

Case Number:	CM15-0073815		
Date Assigned:	04/23/2015	Date of Injury:	02/11/1992
Decision Date:	05/26/2015	UR Denial Date:	04/07/2015
Priority:	Standard	Application Received:	04/17/2015

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 62-year-old woman sustained an industrial injury on 2/11/92. Injury occurred when she slipped backwards, catching herself with a jerking motion. She underwent an L4-S1 fusion, followed by a revision in 1993 due to pseudoarthrosis. The 3/16/15 lumbar spine CT scan showed postsurgical changes from prior fusion and laminectomy at L4/5 and L5/S1 with no evidence of pseudoarthrosis. There was mild canal stenosis at L3/4 centered just below the disc level, as well as borderline foraminal stenosis at L3/4 bilaterally. There was mild left sided neuroforaminal stenosis at L5/S1, and mild sacroiliac joint degenerative change bilaterally. The 3/20/15 treating physician report cited continued pain at the cited of her fusion hardware. She was concerned that she was having an allergic or systemic response to the metal hardware. She had been evaluated by two-neurologist s and an allergist who have ruled-out other reasonable explanations for her persistent symptoms. The MELISA metal implant test on 3/12/15 was strongly positive for chromium, nickel and vanadium in her lymphocyte cells. X-rays of the lumbar spine showed intact hardware at L4, L5, and S1, with grade 1 spondylolisthesis at L3/4. The injured worker wanted the hardware removed and would not consider any hardware replacement. The treatment plan recommended hardware removal at L4/5 and L5/S1 with exploration of the fusion and possible revision fusion without instrumentation if needed. The 4/10/15 utilization review non-certified the request was there was no diagnostic block to support hardware as a pain generator, and no indication that this 1993 fusion would require possible revision. The 4/17/15 appeal letter submitted by the injured worker reported a 4-year history of numbness and tingling in the extremities and joint pain. Symptoms have continued and

progressed to severe joint pain in the elbows, knees, ankles, wrists, and fingers that woke her at night. Tingling had progressed to constant shooting pain in all extremities with intermittent numbness. She had been examined by two neurologist and [REDACTED] for diagnosis and testing. A MELISA metal implant test on 3/12/15 was positive for chromium, nickel and vanadium in her lymphocyte cells due to exposure to titanium implants containing impurities. She reported that she had titanium hardware manufactured by [REDACTED] with current potential adverse warnings that include auto-immune disease consistent with her diagnosis. Additionally, she had an increase in back pain over the past 6 months at the hardware site. The treating physician report saw some "halo" effect surrounding the 3 pedicle screws. She stated that removal of the spinal titanium hardware was critical to eliminate her auto-immune symptoms and potential cancer risk.

IMR ISSUES, DECISIONS AND RATIONALES

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

Removal of hardware L4-L5 and L5-S1, exploration of fusion with possible revision fusion without instrumentation: 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), 2015, Back Chapter, Instrumentation removal and injection.

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 $i\frac{1}{2}$ Lumbar & Thoracic, Hardware implant removal (fixation).

Decision rationale: The California MTUS does not provide recommendations relative to lumbar hardware removal. The Official Disability Guidelines 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. Hardware removal is not recommended solely to protect against allergy, carcinogenesis, or metal detection. Although hardware removal is commonly done, it should not be considered a routine procedure. Guideline criteria have been met. This patient presents with persistent pain located at the hardware site. The MELISA metal implant test on 3/12/15 was strongly positive for chromium, nickel and vanadium in her lymphocyte cells. She has auto-immune symptoms that have been extensively worked up and are now attributed to the implanted titanium hardware. Fusion exploration and revision as indicated following removal of hardware in this 22-year-old fusion is reasonable. Therefore, this request is medically necessary.