

<b>Case Number:</b>	CM13-0061463		
<b>Date Assigned:</b>	12/30/2013	<b>Date of Injury:</b>	06/25/2012
<b>Decision Date:</b>	04/20/2015	<b>UR Denial Date:</b>	10/31/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/05/2013

### 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: Iowa, Illinois, Hawaii

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Public Health & General Preventive 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 (IW) is a 52-year-old female who sustained an industrial injury on 06/25/2012. The lumbar spine was affected. Diagnoses include lumbar disc displacement-herniated disc and lumbar spine radiculopathy. Treatment to date has included medications and physical therapy. X-rays and MRIs were performed. According to the progress notes dated 6/25/13, the IW reported constant burning, radicular low back pain and muscle spasms rated 6-8/10. The notes stated the IW had temporary pain relief with the prescribed medications, improving sleep. The requested service was part of the provider's treatment plan.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**COMPOUNDED KETOPROFEN 20% IN PLO GEL 120 GRAMS, APPLY A THIN LAYER TO AFFECTED AREA TID:** Upheld

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

**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 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." Per ODG and MTUS, Ketoprofen is "not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis and photosensitization reactions." As such, the request for COMPOUNDED KETOPROFEN 20% IN PLO GEL 120 GRAMS, APPLY A THIN LAYER TO AFFECTED AREA TID is not medically necessary.

**COMPOUNDED CYCLOPHENE 5% IN PLO GEL, 120 GRAMS, APPLY A THIN LAYER TO AFFECTED AREA TID:** Upheld

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

**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 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." 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. As such, the request for COMPOUNDED CYCLOPHENE 5% IN PLO GEL, 120 GRAMS, APPLY A THIN LAYER TO AFFECTED AREA TID is not medically necessary.

**SYNAPRYN 10MG/1ML ORAL SUSPENSION 500ML, TAKE 5ML THREE TIMES A DAY OR AS DIRECTED:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation National Library of Medicine.

**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 for SYNAPRYN (Tramadol glucosamine suspension) 10MG/1 ML ORAL SUSPENSION TAKE 1 TSP TID #1 is not medically necessary.

**TABRADOL 1MG/ML ORAL SUSPENSION 250ML, TAKE 5ML TWO-THREE TIMES A DAY OR AS DIRECTED:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Drugs.com.

**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, TABRADOL) and Other Medical Treatment Guidelines UpToDate, Flexeril.

**Decision rationale:** MTUS Chronic Pain Medical Treatment states for Cyclobenzaprine (Tabradol), "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. ODG states regarding cyclobenzaprine, "Recommended as an option, using a short course of therapy. The addition of cyclobenzaprine to other agents is not recommended." The patient has exceeded guideline recommendation of short-term use. As such, the request for TABRADOL 1MG/ML

ORAL SUSPENSION 250ML, TAKE 5ML TWO-THREE TIMES A DAY OR AS DIRECTED is not medically necessary.

**DEPRIZINE 15MG/ML ORAL SUSPENSION 250ML, TAKE 10ML ONCE DAILY OR AS DIRECTED:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Drugs.com.

**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 (200 g 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 for EPRIZINE 15MG/ML ORAL SUSPENSION 250ML, TAKE 10ML ONCE DAILY OR AS DIRECTED is not medically necessary.

**DICOPANOL 5MG/ML ORAL SUSPENSION 150ML, TAKE 1 ML PO AT BEDTIME:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Drugs.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 dicopanol (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." Medical documentation provided does not indicate this patient has been diagnosed with insomnia. As such, the request for DICOPANOL 5MG/ML ORAL SUSPENSION 150ML, TAKE 1 ML PO AT BEDTIME is not medically necessary.

**FANATREX 25MG/ML ORAL SUSPENSION 420ML, TAKE 5ML TID OR AS DIRECTED:** Upheld

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

**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 Fantarex (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 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. Medical documentation provided does not provide the rationale for this compounded suspension form of Gabapentin. As such, the request for FANATREX 25MG/ML ORAL SUSPENSION 420ML, TAKE 5ML TID OR AS DIRECTED is not medically necessary.