

<b>Case Number:</b>	CM15-0114187		
<b>Date Assigned:</b>	07/31/2015	<b>Date of Injury:</b>	09/05/2012
<b>Decision Date:</b>	09/01/2015	<b>UR Denial Date:</b>	05/22/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/12/2015

### 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 31-year-old male who sustained an industrial injury on 9/5/12. Injury occurred when he was carrying a sofa with two co-workers. The other workers dropped their end of the sofa and he held on to avoid breaking a window. He was diagnosed with an L4/5 disc bulge, L5/S1 spinal stenosis, and left leg radiculopathy. Conservative treatment had included medications, physical therapy, activity modification, and injections. The 11/5/14 lumbar spine CT myelogram impression documented levoscoliosis and multilevel disc pathology. At L2/3, there was a 2-3 mm posterior disc bulge encroaching on the thecal sac. At L3/4, there was a 3-4 mm posterior disc protrusion with encroachment on the thecal sac and foramina. There was probable compromise on the traversing nerve roots but no compromise on the exiting nerve roots. At L4/5, there was a 2 mm anterior disc bulge and a 5-6 mm posterior disc protrusion with encroachment on the thecal sac and foramina, and compromise on the traversing and possibly exiting nerve roots bilaterally. There was Putty's tropism of the facet joints which were asymmetrically aligned. At L4/5, there was a 5 mm posterior disc protrusion encroaching on the epidural fat and foramina bilaterally with possible compromise of the exiting nerve roots bilaterally and arthritic changes of the facet joints. Significant psychological issues were noted in the reviewed medical records, with transcranial magnetic stimulation therapy documented on 4/17/15. The 4/18/15 treating physician report cited continued low back pain and radiating left leg pain. Physical exam documented lumbar paraspinal muscle spasms and tenderness. Neurologic exam documented decreased sensation over the left L5 dermatome, 4+/5 left extensor hallucis longus weakness, and 2+ and symmetrical deep tendon reflexes. Straight leg raise was

positive on the left. Imaging showed a disc bulge at L4/5 causing central canal stenosis and bilateral foraminal stenosis. There was encroachment on the thecal sac and foramen with compromise of the traversing and exiting nerve roots. At L5/S1, there was a 5 mm disc protrusion with no stenosis or nerve root compromise. The treating physician indicated that the injured worker had signs/symptoms correlated with clinical exam and imaging findings. He had a significant amount of low back and leg pain, and had failed conservative care. Authorization was requested for L4/5 laminectomy and Coflex procedure, and related surgical services including inpatient stay (length not specified). The 6/23/15 utilization review non-certified the laminectomy and Coflex procedure at L4/5 and associated inpatient stay as the Coflex procedure was not supported by guidelines.

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

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

#### **Laminectomy and Coflex procedure at L4-L5: 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), Low Back Chapter.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 305-307. Decision based on Non-MTUS Citation 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) recommends criteria for lumbar laminectomy 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 California MTUS and ODG do not provide recommendations relative to the Coflex device. The Coflex device is a U-shaped titanium implant used for spinal stabilization. The FDA granted pre-market approval for this device in October 2012 (P110008) as a minimally invasive, motion preserving interlaminar stabilization device for the treatment of moderate to severe spinal stenosis with or without back pain. The Coflex is indicated for 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 low back pain radiating to the left leg. Clinical exam findings are consistent with imaging evidence of nerve root compromise at L4/5. Detailed evidence of a recent, reasonable and/or comprehensive non-operative treatment protocol trial and failure has been submitted. The use of the Coflex device is not addressed by the MTUS or ODG. FDA indications for interlaminar stabilization with the Coflex device include symptom relief in flexion which is not documented. Contraindications include facet hypertrophy that requires extensive bone removal which would cause instability. There is imaging evidence of facet joint structural abnormality that has not been discussed by the treating physician relative to the decompression procedure. Additionally, this injured worker presents with significant psychological issues and a psychosocial screen for surgery is not evidenced. Therefore, this request is not medically necessary at this time.

**Related surgical service: Inpatient stay (length not specified): 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.