

<b>Case Number:</b>	CM15-0042857		
<b>Date Assigned:</b>	04/24/2015	<b>Date of Injury:</b>	01/07/2014
<b>Decision Date:</b>	05/22/2015	<b>UR Denial Date:</b>	02/23/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/06/2015

### 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:

The injured worker is a 45-year-old female who sustained an industrial injury on 1/07/14. An original shoulder injury was sustained but the injured worker sustained a neck injury while attending physical therapy for the shoulder. Past surgical history was positive for anterior interbody fusion at C3/4 and C4/5 on 7/16/03. Past medical history was positive for hypertension. The 10/21/14 cervical spine flexion/extension films documented anterior spinal fixation from C3-C5, with spondylosis at C5/6, C6/7, and T2/3. There was 1-2 mm over movement noted at C5/6. The 12/12/14 cervical MRI documented an anterior decompression and fusion from C3-C5. There was residual spondylosis within the fused segment resulting in mild spinal stenosis without evidence for cord compression. There was a disc-ridge complex at C5/6 causing mild spinal stenosis and flattening the ventral aspect of the cervical cord. There were cord signal abnormalities centered at the level most likely reflecting myelomalacia. The 1/20/15 neurosurgical report cited progressive constant severe cervical pain radiating into the proximal upper right shoulder. She reported progressive hand numbness and clumsiness. Valsalva's increased pain. Physical exam documented normal cervical range of motion, negative Lhermitte's and Spurling's tests, 3-4/5 right extensor carpi radialis longus, and myohyperreflexia at the patella, left greater than right. There was negative clonus. The diagnosis included status post anterior interbody fusion at C3/4 and C4/5, multilevel cervical spondylosis, and myelomalacia secondary to C5/6 disc protrusion and congenital spinal stenosis resulting in clumsy hand syndrome. The treatment plan recommended an artificial disc replacement at C5/6 because she had a plate at C3-C5, and he would not perform a fusion and anterior instrumentation at C5/6.

Authorization was requested for possible conversion to fusion if there was a problem placing the artificial disc. Requests for authorization were made for the following: Placement of artificial disc C5-6; Blood donation; Bone growth stimulator purchase; Possible fusion (total disc arthroplasty; revision, removal); Assistant surgeon; Inpatient hospital stay; Medical clearance; Pre-operative BMP, CBC with diff, PT with INR, PTT & UA; Pre-operative EKG; Pre-operative chest x-ray; Cervical collar Vista; and a Cervical pillow. The 2/23/15 utilization review certified the request for possible fusion (total disc arthroplasty, revision, removal) with assistant surgeon, 1-day hospital stay, medical clearance, pre-operative testing, cervical collar and cervical pillow. The requests for placement of the artificial disc C5/6 was non-certified due to an absence of guideline support. The request for blood donation was non-certified, as the surgeon had not demonstrated the need for autologous blood transfusion. The bone growth stimulator was non-certified, as the patient did not have any documented risk factors for failed fusion.

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

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

#### **Placement of artificial disc C5-6: Upheld**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Neck and Upper Back, Disc prosthesis.

**Decision rationale:** The California MTUS are silent regarding artificial disc replacement. The Official Disability Guidelines indicate that disc prostheses are under study. 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. The general indications for currently approved cervical-ADR devices (based on protocols of randomized-controlled trials) are for patients with intractable symptomatic single-level cervical DDD who have failed at least six weeks of non-operative treatment and present with arm pain and functional/ neurological deficit. Guideline criteria have not been met. There is limited guidelines support for the use of cervical ADR with additional studies required to allow for a recommended status. This patient presents with multilevel cervical degenerative disc disease, which fails to meet the criteria of single level disease. The request (adjacent to a prior fusion) lacks long-term large volume literature studies. Therefore, this request is not medically necessary.

#### **Blood donation: Overturned**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Working Group of the Clinical Practice Guideline for the Patient Safety at Surgery Settings. Clinical practice guideline for the patient safety at surgery settings. Quality plan for the National Health System of the Ministry of Health, Social Policy, and Equality. Barcelona (Spain): Agency for Information, Evaluation, and Quality in Health of Catalonia (AIAQS); 2010. 191 p.

**Decision rationale:** The California MTUS and Official Disability Guidelines do not provide recommendations for autologous blood transfusions. The National Guideline Clearinghouse was referenced. Clinical practice guidelines strongly recommend preoperative autologous blood donation as it can be used to reduce exposure to allogenic blood. Given the magnitude of surgery, this request is medically necessary.

**Bone growth stimulator purchase:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Low Back, Bone Growth Stimulators.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Neck and Upper Back: Bone-growth stimulators (BGS).

**Decision rationale:** The California MTUS guidelines are silent regarding bone growth stimulators. The Official Disability Guidelines indicate that the use of bone growth stimulation remains under study for the cervical spinal fusion. Bone growth stimulators may be considered medically necessary as an adjunct to spinal fusion for patients with any of the following risk factors for failed fusion: one of more previous failed spinal fusion(s); grade III or worse spondylolisthesis; multilevel fusion; current smoking habit; diabetes, renal disease, or alcoholism; or significant osteoporosis. Guideline criteria have not been met. This request is for a one level fusion with no current evidence of risk factors for failed fusion. There was no specific indication provided with the request. Therefore, this request is not medically necessary at this time.