

<b>Case Number:</b>	CM15-0137962		
<b>Date Assigned:</b>	07/27/2015	<b>Date of Injury:</b>	09/27/2008
<b>Decision Date:</b>	10/08/2015	<b>UR Denial Date:</b>	06/15/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/16/2015

### 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: Maryland, Texas, Virginia

Certification(s)/Specialty: Internal Medicine, Allergy and Immunology, Rheumatology

### 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 44 year old male, who sustained an industrial injury on September 27, 2008, incurring head, low back and right lower extremity injuries after a fall from a truck. He was diagnosed with closed head trauma with loss of consciousness, concussion, cervical sprain, cervical disc disease, radiculopathy, lumbar sprain, lumbar disc disease and lumbar radiculopathy. Treatment included pain medications, muscle relaxants, physical therapy, Magnetic Resonance Imaging, diagnostic imaging and work restrictions. Currently, the injured worker complained of persistent low back pain radiating into the right lower extremity and worsened with sitting, standing and walking prolonged periods of time. He complained of neck pain with frequent headaches, coordination problems, anxiety and stress. He has difficulty sleeping due to the constant pain. The treatment plan that was requested for authorization included prescriptions for topical compound Ketoprofen cream, Cyclobenzaprine cream, Synapryn, Tabradol, Deprizine, Dicopanor and Fanatrex.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**1 prescription for topical compound Ketoprofen 20% cream, 165 grams: 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 based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound creams.

**Decision rationale:** Official Disability Guidelines (ODG) Pain, Compound creams. MTUS and ODG recommends 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." Ketoprofen (Not Recommended) Per ODG and MTUS, Ketoprofen is "not currently FDA approved for a topical application. It has an extremely high incidence of photo-contact dermatitis and photosensitization reactions." The topical cream is not recommended. As such, the request for 1 prescription for topical compound Ketoprofen 20% cream, 165 gms is not medically necessary.

**1 prescription for Cyclobenzaprine 5% cream: 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 based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound creams.

**Decision rationale:** MTUS and ODG recommends 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." Cyclobenzaprine Or Muscle Relaxants (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. This cream is not recommended for topical use. As such, the request for 1 prescription for Cyclobenzaprine 5% cream is not medically necessary.

**1 prescription for Synapryn oral suspension 500ml: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, specific drug list.

**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 for 1 prescription for Synapryn oral suspension 500ml is not medically necessary.

**1 prescription for Tabradol oral suspension 250ml: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Cyclobenzaprine (Flexeril). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Cyclobenzaprine (Flexeril®) and Other Medical Treatment Guidelines UpToDate, Flexeril.

**Decision rationale:** Tabradol is an oral suspension of cyclobenzaprine and methylsulfonylmethane (MSM). MTUS Chronic Pain Medical Treatment states for 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 medication is not recommended to be used for longer than 2-3 weeks." 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. ODG 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 ODG recommends against. As such, the request for 1 prescription for Tabradol oral suspension 250ml is not medically necessary.

### **1 prescription for Deprazine oral suspension 250ml: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), NSAIDs, GI symptoms & cardiovascular risk and Other Medical Treatment Guidelines Uptodate.com, NSAIDs (including aspirin): Primary prevention of gastroduodenal toxicity.

**Decision rationale:** Deprazine is a brand name ranitidine. Ranitidine is an H2 antagonist used for the treatment of stomach ulcers and gastroesophageal reflux. 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)." And "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)." Uptodate states regarding H2 antagonist for GI prophylaxis, "Standard doses of H2 receptor antagonists were not effective for the prevention of NSAID-induced gastric ulcers in most reports, although they may prevent duodenal ulcers [33]. Studies that detected a benefit on gastric ulcer prevention were short-term (12 to 24 weeks) and focused on endoscopic rather than clinical endpoints". The patient does not meet the age recommendations for increased GI risk. The medical documents provided establish the patient has experienced GI discomfort, but is nonspecific and does not indicate history of peptic ulcer, GI bleeding or perforation. Medical records do not indicate that the patient is on ASA, corticosteroids, and/or an anticoagulant; or high dose/multiple NSAID. Additionally, uptodate suggests that H2 antagonist at this dose is not useful for to prevent ulcers. As such, the request for 1 prescription for Deprazine oral suspension 250ml is not medically necessary.

### **1 prescription for Dicopanor oral suspension 150ml: 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) 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. (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." 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 documentation of psychiatric diagnoses to include unspecified mood disorder and anxiety disorder. The patient's insomnia has gone on for an extended period of time and based on ODG guidelines a trial of anti-depressants to treat the underlying psychiatric illness should have occurred. As such, the request for 1 prescription for Dicopanor oral suspension 150ml is not medically necessary.

### **1 prescription for Fanatrex oral suspension 420ml: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antiepilepsy drugs (AEDs). 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 op pain. MTUS also recommends a trial of Gabapentin for complex regional pain syndrome. ODG 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, ODG states that Gabapentin "has been shown to be effective for treatment of diabetic painful neuropathy and post-herpetic neuralgia and has been considered as a first-line treatment for neuropathic pain". The treating physician does document neuropathic 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 request for 1 prescription for Fanatrex oral suspension 420ml is not medically necessary.