MAXIMUS Federal Services

Case Number:	CM14-0170269		
Date Assigned:	10/20/2014	Date of Injury:	12/26/2010
Decision Date:	11/26/2014	UR Denial Date:	10/03/2014
Priority:	Standard	Application Received:	10/15/2014

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 Surgeon and is licensed to practice in California. 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 69-year-old female who reported an injury on 12/26/2010. The mechanism of injury involved a fall. The current diagnoses include lumbosacral radiculopathy, cervical sprain/strain, left shoulder tendonitis/bursitis, left knee tendonitis/bursitis, status post left knee surgery on 01/10/2014, and status post left total knee arthroplasty. The injured worker was evaluated on 08/06/2014. Previous conservative treatment is noted to include epidural steroid injections, physical therapy and medications. The injured worker presented with complaints of constant lower back pain with numbness and tingling in the bilateral lower extremities. Physical examination of the lumbar spine revealed an antalgic gait, spasm in the paravertebral muscles, difficulty performing toe and heel walking, difficulty squatting, 60 degree finger to ankle forward flexion, 25 degree extension, 25 degree right and left rotation, 25 degrees lateral flexion, diminished motor strength in the bilateral lower extremities, decreased sensation in the L3-5 dermatome bilaterally, and equal deep tendon reflexes. X-rays of the lumbar spine revealed multilevel degenerative disc disease, dextroscoliosis curvature, and compression of multiple vertebral bodies. Treatment recommendations at that time included a lumbar microdecompression bilaterally at L3-4 and L4-5 with Coflex stabilization. A Request for Authorization form was then submitted on 08/20/2014. It was noted that the injured worker underwent an MRI of the lumbar spine on 04/12/2013, which indicated severe degenerative disc disease with marked decrease in disc height at L3-4, anterior spur formation, discogenic endplate reactive bone marrow edema, 4.4 mm retrolisthesis, thickening of the ligamentum flavum, bilateral facet arthropathy, severe central spinal canal and bilateral inferior neural foraminal stenosis. There was disc desiccation with moderate decrease in disc height, anterior spurs, 2-3 mm retrolisthesis, 3-4 mm diffuse disc bulge, thickening of the ligamentum flavum, moderate

bilateral facet arthropathy, moderate bilateral inferior neural foraminal narrowing, and severe spinal stenosis at L4-5 as well.

IMR ISSUES, DECISIONS AND RATIONALES

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

Bilateral L3-L4 and L4-L5 coreflex stabilization: Overturned

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: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back Chapter, Dynamic neutralization system (Dynesys®) www.fda.gov. US Food and Drug Administration. Last Updated: 01/17/2014. Coflex Interlaminar Technology - P110008 Product Name: coflex® Interlaminar Technology Approval Date: October 17, 2012

Decision rationale: The Official Disability Guidelines state dynamic neutralization systems such as the Coflex system are not recommended for nonspecific low back pain. They may be an option for spondylolisthesis in elderly patients instead of a fusion. According to the U.S. Food and Drug Administration, the Coflex interlaminar technology device was approved on 10/17/2012, and is intended to be implanted in the center between 1 or 2 adjacent segments in the lumbar region of the back to prevent instability following surgical decompression of spinal stenosis at the affected levels. According to an article in the U.S. National Library of Medicine, the Coflex interlaminar stabilization is a safe and efficacious alternative with certain advantages compared with lumbar spinal fusion in the treatment of spinal stenosis and low grade spondylolisthesis. The injured worker's MRI of the lumbar spine reveals severe degenerative disc disease at L3-4 and L4-5 with moderate loss of disc height and 4 mm to 5 mm retrolisthesis. There is evidence of severe central spinal canal stenosis at L3-4 and L4-5. The injured worker has been issued partial certification for a bilateral L3-4 and L4-5 lumbar microdecompression. Based on the clinical information received and the above mentioned peer reviewed literature, the current request can be determined as medically necessary at this time. As such, the request is medically necessary.