

<b>Case Number:</b>	CM14-0030899		
<b>Date Assigned:</b>	06/20/2014	<b>Date of Injury:</b>	08/02/2002
<b>Decision Date:</b>	09/15/2014	<b>UR Denial Date:</b>	02/19/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/11/2014

### 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 California and is licensed to practice in Orthopedic Surgery 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 claimant is a 50-year-old female who sustained an injury to the neck on 06/10/09. The clinical records provided for review include the assessment on 01/08/14 noting ongoing neck complaints; no documentation of physical examination findings were noted. The assessment documented that the claimant had failed conservative care for her cervical complaints and recommended an artificial disc replacement at C5-C6. The report of an MRI of the cervical spine dated 01/24/08 revealed at C5-6 disc desiccation with a mild left foraminal focal disc protrusion resulting in moderate left neuroforaminal stenosis. The report of a follow up MRI dated 03/13/13 showed mild to moderate central stenosis at C5-6 and C6-7 with right neuroforaminal narrowing and facet changes. The documentation did not contain any formal physical examination findings. This review is for an artificial disc replacement procedure.

### IMR ISSUES, DECISIONS AND RATIONALES

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

#### **Anterior cervical discectomy and total disc arthroplasty at C5-6: Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM, Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation ODG-TWC neck and upper back procedure.

**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); Treatment in Worker's Comp, 18th Edition, 2013 Updates: neck procedure -Disc

prosthesis Under study, with recent promising results in the cervical spine, but not recommended in the lumbar spine. While comparative studies with anterior cervical fusion yield similar results, the expectation of a decrease in adjacent segment disease development in long-term studies remains in question. And there is an additional problem with the long-term implications of development of heterotopic ossification. Additional studies are required to allow for a "recommended" status. These should include an evaluation of the subset of patient who will most benefit from this procedure as well as study of advantages/disadvantages of disc design and surgical procedure in terms of outcomes (particularly for development of heterotopic ossification and adjacent segment disease). This recommendation is based on balancing what we know so far about the benefits and the risks for the patient. Adjacent segment disease seems to be a natural aging process, and ADR has not proven any benefit in altering that progression. The risks of heterotopic calcification associated with ADR may make it a sure way to end up with a solid fusion, and major risks also include potential revisions and technical learning curve issues with widespread use. Overall Comparison to Fusion: Overall studies have demonstrated statistically significant non-inferiority of ADR vs. fusion with superior trending on many outcomes but limited evidence of statistical superiority. This has persisted for longer-term follow-up (three to five years). Long-term studies have shown that necessity of adjacent-level surgery is similar in both the fusion and ADR groups along with similar rates of development of adjacent-segment disease. Complication rates are similar. Study quality is often severely limited with high dropout rates and there is no comparison to a non-surgical treatment. Neither treatment has been found to produce complete disappearance of symptoms. Return to work appears earlier in the ADR group but overall employment rate is not different at 2 years (including for a workers' compensation cohort) and 5 years. (Zechmeister, 2011) (Steinmetz, 2008) (Jawahar, 2010) (Kim, 2009) (Garrido, 2010) (Fekete, 2010) (Dettori, 2008) (Pointillart, 2001) (Cinotti, 1996) (Klara, 2002) (Zeegers, 1999) (Sekhon, 2003) (Sekhon, 2004) (Porchet, 2004) (Pimenta, 2004) (Sasso, 2007) (Heller, 2009) (Mummaneni, 2007) (Murrey, 2009) (Burkus, 2010) (ECRIb, 2009) (Tumialán, 2010) (Delamarter, 2010) (Kelly, 2011) See also the complete list, discussion, and rating of other Disc prosthesis references in the Fusion References Chapter.

**Decision rationale:** Based on California ACOEM Guidelines and supportive by the Official Disability Guidelines, the request for Anterior cervical discectomy and total disc arthroplasty at C5-6 is not recommended as medically necessary. Presently the role of artificial disc surgery is not supported by guideline criteria with no long term indication of its efficacy versus other forms of more standardized care including fusion. This individual's records for review also fail to demonstrate clinical correlation between claimant's imaging and physical examination to support the role of any degree of operative intervention at the C5-6 level. The request in this case would not be supported as medically necessary.

**Pre operative medical clearance:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM, Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation ODG-TWC neck and upper back procedure.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004); Chapter 7 Independent Medical Examinations and Consultations, page 127.

**Decision rationale:** The proposed anterior cervical discectomy and total disc arthroplasty at C5-6 is not recommended as medically necessary. Therefore, the request for preoperative medical clearance is also not medically necessary.

**2 to 3 days of inpatient stay:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 2 General Approach to Initial Assessment and Documentation, Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation ODG-TWC neck and upper back procedure.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG); Treatment in Worker's Comp, 18th Edition, 2013 Updates: neck procedure -Artificial Disc (84.62 -- Insertion of total spinal disc prosthesis, cervical)Actual data -- median 1 days; mean 1.4 days ( $\hat{\pm}0.1$ ); discharges 2,146; charges (mean) \$40,203Best practice target (no complications) - 1 day.

**Decision rationale:** The proposed anterior cervical discectomy and total disc arthroplasty at C5-6 is not recommended as medically necessary. Therefore, the request for a two to three day inpatient length of stay is also not medically necessary.

**post operative purchase of neck brace:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM, Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation ODG-TWC neck and upper back procedure.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 173-175.

**Decision rationale:** The proposed anterior cervical discectomy and total disc arthroplasty at C5-6 is not recommended as medically necessary. Therefore, the request for a neck brace is also not medically necessary.

**Post operative Physical therapy for cervical spine three times a week for six weeks:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM, Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation ODG-TWC neck and upper back procedure.

**MAXIMUS guideline:** Decision based on MTUS Postsurgical Treatment Guidelines.

**Decision rationale:** The proposed anterior cervical discectomy and total disc arthroplasty at C5-6 is not recommended as medically necessary. Therefore, the request for postoperative physical therapy is also not medically necessary.