

<b>Case Number:</b>	CM14-0086246		
<b>Date Assigned:</b>	07/23/2014	<b>Date of Injury:</b>	08/09/2007
<b>Decision Date:</b>	09/22/2014	<b>UR Denial Date:</b>	05/19/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/09/2014

### 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 Physical Medicine and Rehabilitation; and is licensed to practice in California. 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 is a female patient with a date of injury of August 9, 2007. A utilization review determination dated May 19, 2014 recommends non-certification of Synapryn 10 mg/mL oral suspension 500 mL, Tabradol 1mg oral suspension 250 mL, Deprizine 15mg/mL oral suspension 250 mL, Dicopanol 5mg oral suspension 150mL, and Fanatrex 25mg/mL oral suspension 420 mL. A progress note dated April 17, 2014 identifies subjective complaints of neck pain with burning, and radicular pain, and muscle spasms. The patient describes her neck pain is being constant moderate to severe, she reports a pain level of 8 - 9/10, the pain is aggravated by looking up, looking down, and side to side as well as with repetitive motion of the head and neck. The patient also complains of bilateral shoulder pain radiating down the arms to her fingers with associated muscle spasms, the patient rates her pain at a 8 - 9/10, her pain is described as constant and moderate to severe, the pain is aggravated by gripping, grasping, reaching, pulling, lifting, and doing work at or above shoulder level. The patient complains of lower back pain that is burning, with radicular low back pain, and with muscle spasms. Patient rates are pain at an 8-9/10, her pain is described as constant and moderate to severe, the pain is aggravated by prolonged positioning including sitting, standing, walking, bending, rising from a seated position, a sending or descending stairs, and stooping. Her low back pain is also aggravated by activities such as getting dressed and performing personal hygiene. The patient also complains of burning pain of bilateral knees with muscle spasms, she rates her knee pain at a 8 - 9/10, she states her pain is constant and moderate to severe, her pain is aggravated with squatting, kneeling, a sending or descending stairs, prolonged positioning including weight bearing, standing, and walking. She also complains of numbness, tingling, and pain radiating to her feet. Patient states that the symptoms persist and that the medications offer temporary relief and improve her ability to sleep. The patient denies any problems with the medications. The patient

states that her pain is also alleviated by activity restrictions. Physical examination identifies tenderness palpation of the paraspinal, trapezius, splenius, and scalene muscles. There is tenderness over the lateral aspect of the occiput. Cervical spine range of motion is decreased, and there is positive cervical distraction, cervical compression, and Spurling's test bilaterally. There is AC joint arthrosis noted, there is tenderness of the trapezius, supraspinatus, rhomboid, and levator scapular muscles. Range of motion of bilateral shoulders is decreased; there is positive Neer's impingement sign, Kennedy Hawkins sign, and Jobe's test. Sensation to pin prick and light touch is slightly diminished over the C5, C6, C7, C8, and T-1 dermatomes in the bilateral upper extremities. Motor strength is slightly decreased secondary to pain and bilateral upper extremities. The lumbar spine reveals tenderness with spasms in the lumbar paraspinal muscles, quadratus lumborum with trigger point noted bilaterally, over at the lumbosacral junction, tenderness to palpation at bilateral PSIS, tenderness at the sciatic notch, and decreased lumbar range of motion. Bilateral knees have +2 effusion, crepitus with motion, tenderness to palpation over the medial lateral joint line, tenderness over the patellofemoral joint bilaterally, decreased of flexion of bilateral knees, positive patella grinding tests, positive Apley's compression test bilaterally, and positive patella ballotement test bilaterally. There is slight decrease in sensation to pin prick and light touch at the L4, L5, and S1 dermatomes bilaterally. The L2, L3, L4, L5, and S1 myotomes are decreased of bilateral lower extremities secondary to pain. Diagnoses include cervical spine pain, cervical radiculopathy, lumbar spine pain, lumbar radiculopathy, bilateral shoulder pain, and bilateral knee pain. The treatment plan recommends refills for the following Synapryn 10 mg/mL oral suspension 500 mL, Tabradol 1mg oral suspension 250 mL, Deprizine 15mg/mL oral suspension 250 mL, Dicopanol 5mg oral suspension 150mL, and Fanatrex 25mg/mL oral suspension 420 mL. The treatment plan also recommends continuing with physical therapy and chiropractic treatment three times per week for six weeks and Terocin patches for pain relief.

### **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:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 75-79 of 127; Page 50 of 127.

**Decision rationale:** Regarding the request for Synapryn (tramadol with glucosamine) 10mg/mL oral suspension 500 ml, California Pain Medical Treatment Guidelines state that Tramadol is a synthetic opiate pain medication. Due to high abuse potential, close follow-up is recommended with documentation of analgesic effect, objective functional improvement, side effects, and discussion regarding any aberrant use. Guidelines go on to recommend discontinuing opioids if there is no documentation of improved function and pain. Regarding glucosamine, the guidelines recommend glucosamine as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Within the documentation available for review, there is no indication that the Synapryn is improving the patient's function (in terms of specific objective

functional improvement) or pain (in terms of reduced NRS, or percent reduction in pain), and no discussion regarding aberrant use. Additionally, there is no documented medical reason for the use of an oral suspension. In the absence of such documentation, the currently requested Synapryn (tramadol with glucosamine) 10 mg/ml oral suspension 500 ml is not medically necessary.

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

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 63-66 of 127.

**Decision rationale:** Regarding the request for Tabradol (Cyclobenzaprine) 1 mg oral suspension 250 ml, Chronic Pain Medical Treatment Guidelines support the use of nonsedating muscle relaxants to be used with caution as a 2nd line option for the short-term treatment of acute exacerbations of pain. Guidelines go on to state that Cyclobenzaprine specifically is recommended for a short course of therapy. Within the documentation available for review, there is no identification of a specific analgesic benefit or objective functional improvement as a result of the Cyclobenzaprine. Additionally, it does not appear that this medication is being prescribed for the short-term treatment of an acute exacerbation, as recommended by guidelines. Additionally, there is no documented medical reason for the use of an oral suspension. In the absence of such documentation, the currently requested Tabradol (Cyclobenzaprine) 1 mg oral suspension 250 ml is not medically necessary.

**Deprizine 15mg/ml 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 Treatment Guidelines Page(s): 68-69 of 127. Decision based on Non-MTUS Citation (ODG), Pain Chapter, Proton Pump Inhibitors (PPIs).

**Decision rationale:** Regarding the request for Deprizine (ranitidine) 15 mg/ml oral suspension 250 ml, Deprizine contains active and inactive bulk materials to compound a ranitidine hydrochloride oral suspension. California MTUS states that proton pump inhibitors are appropriate for the treatment of dyspepsia secondary to NSAID therapy or for patients at risk for gastrointestinal events with NSAID use. Within the documentation available for review, there is no indication that the patient has complaints of dyspepsia secondary to NSAID use, a risk for gastrointestinal events with NSAID use, or another indication for this medication. In light of the above issues, the currently requested Deprizine (ranitidine) 15 mg/ml oral suspension 250 ml is not medically necessary.

**Dicopanor (diphenhydramine 5mg 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 (ODG) Chronic Pain, Sleep Medication, Insomnia treatment.

**Decision rationale:** Regarding the request for Dicopanol (diphenhydramine) 5mg oral suspension 150 ml, California MTUS guidelines are silent regarding the use of sedative over-the-counter medications. ODG states 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. They go on to state the failure of sleep disturbances to resolve in 7 to 10 days, may indicate a psychiatric or medical illness. Within the documentation available for review, there are no subjective complaints of insomnia, no discussion regarding how frequently the insomnia complaints occur or how long they have been occurring, no statement indicating what behavioral treatments have been attempted for the condition of insomnia, and no statement indicating how the patient has responded to treatment with Dicopanol. Finally, there is no indication that Dicopanol is being used for the short term use as recommended by guidelines. Additionally, there is no documented medical reason for the use of an oral suspension. In the absence of such documentation, the currently requested Dicopanol (diphenhydramine) 5mg oral suspension 150 ml, is not medically necessary.

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

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 16-21 of 127.

**Decision rationale:** Regarding request for Fanatrex (Gabapentin) 25mg/mL oral suspension 420 ml, Chronic Pain Medical Treatment Guidelines state that antiepilepsy drugs are recommended for neuropathic pain. They go on to state that a good outcome is defined as 50% reduction in pain and a moderate response is defined as 30% reduction in pain. Guidelines go on to state that 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. Within the documentation available for review, there is no identification of any specific analgesic benefit (in terms of percent reduction in pain or reduction of NRS), and no documentation of specific objective functional improvement. Additionally, there is no documented medical reason for the use of an oral suspension. In the absence of such documentation, the currently requested Fanatrex (Gabapentin) 25 mg/ml oral suspension 420 ml is not medically necessary.