ESWT when: 1) Patients whose pain from calcifying tendinitis of the shoulder has remained despite six months of standard treatment.2) At least three conservative treatments have been performed prior to use of ESWT. These would include: a. Rest, b. Ice, c. NSAIDs, d. Orthotics, e. Physical Therapy, e. Injections (Cortisone)". MTUS, ACOEM, and Official Disability Guidelines were silent as to ESWT treatment of the wrist. Based on the MTUS physical medicine guidelines and a search of pub med for ESWT treatment of wrist injuries no evidence based medicine exists to support treatment of the wrist with ESWT. The Official Disability Guidelines were consulted for ESWT treatment of the knee and state "New data presented at the American College of Sports Medicine Meeting suggest that extracorporeal shockwave therapy (ESWT) is ineffective for treating patellar tendinopathy, compared to the current standard of care emphasizing multimodal physical therapy focused on muscle retraining, joint mobilization, and patellar taping. (Zwerver, 2010). Thus the request for electric shockwave for the right shoulder is not medically necessary based on the MTUS, Official Disability Guidelines, and a pub med search.

### **Shockwave Therapy Left Shoulder, QTY: 3: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Shoulder-ESWT

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 122. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Shoulder and Knee, ESWT; Other Medical Treatment Guideline or Medical Evidence: pub med search ESWT and wrist

**Decision rationale:** MTUS does not specifically refer to Electric Shockwave therapy. The Official Disability Guidelines were consulted for ESWT treatment of the shoulder and only recommended Shoulder ESWT when: 1) Patients whose pain from calcifying tendinitis of the shoulder has remained despite six months of standard treatment. 2) At least three conservative treatments have been performed prior to use of ESWT. These would include: a. Rest, b. Ice, c. NSAIDs, d. Orthotics, e. Physical Therapy, e. Injections (Cortisone)". MTUS, ACOEM, and Official Disability Guidelines were silent as to ESWT treatment of the wrist. Based on the MTUS physical medicine guidelines and a search of pub med for ESWT treatment of wrist injuries no evidence based medicine exists to support treatment of the wrist with ESWT. The Official Disability Guidelines were consulted for ESWT treatment of the knee and state "New data presented at the American College of Sports Medicine Meeting suggest that extracorporeal shockwave therapy (ESWT) is ineffective for treating patellar tendinopathy, compared to the current standard of care emphasizing multimodal physical therapy focused on muscle retraining, joint mobilization, and patellar taping. (Zwerver, 2010). Thus the request for electric shockwave left shoulder is not medically necessary based on the MTUS, Official Disability Guidelines, and a pub med search.