MAXIMUS Federal Services

Case Number:	CM14-0008137		
Date Assigned:	02/12/2014	Date of Injury:	07/08/2011
Decision Date:	07/22/2014	UR Denial Date:	12/24/2013
Priority:	Standard	Application Received:	01/22/2014

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 Orthopaedic Surgery 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:

This is a 55-year-old male patient with a 7/8/11 date of injury. 10/10/13 progress report indicates continued cervical spine symptoms and chronic headaches. Physical exam demonstrates cervical tenderness. Cervical x-rays demonstrate significant spondylosis at C4 to C7 with junctional kyphotic deformity and some instability noted at the levels of C4-5 and C6-7. Treatment to date has included activity modification, physical therapy, pain management. The patient does not wish to have any further considerations for cervical or lumbar epidural blocks.On 11/17/11 cervical MRI demonstrates, at C4-5, maintained disk height and signal, a 3- mm posterior disk extrusion with encroachment on the subarachnoid space, no cord compromise, but encroachment on the foramina with compromise of the exiting nerve roots bilaterally. The facet joints are satisfactory. At C5-6, a 3-mm posterior disk extrusion resulting in bilateral foraminal encroachment with compromise of the exiting nerve roots bilaterally; and, at C6-7, Modic changes in the adjacent endplates, with a 2 mm x 2 mm disk extrusion with compression of the subarachnoid space and encroachment on the bilateral neural foramina.3/6/13 cervical MRI demonstrates, at C4-5, degenerative disk disease and hypertrophy of the right uncovertebral joint resulting in 3 millimeters of encroachment upon the right anterior and lateral aspect of the thecal sac and right neural foramen; at C5-6, there is degenerative disk disease plus hypertrophy of the right uncovertebral joint resulting in 3 millimeter of encroachment upon the right anterior and lateral aspect of the thecal sac and right neural foramen; and, at C6-7, degenerative change but slight posterior hard disk resulting in slight encroachment upon the thecal sac. On 10/31/13 progress report indicates continued cervical spine symptomatology and chronic headaches. The physical exam demonstrates cervical tenderness and spasm, positive axial loading compression test and Spurling maneuver. There is painful and restricted cervical range of motion. The patient does have concurrent signs and symptoms in the hands that are consistent with double crush

syndrome. On 12/11/13 electrodiagnostic study demonstrates mild right carpal tunnel syndrome, no evidence of cervical radiculopathy, brachial plexopathy, or other peripheral nerve entrapment. On 12/13/13 discussion identifies that the surgical plan is to place a ProDisc-C total disk replacement at the C4-5 level, performing an instrumented fusion from C5 to C7. The requesting provider identifies that the ProDisc-C was approved by the FDA. The requesting provider then goes on to cite several studies pertaining to cervical hybrid fusion.There is documenation of a previous 12/24/13 adverse determination for the specific type and level of procedure requested nonspecific hardware requested.

IMR ISSUES, DECISIONS AND RATIONALES

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

CERVICAL SPINE SURGERY AT C4-C7: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Page(s): 180. Decision based on Non-MTUS Citation ODG TWC.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 180. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) (Neck and Upper Back Chapter) Disc prosthesisOther Medical Treatment Guideline or Medical Evidence: Article 'Early results and review of the literature of a novel hybrid surgical technique combining cervical arthrodesis and disc arthroplasty for treating multilevel degenerative disc disease: opposite or complementary techniques?'; CIGNA criteria for intervertebral disc prosthesis.

Decision rationale: The California MTUS criteria for cervical decompression include persistent, severe, and disabling shoulder or arm symptoms, activity limitation for more than one month or with extreme progression of symptoms, clear clinical, imaging, and electrophysiology evidence, consistently indicating the same lesion that has been shown to benefit from surgical repair both in the short and the long term, and unresolved radicular symptoms after receiving conservative treatment. The surgical plan is to place a ProDisc-C total disk replacement at the C4-5 level, performing an instrumented fusion from C5 to C7. However, while emerging evidence suggests that cervical hybrid fusion appears to be a safe and reliable application of combined arthroplasty and arthrodesis during a single surgical procedure; FDA mandated post-approval studies have not been completed at this time. Additional data concerning the use of these devices is required before longterm patient safety, net health outcomes and device durability can be determined. In addition, Official Disability Guidelines states that suggested exclusions include evidence of facet arthritis, spinal instability or significant deformity; whereas the requesting provider notes instability at the levels of C4-5 and C6-7 on 10/10/13 cervical radiographs. It is noted that electrodiagnostic studies were negative for cervical radiclopathy. Therefore, the request for cervical spine surgery at c4-c7 is not medically necessary.