

<b>Case Number:</b>	CM15-0200923		
<b>Date Assigned:</b>	10/16/2015	<b>Date of Injury:</b>	04/25/2015
<b>Decision Date:</b>	12/22/2015	<b>UR Denial Date:</b>	09/09/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/13/2015

### 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: Washington, California

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 44 year old female who sustained an industrial injury on 04-25-2015. A review of the medical records indicated that the injured worker is undergoing treatment for headaches, cervical spine sprain and strain, cervical radiculopathy, bilateral elbow sprain and strain, bilateral shoulder sprain and strain, thoracic sprain and strain, lumbar sprain and strain, lumbago and lumbar radiculopathy. Official reports for lumbar spine, thoracic spine, cervical spine and bilateral elbow magnetic resonance imaging (MRI) performed on 06-08-2015 and bilateral shoulders magnetic resonance imaging (MRI) performed on 07-27-2015 were included in the review and showed degenerative disc disease in cervical, thoracic and lumbar spine, elbow tendonosis consistent with lateral epicondylitis bilaterally and rotator cuff tendinosis of shoulders. Prior treatments have included diagnostic testing, acupuncture therapy, chiropractic therapy, physical therapy, extracorporeal shockwave therapy and medications. According to the treating physician's progress report on 08-05-2015, the injured worker continues to experience temporal throbbing headaches rated 5-6 out of 10 on the pain scale, neck pain with spasms associated with numbness and tingling of the bilateral upper extremities rated at 7 out of 10, bilateral shoulder pain with spasm rated at 6 out of 10, bilateral elbow pain and spasms associated with weakness, numbness and tingling radiating to the hands and fingers rated 5-6 out of 10, mid back pain with spasms rated 7 out of 10 and low back pain with muscle spasms associated with numbness and tingling of the bilateral lower extremities rated at 6 out of 10 on the pain scale. The injured worker stated that the medications offer temporary relief of pain and improve her ability to sleep. She denied any problems with the medications. There was an

anterior head carriage with right lateral head tilt noted on observation. Current medications were listed as Synapryn, Tabradol, Deprizine, Dicopanol, gabapentin, cyclobenzaprine topical gel, and ketoprofen cream. Examination of the cervical spine noted 2 plus tenderness to palpation at the suboccipital, scalene and sternocleidomastoid muscles. Trigger points were noted at the bilateral upper trapezius and rhomboid muscles. Active range of motion was decreased with positive Spurling's and cervical distraction test bilaterally. Bilateral shoulder examination demonstrated tenderness to palpation at the subacromial space, the supraspinatus and acromioclavicular joint. Range of motion was equally decreased bilaterally. The bilateral elbows were tender to palpation at the olecranon processes with mild decreased in range of motion on flexion, pronation and supination. Cozen's and Tinel's (elbow) were negative. Sensation to pinprick and light touch was diminished over the C6 and C7 dermatomes in the upper extremities with decreased motor strength due to pain. Deep tendon reflexes were 1 plus and symmetrical with positive pulses bilaterally. Examination of the thoracic spine noted tenderness to palpation over the spinous process at T3-T5 with guarding, positive Kemp's and decreased range of motion. Dermatomes of the thoracic spine were within normal limits. Evaluation of the lower back documented an abnormal gait, heel-toe walk with pain and squat 10% of normal due to low back pain. Examination of the lumbar spine demonstrated tenderness to palpation at the spinous processes L2-L5 with bilateral lumbar paraspinal muscle guarding and tightness at the quadratus lumborum muscles. Range of motion was decreased with flexion at 40 degrees, extension at 07 degrees, left lateral flexion at 10 degrees and right lateral flexion at 5 degrees. Braggard's test was positive bilaterally and straight leg raise was positive at 60 degrees bilaterally. There was decreased sensation to pinprick and light touch at the L5 and S1 dermatomes bilaterally with decreased motor strength due to pain. Deep tendon reflexes were 1 plus and symmetrical in the lower extremity with pulses intact. Treatment plan consists of continuing extracorporeal shockwave therapy for the bilateral shoulders, cervical, thoracic and lumbar spine, and bilateral elbows, continuing with physical therapy, acupuncture therapy, chiropractic therapy, transcutaneous electrical nerve stimulation (TENS) unit, hot-cold unit, lumbar spine brace, neurology consultation, return to work with modified restrictions and if employer unable to accommodate the injured worker is to be on temporary total disability (TTD) and the current request for oral suspension: Synapryn 10mg per 1ml oral suspension 500ml, Tabradol 1mg per ml oral suspension 250ml, Deprizine 15mg per ml oral suspension 250ml and Dicopanol (diphenhydramine) 5mg per ml oral suspension 1. On 09-09-2015 the Utilization Review determined the request for oral suspension: Synapryn 10mg per 1ml oral suspension 500ml, Tabradol 1mg per ml oral suspension 250ml, Deprizine 15mg per ml oral suspension 250ml and Dicopanol (diphenhydramine) 5mg per ml oral suspension (1) was not medically necessary.

### **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:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS General Approaches 2004, Section(s): Initial Approaches to Treatment, and Chronic Pain Medical Treatment 2009, Section(s):

Medications for chronic pain, Opioids (Classification), Opioids, California Controlled Substance Utilization Review and Evaluation System (CURES) [DWC], Opioids, criteria for use, Opioids for chronic pain, Opioids for neuropathic pain, Opioids for osteoarthritis, Opioids, cancer pain vs. nonmalignant pain, Opioids, dealing with misuse & addiction, Opioids, differentiation: dependence & addiction, Opioids, dosing, Opioids, indicators for addiction,.

**Decision rationale:** Synapryn is a combination product composed of tramadol and glucosamine. Tramadol is a narcotic pain reliever with mu-receptor opioid agonist activity and is used to treat moderate to severe pain. Tramadol ER is an extended release formulation of this medication. Appropriate dosing should not exceed 400 mg/day and it should be used with caution in any patient taking Selective Serotonin Reuptake Inhibitors (SSRI) as together they may cause a potentially fatal condition known as Serotonin Syndrome. There are no studies showing effective use of this medication for chronic pain that lasts greater than 3 months. However, the MTUS describes use of opioids as first-line therapy for chronic nociceptive pain and also recommends their use for control of chronic radicular neuropathic pain. The MTUS notes that when treating chronic radicular pain the chronic use of opioids is a viable alternative only when other therapeutic first-line medications, such as antidepressants and/or antiepileptic drugs, have been tried and failed. Success of this therapy is noted when there is significant improvement in pain or function. The risk with this therapy is the development of addiction, overdose or death. The pain guidelines in the MTUS directly address this issue and have criteria for the safe use of chronic opioids. Glucosamine is a medical nutritional supplement. It is marketed to support the structure and function of joints, however, there is little scientific evidence to support this use. It is important to note that in America it is illegal to market any dietary supplement as a treatment for any disease or condition. The MTUS only recommends its use in low risk patients with moderate arthritis. This patient has nociceptive and probably radicular pain. Use of a opioid analgesic is indicated. She also has moderate degenerative changes in many of her joints so use of glucosamine may also be helpful. Additionally, the provider is appropriately monitoring the patient for safe use of chronic opioid therapy and has noted the medication is effective in lessening the patient's pain. Medical necessity for the continued use of this medication has been established.

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

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS General Approaches 2004, Section(s): Initial Approaches to Treatment, and Chronic Pain Medical Treatment 2009, Section(s): Cyclobenzaprine (Flexeril), Muscle relaxants (for pain).

**Decision rationale:** Tobradol is a compounded medication containing cyclobenzaprine and methylsulfonylmethane (MSM). Cyclobenzaprine is classified as a sedating skeletal muscle relaxant. This class of medications can be helpful in reducing pain and muscle tension thus increasing patient mobility. Muscle relaxants as a group, however, are recommended for short-term use only as their efficacy appears to diminish over time. In fact, studies have shown cyclobenzaprine's greatest effect is in the first 4 days of treatment after which use may actually

hinder return to functional activities. They are considered no more effective at pain control than non-steroidal anti-inflammatory medication (NSAIDs) and there is no study that shows combination therapy of NSAIDs with muscle relaxants have a demonstrable benefit. MSM is a dietary supplement which some researchers have suggested has anti-inflammatory effects and there are some small scale trials that suggest benefit from MSM in patients with osteoarthritis. It is marketed to support the structure and function of joints, however, there is little scientific evidence to support this use. It is important to note that in America it is illegal to market any dietary supplement as a treatment for any disease or condition. This patient has been on Tobradol therapy for over one month. There is no documented provider instruction to use this medication on an intermittent or as needed basis. Instead the patient is using it continuously and yet continues to complain of muscle spasms. Since chronic use of muscle relaxant therapy is not recommended by the MTUS and since there is no documentation that the medication is actually controlling the muscle spasms, continued use of this medication is not indicated. Medical necessity for use of this medication has not been established.

**Deprizine 15mg/ml oral suspension 250 ml:** 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): NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** Deprizine (ranitidine) is a histamine H<sub>2</sub>-receptor antagonist indicated to treat of peptic ulcer disease, gastroesophageal reflux disease, and Zollinger-Ellison syndrome. There is also some evidence that it is effective in the treatment of hives. The MTUS only recommends its use for treatment of NSAID-induced dyspepsia. It does not recommend it used for prophylaxis to prevent NSAID-induced dyspepsia. This patient has no documentation of ongoing symptoms of dyspepsia nor diagnosed conditions of peptic ulcer disease, gastroesophageal reflux disease, or Zollinger-Ellison syndrome. There is no indication to continue its use. Medical necessity has not been established.

**Dicopanol (diphenhydramine) 5 ml/ml oral suspension 1:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness & Stress/Diphenhydramine (Benadryl).

**Decision rationale:** Dicopanol (diphenhydramine) is a first-generation antihistamine possessing anticholinergic, antitussive, antiemetic, and sedative properties. It is used primarily to treat allergies, but also used to manage drug-induced Parkinsonism and other extrapyramidal symptoms and as a FDA-approved nonprescription sleep aid. The MTUS does not comment on its use. The Official Disability Guidelines (ODG) does not recommend sedating antihistamines

for long-term insomnia treatment (over 10 days) as tolerance seems to develop within a few days of use and next-day sedation is common. This patient has been using this medication for over one month. There is no description of ongoing insomnia nor documentation of daytime sleepiness. A work-up for sleep disorders has not been done. At this point in the care of this patient use of this medication is not indicated. Medical necessity has not been established.