

<b>Case Number:</b>	CM15-0195329		
<b>Date Assigned:</b>	10/09/2015	<b>Date of Injury:</b>	02/02/2008
<b>Decision Date:</b>	11/18/2015	<b>UR Denial Date:</b>	09/15/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/05/2015

### 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: Illinois, California, Texas  
 Certification(s)/Specialty: Orthopedic Surgery

### 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 injured worker is a 53-year-old female who sustained an industrial injury on 2/2/08. Injury was reported relative to cumulative trauma as a housekeeper. Past medical history was positive for depression. The 4/22/09 bilateral lower extremity EMG/NCV study impression documented a normal study with no electrophysiologic evidence of lumbar radiculopathy or any peripheral nerve entrapment. The 3/17/15 through 7/21/15 treating physician reports documented on-going lumbosacral pain radiating to the left leg with antalgic gait, decreased and painful range of motion, and lumbosacral paravertebral muscle tenderness to palpation. Conservative treatment included Ibuprofen, Prilosec, Flexeril and Norco, and home exercise program. Physical therapy was recommended but there was no documentation that this was initiated. The 8/20/15 neurosurgical report cited grade 3-6/10 neck pain radiating to both shoulders, and grade 6-7/10 low back pain radiating into the left buttock and lower extremity. She was wearing a back brace. Physical exam documented slow antalgic left leg limp, paraspinal muscle tenderness, restricted and painful range of motion, decreased left L5 and S1 sensation. A lumbar spine MRI was reported on 7/25/15 and reviewed. The diagnosis included L4-S1 disc herniation with severe mechanical axial back pain, bilateral lower extremity S1 radiculopathies, and cervicalgia. The treatment plan recommended continued home exercise and pain management for medications. Authorization was requested for L4-S1 decompression with Coflex and L5/S1 posterior spinal fusion and decompression. The injured worker was to return to clinic once surgery authorized. Authorization was requested for L4/5 decompression with Coflex and L5/S1 posterior spinal fusion and decompression. The 9/15/15 utilization review non-certified a request for L4/5

decompression with Coflex and L5/S1 posterior fusion as there were no significant focal findings on physical exam, no imaging evidence of significant nerve root compression, and no evidence of instability.

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

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

#### **L4-L5 decompression with coflex, RTC L5-S1 PSPD: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Low Back Complaints 2004.

**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 - Lumbar & Thoracic, Discectomy/Laminectomy, Fusion (spinal) and Other Medical Treatment Guidelines FDA Pre-Market Approval. Coflex Interlaminar Technology - P110008. 10/17/12.<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p110008>.

**Decision rationale:** The California MTUS recommend surgical consideration when there is severe and disabling lower leg symptoms in a distribution consistent with abnormalities on imaging studies (radiculopathy), preferably with accompanying objective signs of neural compromise. Guidelines require clear clinical, imaging and electrophysiologic evidence of a lesion that has been shown to benefit both in the short term and long term from surgical repair. The guidelines recommend that clinicians consider referral for psychological screening to improve surgical outcomes. The Official Disability Guidelines (ODG) recommend criteria for lumbar decompression that include symptoms/findings that confirm the presence of radiculopathy and correlate with clinical exam and imaging findings. Guideline criteria include evidence of nerve root compression, imaging findings of nerve root compression, lateral disc rupture, or lateral recess stenosis, and completion of comprehensive conservative treatment. The ODG do not recommend lumbar fusion for patients with degenerative disc disease, disc herniation, spinal stenosis without degenerative spondylolisthesis or instability, or non-specific low back pain. Fusion may be supported for segmental instability (objectively demonstrable) including excessive motion, as in isthmic or degenerative spondylolisthesis, surgically induced segmental instability and mechanical intervertebral collapse of the motion segment and advanced degenerative changes after surgical discectomy. Pre-operative clinical surgical indications require completion of all physical therapy and manual therapy interventions, x-rays demonstrating spinal instability and/or imaging demonstrating nerve root impingement correlated with symptoms and exam findings, spine fusion to be performed at 1 or 2 levels, psychosocial screening with confounding issues addressed, and smoking cessation for at least 6 weeks prior to surgery and during the period of fusion healing. The ODG do not recommend the use of interspinous decompression devices over decompression surgery. Based on FDA approved indications, interspinous decompression devices are indicated for patients aged 50 or older who are suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis, who would otherwise be candidates for laminectomy. The MTUS and ODG guidelines do not provide recommendations relative to interlaminar facet off-loading devices. FDA indications for interlaminar facet off-loading devices, such as the Coflex device,

include use in 1- or 2-level lumbar stenosis from L1-L5 in skeletally mature patients with at least moderate impairment in function, who experience relief in flexion from their symptoms of leg/buttocks/groin pain, with or without back pain, and who have undergone at least 6 months of non-operative treatment. Interlaminar stabilization is performed after decompression of stenosis at the affected level(s). The FDA contraindications include prior fusion or decompressive laminectomy at any index lumbar level, or facet hypertrophy that requires extensive bone removal which would cause instability. Guideline criteria have not been met. This injured worker presents with persistent low back pain radiating into the left buttock and lower extremity. Clinical exam findings documented decreased left L5 and S1 dermatomal sensation. There is no current MRI report in the available records or a detailed discussion of imaging findings including nerve root compromise. Detailed evidence of up to 6 months of a recent, reasonable and/or comprehensive non-operative treatment protocol trial and failure has not been submitted. There is no radiographic evidence of spondylolisthesis or spinal segmental instability on flexion and extension x-rays. There is no discussion or imaging evidence supporting the need for wide decompression that would result in temporary intraoperative instability and necessitate fusion. Potential psychological issues are documented with no evidence of a psychosocial screen. Therefore, this request is not medically necessary.