

Case Number:	CM15-0180788		
Date Assigned:	09/22/2015	Date of Injury:	10/09/2014
Decision Date:	11/12/2015	UR Denial Date:	09/01/2015
Priority:	Standard	Application Received:	09/14/2015

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: Physical Medicine & Rehabilitation, Pain Management

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 an 82 year old female, who sustained an industrial injury on 10-9-14. She reported left ankle pain. The injured worker was diagnosed as having left ankle sprain or strain and rule out left ankle internal derangement. Treatment to date has included operative fixation of the left ankle fracture, use of a CAM boot, physical therapy, acupuncture, chiropractic treatment, a work hardening program, shockwave therapy, and medication. On 5-26-15 physical examination findings included left ankle pain and spasms rated as 7 of 10. Palpable tenderness was noted over the left anterior talofibular ligament and range of motion was decreased. Sensation was intact and motor strength was rated as 4 of 5. Deep tendon reflexes were 2+ and symmetrical. The injured worker had been taking Dicopanol, Deprizine, Fanatrex, Synapryn, and Tabradol since at least May 2015. Currently, the injured worker complains of left ankle pain. The treating physician requested authorization for retrospective Dicopanol 5mg-ml 150ml, Deprizine 5mg-ml 250ml, Fanatrex 25mg-ml 420ml, Synapryn 10mg-ml 500ml, and Tabradol 1mg-ml 250ml all for the date of service 8-5-15. On 9-1-15 the requests were non-certified. Regarding Dicopanol, the utilization review (UR) physician noted "there are no clinical findings such as insomnia that would support the use of an antihistamine." Regarding Deprizine, the UR physician noted, "There is no report of gastrointestinal disorders such as peptic ulcer disease that would indicate a need for a H2 blocker." Regarding Fanatrex, the UR physician noted "there is no rationale provided for the medical necessity of an oral suspension." Regarding Synapryn, the UR physician noted, "There is no clear rationale identifying why a compound or oral suspension is needed for this patient." Regarding Tabradol, the UR physician noted "Tabradol contains

Methylsulfonylmethane which is not FDA approved."

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective Dicopanol 5mg/ml 150ml #1 DOS 8-5-15: 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 and Other Medical Treatment Guidelines X Other Medical Treatment Guideline or Medical Evidence: <http://www.drugs.com/pro/dicopanol.html>.

Decision rationale: Regarding the request for Dicopanol, Dicopanol contains active and inactive bulk materials to compound a diphenhydramine hydrochloride oral suspension. California MTUS guidelines are silent. 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. Furthermore, there is no indication that Dicopanol is being used for short-term use as recommended by guidelines. Finally, there is no clear rationale for the use of this oral suspension compounded kit rather than the FDA-approved oral tablet forms. In the absence of such documentation, the currently requested Dicopanol is not medically necessary.

Retrospective Deprizine 5mg/ml 250ml #1 DOS 8-5-15: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs), NSAIDs, GI symptoms & cardiovascular risk, NSAIDs, hypertension and renal function, NSAIDs, specific drug list & adverse effects. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Proton Pump Inhibitors (PPIs) and Other Medical Treatment Guidelines X Other Medical Treatment Guideline or Medical Evidence: <http://www.drugs.com/pro/deprizine.html>.

Decision rationale: Regarding the request for Deprizine, 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. Finally, there is no clear rationale for the use of this oral suspension compounded kit rather than the FDA-approved oral tablet forms. In light of the above issues, the currently requested Deprezine is not medically necessary.

Retrospective Fanatrex 25mg/ml quantity 420ml #1 DOS 8-5-15: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antiepilepsy drugs (AEDs). Decision based on Non-MTUS Citation X Other Medical Treatment Guideline or Medical Evidence: <http://www.drugs.com/pro/fanatrex.html>.

Decision rationale: Regarding the requested for Fanatrex, Fanatrex contains active and inactive bulk materials to prepare 420 mL of a gabapentin oral suspension containing 25 mg/mL gabapentin. Chronic Pain Medical Treatment Guidelines state that anti-epilepsy 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 discussion regarding side effects from this medication. Finally, there is no clear rationale for the use of this oral suspension compounded kit rather than the FDA-approved oral tablet forms. In the absence of such documentation, the currently requested Fanatrex is not medically necessary.

Retrospective Synaprin 10mg/ml quantity 500 ml #1 DOS 8-5-15: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): 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, Opioids, long-term assessment. Decision based on Non-MTUS Citation X Other Medical Treatment Guideline or Medical Evidence: <http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22416>.

Decision rationale: Regarding the request for Synapryn, this compound is noted to contain tramadol and glucosamine. With regard to opioids such as tramadol, California MTUS Chronic Pain Medical Treatment Guidelines state that, 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. With regard to glucosamine, it is recommended as an option in patients with moderate arthritis pain, especially for knee osteoarthritis. Within the documentation available for review, there is no indication that the medication is improving the patient's pain (in terms of percent reduction in pain or reduced NRS), no discussion regarding aberrant use, no documentation of knee osteoarthritis, and no clear rationale for the use of this oral suspension compounded kit rather than the FDA-approved oral tablet forms. In the absence of such documentation, the currently requested Synapryn is not medically necessary.

Retrospective Tabradol 1mg/ml 250 ml #1 DOS 8-5-15: 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): Muscle relaxants (for pain). Decision based on Non-MTUS Citation X Other Medical Treatment Guideline or Medical Evidence:
<http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=5d19ef8b-eef3-4d52-95f5-929765ca6dc7>.

Decision rationale: Regarding the request for Tabradol, Tabradol contains cyclobenzaprine hydrochloride 1 mg/mL, in oral suspension with MSM - compounding kit. Regarding cyclobenzaprine, Chronic Pain Medical Treatment Guidelines support the use of non-sedating 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. Finally, there is no clear rationale for the use of this oral suspension compounded kit rather than the FDA-approved oral tablet forms. In the absence of such documentation, the currently requested Tabradol is not medically necessary.