

Case Number:	CM14-0135581		
Date Assigned:	08/29/2014	Date of Injury:	06/24/2011
Decision Date:	11/26/2014	UR Denial Date:	07/25/2014
Priority:	Standard	Application Received:	08/22/2014

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 Family Medicine 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:

This is a 50-year-old female who reported an industrial injury on 6/24/2011, over four (4) years ago, attributed to the performance of her usual and customary job tasks. The patient was noted to complain of mid and lower back pain and muscle spasm rated 9/10 with numbness and tingling of the bilateral lower extremities; bilateral knee pain and muscle spasm rated as 8/10; and radicular neck pain and muscle spasm. Patient reported relief from the oral solutions prescribed by the treating physician. The objective findings on examination included tenderness in the paraspinal, occipital, trapezius, and scalene muscles; decreased cervical range of motion with diminished sensation; tenderness and spasm in the bilateral thoracolumbar paraspinal muscles, quadratus, lumbar muscles, and SI joints; decreased lumbar spine range of motion; crepitus with range of motion of the bilateral knees to my: tenderness over the medial and lateral joint lines bilaterally. The patient was prescribed compounded oral medications and medical foods.

IMR ISSUES, DECISIONS AND RATIONALES

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

SYNAPRYN (10NG/1ML) 500ML: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic pain Page(s): 60-61. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter--medical foods

Decision rationale: Evidence-based guidelines report that medical foods are not evaluated for safety or efficacy by the federal FDA. According to the FDA, medical foods have significant health risk that can lead to permanent injury or death. The California state legislature stated: "the legislature hereby declares the need to remove the financial incentive for prescribing costly and questionable compounded drugs, co-packs, and medical foods and create a new process for the prescription of compounded drugs, co-packs, and medical foods." The prescribed medical food Synapryn is not demonstrated to be medically necessary for the treatment of the cited diagnoses of this patient. The prescription for Synapryn Oral (TRAMADOL HCL/GLUCOSAMINE SULF/COMPOUNDING VEHICLE SUSP NO.10) for pain is being continued as an opioid analgesic almost 10 years after the DOI. The chronic use of Tramadol is not recommended by the CA MTUS; the ACOEM Guidelines, or the Official Disability Guidelines for the long-term treatment of back, neck, and knee pain. There is no demonstrated medical necessity for opioid analgesics in the compounded form with glucosamine for the treatment of the back, neck, and knees. There is no objective evidence provided by the treating physician for the prescription of this compounded medication over the prescription of conventional pharmaceuticals. The prescription of opiates on a continued long-term basis is inconsistent with the CA MTUS and the Official Disability Guidelines recommendations for the use of opiate medications for the treatment of chronic pain. There is objective evidence that supports the use of opioid analgesics in the treatment of this patient over the use of NSAIDs for the treatment of chronic pain. The CA MTUS recommends: Chronic back pain: 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. There is no evidence to recommend one opioid over another. In patients taking opioids for back pain, the prevalence of lifetime substance use disorders has ranged from 36% to 56% (a statistic limited by poor study design). Limited information indicated that up to one-fourth of patients who receive opioids exhibit aberrant medication-taking behavior. The ACOEM Guidelines updated chapter on chronic pain state, "Opiates for the treatment of mechanical and compressive etiologies: rarely beneficial. Chronic pain can have a mixed physiologic etiology of both neuropathic and nociceptive components. In most cases, analgesic treatment should begin with acetaminophen, aspirin, and NSAIDs (as suggested by the WHO step-wise algorithm). When these drugs do not satisfactorily reduce pain, opioids for moderate to moderately severe pain may be added to (not substituted for) the less efficacious drugs. A major concern about the use of opioids for chronic pain is that most randomized controlled trials have been limited to a short-term period (70 days). This leads to a concern about confounding issues; such as, tolerance, opioid-induced hyperalgesia, long-range adverse effects, such as, hypogonadism and/or opioid abuse, and the influence of placebo as a variable for treatment effect." The prescription of Glucosamine for the chronic pain issues is not demonstrated to be medically necessary or supported by objective evidence by the treating physician. Glucosamine is recommended for the treatment of osteoarthritis of the knee. The prescription is not consistent with the recommendations of the CA MTUS, the ACOEM Guidelines, and the Official Disability Guidelines. Glucosamine has been demonstrated to have a

small protective effect for the knee joint; however, does not provide any significant pain relief. There are no recommendations for the use of Synapryn oral solution for the cited diagnoses.

TABRADOL 1MG/ML 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 Medications for Chronic pain Page(s): 60-61. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter--medical foods

Decision rationale: Evidence-based guidelines report that medical foods are not evaluated for safety or efficacy by the federal FDA. According to the FDA, medical foods have significant health risk that can lead to permanent injury or death. The California state legislature stated: "the legislature hereby declares the need to remove the financial incentive for prescribing costly and questionable compounded drugs, co-packs, and medical foods and create a new process for the prescription of compounded drugs, co-packs, and medical foods." The prescribed medical food Tabradol is not demonstrated to be medically necessary for the treatment of the cited diagnoses of this patient. The prescription for Flexeril (cyclobenzaprine) in the form of Tabradol in combination with methylsulfonylmethane is not demonstrated to be medically necessary over the readily available alternatives. The chronic use of muscle relaxants is not recommended by the CA MTUS, the ACOEM Guidelines, or the Official Disability Guidelines for the treatment of chronic pain. The use of muscle relaxants are recommended to be prescribed only briefly in a short course of therapy. There is no medical necessity demonstrated for the use of muscle relaxants for more than the initial short-term treatment of muscle spasms. The patient is prescribed Cyclobenzaprine daily on a routine basis in the form of a medical food. There is no demonstrated medical necessity for the prescription of muscle relaxers on a routine basis for chronic back pain. The continued prescription of a muscle relaxant was not consistent with the evidence-based guidelines, but was helpful for the treatment of the perceived chronic pain. The prescription was not consistent with the recommendations of evidence-based guidelines. The use of methylsulfonylmethane is not medically necessary over the readily available anti-inflammatory agents and has no particular functional improvement if compounded with Cyclobenzaprine. There is no demonstrated medical necessity for the prescription of the oral solution Tabradol.

DEPRIZINE 15MG/ML 250MG: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic pain Page(s): 60-61. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter--medical foods

Decision rationale: Evidence-based guidelines report that medical foods are not evaluated for safety or efficacy by the federal FDA. According to the FDA, medical foods have significant health risk that can lead to permanent injury or death. The California state legislature stated: "the legislature hereby declares the need to remove the financial incentive for prescribing costly and questionable compounded drugs, co-packs, and medical foods and create a new process for the prescription of compounded drugs, co-packs, and medical foods." The prescribed medical food Deprizine is not demonstrated to be medically necessary for the treatment of the cited diagnoses of this patient. Deprizine (Ranitidine) 150 mg is prescribed for Gastroesophageal Reflux Disease (GERD) or stomach discomfort when NSAIDs are being prescribed; however, there is no objective evidence that the H2 inhibitor is as effective at protecting the mucosal layer of the stomach as the recommended proton pump inhibitors. Generally, the proton pump inhibitors are prescribed to protect the stomach lining from the chemical effects of NSAIDs. There are no prescribed NSAIDs in the current medical documentation. There are no documented GI issues or side effects to prescribed medications. There is no demonstrated medical necessity for Ranitidine. The protection of the stomach lining from NSAIDs is appropriately provided with the proton pump inhibitors such as Omeprazole. There is no objective evidence provided by the provider to support the medical necessity of the prescribed Deprizine: Ranitidine Capsule - Oral for the treatment of the patient as the H2 blocker is not as effective in protecting the GI mucosa from the effects of NSAIDs as the PPIs. There is no demonstrated medical necessity for the prescription of the oral solution of Deprizine.

DICOPANOL 5MG/ML 150ML: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation
[HTTP://WWW.DRUGS.COM/PRO/DICOPANOL.HTML](http://www.drugs.com/pro/dicopanol.html)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic pain Page(s): 60-61. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter--medical foods

Decision rationale: There is no medical necessity for the prescribed Dicopanlol by for the cited diagnoses. It is not clear why a patient is prescribed medical foods as opposed to conventional medications. There is no documentation of failure of conventional medications. The medical foods are prescribed are not demonstrated to be medically necessary. The compounded medications prescribed by are not demonstrated to be medically necessary for the treatment of the patient and are not supported with subjective/objective evidence or current evidence-based guidelines. There is no demonstrated medical evidence to support the medical necessity of a compounded Benadryl solution for the treatment of the effects of the industrial injury. There is no demonstrated medical necessity for the oral solution containing Benadryl to be prescribed for sleep in order to treat the effects of the industrial injury. The same diphenhydramine is available OTC in 25 mg tablets for allergies or sleep. There is no demonstrated medical necessity for the compound oral solution form of Benadryl. Evidence-based guidelines report that medical foods are not evaluated for safety or efficacy by the federal FDA. According to the FDA, medical foods have significant health risk that can lead to permanent injury or death. The California state legislature stated: "the legislature hereby declares the need to remove the financial incentive for

prescribing costly and questionable compounded drugs, co-packs, and medical foods and create a new process for the prescription of compounded drugs, co-packs, and medical foods." The prescribed medical food Dicopanol is not demonstrated to be medically necessary for the treatment of the cited diagnoses of this patient. There is no demonstrated medical necessity for the prescription of the oral solution of Dicopanol.

FANATREX 25MG/ML 420ML: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic pain Page(s): 60-61. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter--medical foods

Decision rationale: Evidence-based guidelines report that medical foods are not evaluated for safety or efficacy by the federal FDA. According to the FDA, medical foods have significant health risk that can lead to permanent injury or death. The California state legislature stated: "the legislature hereby declares the need to remove the financial incentive for prescribing costly and questionable compounded drugs, co-packs, and medical foods and create a new process for the prescription of compounded drugs, co-packs, and medical foods." The prescribed medical food Fanatrex is not demonstrated to be medically necessary for the treatment of the cited diagnoses of this patient. The CA MTUS and the Official Disability Guidelines and the CA MTUS state that there is insufficient evidence to support the use of Gabapentin for the treatment of non-neuropathic pain. The prescription for Gabapentin in the form of Fanatrex appears to be prescribed for the treatment of back with no evidence of a neuropathic pain. There is no evidence of a nerve impingement radiculopathy or neuropathic pain to justify the use of Gabapentin. There is no objective evidence to support the medical necessity of Gabapentin for the cited diagnoses for this patient. The prescription of Gabapentin/Fanatrex for chronic knee pain due to reported back pain s/p microdiscectomy was not supported with objective findings on physical examination, as there were no demonstrated neurological deficits. There is no objective evidence on examination for significant neurogenic pain issues. There were no demonstrated neurological deficits along a dermatomal distribution. The use of Gabapentin is not documented to be for neuropathic pain and is prescribed by for subjective pain and arthritic pain issues. There is no demonstrated medical necessity for the medical food Fanatrex. The prescription of Gabapentin/Fanatrex is recommended for neuropathic pain and is used to treat postherpetic neuralgia and painful polyneuropathy such as diabetic polyneuropathy. The patient is not demonstrated to have neuropathic pain. Anti-epilepsy drugs (AEDs) are recommended on a trial basis (gabapentin/pregabalin) as a first-line therapy for painful polyneuropathy such as diabetic polyneuropathy. The prescription of Gabapentin for neuropathic pain was not supported with objective findings on physical examination. There is no objective evidence that the recommended conservative treatment with the recommended medications have been provided prior to the prescription of Gabapentin for chronic pain. The use of Gabapentin should be for neuropathic pain. Presently, there is documented no objective evidence of neuropathic pain for which the use of Gabapentin is recommended. Mechanism of action: This medication appears to be effective in reducing abnormal hypersensitivity (allodynia and hyperalgesia), to have anti-

anxiety effects, and may be beneficial as a sleep aid. Specific pain states: "There is limited evidence to show that this medication is effective for postoperative pain, where there is fairly good evidence that the use of gabapentin and gabapentin-like compounds results in decreased opioid consumption. This beneficial effect, which may be related to an anti-anxiety effect, is accompanied by increased sedation and dizziness." (Peng, 2007) (Buvanendran, 2007) (Menigaux, 2005) (Pandey, 2005) Spinal cord injury: Recommended as a trial for chronic neuropathic pain that is associated with this condition. (Levendoglu, 2004) CRPS: Recommended as a trial. (Serpell, 2002) Fibromyalgia: Recommended as a trial. (Arnold, 2007) Lumbar spinal stenosis: Recommended as a trial, with statistically significant improvement found in walking distance, pain with movement, and sensory deficit found in a pilot study. (Yaksi, 2007) Side-Effect Profile: Gabapentin has a favorable side-effect profile, few clinically significant drug-drug interactions and is generally well tolerated; however, common side effects include dizziness, somnolence, confusion, ataxia, peripheral edema, and dry mouth. (Eisenberg, 2007) (Attal, 2006) Weight gain is also an adverse effect. It is believed that the pharmacology is related to its ability, documented in in-vitro experiments, to enhance the activity of gamma aminobutyric acid (GABA), the major inhibitory neurotransmitter in the central nervous system. These experiments have shown that tiagabine binds to recognition sites associated with the GABA uptake carrier. It is thought that, by this action, tiagabine blocks GABA uptake into presynaptic neurons, permitting more GABA to be available for receptor binding on the surfaces of post-synaptic cells. Evidence is available that it operates as a selective GABA reuptake inhibitor. There is no demonstrated medical necessity for the prescribed oral solution Fanatrex for the treatment of chronic neck, back, and knee pain.