

<b>Case Number:</b>	CM14-0101586		
<b>Date Assigned:</b>	08/08/2014	<b>Date of Injury:</b>	01/26/2012
<b>Decision Date:</b>	09/19/2014	<b>UR Denial Date:</b>	06/19/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/01/2014

### 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 Orthopedic Spine Surgery 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 injured worker is a 48-year-old male who reported injury on 01/26/2012. The mechanism of injury and diagnostic studies were not provided. The injured worker underwent a lumbar fusion in 07/2013. The injured worker's medication history included FluriFlex and TG Ice which includes tramadol, gabapentin, menthol and camphor, as of at least 12/2013. Prior therapies included physical therapy and aquatic therapy. The documentation of 05/23/2014 revealed the injured worker had complaints of neck and low back pain. The injured worker indicated his pain ranged between 6/10 and 7/10 upon waking in the morning. The injured worker was noted to be utilizing transdermal creams which were helping. The physical examination revealed the injured worker had mild torticollis bilaterally. The head compression sign was markedly positive. The Spurling's maneuver was positive bilaterally. The injured worker had exquisite tenderness at rest and on range of motion. The injured worker had pain on scapular retraction. There was swelling and inflammation in the levator scapula bilaterally. The injured worker had decreased range of motion. The bicep and triceps reflexes were diminished. There was no gross physical evidence of instability. The bicep strength and wrist extensor strength were diminished. The injured worker had weak wrist flexors and finger flexors. The thumb opposition was noted to be slightly weak. There was weakness in the upper extremities. The sensation in the dorsum of the hand was diminished, as were the lower aspect of the forearm and the palm. There was decreased sensation at C5-6 levels. The documentation indicated the injured worker underwent x-rays of the cervical spine which revealed a loss of actual lordosis of the cervical spine. The injured worker's cervical spine was noted to be kyphotic in nature. At the level of C5-6 and C6-7 there was noted to be severe spondylosis and prominent osteophytes. At C7-T1 there was very mild spondylolisthesis. The diagnoses included C5-6 disc herniation with bilateral radiculopathy and cervicalgia. The treatment plan included an anterior cervical discectomy and fusion at C5-6, C6-

7 and C7-T1. The documentation indicated the injured worker had been experiencing significant neck pain that was debilitating. Additionally, the treatment plan included durable medical equipment and postoperative medications, as well as physical therapy. Additionally, there was a request for FluriFlex 240 g cream and Gabatramadol 240 g cream for topical pain relief. The injured worker was to apply a thin layer to the affected area twice daily as directed by the physician. There were multiple, detailed Request for Authorization forms submitted for the requested procedures, durable medical equipment, physical medicine treatment, and medications.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**C5-C6, C6-C7 and C7-T1 anterior cervical discectomy and fusion with allograft and instrumentation:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 179-181. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Neck & Upper Back Chapter, Fusion, Anterior cervical.

**Decision rationale:** The American College of Occupational and Environmental Medicine indicate that a surgical consultation may be appropriate for injured workers who have persistent severe and disabling shoulder and arm symptoms, activity limitations for more than one month or with an extreme progression of symptoms. There should be documentation of clear clinical, imaging and electrophysiological evidence consistently indicating the same lesion that has been shown to benefit from surgical repair in both the short and long term. There should be documentation of unresolved radicular symptoms after receiving conservative treatment. The clinical documentation submitted for review indicated the injured worker had undergone conservative treatment. There were objective findings upon clinical examination. There was no notation of an EMG/NCV or MRI findings and official EMG/NCV and MRI reports. The discectomy would not be supported. The American College of Occupational and Environmental Medicine does not address cervical fusions. As such, secondary guidelines were sought. The Official Disability Guidelines indicates that cervical fusions are recommended as an option in combination with an anterior cervical discectomy for approved indications. The discectomy was not approved and as such, the fusion would not be supported. Given the above, the request for a C5-C6, C6-C7 and C7-T1 anterior cervical discectomy and fusion with allograft and instrumentation is not medically necessary.

**Cervical collar- Philadelphia:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not cite any medical evidence for its decision.

**Decision rationale:** Since the primary procedure is not medically necessary, none of the associated services are medically necessary.

**Bone stimulator:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not cite any medical evidence for its decision.

**Decision rationale:** Since the primary procedure is not medically necessary, none of the associated services are medically necessary.

**Two day stay:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not cite any medical evidence for its decision.

**Decision rationale:** Since the primary procedure is not medically necessary, none of the associated services are medically necessary.

**Post- op evaluation by RN:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not cite any medical evidence for its decision.

**Decision rationale:** Since the primary procedure is not medically necessary, none of the associated services are medically necessary.

**Duracef (post-op medication):** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not cite any medical evidence for its decision.

**Decision rationale:** Since the primary procedure is not medically necessary, none of the associated services are medically necessary.

**Zofran (post -op medication):** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not cite any medical evidence for its decision.

**Decision rationale:** Since the primary procedure is not medically necessary, none of the associated services are medically necessary.

**Norco (post -op medication):** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not cite any medical evidence for its decision.

**Decision rationale:** Since the primary procedure is not medically necessary, none of the associated services are medically necessary.

**Home Help:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not cite any medical evidence for its decision.

**Decision rationale:** Since the primary procedure is not medically necessary, none of the associated services are medically necessary.

**Post-op Sprix spray 15.75, 40 units ( five bottles):** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not cite any medical evidence for its decision.

**Decision rationale:** Since the primary procedure is not medically necessary, none of the associated services are medically necessary.

**Post-op follow up for three to four days:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not cite any medical evidence for its decision.

**Decision rationale:** Since the primary procedure is not medically necessary, none of the associated services are medically necessary.

**Post-op Physical therapy two times a week for four weeks to the cervical spine:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not cite any medical evidence for its decision.

**Decision rationale:** Since the primary procedure is not medically necessary, none of the associated services are medically necessary.

**FluriFlex cream 240gm cream apply a thin layer to the affected area twice daily:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 72, 111, 41.

**Decision rationale:** The California MTUS guidelines indicate that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety, and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. This agent is not currently FDA approved for a topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine - National Institute of Health (NLM-NIH) database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration. The guidelines do not recommend the topical use of cyclobenzaprine as a topical muscle relaxant as there is no evidence for use of any other muscle relaxant as a topical product. The addition of cyclobenzaprine to other agents is not recommended. The clinical documentation submitted for review indicated the injured worker has been utilizing the medication since at least 12/2013. There was a lack of objective functional benefit and an objective decrease in pain. Given the above, the request for FluriFlex cream 240gm cream is not medically necessary.

**Gaba/Tramadol cream 240gm cream:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 82,113, 111.

**Decision rationale:** The California MTUS guidelines indicate that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety, and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. A thorough search of FDA.gov, did not indicate there was a formulation of topical Tramadol that had been FDA approved. The approved form of Tramadol is for oral consumption, which is not recommended as a first line therapy. Gabapentin is not recommended. There is no peer-reviewed literature to support its use. The clinical documentation submitted for review indicated the injured worker had utilized the medication since at least 12/2013. There was a lack of documented efficacy including objective functional benefit and an objective decrease in pain. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Gabatramadol cream 240 g is not medically necessary.