

Case Number:	CM15-0213251		
Date Assigned:	11/03/2015	Date of Injury:	08/16/2001
Decision Date:	12/15/2015	UR Denial Date:	10/24/2015
Priority:	Standard	Application Received:	10/29/2015

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 52-year-old female sustained an industrial injury on 8/16/01, relative to repetitive work duties. She was status post C5/6 anterior cervical discectomy and fusion, and L4-S1 posterior lumbar interbody fusion on 9/26/14. The 1/12/15 lumbar spine x-rays with flexion/extension views did not reveal any hardware failure. There was excellent position and alignment was maintained. There was posterior lumbar interbody fusion from L4-S1. The 6/22/15 agreed medical examiner report documented that the injured worker had completed 10/14 visits of post-operative physical therapy and that hardware removal was planned one year after surgery as the screws were causing her significant pain. The injured worker had been diagnosed with hypertension and was on daily medications. The 9/21/15 treating physician report cited constant grade 8/10 left non-radicular low back pain. Pain was aggravated by prolonged lying flat, sitting, or damp/humid weather. Pain was reported increasing and substantially affecting her quality of life. Pain was reported hardware related. A hardware block resulted in almost 100% reduction in symptoms. Physical exam documented exquisite tenderness to palpation adjacent to the surgical scar over hardware. There was pain with terminal motion, no evidence of instability, and intact lower extremity strength and sensation. X-rays were obtained and showed rod and screw fixation from L4-S1 with solid bone grafting of the interspace and some osteolysis around the screws. Authorization was requested for L4 through S1 removal of lumbar spinal hardware with inspection of fusion mass, nerve root exploration, and possible re-grafting of pedicle screw holes with associated surgical services, including medical clearance with an internist. The 10/23/15 utilization review recommended the request for L4 through S1

removal of lumbar spinal hardware with inspection of fusion mass, nerve root exploration, and possible re-grafting of pedicle screw holes be modified to L4 through S1 removal of lumbar spinal hardware. The medical necessity of a revision lumbar fusion (based on the submitted CPT codes) was not supported as there was no evidence of instability, pseudoarthrosis, or hardware breakage/malposition. The request for medical clearance with an internist was non-certified as there was no evidence of co-morbidities or complications that pose a significant surgical risk to the patient.

IMR ISSUES, DECISIONS AND RATIONALES

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

L4 through S1 removal of lumbar spinal hardware with inspection of fusion mass, nerve root exploration, and possible re-grafting of pedicle screw holes: 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 - Lumbar & Thoracic (acute & chronic): Hardware implant removal (fixation) (2015).

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: Fusion (spinal); Hardware injection (block); Hardware implant removal (fixation).

Decision rationale: The California MTUS does not provide recommendations relative to lumbar hardware removal or revision lumbar fusion. The Official Disability Guidelines (ODG) do not recommend the routine removal of hardware implanted for fixation, except in the case of broken hardware or persistent pain, after ruling out other causes of pain such as infection and nonunion. Guidelines recommend the use of a hardware injection (block) for diagnostic evaluation in patients who have undergone a fusion with hardware to determine if continued pain was caused by the hardware. If the steroid/anesthetic medication can eliminate the pain by reducing the swelling and inflammation near the hardware, the surgeon may decide to remove the patient's hardware. The ODG recommend revision lumbar fusion surgery at the same disc level if there are ongoing symptoms and functional limitations that have not responded to non-operative care; there is imaging confirmation of pseudoarthrosis and/or hardware breakage/malposition; and significant functional gains are reasonably expected. Revision surgery for purposes of pain relief must be approached with extreme caution due to the less than 50 percent success rate reported in medical literature. 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. Guideline criteria have been met. This injured worker presents with persistent non-radicular lower back pain following L4-S1 posterior lumbar interbody fusion in June 2014. Clinical exam findings are consistent with a positive hardware block. There is no clinical evidence of nerve root compromise. X-rays have documented a solid fusion with no evidence of pseudoarthrosis and/or hardware breakage or malposition. There is

no radiographic evidence of spinal segmental instability on flexion and extension X-rays. There is plausible evidence of loosening of the screws. The 10/23/15 utilization review modified this request to include hardware removal only. There is a compelling rationale to support the medical necessity of fusion revision and certification of additional surgical procedures. Therefore, this request is medically necessary.

Associated surgical service: Medical clearance with an internist: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Surgery General Information and Ground Rules, California Official Medical Fee Schedule, 1999 edition, pages 92-93.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Institute for Clinical Systems Improvement (ICSI). Preoperative evaluation. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2010 Jun. 40 p.

Decision rationale: The California MTUS guidelines do not provide recommendations for pre-operative medical clearance. Evidence based medical guidelines indicate that a basic pre-operative assessment is required for all patients undergoing diagnostic or therapeutic procedures. Middle-aged females have known occult increased medical/cardiac risk factors. Guideline criteria have been met based on patient age, long-term use of non-steroidal anti-inflammatory and opioid medications, hypertension, and the risks of undergoing anesthesia. Therefore, this request is medically necessary.