

<b>Case Number:</b>	CM14-0204310		
<b>Date Assigned:</b>	12/18/2014	<b>Date of Injury:</b>	09/25/2012
<b>Decision Date:</b>	02/10/2015	<b>UR Denial Date:</b>	12/04/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/06/2014

### 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 Occupational Medicine, has a subspecialty in ENTER SUBSPECIALTY 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:

Injured worker (IW) sustained an industrial injury on 09/25/12. Documented treatment to date has included medications, acupuncture, and physical therapy. 01/08/14 orthopedic AME report states that IW sustained a low back injury when he fell from the back of a truck and landed on his back. Current complaints of included low back pain which was worse with bending, lifting, and twisting. Pain radiated down the left leg to the level of the knee, with weakness, numbness, and tingling. IW also reported some urinary and stool incontinence starting in December 2012. Prior history of burns to the extremities with skin grafts and 1989 gunshot wound to the upper back were noted. On physical exam, focal sensory deficits were noted in the left lower extremity and left Achilles reflex was diminished. Future medical care recommendations included orthopedic consultations for exacerbations, with short courses of physical therapy, (unspecified) prescription medications, and possible epidural steroid injections (ESIs) depending on diagnostic study results. Examiner stated that records indicated that IW had injured the right knee as well, but there were no current complaints relating to the knee and the right knee was not fully examined. Per records review, IW was prescribed topical creams, Synapryn, Tabradol, Deprezine, Dicopanol, and Fenatex beginning on 05/13/13. 06/03/14 lower extremity electrodiagnostic studies were interpreted as consistent with radiculopathy at multiple levels, as well as bilateral axonal demyelinating peripheral neuropathy. 06/06/13 right knee x-rays revealed mild degenerative arthrosis and degenerative patellar enthesopathy. 06/02/14 right knee MRI revealed complex tear of the posterior body and posterior horn of the medial meniscus. Patellar, popliteus, and quadriceps tendons were intact with normal signal. 06/02/14 supplemental AME report documented 01/17/14 lumbar MRI which revealed disc herniations at multiple levels. 06/06/14 office note documented complaints of low back pain radiating to the

legs and sharp, stabbing pain in both knees. IW reported that medications offered temporary relief and improved ability to have restful sleep. Examination of the knees revealed medial and lateral joint line tenderness and positive McMurray and Lachman tests. IW was prescribed Dicoprofen 5mg/mL oral suspension 1 mL po at bedtime, Deprizine 5mg/mL oral suspension 10 mL once daily, Fanatrex 25mg/mL oral suspension 5 mL tid, Synapryn 10mg/mL oral suspension 5 mL tid, and Tabradol 1mg/mL oral suspension 5mL 2-3 times daily. 06/10/14 office note documented medial and lateral joint line tenderness of both knees with positive bilateral Lachman and McMurray tests. Urine drug screen (UDS) collected 06/06/14 tested positive for tramadol and its metabolite, as well as hydrocodone. Current medications were listed as Synapryn, Vicodin, Norco. 07/21/14 right knee MRI was interpreted as consistent with grade I medial collateral ligament (MCL) sprain, myxoid degeneration in posterior horn of medial meniscus, degenerative medial tibiofemoral joint arthritis, and small knee joint effusion. 07/21/14 lumbar MRI showed disc protrusions at multiple levels. 09/29/14 left knee MRI was interpreted as consistent with degenerative arthritic changes, small effusion, grade II chondromalacia patella and chronic medial meniscus tear. 10/03/14 UDS was positive for acetaminophen, amphetamine, methamphetamine, cotinine, and hydrocodone and its metabolite. 10/15/14 pain management consultation note documented only temporary relief with physical therapy modalities and acupuncture. IW reported 9/10 back pain and 6-8/10 bilateral knee pain, as well as anxiety, stress, depression, difficulty falling asleep and frequent awakening due to pain. IW reported difficulty with activities of daily living including grooming, bathing, dressing, household chores, and driving. Recent UDS results were not mentioned. Lumbar ESIs were recommended. 11/05/14 office note documented complaints of low back pain radiating into both legs and sharp bilateral knee pain. Pain was 6-7/10 in the back, 8/10 in the right knee, and 5/10 in the left knee. IW reported medications offered temporary relief of pain and improved ability to have restful sleep. Medications were refilled. 12/03/14 office note documented diagnoses including low back pain, lumbar spine HNP, lumbar facet arthropathy, hemangioma at L3, lumbar radiculopathy, right knee medial meniscus tear, osteoarthritis of the left knee, and right knee internal derangement per MRI. Medications were ordered and PRP injection of both knees were requested. A letter of medical necessity for medications stated that Dicoprofen was prescribed for insomnia, Deprizine was prescribed as a gastroprotective agent, Fanatrex was for neuropathic pain, Synapryn is for pain, and Cyclobenzaprine/Tabradol was for musculoskeletal conditions and osteoarthritis.

### **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 250ml qty:1.00: 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 Opioids; Opioids, criteria for use; Opioids for chronic pain; Glucosamine (and Chondroitin Sulfa). Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Labeling information for Synapryn accessed at <http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22416>.

**Decision rationale:** Synapryn contains tramadol with glucosamine sold in a compounding kit by Fusion Pharmaceuticals. When compounded according to directions the kit makes 500 ml of oral suspension containing 10 mg/ml tramadol hydrochloride with glucosamine (unspecified amount). Per office notes, IW has been prescribed Synapryn 5 mL tid (total daily dosage of 150 mg of tramadol and an unknown amount of glucosamine). MTUS notes no trials of long-term opioid use for neuropathic pain. Concerning chronic back pain, MTUS states that opioid therapy "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy." MTUS states monitoring of the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors) over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of controlled drugs. Due to lack of documented functional improvement with use of Synapryn and inconsistent recent drug screen results, medical necessity is not established for continued use of tramadol in this case. In addition, no rationale is documented for use of tramadol or glucosamine in compounded liquid form, as opposed to readily available forms of oral tramadol and OTC glucosamine supplements. Medical necessity is not established for the requested Synapryn.

**Tabradol 1mg/ml oral suspension 250ml qty:1.00:** 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 Cyclobenzaprine (Flexeril); MSM (methylsulfonylmethane); CRPS, medications; DMSO (dimethylsul. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Labeling information for Tabradol accessed at <http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22434>.

**Decision rationale:** Tabradol contains cyclobenzaprine hydrochloride and methyl sulfonyl methane (MSM), sold in a compounding kit by Fusion Pharmaceuticals. When compounded according to directions, this kit makes 250 mL of an oral suspension containing 1 mg/mL cyclobenzaprine hydrochloride with MSM (amount unknown). MTUS recommends cyclobenzaprine for short-term use only, and notes that effect is greatest in the first 4 days of treatment. MTUS recommends topical MSM or DMSO cream as an option for treatment of complex regional pain syndrome (CRPS), a condition not documented in this case. Due to lack of support for chronic use of cyclobenzaprine by MTUS and lack of a condition for which MTUS would support use of MSM, medical necessity is not established for use of cyclobenzaprine or MSM in this case. In addition, no rationale is documented as to why standard forms of oral cyclobenzaprine or OTC MSM supplements cannot be used in this case. Medical necessity is not established for the requested Tabradol.

**Deprizine 15mg/ml oral suspension 250ml qty:1.00:** 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 NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: --Rostom A, et al. Prevention of NSAID-induced gastroduodenal ulcers. Cochrane Database Syst Rev. 2002;(4):CD002296. --Tuskey A, Peura D. The use of H2 antagonists in treating and preventing NSAID-induced mucosal damage. Arthritis Res Ther. 2013;15 Suppl 3:S6. doi: 10.1186/ar4178. Epub 2013 Jul 24. --Labeling information for Deprizine accessed at <http://dailymed.nlm.nih.gov/dailymed/archives/fdaD>

**Decision rationale:** Deprizine contains ranitidine hydrochloride, sold in a compounding kit by Fusion Pharmaceuticals. When compounded according to directions, this kit makes 250 mL of an oral suspension containing 16.8 mg/mL of ranitidine hydrochloride (15mg/mL as ranitidine). Per manufacturer's disclaimer, "This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA." MTUS supports use of an H2 blocker for patients who experience dyspepsia with oral NSAIDs. No history of gastrointestinal complaints is documented in this case and no current use of oral NSAIDs is documented. MTUS recommends use of proton pump inhibitors (PPIs) and/or selection of a COX-2 selective NSAID for prevention of GI bleeding for at risk patients receiving oral NSAIDs. There is some evidence that high-dose H2 blockers (but not H2 blockers at standard doses) may reduce risk for duodenal and gastric ulcers for patients receiving oral NSAIDs. IW has been prescribed Deprizine 5mg/mL, 10 mL once daily (equivalent to 50 mg of oral ranitidine). This is well below the standard dosage of 75 to 150 mg of ranitidine recommended for OTC Zantac. Significant gastroprotective effect is not anticipated at this dosage of ranitidine, and no rationale has been documented as to why Deprizine is necessary in this case, as opposed to readily available and cost-effective OTC H2 blockers. Medical necessity is not established for the requested Deprizine.

#### **Dicopanol 5mg/ml 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) Pain Chapter, Insomnia treatment Other Medical Treatment Guideline or Medical Evidence: Labeling information for Dicopanol accessed at <http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=76c12e0d-735b-44d1-aa82-73e3f3a09d1b>.

**Decision rationale:** Dicopanol contains diphenhydramine hydrochloride, sold in a compounding kit by Fusion Pharmaceuticals. When compounded according to directions, this kit makes 150 mL of an oral suspension containing 5 mg/ml diphenhydramine hydrochloride. Per provider notes, IW is receiving Dicopanol for insomnia. Current dosage of Dicopanol is

5mg/mL suspension 1mL at bedtime (equivalent to 5 mL of diphenhydramine). 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. Side effects include urinary retention, blurred vision, orthostatic hypotension, dizziness, palpitations, increased liver enzymes, drowsiness, dizziness, grogginess and tiredness." ODG notes rapid development of tolerance to the hypnotic effects of diphenhydramine, as well as potential for side effects with this medication. Diphenhydramine liquid is readily available in cost-effective OTC products, and no rationale is documented as to why use of a compounded diphenhydramine suspension is necessary in this case. Due to lack of evidence of long-term efficacy and lack of rationale to support a compounded product, medical necessity is not established for the requested Dicopanol.

**Fanatrex (Gabapentin) 25mg/ml 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 Treatment Guidelines Antiepilepsy drugs (AEDs) Page(s): 16-19. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Prescribing information for Fanatrex accessed at <http://www.drugs.com/pro/fanatrex.html>.

**Decision rationale:** Fanatrex contains gabapentin, sold in a compounding kit by Fusion Pharmaceuticals. When compounded according to directions, this kit makes 420 mL of an oral suspension containing 25 mg/mL gabapentin. MTUS supports use of gabapentin for treatment of neuropathic pain. Starting dose of 300 mg once daily is recommended by MTUS, with increase to 300 mg 3 times daily on day 3, and titration as high as 1800 mg in divided doses. IW has been prescribed Fanatrex 25 mg/mL 5mL tid (equivalent to 375 ml of gabapentin daily). IW is currently receiving gabapentin at doses well below those recommended by MTUS, and no rationale is documented to support the necessity for use of a compounded preparation of gabapentin, as opposed to standard oral forms of gabapentin, which are available as tablets or an oral solution. Medical necessity is not established for the requested Fanatrex.

**Platelet rich plasma injection (right knee) qty:1.00: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Platelet-rich plasma (PRP)

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Knee & Leg Chapter, Platelet-rich plasma (PRP).

**Decision rationale:** ODG considers PRP injections for the knee to be under study. ODG notes some evidence for effectiveness of PRP injections for chronic refractory patellar tendinopathy, a condition not present in this case. ODG states: "A study of PRP injections in patients with early

arthritis compared the effectiveness of PRP with that of low-molecular-weight hyaluronic acid and high-molecular-weight hyaluronic acid injections, and concluded that PRP is promising for less severe, very early arthritis, in younger people under 50 years of age, but it is not promising for very severe osteoarthritis in older patients. (AAOS, 2010) Platelet-rich plasma injections can benefit patients with cartilage degeneration and early osteoarthritis (OA) of the knee, according to this RCT. In patients with minimal OA, platelet-rich plasma (PRP) works better than hyaluronic acid. The evidence shows that young patients in the PRP group continued to improve a little between follow-ups and that the patients receiving hyaluronic acid get a little worse. So far, however, no medical studies support using PRP for prevention in sports medicine. (Kon, 2012) After 2 decades of clinical use, results of PRP therapy are promising but still inconsistent. (Cohen, 2012) This pilot study suggests that platelet-rich plasma may play a role in improving clinical outcomes in patients with early onset osteoarthritis at both 6 months and 1 year, and PRP seemed to result in no change by MRI per knee compartment in at least 73% of cases at 1 year, in contrast to an expectation that OA would worsen. (Halpern, 2013) Per AME report, as of 01/08/14 IW was 58 years old. Based upon his age and the severity of knee osteoarthritis documented on imaging, he appears unlikely to benefit from PRP injections. Medical necessity is not established for the requested PRP injection for the right knee.