

Case Number:	CM14-0149954		
Date Assigned:	10/23/2014	Date of Injury:	07/13/2013
Decision Date:	11/21/2014	UR Denial Date:	08/15/2014
Priority:	Standard	Application Received:	09/15/2014

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 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 47 years old male with a date of injury on 7/13/2013. Injury occurred when the injured worker fell asleep while driving and crashed into two parked cars. Past surgical history was positive for C4-C7 anterior cervical discectomy and fusion on 3/31/08, C4-C7 segmental fixation and posterior fusion on 12/8/09, and posterolateral fusion without instrumentation for L5/S1 isthmic spondylolisthesis in 1997. The 9/9/13 lumbar spine magnetic resonance imaging (MRI) impression documented postsurgical changes at L5/S1 with solid bilateral posterolateral bone fusion masses. There was grade 1 anterolisthesis of L5 on S1. There was bilateral dorsolateral annular fissures that were potential pain generators and sources of bilateral L5 nerve root irritation. There was L2/3 through L4/5 degenerative disc disease with no more than mild spinal and foraminal stenosis. The left L2/3 foraminal annular fissure was a potential pain generator and source of left L2 nerve root irritation. Findings documented grade 1 retrolisthesis of L3 on L4 and concentric disc bulge measuring 2 to 3 mm in anteroposterior dimension causing mild spinal stenosis and mild bilateral foraminal stenosis. There was a grade 1 retrolisthesis of L4 on L5 and concentric disc bulging measuring 2 to 3 mm posteriorly. The spinal canal was widely patent with mild bilateral foraminal stenosis and right facet degenerative disease. The 1/20/14 lumbar x-ray impression documented post-surgical L5/S1 solid bilateral posterolateral bone fusion masses, grade 1 anterolisthesis of L5 on S1 with severe L5/S1 intervertebral disc narrowing, moderate L4/5 intervertebral disc narrowing with grade 1 retrolisthesis of L4 on L5. There was mild retrolisthesis of L3 on L4 with no pathological motion in flexion and extension, with limited excursion. The 7/25/14 treating physician report cited increased low back and bilateral leg pain worse on the right. A physical exam documented 4/5 left posterior tibial strength and restricted lumbar range of motion with pain. The injured worker was able to walk on his heels and toes without difficulty. Given the persistent complaints for

more than one year, surgical intervention was requested for L3/4 artificial disc replacement and simultaneous L4/5 interbody fusion and fixation. The 8/15/14 utilization review denied the lumbar spine surgery and associated requests as there was no guideline support for artificial disc replacement and there was no evidence of spinal instability to support fusion at L4/5. The 8/18/14 appeal letter indicated that the injured worker had been symptomatic for more than one year with persistent and refractory lower back and radicular leg complaints. He underwent one bilateral L4 epidural steroid injection on 12/4/13 with 2 to 3 months of relief of his leg symptoms. Lumbar spine x-rays and magnetic resonance imaging (MRI) studies demonstrated structural pathology which corroborates with his clinical complaints and findings. There was worsening retrolisthesis and more severe foraminal narrowing at L4/5 on the extension lateral view compared to the neutral lateral or flexion lateral view. The treating physician stated that there was no justification for denial of artificial disc replacement as investigational and experimental when there has been Food and Drug Administration (FDA) approval since 2001 with minimum 5-year follow-up results published in March 2012. Reconsideration of the request for L3/4 artificial disc replacement and L4/5 anterior fusion with instrumentation was requested.

IMR ISSUES, DECISIONS AND RATIONALES

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

L3-4 artificial disc replacement: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines: Low Back Chapter; regarding Disc prosthesis

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 219-220.

Decision rationale: The American College of Occupational and Environmental Medicine (ACOEM) Revised Low Back Disorder guidelines state that artificial disc replacement (ADR) is not recommended as a treatment for chronic non-specific lower back pain or any other spinal pain syndrome. The Official Disability Guidelines, updated 10/28/14, do not recommend artificial disc replacement (ADR). Current US treatment coverage recommendations were listed. Indications for lumbar artificial disc replacement (ADR) include primary back and/or leg pain in the absence of nerve root compression with single level disease. Injured worker exclusions also include spondylolisthesis, stenosis, facet mediated pain, and osteoporosis. Food and Drug Administration (FDA) approved indications are listed as failure of 6 months non-operative treatment, skeletally mature injured worker, single disc only, no infection, no sensitivity to implant materials, and no osteoporosis or spondylosis. Guideline criteria have not been met. Imaging evidence noted grade 1 retrolisthesis at L3/4 with mild spinal and foraminal stenosis and multilevel disc disease. Given the absence of guideline support for use and current injured worker exclusion criteria, this injured worker does not meet current indications for use of artificial disc replacement. Therefore, this request is not medically necessary.

L4-L5 anterior fusion with instrumentation: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines: Low Back Chapter: regarding Fusion (spinal) / Patient Selection Criteria for Lumbar Spinal Fusion

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 209-211.

Decision rationale: The American College of Occupational and Environmental Medicine (ACOEM) revised low back guidelines state that lumbar fusion is recommended as an effective treatment for degenerative spondylolisthesis. Lumbar fusion is not recommended as a treatment for spinal stenosis unless concomitant instability or deformity has been proven. The Official Disability Guidelines (ODG) state that spinal fusion is not recommended for injured workers who have less than six months of failed recommended conservative care unless there is objectively demonstrated severe structural instability and/or acute or progressive neurologic dysfunction. Fusion is recommended for objectively demonstrable segmental instability, such as excessive motion with degenerative spondylolisthesis. Spinal instability criteria includes lumbar inter-segmental movement of more than 4.5 mm. Pre-operative clinical surgical indications require completion of all physical therapy and manual therapy interventions, x-rays demonstrating spinal instability, spine pathology limited to 2 levels, and psychosocial screening with confounding issues addressed. Guideline criteria have not been met. There is no radiographic or imaging evidence of spinal instability consistent with guideline indications for fusion. There is no current clinical evidence of acute or progressive neurologic dysfunction. There is no evidence of psychosocial screening. Evidence of 6 months of a recent, reasonable and/or comprehensive non-operative treatment protocol trial and failure has not been submitted. Therefore, this request is not medically necessary.

2-3 day inpatient stay,: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG hospital length of stay (LOS) guidelines; Lumbar Fusion/Artificial disc

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, Hospital length of stay (LOS)

Decision rationale: As the surgical request is not supported, this request is not medically necessary.

Vascular surgeon assistant: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Centers for Medicare and Medicaid services, Physician Fee Schedule

Decision rationale: As the surgical request is not supported, this request is not medically necessary.

Preop H&P, including labs: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Practice advisory for preanesthesia evaluation: an updated report by the American Society of Anesthesiologists Task Force on Preanesthesia Evaluation. Anesthesiology 2012 Mar; 116(3): page(s) 522-538

Decision rationale: As the surgical request is not supported, this request is not medically necessary.