

<b>Case Number:</b>	CM15-0121023		
<b>Date Assigned:</b>	07/08/2015	<b>Date of Injury:</b>	01/30/2014
<b>Decision Date:</b>	09/22/2015	<b>UR Denial Date:</b>	06/08/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/23/2015

### 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: Indiana

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

### 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 47-year-old female, who sustained an industrial injury on 1/30/14. The injured worker has complaints of headaches; right shoulder pain; bilateral elbow pain and muscle spasms; bilateral wrist pain and muscle spasms; bilateral knee pain and muscle spasms and achy pain at the soles of her feet. Right shoulder examination revealed +2 tenderness to palpation at the subacromial space and the supraspinatus muscle and tendon attachment sites and tenderness to palpation at the acromioclavicular (AC) joint and subacromial space. Bilateral elbow examination revealed tenderness to palpation at the medial epicondyles and at the ulnar groove. Bilateral wrist examination revealed +2 tenderness to palpation over the carpal bones and over the thenar eminence and +2 tenderness at the flexor tendon attachment sites. Bilateral knee examination revealed tenderness to palpation over the medial and lateral joint line and to the patellofemoral joint, bilaterally. Bilateral foot/ankle examination revealed +2 tenderness along the course of the plantar fascia. The diagnoses have included headaches; right shoulder sprain/strain; right shoulder acromioclavicular (AC) joint arthrosis; right shoulder bursitis; bilateral elbow sprain/strain/ cubital tunnel syndrome, right elbow; synovitis and tenosynovitis, bilateral wrist; carpal tunnel syndrome, bilateral upper limb; right wrist scapholunate ligament tear and sprain of unspecified site of bilateral knee. Treatment to date has included Deprizine; Dicoprofanol; Fanatrex; Synapryn; Tabradol; cyclobenzaprine and ketoprofen cream. The request was for Terocin patches; Fanatrex (gabapentin) 25mg/ml oral suspension 420ml; Tabradol 1mg/ml oral suspension 250ml; Deprizine 15mg/ml oral suspension 250ml; Dicoprofanol

(diphenhydramine) 5mg/ml oral suspension 150ml and Synapryn 10mg/1ml oral suspension 500ml.

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

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

#### **Terocin Patches: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.drugs.com/cdi/terocin-patch.html>.

**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:** Terocin lotion is topical pain lotion that contains lidocaine and menthol. According to the ODG lidocaine topical patch, 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. The Chronic Pain Medical Treatment Guidelines states that 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, the request is not medically necessary.

#### **Fanatrex (Gabapentin) 25mg/ml oral suspension 420ml: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.drugs.com/pro/fanatrex.html>.

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

**Decision rationale:** The Chronic Pain Medical Treatment Guidelines considers Gabapentin as a first-line treatment for neuropathic pain and effective for the treatment of spinal cord injury, lumbar spinal stenosis, and post op pain. Guidelines also recommend a trial of Gabapentin for complex regional pain syndrome. The ODG states that one recommendation for an adequate trial with Gabapentin is three to eight weeks for titration, then one to two weeks at maximum tolerated dosage. 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, ODG 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 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, the medication is not medically necessary.

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

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo>.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41-66. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Cyclobenzaprine (Flexeril).

**Decision rationale:** MTUS Chronic Pain Medical Treatment states that cyclobenzaprine is 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. Treatment should be brief. The medical documents indicate that the patient is far in excess of the initial treatment window and period. Additionally, MTUS outlines that the 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. UpToDate also recommends not to 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. The ODG states that cyclobenzaprine is 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 ODG recommends against. As such, the request is not medically necessary.

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

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.drugs.com/ranitidine.html>.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS; GI 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.

The MTUS states the patient is at risk for gastrointestinal events if: (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 (200g four times daily); 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 is not medically necessary.

**Dicopanol (Diphenhydramine) 5mg/ml oral suspension 150ml: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.ndrugs.com>.

**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. ODG discusses the use of diphenhydramine as an over the counter sleep aid in the chronic pain segment. For insomnia, ODG 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. 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. ODG 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 no discussion of the potential causes of insomnia or other sleep disturbances and what lifestyle and other modifications have been tried and failed. There is no plan for what to do after the short-term period when tolerance may develop. Therefore, the request is not medically necessary.

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

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo>.

**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 MTUS does state 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 is not medically necessary.