

<b>Case Number:</b>	CM13-0059448		
<b>Date Assigned:</b>	12/30/2013	<b>Date of Injury:</b>	12/29/2006
<b>Decision Date:</b>	04/10/2014	<b>UR Denial Date:</b>	11/19/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/02/2013

### 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 Physical Medicine and Rehabilitation has a subspecialty in Pediatric Rehabilitation Medicine and is licensed to practice in Texas. 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:

The patient is a 41-year-old male who reported an injury on 12/29/2006. The patient was reportedly injured while driving down the highway when an SUV came into his lane and hit the driver's side of the truck. It knocked both tires of the truck, causing the driver of the SUV to fly over the curb. Paramedics arrived on the scene and took the driver of the SUV to emergency room. The patient remained to wait for the [REDACTED] and later asked a coworker to drive him to the emergency room, where he was evaluated and given pain medications and then referred to his private medical doctor. His doctor told him he had a post concussion syndrome and a sprain of his neck and took him off work. No physical therapy was ordered, and the patient later returned to work; however, his pain was increasing with the workload. He subsequently retained an attorney and was referred to [REDACTED], where he underwent x-rays and an MRI scan. The patient was also referred to a specialist regarding the meniscal and ligamentous tear of his right knee. The patient subsequently underwent right knee surgery and received postsurgical physical therapy treatments. The patient was most recently seen on 12/02/2013 with complaints of headaches, as well as burning, radicular neck pain, and muscle spasms.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**X-Rays times 6 views for the Cervical Spine:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation CA MTUS American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004), Occupational Medicine Practice Guidelines, chapter 8, pages 177-178

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation CA MTUS American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004) Special Studies and Diagnostic and Treatment Considerations - Neck and Upper back Complaints, pages 177-179

**Decision rationale:** According to California MTUS and ACOEM, it states that cervical radiographs are most appropriate for patients with acute trauma associated with midline vertebral tenderness, head injury, drug or alcohol intoxication, or neurologic compromise. In the case of this patient, the current physical examination did not note any significant deficits in the patient's cervical spine or related dermatomes. The patient had normal active range of motion in all planes, with negative cervical distraction and compression, with sensory response intact to light touch bilaterally in the C5, C6, C7, C8, and T1 dermatomes. The patient's motor strength was slightly decreased at 4/5 in all muscle groups in the bilateral upper extremities; however, his deep tendon reflexes were 2+ and symmetrical and vascular pulses were 2+ and symmetrical in the bilateral upper extremities. Without having any significant neural deficits in regards to the cervical spine, the medical necessity cannot be determined. Furthermore, the patient has already undergone previous radiographs and without any 'red flags', the patient does not meet guideline criteria for repeat radiographs at this time. As such, the requested service is non-certified.

**MRI of the Cervical Spine:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 177-178. Decision based on Non-MTUS Citation CA MTUS American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004), Occupational Medicine Practice Guidelines

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 182. Decision based on Non-MTUS Citation CA MTUS American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004) Summary of Recommendations and Evidence

**Decision rationale:** According to California MTUS and ACOEM, MRIs are recommended for acute neck and upper back conditions when red flags for fracture or neurologic deficit associated with acute trauma, tumor, or infection are suspected. In the case of this patient, the current clinical examination did not note any significant neural deficits or red flags that would necessitate an MRI of the cervical spine. The only abnormality was a slight decrease in motor strength of 4/5 in the muscle groups. Final Determination Letter for IMR Case Number [REDACTED] Without any 'red flags' indicating a significant change in the patients pathology to warrant repeat imaging, the patient does not meet guideline criteria for the requested service. As such, the requested service is not considered medically necessary and is non-certified.

### **Shockwave Therapy Unspecified duration for the Cervical Spine: 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), Treatment Index, 11th Edition(web), 2013, Shoulder Chapter, Extracorporeal Shockwave Therapy (ESWT)

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back Chapter, Shock wave therapy

**Decision rationale:** Under Official Disability Guidelines in the Low Back Chapter, it states that shockwave therapy is not recommended. There is little evidence to support the effectiveness of ultrasound or shockwave for treating "low back pain." In the absence of such evidence, the clinical use of these forms of treatment is not justified and should be discouraged. In the case of this patient, although he had ongoing complaints of neck pain, without support from the guidelines for the use of shockwave therapy, the requested service cannot be warranted at this time. As such, the requested service is non-certified.

### **TENS Unit: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 116.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TENS, chronic pain (transcutaneous electrical nerve stimulation) Page(s): 114-117.

**Decision rationale:** According to California MTUS Guidelines, the use of a TENS unit is not recommended as a primary treatment modality, but a 1 month home-based TENS trial may be considered as a non-invasive conservative option if used as an adjunct to a program of evidence based functional restoration. The request and documentation does not indicate the patient will be utilizing this on a 1 month home-based trial. Without having a complete treatment plan involving a TENS unit to use as an adjunct to an objective based functional restoration program, as well as documentation indicating the patient will not be using this beyond one month, the requested service does not meet guideline criteria at this time. As such, the requested service is non-certified.

### **Compounded Ketoprofen 20% in PLO gel 120gm: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** According to California MTUS Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Furthermore, there is little to no research to support the use of many of these agents, and compounded products that contain at least 1 drug or drug class are not supported under the guidelines. Referring to Ketoprofen itself, this agent is not currently FDA approved for a topical application. This is because it has extremely high incidence of photo contact dermatitis. Due to the non-recommendation for the use of this medication, the requested service cannot be warranted at this time. As such, the requested service is non-certified.

**Compounded Cyclophene 5% in PLO Gel, 120 gm:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** Under California MTUS Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. There is little to no research to support the use of many of these agents, and any compounded product that contains at least 1 drug or drug class that is not recommended is not supported under the guidelines. Furthermore, regarding the use of muscle relaxants as a topical product, California MTUS does not recommend the use of compounded topical analgesics; therefore, due to the non-recommendation per California MTUS for the use of this product, the requested service cannot be warranted at this time and is non-certified.

**Synopryn 10mg/1ml oral suspension 50ml:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol, Glucosamine Page(s): 50. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Treatment Index, 11th Edition (web), 2013, Pain Chapter, Medical foods and Compound drugs

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Glucosamine (and Chondroitin Sulfate) Tramadol Page(s): 74-96,50,113.

**Decision rationale:** Synopryn contains tramadol and glucosamine as well as other ingredients, and these are medical foods which are comprised of a number of amino acids, neurotransmitter metabolites, and herbals. Under California MTUS Guidelines, it states that tramadol is a centrally active synthetic opioid analgesic and is not recommended as a first line oral analgesic. It also states that glucosamine is recommended as an option given its low risk in patients with moderate arthritic pain, especially for knee osteoarthritis. In the case of this patient, without having a thorough rationale for the medical necessity for the use of this medication, the requested service is not deemed medically necessary and is non-certified.

**Tabradol 1 mg/ml Oral Suspension 250 ml: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 63-64. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Treatment Index, 11th Edition(web), 2013, Pain Chapter, Medical foods and Compound drugs

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril®), CRPS, medications Page(s): 41-42 37-38.

**Decision rationale:** Tabradol contains cyclobenzaprine, methyl sulfonyl methane (MSM), and other ingredients which are medical foods. Also, according to California MTUS Guidelines, the guidelines recommend non-sedating muscle relaxants with caution as a second line option for short term treatment of acute exacerbations in patients with chronic low back pain.

Cyclobenzaprine itself is recommended for a short course of therapy, limited, as there was mixed evidence which does not allow for recommendation for long term use. The patient was noted to have muscles spasms in his neck which could benefit from a short course of muscle relaxants. However, the request does not provide the dosage to be taken on a daily basis. And as long-term use is not recommended, an appropriate plan of treatment should accompany the request. As such, the request is not certified.

**Deprisine 15mg/ml Oral Suspension 250ml: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Treatment Index, 11th Edition (web), 2013, Pain Chapter, Medical foods and Compound drugs

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.drugs.com/search.php?searchterm=Deprizine>

**Decision rationale:** According to the online web site, drugs.com, Deprizine is also known as ranitidine. Ranitidine is in a group of drugs called histamine-2 blockers. Ranitidine works by reducing the amount of acid your stomach produces. Ranitidine is used to treat and prevent ulcers in the stomach and intestines. It also treats conditions in which the stomach produces too much acid, such as Zollinger-Ellison syndrome. Ranitidine also treats gastroesophageal reflux disease (GERD) and other conditions in which acid backs up from the stomach into the esophagus, causing heartburn. Without having a thorough rationale for the indication of this medicine for treating the patient, the medical necessity cannot be established. The documentation does not indicate the patient has any type of GI issues diagnosed as an individual condition or related to medication use. Therefore, the request is not considered medically necessary and is non-certified.

**Dicopanol (Diphenhydramine) 5mg/ml Oral Suspension 150ml: 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), Treatment Index, 11th Edition (web), 2013, Pain Chapter, Medical foods and Compound drugs

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation  
<http://www.drugs.com/search.php?searchterm=Deprizine>

**Decision rationale:** According to the online web site, drugs.com, Dicopanol, which is also known as diphenhydramine, is an antihistamine that reduces the effects of natural chemical histamine in the body. Diphenhydramine is used to treat sneezing, runny nose, watery eyes, hives, skin rash, itching, and other cold or allergy symptoms, and is also used to treat motion sickness, to induce sleep, and to treat certain symptoms of Parkinson's disease. In the case of this patient, a thorough rationale for the intended use of this medication has not been provided. Without having a rationale for the use of this medication in treating this patient, the medical necessity cannot be established. As such, the request is non-certified.

**Fanatrex (Gabapentin) 25mg/ml Oral Suspension 20ml: 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), Treatment Index, 11th Edition (web), 2013, Pain Chapter, Medical foods and Compound drugs

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs) Page(s): 18.

**Decision rationale:** According to California MTUS Guidelines, Gabapentin 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. In the case of this patient, without having a thorough rationale for the use of this medication, and as the patient has only been noted to have some discomfort in the cervical spine region without any significant neurological deficits noted, the requested service is not considered medically necessary and is non-certified.