

Case Number:	CM15-0120879		
Date Assigned:	07/01/2015	Date of Injury:	05/17/2007
Decision Date:	08/06/2015	UR Denial Date:	05/21/2015
Priority:	Standard	Application Received:	06/22/2015

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: New York
 Certification(s)/Specialty: Pediatrics, Internal 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 61 year old male, who sustained an industrial injury on March 26, 2003. He reported lifting a bucket with water and lettuce when he felt a sharp pain in his lower back. The injured worker was diagnosed as having low back pain, status post lumbar spine surgery, lumbar spine sprain/strain rule out herniated nucleus pulposus (HNP), rule out radiculitis of the lower extremity, and hypertension. Treatments and evaluations to date have included lumbar spine surgery, shockwave therapy, trigger point impedance imaging (TPII), x-rays, MRI, physical therapy, and medication. Currently, the injured worker complains of low back pain with numbness and tingling of the bilateral lower extremities. The Primary Treating Physician's report dated April 20, 2015, noted the injured worker status post lumbar spine surgery with residual pain, rated by the injured worker as 7/10 on a pain analog scale. The injured worker reported the medications did offer temporary relief from pain and improved his ability to have restful sleep. Physical examination was noted to show palpable tenderness with spasms in the lumbar paraspinal muscles and the lumbosacral junction. Straight leg raise was positive at 40 degrees bilaterally. The sensory examination was noted to show slightly decreased sensation to pinprick and light touch at the L4, L5, and S1 dermatomes. The treatment plan was noted to include the injured worker awaiting a pain management specialist, acupuncture, physical therapy, continued shockwave therapy, request for Terocin patches, and request for authorization for medications including Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol. The worker was noted to be temporarily totally disabled.

IMR ISSUES, DECISIONS AND RATIONALES

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

Synapryn 10 mg/1 ml, Qty 500 ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain - Compound drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine, Tramadol, Opioids Page(s): 50, 93, 94, 113. Decision based on Non-MTUS Citation <http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22416>.

Decision rationale: Synapryn is a compounded medication containing Tramadol Hydrochloride in oral suspension with glucosamine. Tramadol (Ultram) is a centrally acting synthetic opioid analgesic not recommended as a first-line oral analgesic. Glucosamine is recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. The injured documentation provided did not identify the injured worker with arthritis, for which glucosamine would be prescribed. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. The documentation provided failed to identify the injured worker's response to the use of the Synapryn with no documentation of an improvement in the injured worker's pain, function, or quality of life, as the injured worker continued to be off work, with reported 7-8/10 pain on a pain analog scale over the previous three months. Based on the MTUS guidelines, the documentation provided did not support the medical necessity of the requested Synapryn 10 mg/1 ml, Qty 500 ml.

Tabradol 1mg, Qty 250 ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain - Compound drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Muscle relaxants Page(s): 41, 42, 64, 111. Decision based on Non-MTUS Citation <http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22434>.

Decision rationale: Tabradol is a compounded medication containing Cyclobenzaprine Hydrochloride in oral suspension with methyl sulfonyl methane (MSM). Cyclobenzaprine is an antispasmodic recommended for a short course of therapy, with brief treatment recommended. The documentation provided noted the injured worker had been using Tabradol since at least September 2014. The documentation provided failed to identify the injured worker's response to the use of the Tabradol with no documentation of an improvement in the injured worker's pain, function, or quality of life, as the injured worker continued to be off work, with reported 7-8/10 pain on a pain analog scale over the previous three months. Based on the MTUS guidelines, the documentation provided did not support the medical necessity of the requested Tabradol 1mg, Qty 250 ml.

Deprizine 15mg/ml, Qty 250 ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain - Compound drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Functional restoration approach to chronic pain management Page(s): 9. Decision based on Non-MTUS Citation Deprizine-<http://www.drugs.com/pro/deprizine.html>Ranitidine-<http://www.drugs.com/ranitidine.html>.

Decision rationale: The MTUS Chronic Pain Medical Treatment Guidelines notes that "all therapies are focused on the goal of functional restoration rather than merely the elimination of pain and assessment of treatment efficacy is accomplished by reporting functional improvement." Deprizine is a compounded medication containing Ranitidine Hydrochloride in oral suspension. Ranitidine is an H2 antagonist used to treat and prevent heartburn, stomach ulcers, gastroesophageal reflux disease, and inhibits stomach acid production. The documentation provided noted the injured worker had been using Deprizine since at least September 2014, without documentation of gastrointestinal (GI) symptoms, or risk factors. Based on the MTUS guidelines, the documentation provided did not support the medical necessity of the requested Deprizine 15mg/ml, Qty 250 ml.

Dicopanol (diphenhydramine) 5 mg/ml, Qty 150 ml: 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) Insomnia treatment and Other Medical Treatment Guidelines <http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22548>.

Decision rationale: The MTUS is silent on Dicopanol. The Official Disability Guidelines (ODG) chapter on insomnia treatment notes the pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness. Dicopanol is a compounded medication containing diphenhydramine hydrochloride in oral suspension. The Physician documented that Dicopanol has been shown to be an effective and safe treatment of mild to moderate insomnia. The injured worker was noted to have been using Dicopanol since at least September 2014. No physician reports describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of that in this case. For the treatment of insomnia, pharmacologic agents should only be used after careful evaluation of potential causes of sleep disturbance. Specific components of insomnia should be addressed. There was no documentation of evaluation of sleep disturbance in the injured worker, and components of insomnia were not addressed. The treating physician has not addressed major issues affecting sleep in this patient, including the use of other psychoactive agents like opioids, which significantly impair sleep architecture, and depression. There was no documentation of the injured worker's inability to swallow tablets, or of the necessity for an oral suspension. Based on the MTUS guidelines, the documentation provided did not support the medical necessity of the requested Dicopanol (diphenhydramine) 5 mg/ml, Qty 150 ml.

Fanatrex (Gabapentin) 25 mg/ml Qty 420 ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines: Pain - Compound drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin, Antiepilepsy drugs Page(s): 17-19, 49.

Decision rationale: The MTUS Chronic Pain Medical Treatment Guidelines notes that after initiation of anti-epilepsy drug treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. Fanatrex is a compound medication containing Gabapentin in an oral solution. Gabapentin is an anti-epilepsy drug (AED), which has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. The documentation provided failed to include documentation of objective, measurable improvements in the injured worker's pain, function, or quality of life with the use of the Fanatrex. The documentation noted the injured worker had been using the Fanatrex since at least September 2014, without documentation of a decreased need for medication, change in activities of daily living (ADLs), or ability to return to work. There was no documentation of the injured worker's inability to swallow tablets, or of the necessity for an oral suspension. Based on the MTUS guidelines, the documentation provided did not support the medical necessity of the requested Fanatrex (Gabapentin) 25 mg/ml Qty 420 ml.