

<b>Case Number:</b>	CM15-0031705		
<b>Date Assigned:</b>	02/25/2015	<b>Date of Injury:</b>	08/29/2013
<b>Decision Date:</b>	04/14/2015	<b>UR Denial Date:</b>	01/23/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/19/2015

### 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: California

Certification(s)/Specialty: Internal 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 58-year-old male who sustained an industrial related injury on 8/29/13. The injured worker had complaints of radicular neck pain and low back pain with burning and muscle spasms. The pain radiated to bilateral upper extremities associated with numbness and tingling. Diagnoses included cervicalgia, cervical disc displacement, cervical spine radiculopathy, sprain of ligaments of cervical spine, lumbago, lumbar spine multilevel disc displacement, lumbar spine degenerative disc disease, lumbar spine radiculopathy, anxiety, and other reactions to severe stress. Treatment included physical therapy, acupuncture, and shockwave therapy. The treating physician requested authorization for Synapryn 10mg/1ml oral suspension 500ml one tsp 5ml 2-3 times per day, Tabradol 1mg/ml oral suspension 250ml one tsp 5ml 2-3 times per day, Deprizine 15mg/ml oral suspension 250ml 2 tsp every day, Dicopanol 5mg/ml oral suspension 150ml one ml per mouth at bedtime, Fanatrex 25mg/ml oral suspension 420ml one tsp 5ml 3 times per day. On 1/23/15, the requests were non-certified. The utilization review (UR) physician cited the Medical Treatment Utilization Schedule guidelines. Regarding Synapryn and Tabradol the utilization review (UR) physician cited the medical records do not provide information as to why the injured worker requires this compounded oral suspension form of medication versus the supported oral capsule form. Regarding Deprizine, Dicopanol, and Fenatrex the UR physician noted there is no medical rationale given for these medications. There is also no documentation why a compounding kit is needed rather than the standard oral capsule forms of these medications. Therefore the requests were non-certified.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Synapryn (10mg/1ml oral suspension 500ml) one tsp (5ml) 2-3 times a day: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Criteria for Use of Opioids.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol (Ultram) Pages 93-94, 113, 123. Glucosamine (and Chondroitin Sulfate) Page 50. Decision based on Non-MTUS Citation Official Disability (ODG) Low Back - Lumbar & Thoracic (Acute & Chronic) Glucosamine. ODG Shoulder (Acute & Chronic) Glucosamine. ODG Pain (Chronic) Compound drugs. Synapryn  
<http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22416>.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines indicates that Tramadol is a synthetic opioid affecting the central nervous system. MTUS Chronic Pain Medical Treatment Guidelines indicates that regarding glucosamine and chondroitin sulfate, controversy on efficacy related to symptomatic improvement continues. Official Disability (ODG) indicates that glucosamine is not recommended for low back pain. Glucosamine is not significantly different from placebo for reducing pain-related disability or improving health-related quality of life in patients with chronic low back pain and degenerative lumbar osteoarthritis, and it should not be recommended for patients with lower back pain. Official Disability (ODG) indicates that glucosamine is not recommended for shoulder disorders as there is no evidence to support it. Official Disability Guidelines (ODG) indicates that compound drugs are not recommended as a first-line therapy. Criteria for compound drugs were presented. Include at least one drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including OTC drugs. Is not a copy of a commercially available FDA-approved drug product. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The primary treating physician's progress report dated 12/15/14 documented a history of cervical spondylosis, lumbar spondylosis, and bilateral acromioclavicular joint arthritis. Regarding subjective complaints, no musculoskeletal complaints were documented. No musculoskeletal physical examination was documented. Synapryn is a compounding oral suspension containing Tramadol and Glucosamine sulfate. The Official Disability Guidelines (ODG) criteria for compound drugs indicate that the compound drug should not be a copy of a commercially available FDA-approved drug product. Tramadol is a commercially available FDA-approved drug. Therefore, Synapryn is a copy of the commercially available FDA-approved drug Tramadol. Official Disability (ODG) indicates that glucosamine is not recommended for or shoulder and low back pain. Per ODG, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, the request for Synapryn is not medically necessary.

**Tabradol 1mg/ml oral suspension 250 ml: one tsp (5ml) 2-3 times a day: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain).

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 1 Prevention, Chapter 3 Initial Approaches to Treatment Page(s): 47-49, Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril) Pages 41-42. Muscle relaxants Pages 63-66. Decision based on Non-MTUS Citation FDA Prescribing Information Cyclobenzaprine <http://www.drugs.com/pro/flexeril.html> TABRADOL <http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22434>.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) addresses muscle relaxants. American College of Occupational and Environmental Medicine (ACOEM) 2nd Edition (2004) states that muscle relaxants seem no more effective than NSAIDs for treating patients with musculoskeletal problems, and using them in combination with NSAIDs has no demonstrated benefit. Muscle relaxants may hinder return to function by reducing the patient's motivation or ability to increase activity. Table 3-1 states that muscle relaxants are not recommended. Chronic Pain Medical Treatment Guidelines addresses muscle relaxants. Muscle relaxants should be used with caution as a second-line option for short-term treatment. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. According to a review in American Family Physician, muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. Chronic Pain Medical Treatment Guidelines state that Cyclobenzaprine (Flexeril) is an option for a short course of therapy. Treatment should be brief. The addition of Cyclobenzaprine to other agents is not recommended. FDA guidelines state that Cyclobenzaprine is indicated for acute musculoskeletal conditions. Cyclobenzaprine should be used only for short periods (up to two or three weeks) because adequate evidence of effectiveness for more prolonged use is not available. Medical records document that the patient's occupational injuries are chronic. Medical records document the long-term use of the muscle relaxant Cyclobenzaprine. MTUS, ACOEM, and FDA guidelines do not support the use of Cyclobenzaprine for chronic conditions. Medical records indicate the long-term use of the muscle relaxant Cyclobenzaprine, which is not supported by MTUS and FDA guidelines. Tabradol is Cyclobenzaprine in oral suspension. The use of Tabradol (Cyclobenzaprine) is not supported by MTUS or ACOEM guidelines. Therefore, the request for Tabradol is not medically necessary.

**Deprizine (ranitidine) 15mg/ml oral suspension 250 ml: 2 tsp every day: 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 symptoms & cardiovascular risk Page 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Compound drugs. American College of Gastroenterology <http://s3.gi.org/physicians/guidelines/NSAIDJournalPublicationFebruary2009.pdf> Deprizine <http://www.drugs.com/pro/deprizine.html>.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines address NSAIDs and gastrointestinal risk factors. Proton Pump Inhibitor (PPI), e.g. Omeprazole (Prilosec), is recommended for patients with gastrointestinal risk factors. MTUS does not address Deprizine (Ranitidine). American College of Gastroenterology Guidelines for Prevention of NSAID-Related Ulcer Complications (2009) reported that systematic reviews have shown that H2RA histamine-2-receptor antagonist medications are effective in reducing the risk of NSAID-induced endoscopic gastric ulcers. Official Disability Guidelines (ODG) indicates that compound drugs are not recommended as a first-line therapy. Criteria for compound drugs were presented. Include at least one drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including OTC drugs. Is not a copy of a commercially available FDA-approved drug product. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The primary treating physician's progress report dated 12/15/14 did not document gastrointestinal complaints or conditions. No abdominal physical examination was documented. Deprizine is a compounding oral suspension containing Ranitidine, which is available over-the-counter. The Official Disability Guidelines (ODG) criteria for compound drugs indicates that the compound drug should include at least one drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including OTC over-the-counter drugs. Ranitidine is over-the-counter. Per ODG, the compound drug should not be a copy of a commercially available FDA-approved drug product. Ranitidine is a commercially available FDA-approved drug. Therefore, Deprizine is a copy of the commercially available FDA-approved drug Ranitidine. The request for Deprizine, which is a compounding oral suspension containing Ranitidine, is not supported by ODG guidelines. Therefore, the request for Deprizine is not medically necessary.

**Dicopanол (diphenhydramine) 5mg/ml oral suspension 150ml: one ml per mouth at bedtime:** 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/diphenhydramine.html>.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Insomnia treatment. ODG Pain (Chronic) Compound drugs. Dicopanол (Diphenhydramine)  
<http://www.drugs.com/pro/dicopanол.html>.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) does not address Dicopanол (diphenhydramine) for insomnia treatment. Official Disability Guidelines (ODG) guidelines state that over-the-counter 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. Regarding insomnia treatment, after a few weeks, the recommendation is to discontinue the medication. Patients do better in the long term if medication is stopped after 6 weeks. Dicopanол is Diphenhydramine

(Benadryl) compounding oral suspension. Official Disability Guidelines (ODG) indicates that compound drugs are not recommended as a first-line therapy. Criteria for compound drugs were presented. Include at least one drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including OTC drugs. Is not a copy of a commercially available FDA-approved drug product. The primary treating physician's progress report dated 12/15/14 did not document sleep complaints. Ambien was prescribed 12/15/14. Medical records indicate that Dicopanol, which is a Diphenhydramine (Benadryl) suspension, was requested for the patient's sleep complaints. Medical records document the long-term use of Diphenhydramine for sleep complaints. ODG guidelines do not support the use of over-the-counter antihistamines such as Diphenhydramine. The use of Dicopanol (Diphenhydramine) is not supported by ODG guidelines. Therefore, the request for Dicopanol (Diphenhydramine) is not medically necessary.

**Fanatrex (gabapentine) 25mg/ml oral suspension 420ml: one tsp (5ml) three times a day:**  
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 Antiepilepsy drugs (AEDs) Pages 16-22. Gabapentin (Neurontin) Page 18-19. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Compound drugs. Fanatrex (Gabapentin) <http://www.drugs.com/pro/fanatrex.html>.

**Decision rationale:** Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines state that Gabapentin (Neurontin) is considered as a treatment for neuropathic pain. A good response to the use of antiepilepsy drugs (AEDs) has been defined as a 50% reduction in pain and a moderate response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients. After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. Official Disability Guidelines (ODG) indicates that compound drugs are not recommended as a first-line therapy. Criteria for compound drugs were presented. Include at least one drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including OTC drugs. Is not a copy of a commercially available FDA-approved drug product. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The primary treating physician's progress report dated 12/15/14 documented a history of cervical spondylosis, lumbar spondylosis, and bilateral acromioclavicular joint arthritis. Regarding subjective complaints, no musculoskeletal complaints were documented. No musculoskeletal physical examination was documented. Per MTUS, a clinically important response to the use of antiepilepsy drugs (AEDs) should be documented. Per MTUS, there should be documentation of pain relief and improvement in function. The continued use of AEDs depends on improved outcomes. The Official Disability Guidelines (ODG) criteria for compound drugs indicates that the compound drug should not be a copy of a commercially available FDA-approved drug product. Gabapentin is a commercially available FDA-approved drug. Fanatrex is Gabapentin

oral suspension. Fanatrex is a copy of the commercially available FDA-approved drug Gabapentin. The request for Fanatrex (Gabapentin) is not supported by ODG guidelines. Therefore, the request for Fanatrex (Gabapentin) is not medically necessary.