

<b>Case Number:</b>	CM14-0060055		
<b>Date Assigned:</b>	09/12/2014	<b>Date of Injury:</b>	04/01/2009
<b>Decision Date:</b>	10/16/2014	<b>UR Denial Date:</b>	04/01/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/30/2014

### 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 52-year-old female who reported injury on 04/01/2009. The mechanism of injury was a motor vehicle accident. The injured worker underwent a microscopic decompression and discectomy and other surgeries were noncontributory. Prior therapies included physical therapy, a functional restoration program, activity modification, an epidural steroid injection, trigger point injections and medications. The injured worker's medications included Celexa, Mirapex, Seroquel, Zanaflex, and Tramadol. The injured worker underwent x-rays on 12/12/2013 which was unremarkable for a new deformity, instability, or traumatic changes. The injured worker underwent an electromyogram and nerve conduction studies on 05/28/2014 which revealed there was no evidence of active denervation, potential at the right lower and left lower extremities and bilateral paralumbar spinal muscles. There was no electrical evidence of compromise of the peroneal or tibial nerves at the bilateral lower extremities. There was no response at the left side tibial nerve H reflex latency compared to normal response on the right side tibial nerve H reflex latency. The physician opined this might be present with lumbosacral radiculopathy involving the left side S1 root distribution that was probably at a chronic stage. The injured worker underwent a CT myelogram on 05/29/2014 which revealed the injured worker was status postlaminectomy at L5-S1. The injured worker had facet joint degenerative changes, most notably at L4-5 and L5-S1. The remaining levels otherwise appeared patent with focal protrusion, extrusion, or significant stenosis. At the level of L5-S1, there was a left lateral recess containing soft tissue density material consistent with granulation or scar formation. This was noted to deform the left ventrolateral thecal sac. The right lateral recess and central canal were otherwise widely patent. The left neuroforamen contained mild to moderate stenosis due to a left foraminal broad based disc protrusion. The right neuroforamen was widely patent. There was mild to moderate facet joint degenerative changes. The

documentation of 03/18/2014 revealed the injured worker had exhausted all nonsurgical options and had been offered a lesser surgery than what was requested. The documentation indicated the original request was for a fusion at L5-S1. The physical examination revealed the injured worker was intact globally with sensation. Muscle strength was 4/5 in the left lower and right lower extremity. The injured worker had 4/5 reduced muscle strength in the left lower extremity. The injured worker had a markedly antalgic gait. The injured worker had a positive Faber test on the left hip. The physician documented the injured worker was still symptomatic with local tenderness to palpation over the L5-S1. The injured worker had a positive straight leg raise leg raise along the S1 dermatomal pattern. The physician further documented the MRIs and x-rays revealed continued degenerative changes of the L5-S1. The physician further documented another physician had recommended an L5-S1 anterior lumbar interbody fusion in the past, and was requesting it again. Additionally, it was documented the transdermal compounded pain cream medications were to provide targeted pain relief and treatment with reduced side effects associated with oral medications, allowing the injured worker to function while driving or during the day. The diagnoses included lumbar stenosis, lumbar degenerative disc disease, lumbar herniated disc, and status postoperative. The treatment plan included an anterior lumbar interbody fusion at L5-S1, postoperative x-rays of the lumbar spine, start on Tramadol 15%/Dextromethorphan 10%/ Capsaicin 0.5035%) apply every 12 hours on the affected skin areas of pain 1 tube no refills, start Flurbiprofen 20%/Lidocaine 5%/Menthol 5%/Camphor 1% one layer of ointment apply every 8 hours as needed for pain and inflammation. There was a detailed Request for Authorization submitted for review.

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

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

#### **Anterior Lumbar Interbody Fusion at L5-S1: Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 307. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Low Back ChapterAMA Guides to the Evaluation of Permanent Impairment, Fifth Edition Criteria for Instability (page 379)

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 305-307.

**Decision rationale:** The American College of Occupational and Environmental Medicine indicate a surgical consultation may be appropriate for injured workers who have severe and disabling lower leg symptoms in a distribution consistent with abnormalities on imaging studies preferably with accompanying objective signs of neural compromise. There should be documentation of activity limitations due to radiating leg pain for more than 1 month or the extreme progression of lower leg symptoms, and clear clinical, imaging and electrophysiologic evidence of a lesion that has been shown to benefit in both the short and long term from surgical repair and documentation of a failure of conservative treatment to resolve disabling radicular symptoms. Additionally, there is no good evidence from controlled trials that spinal fusion alone is effective for treating any type of acute low back problem, in the absence of spinal fracture, dislocation, or spondylolisthesis if there is instability and motion in the segment operated on. Electrophysiologic evidence would not be necessary to support a fusion. There was

documentation the injured worker had exhausted all conservative care. The clinical documentation submitted for review failed to include the MRI to support imaging findings. The x-rays failed to indicate the injured worker had instability on flexion and extension studies. The physical examination failed to support instability of the lumbar spine. Given the above, the request for an Anterior Lumbar Interbody Fusion at L5-S1 is not medically necessary.

**Inpatient Stays for 1-2 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.

**Assistant Surgeon: 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.

**Co-Surgeon: 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.

**1 LSO Brace Purchase: 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.

**1 Vascutherm 4 DVT System with Hot/old Compression Rental QTY: 2 Weeks: 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.

**Pre-Op One Time Visit with an Internist or General Practitioner / Surgical Clearance:**

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.

**Flubiprofen 20% / Lidocaine 5% / Menthol 5% / Camphor 1%, Unknown Quantity:**

Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Lidocaine Page(s): 111, 112-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Salicylates Topical Analgesics Flurbiprofen Lidocaine, Page(s): 105 111 72 112.

**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. 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 Salicylates are 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. The guidelines indicate that topical Lidocaine (Lidoderm) may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI antidepressants or an AED such as Gabapentin or Lyrica). No other commercially approved topical formulations of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. The clinical documentation submitted for review failed to indicate the injured worker had a trial of an antidepressant and anticonvulsant that had failed. There was a lack of documentation of exceptional factors to warrant nonadherence to guideline recommendations. The request as

submitted failed to indicate the frequency, quantity, and body part to be treated with the medication. Given the above, the request for Flubiprofen 20% / Lidocaine 5% / Menthol 5% / Camphor 1%, Unknown Quantity is not medically necessary.

**Tramadol 15% / Dextromethorphan 10% / Capsaicin 0.5035%, Unknown Quantity:**  
Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Ketoprofen, Capsaicin Page(s): 111, 112-113.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Tramadol Capsaicin Page(s): 111 82 28. Decision based on Non-MTUS Citation FDA.gov, <http://www.drugs.com/dextromethorphan.html>

**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...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... Capsaicin: Recommended only as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. 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. Per Drugs.com, "Dextromethorphan is a cough suppressant. It affects the signals in the brain that trigger cough reflex". The clinical documentation submitted for review failed to indicate the injured worker had a trial and failure of anticonvulsants and antidepressants. Additionally, the physician documented the topical cream included capsaicin 0.025%. There was a lack of documented clarity. The request as submitted included capsaicin 0.5035%. Additionally, the request as submitted failed to indicate the frequency, quantity, strength, and body part to be treated. Given the above, the request for Tramadol 15% / Dextromethorphan 10% / Capsaicin 0.5035%, Unknown Quantity is not medically necessary.