

Case Number:	CM15-0051349		
Date Assigned:	03/24/2015	Date of Injury:	08/13/2014
Decision Date:	05/13/2015	UR Denial Date:	02/24/2015
Priority:	Standard	Application Received:	03/18/2015

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

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 48-year-old male who reported an injury on 08/13/2014. The mechanism of injury was the injured worker was a passenger when a driver went over train tracks at a high speed. The diagnoses included lumbar spine sprain and strain, lumbar radiculopathy, and status post lumbar spine surgery. There was a Request for Authorization submitted for review, dated 01/21/2015. The documentation of 01/21/2015 was the initial comprehensive orthopedic consultation report. The injured worker had complaints of pain that was a 7/10. Prolonged positioning aggravated pain. The surgical history included 7 lumbar spine fusions. The injured worker was noted to currently be taking naproxen. The physical examination revealed tenderness to palpation at the lumbar paraspinal muscles and quadratus lumborum with a trigger point at the lumbosacral junction. There was sciatic notch tenderness noted. The injured worker had decreased range of motion of the lumbar spine. The injured worker had a positive tripod's test, flip test, and Lasegue's differential. The injured worker had slightly decreased sensation to pinprick and light touch at L4-S1. The motor strength was decreased at the bilateral lower extremities secondary to pain. The treatment plan included a continuation of medications and that the injured worker would undergo a urine toxicology evaluation. Additionally, the treatment plan included an EMG/NCV of the bilateral lower extremities, acupuncture, chiropractic care, physical therapy, and x-rays. The injured worker's medications were noted to include opiates and NSAIDs as well as muscle relaxants in 11/2013. Additionally, anti-epilepsy medications were provided.

IMR ISSUES, DECISIONS AND RATIONALES

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

Synapryn 10mg/1ml oral 500ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine Sulfate, Ongoing Management, Tramadol Page(s): 50, 78, 82, 93, 94. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Synapryn online drug insert.

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines recommend tramadol for pain; however, they do not recommend it as a first line oral analgesic and they recommend glucosamine sulfate for patients with moderate arthritis pain, especially knee osteoarthritis, and that only one medication should be given at a time. Synapryn, per the online package insert, includes tramadol and glucosamine sulfate. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. As tramadol is a form of an opiate, the California Medical Treatment Utilization Schedule Chronic Pain Guidelines recommend opiates for chronic pain. There should be documentation of an objective improvement in function, an objective decrease in pain, and evidence that the patient is being monitored for aberrant drug behavior and side effects. The clinical documentation submitted for review failed to indicate the injured worker had an inability to swallow or tolerate a pill. There was a lack of documentation indicating the injured worker had objective functional benefit and an objective decrease in pain with the use of opiates. The request as submitted failed to indicate the frequency and the specific dosing for the requested medication. Given the above, the request for Synapryn 10 mg/1 mL oral 500 mL is not medically necessary.

Tabradol 1mg 250ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine Page(s): 41.

Decision rationale: Tabradol is a compounding kit for oral suspension of cyclobenzaprine and methylsulfonylmethane. A search of ACOEM, California Medical Treatment Utilization Schedule Guidelines, and the Official Disability Guidelines, along with the National Guideline Clearinghouse (NCG) and the PubMed database, returned no discussion on Tabradol. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. There was a lack of evidence-based literature for the oral compounding of cyclobenzaprine and methylsulfonylmethane over the commercially available oral forms and the

lack of medical necessity requiring an oral suspension of these medications. The clinical documentation submitted for review failed to provide documentation of exceptional factors. There was a lack of documentation indicating the injured worker had an inability to swallow or tolerate a pill. Additionally, the injured worker was noted to utilize muscle relaxants since at least late 2014. There was a lack of documented efficacy. The request as submitted failed to indicate the frequency and the specific dosing for the requested medication. Given the above, the request for Tabradol 1 mg 250 mL is not medically necessary.

Deprizine 15mg mg/ml 250ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 69. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: <http://www.drugs.com/search.php?searchterm=Deprizine>.

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines recommend histamine 2 blockers for treatment of dyspepsia secondary to NSAID therapy. The medication Deprizine includes ranitidine, which is a histamine 2 blocker and can be used for the treatment of dyspepsia. However, per Drugs.com, Deprizine (generic name: ranitidine hydrochloride) has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. The clinical documentation submitted for review failed to indicate the injured worker had an inability to swallow or tolerate a pill. There was a lack of documentation indicating the injured worker had dyspepsia. Additionally, there was a lack of documentation indicating exceptional factors to support nonadherence to FDA guidelines. The request as submitted failed to indicate the frequency and the specific dosing for the requested medication. Given the above, the request for Deprizine 15 mg mg/mL 250 mL is not medically necessary.

Dicopanor 5mg/ml 150ml: Upheld

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

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 Treatments and Other Medical Treatment Guidelines Other Medical Treatment Guideline or Medical Evidence: <http://www.drugs.com/search.php?searchterm=Dicopanor>.

Decision rationale: The Official Disability Guidelines indicate that sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine) and that tolerance seems to develop within a few days. Per Drugs.com, dicopanor is diphenhydramine hydrochloride and it was noted that this drug has not been found by the FDA to be safe and effective, and the FDA

did not approve the labeling. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. The clinical documentation submitted for review failed to provide documentation of exceptional factors to support usage as the medication has not been found to be safe and effective per the FDA. There was a lack of documentation indicating the injured worker had an inability to swallow or tolerate a pill. The request as submitted failed to indicate the frequency and the specific dosing for the requested medication. Given the above, the request for dicopanol 5 mg/mL 150 mL is not medically necessary.

Fanatrex 35mg/ml 420ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 16. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: <http://www.drugs.com/search.php?searchterm=Fanatrex>.

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines indicate that gabapentin is used in the treatment of neuropathic pain. Per Drugs.com, Fanatrex is an oral suspension of gabapentin that has not approved by the FDA. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. The clinical documentation submitted for review indicated the injured worker had previously utilized gabapentin. There was a lack of documentation indicating the injured worker had an inability to swallow or tolerate a pill. The efficacy was not provided. As the FDA has not approved this medication, there was a lack of documentation of exceptional factors. The request as submitted failed to indicate the frequency and the specific dosing. Given the above, the request for Fanatrex 35 mg/mL 420 mL is not medically necessary.