

<b>Case Number:</b>	CM13-0009719		
<b>Date Assigned:</b>	03/24/2014	<b>Date of Injury:</b>	03/26/2009
<b>Decision Date:</b>	04/14/2015	<b>UR Denial Date:</b>	07/24/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/12/2013

### 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: Minnesota, Florida

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:

The injured worker is a 51-year-old female, who sustained an industrial injury on 3/26/2009. The diagnoses have included sprain of neck and spinal stenosis in cervical region. Treatment to date has included cervical disc arthroplasty at C4-5 and anterior cervical discectomy and fusion at C5-6, and C6-7 on 11/07/2011 per Utilization Review report and conservative measures. After the surgical procedure of 11/7/2011, there was marked and significant improvement of symptomatology reported. However, on 4/10/2012 the documentation indicates presence of neck pain, low back pain and right shoulder pain. On examination there were spasms noted but no neurologic deficit was documented in the upper extremities. On 11/9/2012 a right carpal tunnel release was performed. Per the Utilization Report, the magnetic resonance imaging of the cervical spine, dated 3/14/2013 showed significant metallic susceptibility artifact at C4-5, C5-6, and C6-7 levels. The study was therefore not reliable. There was a 2-3mm posterior disc protrusion/extrusion at C2-3, and unconfirmed compromise of the cord and exiting nerve roots at C4-5 and C5-6 bilaterally which may have been entirely due to the artifact, and true compromise could not be reliably ruled in or out. At C6-7, there was intrinsic impression on the ventral aspect of the thecal sac, considered to be residual disc bulge and encroachment on the right foramen, without cord compromise. There was compromise of the right exiting nerve root, but not left. A CT scan was not performed. A PR2 supplemental progress note, dated 5/16/2013, noted that there was concrete physical evidence of hardware disrupting nerve roots and the cord, noting progressive dysphagia. A physical examination was not noted. Neurologic findings were not documented. Video-fluoroscopic swallow evaluation has not been performed. Flexion/extension

films have also not been performed. On 7/24/2013, Utilization Review non-certified a request for a surgical procedure, C5 through C7 removal of anterior cervical hardware with inspection of fusion, possible regrafting of screw holes, and repair of pseudoarthrosis if one is found intraoperatively, with length of inpatient stay 1-3 days, noting the lack of compliance with Official Disability Guidelines.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

#### **C5 Through C7, Removal of Interior Cervical Hardware with Inspection of Fusion, Possible Regrafting of Screw Holes and Repair of Pseudoarthrosis if one is found Intraoperatively: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG-TWC Low Back Procedure Summary.

**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) Low Back Chapter, Hardware Implant Removal; and on Clinical Orthopedics and Related Research March 2011, 469 (3) 658-665.

**Decision rationale:** ODG guidelines indicate hardware removal is not recommended routinely except in cases of broken hardware or persistent pain after ruling out other causes of pain such as infection and nonunion. Although hardware removal is commonly done, it should not be considered a routine procedure. Implant removal may be challenging and lead to complications such as neurovascular injury, or recurrence of deformity. Postoperative dysphagia after anterior cervical discectomy and fusion is a relatively common occurrence in the early postoperative period. It is however, a relatively transient finding with the vast majority of cases resolving within 3 months. In a controlled analysis of postoperative dysphagia by [REDACTED], 47% of patients having anterior cervical spine surgery had evidence of dysphagia on postoperative Video fluoroscopic swallow evaluation (VSE). The dysphagia in 70% of these patients resolved within 2 months from surgery, whereas 23% had some degree of dysphagia that persisted up to 10 months. Dysphagia lasting beyond 10 months has also been reported. In the March 2011 issue of Clinical Orthopedics and Related Research, studies suggest a relatively high incidence of dysphagia after anterior cervical decompression and fusion. Video fluoroscopic swallow evaluation is often considered the gold standard in the evaluation of swallowing function; such objective measures of dysphagia are extremely sensitive in patients undergoing anterior cervical surgery. Although the nature of dysphagia is more commonly a transient finding in early postoperative period, there is a minority of patients who develop long-term issues with swallowing. A prospective study performed on 221 patients on dysphagia after anterior cervical surgery. These authors reported an overall incidence of postoperative dysphagia of 50% at 1 month, 32% at 2 months, and 18% at 6 months. The incidence of moderate to severe dysphagia at 6 months was 5%. Chin et al prospectively studied the effect of plate thickness on postoperative dysphagia after anterior cervical fusion surgery. Patients with a plate that did not protrude past the anterior margin of the preoperative anterior osteophyte had a 30% incidence of dysphagia lasting a mean of 38 days compared with 38% incidence of dysphagia lasting a mean

of 76 days in patients in whom the plate extended past the anterior margin of preoperative anterior osteophytes. The proposed causes of postoperative dysphagia include recurrent laryngeal nerve palsy, esophageal ischemia and reperfusion injury, and local soft tissue swelling. Risk factors for developing postoperative dysphagia are debated in the literature. Several studies have suggested that deflating and reinflating the endotracheal cuff after placement of retractors, minimizing endotracheal cuff pressure, and minimizing the duration and pressure of intraoperative retraction may decrease the incidence of postoperative dysphagia. Other studies suggest however, that these interventions have no effect on postoperative dysphagia. Various intraoperative and patient factors such as age, gender, body mass index, operative time, estimated blood loss, number of levels of surgery, location of surgery, and plate thickness have been investigated as potential risk factors for postoperative dysphagia with inconsistent findings. Fortunately, postoperative dysphagia is typically a transient phenomenon. Persistent debilitating dysphagia is relatively uncommon. The diagnostic testing including x-rays do not show mechanical causes such as protrusion of the plate beyond the anterior osteophytes level that could be contributing to the dysphagia. A VSE study has not been performed. There is no indication that plate removal will relieve the dysphagia symptoms. In fact, there is certainly a possibility that additional surgery would lead to worsening of the dysphagia. California MTUS guidelines indicate that the efficacy of cervical fusion for patients with chronic cervical pain without instability has not been demonstrated. The available documentation does not indicate the presence of hardware failure or instability. Flexion/extension x-rays or a CT scan have not been submitted. There is no pseudoarthrosis documented. The guidelines indicate a CT for documentation of a pseudoarthrosis. There is no clear clinical, imaging, and electrophysiologic evidence, consistently indicating the same lesion that has been shown to benefit from surgical repair in both the short and long-term. As such, the request for removal of hardware and revision of the fusion is not supported and the medical necessity of the request has not been substantiated.

**Inpatient Stay (1-3 days):** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not cite any medical evidence for its decision.

**Decision rationale:** Since the primary procedure is not medically necessary, none of the associated services are medically necessary.